

4. The therapeutic use of cannabinoids

287. A growing number of Governments around the world are authorizing the use of cannabinoids for medicinal purposes. Such use is permissible under the 1961 Convention as amended by the 1972 Protocol provided that a number of conditions are met. In several cases, the issue of legitimate access to cannabinoids for medical purposes has been brought to the attention of national and local legislatures and sometimes the courts. In some situations, legislative bodies have passed legislation in an attempt to regulate access and use, or the courts have handed down judgments confirming the right of people to access the medication they need.

288. The 1961 Convention addresses cannabis, cannabis resin and extracts and tinctures of cannabis, and places them in Schedule I (substances whose use should be limited to medical and scientific purposes), and cannabis and cannabis resin are also controlled under schedule IV (substances liable to abuse and to produce ill effects and such liability is not offset by substantial therapeutic advantages). The 1971 Convention lists in Schedule II *delta-9-tetrahydrocannabinol* (THC) obtained through chemical synthesis.

289. There is a large variety of preparations containing cannabinoids in various regions of the world, with different dosage forms and concentrations of active and psychoactive ingredients, and using different routes of administration. They are used for the alleviation of a wide range of symptoms. While there are indications that some cannabinoids could be used for the treatment of certain health conditions and while some countries have authorized their medical use, evidence for their therapeutic value is not conclusive and — more importantly — there is no clarity about the composition of medications containing cannabinoids (active principles and dosage), the best route of administration (the medical community generally agrees that smoking is not recommended), or the side effects.

290. Even though there is still insufficient evidence for the therapeutic value of cannabinoids, the 1961 Convention as amended assigns national authorities the responsibility for permitting its use for medical purposes, as the Board stated in its annual report for 2003. That implies that the requirements of the 1961 Convention as amended are to be fulfilled.

291. The Board is mandated to monitor the implementation of the international drug control conventions. The conventions require parties to ensure the adequate availability of narcotic drugs and psychotropic substances for

medical and scientific purposes, while ensuring that they are not diverted for illicit purposes. In its annual report for 2014, the Board devoted a special topic to the control measures applicable to programmes for the use of cannabinoids for medical purposes pursuant to the 1961 Convention as amended.

292. After detailing the requirements and provisions contained in the Convention, the Board urged “all Governments in jurisdictions that have established programmes for the use of cannabis for medical purposes to ensure that the prescription of cannabis for medical use is performed with competent medical knowledge and supervision and that prescription practice is based on available scientific evidence and consideration of potential side effects”.

293. Article 4 of the 1961 Convention as amended requires parties to take legislative and administrative measures to limit exclusively to medical and scientific purposes the production, manufacture, export, import and distribution of, trade in, use and possession of drugs.

294. According to the Commentary on the Single Convention on Narcotic Drugs, 1961, the term “medical purposes” has not been uniformly interpreted by Governments when applying the provisions of the Convention. The Commentary states: “Its interpretation must depend on the stage of medical science at the particular time in question; and not only modern medicine, sometimes also referred to as ‘western medicine’, but also legitimate systems of indigenous medicine such as those which exist in China, India and Pakistan, may be taken into account in this connexion.”

295. In its annual report for 2003, the Board stated that, because of the differences in the experience of therapeutic usefulness, safety and efficacy of a drug between countries, “it seems that the drafters of the international drug control conventions did not purposely leave the term ‘medical use’ ambiguous but it is that they could not reach agreement on a universal definition.” In the same report, the Board, while reminding parties that the 1961 Convention as amended leaves the definition of the term up to them, stressed that the 1971 Convention requires from WHO an assessment of the “usefulness” of a substance when it is considered for international control. The 1961 Convention as amended also assigns WHO the responsibility of establishing the substance’s liability to abuse and potential therapeutic advantages as part of the scheduling process.

296. In its annual report for 2003, the Board stated that “the usefulness of the drug must take into account the balance between risk and benefit. ... Therapeutic efficacy

and safety are basic conditions that have to be established before the drug can be marketed. Many Governments have accepted the responsibility of ensuring that the drugs made available comply with established standards of efficacy and safety.”

297. In addition to the specific references in the international drug control conventions, the WHO Constitution states that the mandate of WHO is to “develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products” (article 2). Over the years, Member States have relied on WHO for expertise and guidance regarding the regulation, safety and quality assurance of medicines through the development and promotion of international norms, standards, guidelines and nomenclature.

298. In 1999, the World Health Assembly, in its resolution on the revised drug strategy (WHA52.19), urged member States “to establish and enforce regulations that ensure good uniform standards of quality assurance for all pharmaceutical materials and products manufactured in, imported to, exported from, or in transit through their countries” and “to enact and enforce legislation or regulations in accordance with the principles of the WHO Ethical Criteria for Medicinal Drug Promotion, to encourage the pharmaceutical industry and the health community to establish an ethical code, and to monitor drug promotion in collaboration with interested parties”.

299. In the past, the Board has invited WHO to evaluate the potential medical utility of cannabinoids and the extent to which cannabis poses a danger to human health, in line with its mandate under the 1961 Convention as amended. The Board takes note of the recommendation of the thirty-eighth meeting of the WHO Expert Committee on Drug Dependence, held from 14 to 18 November 2016, to conduct pre-reviews of the cannabis plant, cannabis resin, extracts of cannabis and tinctures of cannabis to establish their abuse and dependence potential as well as their therapeutic efficacy and safety for a number of specific medical conditions. The Board also takes note of the 2016 WHO report entitled “The health and social effects of nonmedical cannabis use”.

300. WHO has provided guidance on good manufacturing practice with guidelines on the development of quality management, which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization, clinical trial authorization or product specification. WHO has also developed guidelines on good clinical practice for trials on pharmaceutical products.

301. The medical use of narcotic drugs is considered “indispensable” in the preamble of the 1961 Convention as amended. Therefore, if the symptoms of certain clinical conditions may be relieved by treatment with cannabinoids, it is important for countries to carefully establish the therapeutic value of such treatment through the collection of concrete evidence, and to clearly establish the active principles and the dosages to be used. Several countries have conducted or are conducting studies and trials to establish the best therapeutic applications of cannabinoids for the treatment of certain health conditions.

302. The Board recommends Governments that are considering such medical use of cannabinoids to examine the results of those studies and trials and to ensure that the prescription of cannabinoids for medical use is performed with competent medical knowledge and supervision and that prescription practice is based on available scientific evidence and the consideration of potential side effects. Also, Governments should ensure that pharmaceutical material containing cannabinoids is made available to patients in line with the WHO guidelines mentioned above and with the international drug control conventions.

5. New psychoactive substances

303. Since the publication of its annual report for 2010, the Board has been warning the international community about the problem of trafficking in and abuse of new psychoactive substances. New psychoactive substances are substances that are abused either in their pure form or in a preparation and that may pose a threat to public health, although they are not controlled under the 1961 Convention as amended by the 1972 Protocol, or under the 1971 Convention.⁸⁵ They can be made of natural materials or synthetic substances and are often deliberately chemically engineered to circumvent existing international and domestic drug control measures.

304. New psychoactive substances are a very heterogeneous category. Their number continues to grow in every region of the world. As at September 2017, the UNODC early warning advisory on new psychoactive substances, a system that monitors the emergence of new psychoactive substances as reported by Member States, listed 796 unique substances, a steady increase from the 739 substances reported by 2016. The most reported substances continued to be synthetic cannabinoids, synthetic

⁸⁵Other definitions of new psychoactive substances may also be used occasionally. For example, the definition used for the UNODC early warning advisory encompasses both synthetic and plant-based substances, as well as substances with established medical use.