Commission on Narcotic Drugs, 62nd session

Questions to INCB
in preparation of the 5th Intersessional Meeting
on 23 September 2019[1]
submitted by 19 August 2019

Statement by Stefano Berterame, Secretariat of the International Narcotics Control Board

[1] These questions built up on the answers already provided by WHO, INCB and UNODC during and after the 4th intersessional meeting on 24 June 2019, namely (1) WHO's answers to questions submitted before the 4th intersessional meeting, circulated on 2 July 2019; (2) INCB's answers to questions submitted before the 4th intersessional meeting, circulated on 2 July 2019; (3) WHO's answers to the follow-up questions asked during the 4th intersessional meeting and submitted in writing by 27 June 2019, circulated on 30 July 2019; (4) UNODC's answers to the follow-up questions asked during the 4th intersessional meeting and submitted in writing by 27 June 2019, circulated on 30 July 2019.

Excellency Ambassador Bakhet thank you for giving me the floor. Distinguished delegates.

I would like once more to clarify that as it was the case in the previous intersessional in June, I will provide some initial considerations from the INCB Secretariat in relation to the implications of the ECDD recommendations for the work of the Board.

The Board will review thoroughly the implications of the recommendations for the work of the Board at its 126th session in November 2019. I can therefore only provide some clarification from the Secretariat viewpoint in relation to the specific treaty-based function of the Board and this is not an official statement from the Board.

I would like to address the recommendations one by one and try also to address, if possible, some of the requests of clarifications by Member States in which the INCB is also mentioned.

5.7 Questions addressed to INCB

5.0 General questions

United States: What will be the practical impact of the recommendations for member states if all the recommendations are adopted, including on our relationships with the INCB and WH0?

The recommendations of the ECDD if endorsed by the CND will have implications for the daily work of the INCB and of the competent national authorities in each country.

In some cases, there will be more clarity in relation to reporting (5.2. and 5.3 move to 1961 and deletion from 1971 of dronabinol and Tetrahydrocannabinol (isomers of delta-9-tetrahydrocannabinol). Endorsement of the recommendations by the CND will result in some changes in the control of these drugs. Instead of assessments which are required for drugs in Schedules II, III and IV of the 1971 Convention, pursuant some ECOSOC resolutions, Governments will need to submit estimates, pursuant to article 19 of the 1961 Convention.

Recommendation 5.1 (deletion of cannabis and cannabis resin from schedule IV) will not have impact on the control measures already applied because the two substances will remain in schedule I of the 1961 convention.

The deletion of extract and tinctures (5.4) may be problematic for the monitoring of other cannabinoids that are not explicitly scheduled. The secretariat notes that the lack of a definition of extracts and tinctures has not facilitated control over these substances. However, this broad category if retained could be used to cover intermediate products of cannabis or it could allow the control of preparations with cannabinoids other than those explicitly listed in the schedule. This, however, would require a clearer and unequivocal operational definition of this category to be agreed upon by Member States to avoid differences in the understanding of the drugs under control.

Recommendation 5.5 on cannabidiol preparations. The main question in regard to this recommendation relates to its practical implementation at the national level. In most countries, chemical analysis down to the required threshold will not be possible because of lack of access to appropriate identification techniques. In those countries where chemical analysis to the required accuracy of 0.2 per cent of THC is possible, it might not be feasible, or considered not to be a good use of resources and may not be employed. In addition, this recommendation will also give rise to an important question on the control of cannabis that is being cultivated for the extraction of CBD to be used for the mentioned CBD preparations.

It is not clear to which preparations recommendation 5.6. would apply. The term “compounded pharmaceutical preparations” is applicable to a large number of preparations. It is not defined what “readily available means”. The convention states that if the drug in the preparations ‘is not readily recoverable”, the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III. If this recommendation is endorsed by the Commission on Narcotic Drugs, the inclusion of these preparations in Schedule III will eliminate the need for some controls, such as those applicable to the international trade of these preparations but not for the controlled substance contained in the preparations (delta-9-THC).

Manufacture of delta-9-THC will need to be monitored and Governments will have to report statistics on its utilization for Schedule III preparation

United States: How will this change what we do now, and will we be undertaking any additional burdens?

With cannabis, cannabis resin, THC and other components all listed in one Convention, instead of two, monitoring and reporting of these drugs might actually be easier as only one control system, namely that of the 1961 Convention, will apply, eliminating a possible source of confusion and misunderstanding of whether a particular component of cannabis will be under one or the other Convention. This may lead to more clarity in reporting and facilitate international transactions among Governments. As regards the INCB and its secretariat, the emergence and continuous increase of the cultivation of cannabis for medical purposes, has placed additional burden on the secretariat as there is an increasing need to provide advice on the treaty provisions to new producers of cannabis and review data estimates and statistics submitted by Governments.

United States: Does the INCB have the necessary resources to handle the additional information the INCB will receive?

The limited resources of the INCB and its secretariat have been strained by the need to monitor at the global level the cultivation, manufacturing, trade and consumption of cannabis and cannabis-derivatives, leading to problems in terms of timely and effective processing of the governments' requests. The Secretariat believes that it will need more regular budget resources to effectively perform the functions mandated by the conventions. This would be true especially in the first years after the approval of the recommendations. There would be the need for the Board and governments to make some changes in their respective operations including the implementation of new legislation. In future, if the cultivation of cannabis for medical and scientific purposes will continue to grow there will continue to be the need for effective monitoring at global level.

At country level Parties permitting the cultivation of the cannabis plant for the production of cannabis or cannabis resin, are required to apply to such cultivation the system of controls as provided in article 23. This includes the establishment of an agency responsible for designating areas and issuing licences for cultivation, purchasing and taking physical possession of such crops as soon as possible, as well as having the exclusive right of importing, exporting and whole sale trading and maintaining stocks other than those held by manufacturers. INCB has the obligation to monitor these provisions

United States: How will the INCB use it?

The information will be used to monitor the global cultivation, manufacture, trade and consumption as it is the case for all controlled substances as well as to ensure a balance between supply and demand of cannabis raw material and cannabis derivatives to ensure availability for medical and scientific purposes but also to avoid, as prescribed by the conventions, the accumulation of quantities in excess of those required for the normal conduct of business, having regard the prevailing market conditions.

United States: The INCB stated that the industrial uses are limited to fibres and seeds. The Convention does not expressly state a limitation. What is the basis for the INCB interpretation that the phrase "(fibres and seeds)" means exclusively fibres and seeds?

The international drug control conventions do not establish a threshold of cannabinoids, under which the cannabis plant could not be considered to be under international control. The purposes of cultivation of the cannabis plant remain relevant for the determination of applicable measures.

The Board has stated in its 2018 report that the 1961 Convention limits the cultivation of cannabis for industrial purposes to fibre and seed. The cultivation of the cannabis plant for industrial purposes other than those explicitly indicated in article 28, paragraph 2, should not be considered licit.

The adoption of a practical threshold related to capability of detection or liability to abuse may be considered as a possible method through

which a State party could differentiate cannabis plant cultivated for purposes of the production of cannabis or cannabis resin, from other purposes, as long as this method is used in line with the objectives of the 1961 Convention, including to prevent the misuse of and illicit trafficking of cannabis. However, the extraction of the cannabinoids from the plant would require the use not only of the leaves but of the whole plant including the flowering top (under control as cannabis) that may contain small percentages of THC that in the plant itself may not be considered suitable for abuse but in the process of extraction of the cannabinoids may result in significant quantities becoming available.

5.1 Cannabis and cannabis resin

• To be deleted from Schedule IV of the 1961 Convention

United States: Cannabis and cannabis resin are currently scheduled under the '61 Convention. Does this also trigger the estimate and statistical system or does the fact that the plant is scheduled exclude the estimate system which is why it is now needed to move THC to the '61?

Estimates and statistics need to be provided for drugs scheduled in Schedule I of the 1961 Convention. If THC is moved to Schedule I of the 1961 Convention, an estimate will be required. Currently, Governments submit assessments for delta-9-THC quantities and Governments have to apply a different control system to the plant and some of its associated components.

5.2 Delta-9-tetrahydrocannabinol (dronabinol)

• To be added to Schedule I of the 1961 Convention

• To be deleted from Schedule II of the 1971 Convention, subject to the adoption by the Commission on Narcotic Drugs of the recommendation to add dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol) to Schedule I of the 1961 Convention

Singapore: It was stated in INCB's comments that the endorsement of these 2 recommendations by the CND will result in a number of additional control measures required for States under the 1961 Convention. One of these requirements is that Member States will be required to submit estimates for these

isomers. Can INCB elaborate on the other control measures which Member States will be required to implement in the event that recommendation 5.2 is accepted?

Endorsement of recommendation 5.2 by the Commission on Narcotic Drugs will result in some changes in the control of these drugs. Instead of assessments which are required for drugs in Schedules II, III and IV of the 1971 Convention, pursuant some ECOSOC resolutions, Governments will need to submit estimates, pursuant to article 19 of the 1961 Convention. The obligation to submit estimates is stricter than for assessments, as it is a treaty mandated. Submitted estimates are subject to confirmation by the Board and Governments must furnish estimates annually (instead of three-year intervals under the assessment system).

If cannabis and its active principles are controlled under the same Convention, this will facilitate the control and reporting at the level of Governments as the same set of control measures will apply to cannabis, cannabis resin, dronabinol and its stereoisomers as well as tetrahydrocannabinol and its stereoisomers (as per the next recommendation). This will also facilitate the work of the Board to monitor the global situation and to provide Governments with a comprehensive overview of the global production, consumption and trade of cannabis and its active components.

United States: It was explained that a justification to move Delta-9-THC from the '71 Convention to the '61 Convention is that member states are encountering difficulties enforcing the convention arising from the scheduling of cannabis and THC under two separate conventions. Please give more information on the negative impact [of the current scheduling arrangement] on member states, and on the breadth of impact.

Currently, it is not always clear to Member States which control provisions apply to cannabis-based preparations containing THC or delta-9-THC and if these should be reported as cannabis extracts (1961 Convention) or THC (1971 Convention). In the last years there are an increasing number of products containing these drugs.

Originally when scheduled, delta-9-THC was considered a synthetic compound, obtained from chemical synthesis (dronabinol). However, in recent years, delta-9THC has also been prepared by extraction from cannabis, and as such could also be considered as a substance prepared by purification (refining) of cannabis extract (controlled under the 1961 Convention). Manufacture of delta-9-THC from natural extractions has advanced to the point where they are chemically indistinguishable from synthetically derived delta-9-THC. With regard to international trade, it became difficult to report correctly given that some consignments do not specify the type of derivation of the substance in trading details. In addition, preparations containing a mixture of naturally and synthetically derived delta-9-THC are now entering the market. These preparations are particularly difficult to provide accurate figures for given that natural and synthetic derivations are reported under different conventions. Therefore, delta-9-THC figures analysed and published do not necessarily provide an accurate image of international trade in the substance.

When considering delta-9-THC of purely natural origin – in practical terms this means that the cultivation of cannabis plant, estimates or manufacture is undertaken in line with provisions of the 1961 convention. However, the import of the final product is reported under 1971 convention (including assessments of annual requirements, import licenses etc). There is a disconnect between the processes that makes monitoring difficult and data received do not provide for a full picture.

United States: This may be more of a philosophical question, but if the drafters of the 1971 Convention intended to put Delta-9-THC in the '71 Convention knowing that it was the active component of cannabis, and if the drafters of the '61 Convention did not include cannabis in the estimate system, if we amend the schedules with respect to THC are we not in effect amending the conventions but not using the amendment processes contained in those treaties?

This question is for UNODC legal services.

United States: Are the current control measures placed on delta-9-THC under Schedule II of the 1971 Convention insufficient to deter abuse or illicit use?

The control mechanism of psychotropic substances established by the 1971 convention and relevant ECOSOC resolutions, is generally a well-established and functioning regime. Substances in schedule II are subjected to quarterly statistical return reporting and require an import/export authorization, which should always be in line with declared assessments of annual medical/scientific requirements.

However, regarding delta-9-THC, there is a general discrepancy in data due to the disconnect mentioned earlier and thus in global monitoring of the actual trade in and consumption of the substance. It is thus difficult to evaluate to what extent are the control measures effective.

United States: What specific new control measures does the 1961 Convention place on delta-9-THC that would decrease the extent or likelihood of abuse?

Instead of assessments which are required for drugs in Schedules II, III and IV of the 1971 Convention, pursuant some ECOSOC resolutions, Governments will need to submit estimates, pursuant to article 19 of the 1961 Convention. The obligation to submit estimates is stricter than for assessments, as it is a treaty obligation. Submitted estimates are subject to confirmation by the Board and Governments must furnish estimates annually (instead of three-year intervals under the assessment system).

United States: Would any additional control measures placed on delta-9-THC as a result of controlling it under the 1961 Convention place any additional limits on the availability of preparations containing delta-9-THC for legitimate medical and scientific purposes?

No.

United States: Currently, cannabis extracts that contain delta-9-THC are internationally controlled as preparations under Article

3 of the 1971 Convention. If the Commission were to accept the recommendation to move delta-9-THC from the 1971 Convention to the 1961 Convention, would some degree of controls over these preparations be lost?

No. As already said the control requirements under the 1961 Convention are stricter.

Article 3 of the 1971 Convention refers to exempted preparations and it permits a State party to exempt from some controls preparations that contain psychotropic substances other than those listed in Schedule I. An exemption may be made only when the preparation presents negligible or no risk of abuse and the psychotropic substance cannot be readily recovered in a quantity liable to abuse. To take advantage of that provision, a State party must notify the Secretary-General in writing of the name and composition of the exempted preparation and the measures of control from which it is exempted.

5.4 Extracts and tinctures of cannabis

• ***To be deleted from Schedule I of the 1961 Convention***

United States: Please explain the rationale to remove extracts and tinctures? Does the INCB get information from member states currently through the estimate system, and is it useful? If tinctures and extracts are removed, does the INCB lose anything? Please explain what is meant by "the category is no longer adequate."

The secretariat receives estimates mentioning extracts (more often) and tinctures that need to be converted into quantity of cannabis. However, the nature and characteristics of this extracts and tinctures varies considerably with different brand names and packaging and different contents. The use of such a broad and general category that fits a large number of cannabis-based drugs may no longer be adequate to ensure proper control.

The ECDD position that “preparations”, as defined in the 1961 Convention, may cover all products that are “extracts and tinctures” of cannabis would require the insertion of a specific footnote in the

schedule to appropriately define the level of control to the “preparations of cannabis”.