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Item 5 (c) of the provisional agenda*
Best practices in promoting measures to ensure the availability and accessibility of internationally controlled drugs for medical and scientific purposes

Working group on best practices in promoting measures to ensure the availability and accessibility of internationally controlled drugs for medical and scientific purposes

Background note by the Secretariat

I. Introduction

1. The present note provides information on the objective of the working group as well as guiding questions for discussion and background information on the topic of availability and accessibility of internationally controlled drugs for medical and scientific purposes. The note also highlights the linkages between the topic of the working group and the 2030 Agenda for Sustainable Development as well as the outcome document of the special session of the General Assembly on the world drug problem (UNGASS), held in 2016.

2. Member States have increasingly recognized their obligation under the international drug control conventions to ensure the availability of internationally controlled drugs for medical and scientific purposes, while simultaneously preventing their diversion, abuse and trafficking. Both the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971 establish a control regime to serve this dual purpose, with the overarching goal of protecting the health and welfare of humankind.

3. This increase in attention to the subject is reflected in General Assembly resolution S-30/1, which contains the outcome document of the special session of

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the Assembly on the world drug problem, as well as in Commission on Narcotic Drugs resolutions 53/4 and 54/6, and Goals 3.8 and 3.b of the 2030 Agenda for Sustainable Development.

II. Objective of the working group

4. The working group aims to highlight the interlinkages between the need to have essential drugs under international control readily available for medical purposes and the need to prevent diversion or abuse. The working group will gain an overview of the current discussion on the subject matter as well an insight into the specifics of the region in this regard.

5. Participants are encouraged to share national experiences in the effort to ensure availability while preventing abuse and diversion. The working group further aims to serve as a platform to share best practices and lessons learnt regarding national initiatives to overcome impediments to the availability of narcotic drugs and psychotropic substances, including from a regulatory and law enforcement perspective. Participants are also encouraged to draw conclusions and make recommendations from a regional perspective with a view to submitting this information to the Commission on Narcotic Drugs.

6. States in the African region have been very involved in supporting palliative care and the access to essential medicines for patients suffering from cancer, HIV/AIDS and other conditions. The working group may wish to discuss national best practices in legislation and policymaking, in building the capacity and in engaging communities.

7. The working group may wish to consider the following guiding questions:

- How can Member States improve access for medical purposes without creating an environment of overuse and misuse?
- What role can law enforcement play in support of improving access to controlled medicines? Can you provide examples of successful activities?
- Describe any evidence-based strategies that can be implemented to prevent diversion, misuse and abuse.

III. Implementation of the provisions of the UNGASS and the 2030 Agenda for Sustainable Development

A. UNGASS

8. The outcome document of the General Assembly special session on the world drug problem (S-30/1) highlights the important linkages between the 2030 Agenda and the work of the Commission on Narcotic Drugs (CND) with an entire sub-section of the document devoted to operational recommendations on ensuring the availability of and access to controlled substances exclusively for medical and scientific purposes, while preventing their diversion (see annex).

9. While availability and access have not always featured prominently in discussions about the world drug problem, the Commission on Narcotic Drugs, as the main policy making body in the United Nations system for drug-related matters, has in particular in the lead up to the UNGASS paid attention to this issue. It, among others, held a special event jointly with WHO on "The global crisis of untreated pain: how to tackle it together" as part of the preparatory process for the special session (see www.unodc.org/ungass2016/en/cnd_preparations.html).

B. 2030 Agenda for Sustainable Development

10. With the adoption of the 2030 Agenda for Sustainable Development, Member States have committed to a multidimensional approach to development and to work together in a spirit of common and shared responsibility — also in addressing the world drug problem.

11. Goal 3 focuses on good health and well-being for all at all ages and Member States committed to "Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse" (3.5) as well as to "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all" (3.8).

12. Information on the contribution made by the Commission on Narcotic Drugs relating to the implementation of the 2030 Agenda for Sustainable Development can be found on www.unodc.org/unodc/en/commissions/commissions-2030.html.

IV. Availability of and access to controlled drugs for medical purposes

13. Over the past 20 years, the global consumption of opioids for medical purposes has more than tripled.[1] However, the data collected and analysed by the International Narcotics Control Board (INCB) in its 2015 report on *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes* show that the consumption of drugs for pain relief and other medical purposes is still low in most countries. Access to these drugs is uneven, with consumption concentrated primarily in some countries.

14. Today, around 5.5 billion people still have limited or no access to medicines containing narcotic drugs, such as morphine, leaving 75 per cent of the world population without access to proper pain relief treatment. Around 92 per cent of morphine used worldwide is consumed in countries in which only 17 per cent of the world population lives: primarily the United States of America, Canada, Western Europe, Australia and New Zealand.[2]

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[1] INCB (2015), *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes* (www.unodc.org/documents/drug-prevention-and-treatment/INCB_Access_Supplement-AR15_availability_English.pdf).

[2] Ibid.

15. The latest data show that many of the conditions requiring pain management, particularly cancer, are increasing in low- and middle-income countries. At the same time, there has been an increase in the abuse of prescription drugs and related overdose deaths in countries with a high per capita consumption of opioid analgesics in recent years.[3]

16. The INCB found that the inequitable use of pain relief medication was not due to the lack of raw material, which was in fact available at sufficient levels, but that other barriers negatively affected availability and access, such as "regulatory, attitudinal, knowledge-related, economic and procurement-related factors".[4]

17. Among the impediments most often cited by countries were concerns about addiction, reluctance to prescribe or stock, and insufficient training for health professionals. Unduly restrictive laws and burdensome regulations were also commonly perceived as playing a significant role in limiting the availability of opioids. A smaller number of Governments reported that difficulties involving distribution, supply and the cost of opioids were major obstacles to making opioids adequately available.

18. Access to opioids, including codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine, increased in Latin America and the Middle East. However, the situation across the continents of Africa and Asia has seen little improvement with a majority of the population still under 100 defined daily doses for statistical purposes (S-DDD) per million inhabitants per day. In comparison, the United States, Canada and Australia report greater than 10,000 S-DDD per million inhabitants per day.

V. Technical cooperation to increase the availability of internationally controlled drugs

19. UNODC has created a Joint Global Programme in response to requests by the Commission on Narcotic Drugs resolution 53/4 on availability of internationally controlled licit drugs for medical and scientific purposes and resolution 54/6 on availability of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes. The programme is also in line with the findings of the 2010 and 2015 reports of the International Narcotics Control Board on *Availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes*.

20. The Joint Global Programme is a partnership between the United Nations Office on Drugs and Crime (UNDOC), World Health Organization (WHO) and the Union for International Cancer Control (UICC), with the overall objective of leading a coordinated worldwide response to improving access to controlled drugs for medical purposes, while controlling for abuse and diversion, therefore increasing the number of patients globally receiving appropriate treatment for conditions requiring the use of such medication.

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[3] Ibid.

[4] Ibid.

21. Work on the Joint Global Programme has been piloted in Ghana, with the next phase of implementation focused on Timor-Leste. Currently, funding is available to expand to include the Democratic Republic of the Congo, Panama and Antigua and Barbuda in late 2016.

22. There are three main components around which activities are organized at the country level, upon availability of funding.

Component 1: Undertake regional/country level education and advocacy to increase awareness of the need to improve access to controlled medicines and give momentum to a health systems model of palliative care, including access to controlled drugs for medical purposes.

Component 2: Following evidence-based recommendations, policy guidance and legislative best practices for implementing a national control system allowing for improved access to controlled drugs for medical purposes, review and revise existing regulations and policies.

Component 3: Develop training materials/training package and build capacities in countries to manage controlled drugs with medically sound policy and procedures to ensure patients suffering from pain will be able to access safe, secure and medically monitored pain medication.

Annex

The relevant section of the UNGASS outcome document (S-30/1) "**Operational recommendations on ensuring the availability of and access to controlled substances exclusively for medical and scientific purposes, while preventing their diversion**" contains the following provisions:

"*2. We reiterate our strong commitment to improving access to controlled substances for medical and scientific purposes by appropriately addressing existing barriers in this regard, including those related to legislation, regulatory systems, health-care systems, affordability, the training of health-care professionals, education, awareness-raising, estimates, assessment and reporting, benchmarks for consumption of substances under control, and international cooperation and coordination, while concurrently preventing their diversion, abuse and trafficking, and we recommend the following measures:*

(a) Consider reviewing, within the framework of national legal systems, domestic legislation and regulatory and administrative mechanisms, as well as procedures including domestic distribution channels, with the aim of simplifying and streamlining those processes and removing unduly restrictive regulations and impediments, where they exist, to ensure access to controlled substances for medical and scientific purposes, including for the relief of pain and suffering, as required by the three international drug control conventions and defined by national legislation, while preventing their diversion, abuse and trafficking, and encourage the exchange of information, lessons learned and best practices in designing and implementing regulatory, financial, educational, administrative and other related measures;

(b) Strengthen, as appropriate, the proper functioning of national control systems and domestic assessment mechanisms and programmes, in cooperation with the International Narcotics Control Board, the United Nations Office on Drugs and Crime, the World Health Organization and other relevant United Nations system agencies, to identify, analyse and remove impediments to the availability and accessibility of controlled substances for medical and scientific purposes, within appropriate control mechanisms, as required by the three international drug control conventions and taking into account the publication entitled "Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines" and, for that purpose, consider the provision of technical and financial assistance, upon request, to developing countries;

(c) Expedite, in accordance with national legislation, the process of issuing import and export authorizations for controlled substances for medical and scientific purposes by using the above-mentioned guidance and the International Import and Export Authorization System of the International Narcotics Control Board;

(d) Address, at the national and international levels, issues related to the affordability of controlled substances for medical and scientific purposes, while ensuring their quality, safety and efficacy, including limited financial resources and problems in sourcing with regard to these substances, including in cooperation, as appropriate, with the private sector through, inter alia and where needed, expanding the national coverage of distribution networks to rural areas, addressing the link with government regulations, licences and taxation and allowing

appropriately trained and qualified professionals to prescribe, dispense and administer controlled medicines based on their general professional licence, as well as, where appropriate, the manufacture of generic pharmaceutical preparations that are bioequivalent and cost-effective;

(e) Take measures, in accordance with national legislation, to provide capacity-building and training, including with the support of relevant United Nations entities such as the World Health Organization and the United Nations Office on Drugs and Crime, targeted at competent national authorities and health-care professionals, including pharmacists, on adequate access to and use of controlled substances for medical and scientific purposes, including the relief of pain and suffering, consider the development and wider implementation of relevant clinical guidelines on the rational use of controlled medicines, and conduct appropriate awareness-raising campaigns under the coordination of relevant national health authorities and in cooperation with other relevant stakeholders;

(f) Develop national supply management systems for controlled substances that comprise selection, quantification, procurement, storage, distribution and use, strengthen the capacity of competent national authorities to adequately estimate and assess the need for controlled substances and paying special attention to essential medicines, as defined by national legislation, taking due note of the Guide on Estimating Requirements for Substances under International Control,[8] *and enhance domestic data-collection mechanisms in order to present the International Narcotics Control Board with estimates on the consumption of drugs used for medical and scientific purposes;*

(g) Continue to regularly update the Model Lists of Essential Medicines of the World Health Organization, enhance collaboration among Member States and the treaty bodies with scheduling responsibilities, leading to informed and coordinated scheduling decisions by the Commission on Narcotic Drugs that take due account of all relevant aspects to ensure that the objectives of the conventions are met, and review national lists of controlled substances and national lists of essential medicines, as appropriate."

8 International Narcotics Control Board and World Health Organization (Vienna, 2012).