

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.

cathinones and phenethylamines, which together accounted for over two thirds of all the substances reported. While many of the detected substances do not stay on the market for a long time, at least 76 different types of substances have been involved in incidents taking place in 2017 as at 1 November, according to the INCB Project Ion Incident Communication System (IONICS).⁸⁶

305. To assist Member States in coping with the ever-growing number of new psychoactive substances and the challenges associated with their transient nature, the Board, through Project Ion, provides national authorities with infrastructure to share information in real time on incidents involving new psychoactive substances (such as suspicious shipments, trafficking and manufacture or production) and to follow up on those incidents. The aim of Project Ion is to prevent new psychoactive substances from reaching consumer markets by assisting Governments to conduct their investigations and devising practical solutions. The Project Ion global network of focal points for new psychoactive substances has expanded to 125 countries and territories in every region of the world. The INCB task force on new psychoactive substances, which steers Project Ion activities, held two meetings in 2017.

306. IONICS was launched in December 2014. IONICS is a secured web-based platform for the real-time communication of incidents involving suspicious shipments, or involving trafficking in, the manufacture of or the production of new psychoactive substances. As at 1 November 2017, after almost three years of operation, the system had over 210 users from 75 countries, and almost 1,100 incidents had been communicated through the system. The majority of those incidents involved synthetic cathinones (e.g., methylone (*beta*-keto-MDMA), mephedrone, 4-chloromethcathinone (4-CMC), *alpha*-pyrrolidinopentiophenone (*alpha*-PVP), 3-methyl-*N*-methylcathinone (3-MMC) and *N*-ethylbuphedrone (NEB)) and synthetic cannabinoids (e.g., 5-fluoro-AMB and 5F-APINACA). Since 2016, IONICS has received reports of at least 25 incidents involving five types of fentanyl analogues: acryl fentanyl, carfentanil, furanyl fentanyl, (iso)butyryl fentanyl and *para*-fluorofentanyl. The incidents were communicated by three countries in Europe. Information communicated through IONICS has triggered several follow-up investigations in the countries of destination and origin.

⁸⁶As IONICS is a communication platform through which registered users from participating national authorities voluntarily exchange information related to a limited number of incidents, data from IONICS, including the number of substances reported during a certain period of time, do not represent a comprehensive view of NPS situations in the world.

307. In March 2016, in response to growing concerns over risks of synthetic opioid abuse and overdoses in North America spreading worldwide, the INCB task force on new psychoactive substances decided to pursue operational activities to examine global patterns in the sources of, the flows of, the illicit manufacture of and trafficking in fentanyl, designer fentanyls, other opioid-type new psychoactive substances and their precursors. Following the task force's decision, the Board, in early 2017, conducted a survey on fentanyls. The survey was focused on target substances encountered in 2015 and 2016.

308. Forty-nine countries and territories, as well as the European Commission, returned the questionnaire, providing information about the situation in 58 countries and territories. Twenty countries from Europe returned the questionnaire and the European Commission supplemented information on nine countries that did not return the questionnaire directly. The results therefore describe the situation in Europe in greater detail than they do for other regions, and they should not be understood to give a comprehensive picture of opioid prevalence in the world.

309. Forty types of opioids (fentanyl, fentanyl analogues and other opioids) were encountered in 37 countries and territories; 26 of those were in Western and Central Europe, 2 in South-Eastern Europe, 2 in East and South-East Asia, 3 in West Asia, 3 in North America and 1 in Oceania. The substances had originated from 18 countries and territories; 13 of those were in Western and Central Europe, 2 in East and South-East Asia, 2 in North America and 1 in Eastern Europe. The risks of synthetic opioid abuse and overdoses spreading worldwide appear to be serious, as synthetic opioids are being seized in various parts of the world.

310. New psychoactive substances are traded in part through online platforms. Unlike narcotic drugs and psychotropic substances under international control, which are often traded through the so-called darknet, new psychoactive substances, in most cases, are openly sold on the ordinary Internet, such as in online new psychoactive substances shops and business-to-business trading platforms. Dedicated online shops selling new psychoactive substances are sometimes closed down by the law enforcement authorities of the countries where they are located. By contrast, sale offers and purchase requests regarding new psychoactive substances exchanged through legitimate business-to-business trading platforms are often not investigated because the platforms themselves are legitimate and are often located in third-party jurisdictions where neither the sellers nor the buyers are located.

311. As national control is expanded to cover more new psychoactive substances, there is an increased risk of

legitimate business-to-business trading platforms being used for the sale and purchase of substances under national control. While misuse of legitimate platforms for illicit purposes needs to be prevented, hindering the development of legitimate economic activities through the Internet needs to be avoided. **The Board encourages Governments to consider appropriate measures, in accordance with national law, to monitor and act on attempts to trade in new psychoactive substances through online trading platforms, including, possibly, voluntary monitoring and information-sharing, and to consider involving the operators of trading platforms.**

6. Illegal Internet pharmacies and the sale of internationally controlled drugs on the Internet

312. The Internet has permeated every aspect of people's lives in recent years and that includes matters of health. This has made it possible to buy medicines online, including those containing internationally controlled drugs. Unfortunately the online sale of medicines is sometimes conducted illegally, since some Internet pharmacies operate without licenses or registration and dispense pharmaceutical preparations containing narcotic drugs and psychotropic substances without requiring a prescription.

313. Illegal Internet pharmacies usually have dedicated websites. Those may be portal sites that advertise drugs and act as conduits to other websites where customers place their actual orders and pay. The drugs most frequently sold online include narcotic drugs, mostly oxycodone, hydrocodone, dextropropoxyphene and other opioids, and psychotropic substances, in particular benzodiazepines, stimulants and barbiturates. Precursors, i.e. chemicals that are frequently used in the illicit manufacture of narcotic drugs and psychotropic substances, are also traded online. In recent years the Internet-facilitated trade in precursors has expanded, an issue that is further examined in a special section of the report of the Board for 2017 on the implementation of article 12 of the 1988 Convention.⁸⁷

314. The scope of the phenomenon and the number of customers frequenting illegal Internet pharmacies is hard to gauge, as there have been no global data surveys or extensive clinical case studies on the matter. The Alliance for Safe Online Pharmacies, a non-governmental organization based in the United States, estimates that some

36 million Americans have purchased medications without a prescription at some point in their lives. A scientific systematic review has found that the number of people reporting that they have purchased medicines online, mostly from studies in the United States, ranges between 1 and 6 per cent of the population, a figure that is slightly higher in studies where the intention to buy online was also considered.

315. Illegal Internet pharmacies are often international operations with servers, pharmacy shipping operations and other parts of the business located in different countries. Most illegally operating Internet pharmacies do not require prescriptions from their customers at all, while some issue "prescriptions" after a brief online consultation or the completion of a short questionnaire. Illegally operating Internet pharmacies are the main sources of prescription-only medicines sold without prescriptions and of falsified prescription-only medicines.

316. Actions taken against illegal Internet pharmacies include helping the general public to identify websites that sell medicines legally. In the European Union, a common logo has been established indicating in which member State an online pharmacy or other type of online medicine retailer is based. The logo appears on the websites of all online medicine retailers registered with one of the national regulatory authorities in the European Union. A similar scheme exists in the United States, where the dot-pharmacy programme of verified websites is operated by the National Association of Boards of Pharmacy with the aim of ensuring that participating pharmacies are operating safely and legitimately.

317. To assist Governments in their endeavours to address the challenge of illegal Internet pharmacies, the Board has published the *Guidelines for Governments on Preventing the Illegal Sale of Internationally Controlled Substances through the Internet*,⁸⁸ available on the Board's website (www.incb.org). The *Guidelines* were developed with the help of national experts and relevant international organizations such as the International Criminal Police Organization (INTERPOL), the Universal Postal Union, Internet service providers, financial service providers and pharmaceutical associations. The publication contains 25 individual guidelines that cover legislative and regulatory provisions, general measures and national and international cooperation. Their aim is to provide authorities assistance in formulating national legislation and policies to prevent the illegal sale of internationally controlled drugs through the Internet. Illegal Internet pharmacies are a growing phenomenon that has the potential to cause serious public health problems.

⁸⁷E/INCB/2017/4, chap. IV.

⁸⁸United Nations publication, Sales No. E.09.XI.6.