IV. Implementation of recommendations made by the Board and of the recommendations contained in the outcome document of the special session of the General Assembly on the world drug problem held in 2016

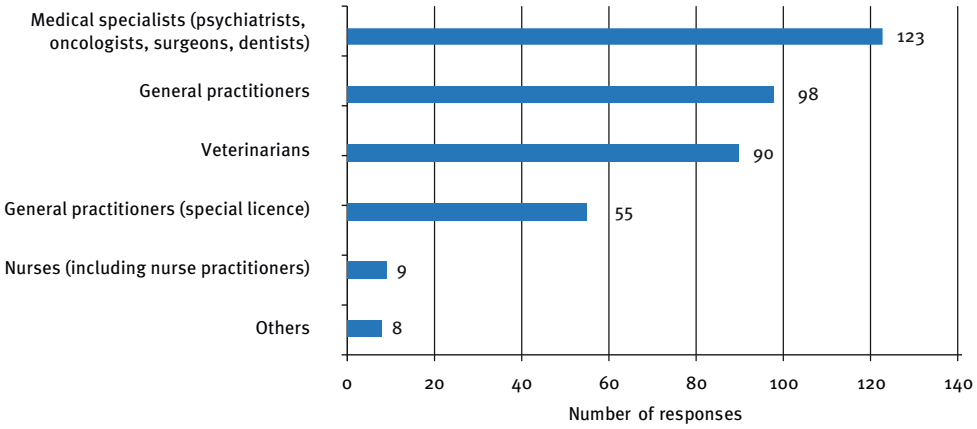
A. Member States

Legislation and regulatory systems

51. Both the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016 contain recommendations related to legislation and regulatory systems. Some of the recommendations concern the need for Governments to review national legislation and regulatory and administrative mechanisms to simplify processes and remove unduly restrictive regulations. In the responses to the questionnaire by INCB in 2018, 40 per cent of the 130 competent national authorities that responded reported that, in the last five years, legislation and/or regulatory systems in their countries had been reviewed and/or changed. The same percentage reported that those reviews and/or changes had affected the availability of controlled drugs. The competent authorities of most of the countries where changes had been made to legislation and/or regulations referred to general changes, while some specified that changes had been made to the status of control of some substances or that electronic measures to facilitate prescription and procurement had been introduced.

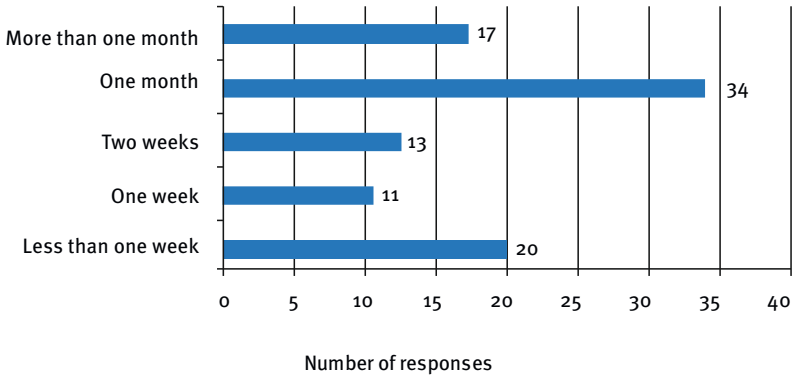
52. In a much smaller percentage of the countries for which responses were submitted (16 per cent), legislation and regulations had been modified in order to implement the recommendation to increase the base of health-care professionals able to prescribe controlled substances (opioid analgesics and psychotropic substances). Prescription of opioid analgesics and psychotropic substances were allowed by medical specialists in 123 countries and by general practitioners without a special licence in 98 countries. By contrast, nurses, including nurse practitioners, can prescribe controlled substances in only 9 countries (see figure XII). That

Figure XII. Who can prescribe opioid analgesics and psychotropics



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

Figure XIII. Prescription validity for opioid analgesics



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

limitation was reported as having a negative impact on access to services for people in need of palliative care and other treatment, in particular in low- and middle-income countries without decentralized health-care services and where the number of doctors is insufficient.

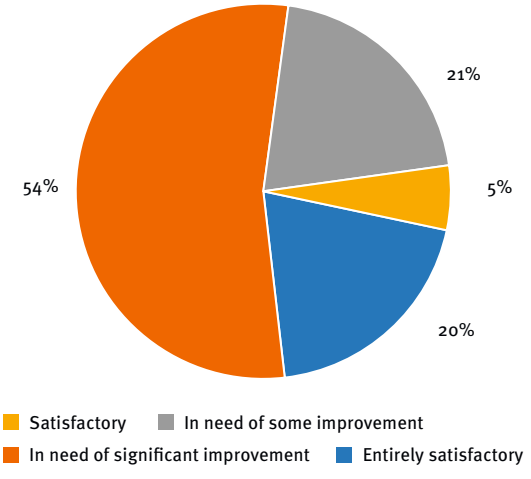
53. A second medical opinion for the prescription of opioid analgesics was required in 12 per cent of countries and in 9 per cent of countries for the prescription of psychotropic substances. In 22 per cent of countries, the prescription of opioid analgesics and psychotropic substances was subject to special regulatory requirements and legal sanctions existed in 26 per cent for unintentional mistakes made during the handling of opioid analgesics. That legal threat was reported as a major factor in the decision of some doctors not to procure, stock or prescribe opioid analgesics, thereby contributing to limiting access to those substances.

54. In most of the countries from which replies to the questionnaire were submitted (65 per cent for opioid analgesics and 60 per cent for psychotropic substances), measures had been taken to prevent the emergence of unregulated markets, the illicit manufacture of controlled substances and the manufacture of counterfeit medicines.

55. In relation to prescription policies for opioid analgesics, information on the validity period of prescriptions was provided for 95 countries (see figure XIII). In most of the 27 countries for which a period was not specified, the competent national authority indicated that the validity was either open for the prescriber to define or that the issue was not addressed in legislation or regulations.

56. The questionnaire also included a question on whether the medical and pharmaceutical sectors were aware of new legislative and administrative measures related to controlled substances. Most (75 per cent) of the competent national authorities that replied considered the level of awareness to be either in need of some improvement or in need of significant improvement (see figure XIV).

Figure XIV. Awareness of medical and pharmaceutical sectors of new measures, assessment by competent national authorities of responding countries



Health systems

57. The procurement of opioid analgesics and psychotropic substances alone will not solve the problem of the limited access experienced in many countries. For that reason, both the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016 contain recommendations on improving health systems to ensure that controlled substances are prescribed and administered in a rational and efficient manner. In relation to opioid analgesics, it is important for Governments to have a palliative care policy and an appropriate infrastructure in place. In the INCB questionnaire from 2018, competent national authorities were asked whether new palliative care policies had been introduced in response to resolution WHA67.19, adopted by the sixty-seventh World Health Assembly on 24 May 2014, entitled "Strengthening of palliative care as a component of comprehensive care throughout the life course". A slight majority (53 per cent) of the responding authorities indicated that new palliative care policies and measures had been introduced in their countries.

58. Another question was whether the health-care infrastructure of the country was appropriate and well resourced to ensure not only the availability of opioid analgesics but also their provision in the context of the broader delivery of palliative care. Of the competent national authorities that responded, 43 per cent reported that their country's health-care infrastructure was appropriate and 13 per cent reported that their country's health-care infrastructure was entirely appropriate; 30 per cent stated that their country's health-care infrastructure needed some improvement and 14 per cent reported that it needed significant improvement. More than two thirds of the responding competent national authorities stated that low-cost, home-based palliative care was considered a means of addressing the limitations of the national health-care systems.

Affordability

59. Another important aspect of improving availability is ensuring that opioid analgesics are affordable and easy to access by patients. In that connection, INCB has recommended that countries:

(a) Improve access to essential drugs in general, and to opioid analgesics in particular;

(b) Ensure funding for the purchase of opioid analgesics;

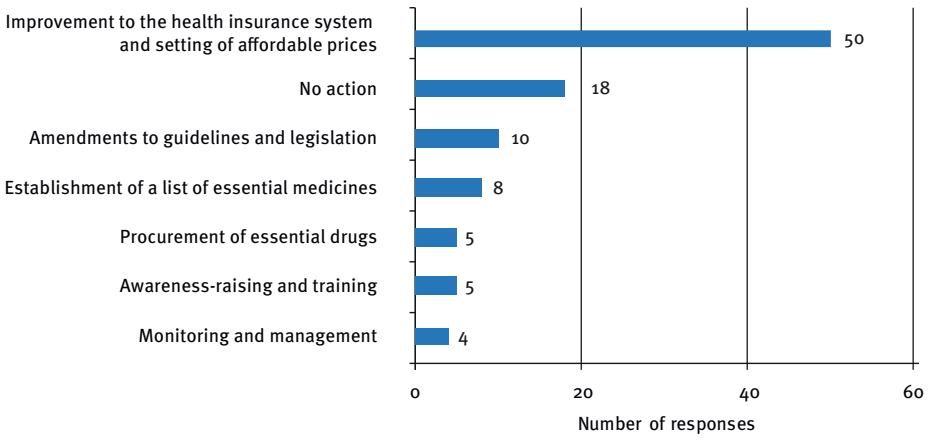
(c) Develop and improve health insurance and reimbursement schemes that guarantee access to medications.

60. Of the 104 competent national authorities that responded to the question on accessibility, 50 said that steps had been taken towards improving the health insurance system of their countries and setting affordable prices; 18 reported that no action had been taken in their countries in that regard, as the situation was satisfactory. For more detailed information on the measures taken in the countries for which responses were submitted, see figure XV.

61. Of the 115 competent national authorities that provided data on the availability of budget and resources, the majority (77 per cent) stated that they had sufficient resources for the purchase of opioid analgesics.

62. Mostly citing limited or reduced budget and a general lack of resources, 23 per cent of responding competent national authorities stated that they did not have sufficient resources for the purchase of opioid analgesics.

Figure XV. Steps taken to improve accessibility by patients to essential medicines, including opioid analgesics



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

63. Again, the procurement of pain relief drugs or psychotropic substances and the existence of appropriate health systems alone will not ensure access to medications for pain management or mental health treatment. The affordability of such drugs and substances for patients and the existence of health insurance and reimbursement schemes play a crucial role in ensuring availability. The majority of competent national authorities (76 per cent) indicated that a health insurance scheme existed in their country. Some authorities stated that the absence of health insurance schemes was because the Government provided free medicines to patients. In the countries with health insurance schemes in place, 31 per cent had reimbursement systems and 33 per cent had governmental and private health insurance systems. Some authorities (21 per cent) reported that it was obligatory for all citizens and non-citizens to have health insurance. In 15 per cent of the countries for which responses were provided, Governments encouraged companies to offer health insurance schemes for their employees.

Training of health-care professionals

64. Two of the recommendations contained in the supplement to the INCB annual report for 2015 were for palliative care to be included in the educational curricula of medical schools and for continued education, training and information on palliative care, including on rational use and on the importance of reducing prescription drug abuse, to be provided for health-care professionals.

65. The responses to the 2018 questionnaire indicated that palliative care was included in the curricula of medical schools in 71 countries (62 per cent of those for which responses were provided); palliative care was not included as a discipline of the medical education programme in 43 countries (38 per cent). In those 43 countries, palliative care education was provided in 11 countries only for a limited number of medical specialities (e.g., oncology), medical schools did not exist in 9 countries and plans to include palliative care in the curriculum of medical schools in the future existed in 4 countries. In their responses, some authorities mentioned that medical schools were responsible for organizing their own programmes, some mentioned an absence of political willingness and some mentioned a lack of financial and human resources as justification for a lack of action in that area.

66. Continued education, training and information on palliative care, including on rational use and the importance of reducing prescription drug abuse, were provided to health-care professionals in 76 countries (68 per cent); continuous education was not implemented in 36 countries (32 per cent). Doctors and health-care professionals were educated on the rational use of controlled drugs in 72 countries (63 per cent); such education was not provided in 41 countries (37 per cent) owing to a lack of resources or because it was not a priority for the Government.

67. A number of authorities responding to the questionnaire were not aware of improvements in the education curricula of medical schools in the previous five years in terms of the importance of reducing prescription drug abuse (37 per cent), the rational use of narcotic drugs and psychotropic substances (31 per cent) and prevention of misdiagnoses and inappropriate prescribing (33 per cent). About 18 per cent of the authorities responded that the curricula in the above-mentioned areas had not been updated.

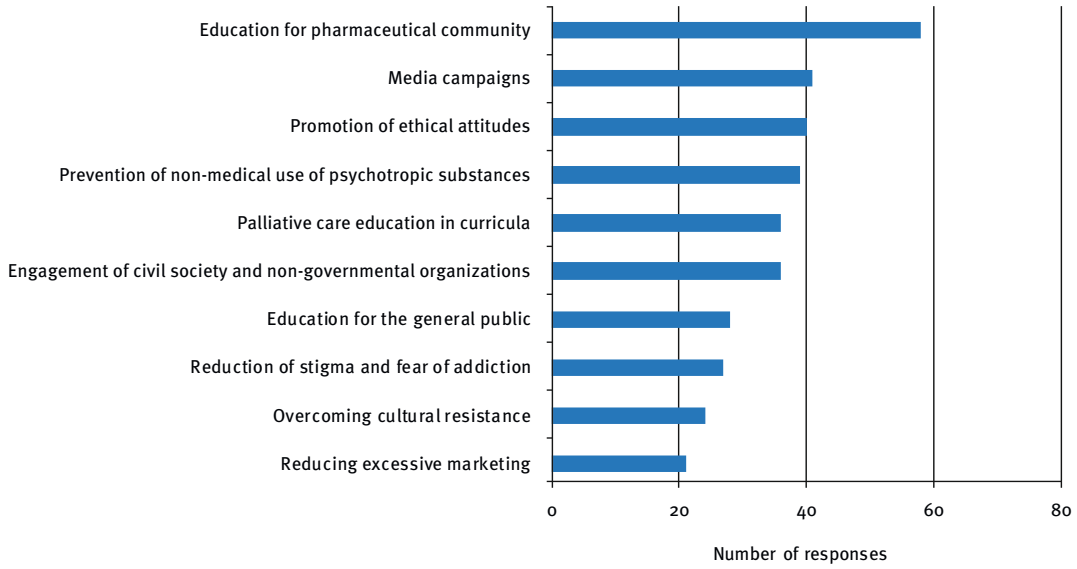
68. The majority of responding authorities (92 authorities, or 81 per cent) stated that narcotic drugs and psychotropic substances were prescribed in conformity with sound medical practice and that the rational use of such substances was promoted in their countries, alongside the need to take the measures necessary to limit their use to actual medical needs.

Education and awareness-raising

69. The analysis of the impediments to access to controlled substances shows that lack of awareness and fear of addiction are the main factors mentioned by the competent national authorities responding to the INCB questionnaire. The importance of cultural attitudes as a factor has been declining since 2014 but is still reported by some competent national authorities. For those reasons, both the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016 contained recommendations on using awareness-raising campaigns and educational programmes to overcome cultural resistance and the stigma associated with the consumption of opioid analgesics or psychotropic substances.

70. Most of the competent national authorities reported that action had been taken in their countries through specific campaigns and awareness-raising programmes targeting pharmaceutical companies and involving competent national authorities and interest groups (e.g., professionals and consumers). In addition, public awareness-raising campaigns through the media and the promotion of ethical attitudes among medical doctors and pharmaceutical companies were mentioned by a significant number of competent national authorities responding to the questionnaire. A smaller number of authorities reported that specific initiatives to reduce excessive marketing and overcome cultural resistance had been carried out (see

Figure XVI. Education and awareness-raising initiatives reported by competent national authorities



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

figure XVI). The responses provided show that the majority of Governments are taking serious steps regarding education and awareness-raising. However, the information submitted on the questionnaires does not permit the impact of the various initiatives to be evaluated.

Estimates, assessments and reporting

71. In the supplement to its annual report for 2015, INCB noted that some competent national authorities were unable to properly estimate their needs for opioid analgesics and to monitor the consumption of those substances. Consequently, the Board recommended that authorities made use of the *Guide on Estimating Requirements for Substances under International Control*, developed in 2012 by INCB and WHO, and to use improved electronic tools, such as the electronic International Import and Export Authorization System (I2ES) for narcotic drugs and psychotropic substances, which had been developed by INCB in cooperation with the United Nations Office on Drugs and Crime (UNODC). As noted earlier, import and export control measures are one of the main impediments to ensuring the availability of controlled substances for medical uses reported by Member States, and the I2ES system has been developed by INCB to streamline and simplify the import and export processes and facilitate the availability of medications containing controlled substances.

72. In the 2018 survey, the vast majority of responding authorities (105) reported that they were aware of the existence of the *Guide on Estimating Requirements for Substances under International Control*. Two thirds of them found it to be extremely useful for their work and one third found it helpful to some extent.

73. Among the authorities making use of the *Guide on Estimating Requirements for Substances under International Control* to estimate their country's requirements for narcotic drugs and assess the availability of psychotropic substances, 48 reported using the consumption-based method (i.e., the average from the past three years' consumption, increased by 10 per cent to cater for possible variations in demand). That method was also used by another 30 authorities in combination with an analysis of other factors such as overall medical needs, total imports, exports and morbidity. Sixteen authorities reported establishing their estimates by compiling the requirements of pharmaceutical companies, pharmacies or hospitals; only two authorities reported calculating estimate requirements from import data.

74. Furthermore, 110 authorities reported that their estimates of requirements of narcotic drugs and assessment of the availability of psychotropic substances were appropriate and realistic. They confirmed that they considered variations in demand, including a margin for unforeseeable increases. Only 10 authorities replying to the questionnaire affirmed that their estimates and assessments were not appropriate or realistic.

75. The competent national authorities of 76 countries reported that they regularly contacted pharmaceutical companies or other stakeholders licensed to manufacture, import, export or stock controlled substances. Most of the

authorities sent out forms in order to receive information and others shared databases with licensed institutions; 28 authorities reported that they extracted estimates and assessment figures from import and export authorizations and consumption data.

76. The competent national authorities of 50 countries reported that they had established electronic tools for processing import and export authorizations. Among those, 17 countries used a national system, 14 countries used the UNODC National Database System (NDS), 4 countries used NDS combined with I2ES, 4 countries used I2ES alone and 6 countries were in the process of introducing I2ES.

77. Electronic systems to process import and export authorizations did not exist in 66 countries. The reasons for that included: *(a)* a lack of awareness of I2ES (11 countries); *(b)* a lack of resources (9 countries); *(c)* the installation of I2ES had been requested (7 countries); *(d)* a system was not needed because few authorizations were processed (4 countries); *(e)* I2ES was not used by trading counterparts (2 countries); and *(f)* paper documentation was needed by law (1 country).

B. Civil society organizations

78. The present section presents the viewpoint of civil society regarding the implementation of the recommendations contained in the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016. It includes information submitted to INCB by 30 civil society organizations based in 23 countries in Asia, Africa, Europe and the Americas, with geographical representation at the local, national, regional and global levels.

79. In the context of their work, civil society organizations reported several factors that unduly limited the availability of narcotic drugs and psychotropic substances needed for medical or scientific purposes. Restrictive legislation and policies were mentioned by six organizations as impediments to availability. However, most of those replies referred to difficulties related to the use of cannabis for medical and scientific purposes. An onerous regulatory framework for the prescription of narcotic drugs for medical use was mentioned by five organizations. That included an insufficient number of doctors prescribing, a lack of prescription forms and cumbersome processes for obtaining prescription forms. A lack of financial resources was mentioned by four organizations in relation to the prices of medication and to insufficient government resources to support availability. Four organizations reported that they perceived no obstacles to availability in their countries.

Legislation and regulatory systems

80. Civil society organizations responding to the questionnaire reported positive changes in the area of legislation and regulations aimed at simplifying and streamlining processes in order to remove unduly restrictive regulations to ensure accessibility of controlled substances and maintain adequate control systems. In some cases, those changes had improved the availability of medicines for cancer pain and palliative care in particular. Approximately 57 per cent of civil society organizations that responded to the questionnaire reported having observed changes to or reviews of legislation or regulations in order to simplify and streamline processes and remove unduly restrictive regulations to ensure accessibility of controlled substances and maintain adequate control systems in their countries. Some of the organizations that reported no such action explained that their country already had a high level of availability and access to medicines containing controlled substances and that there was no need for further improvements.

81. About 40 per cent of respondents reported the introduction of new palliative care policies or measures, for example, in response to World Health Assembly resolution WHA67.19. The development of national programmes focusing on or including palliative care was frequently mentioned in the context of removing barriers to access. The creation of medical specialization programmes in pain treatment and palliative care, as well as partnerships with civil society, was also mentioned.

82. About 43 per cent of the responding organizations observed measures implemented by Governments to allow a larger base of health-care professionals (including trained general practitioners and nurses) to prescribe opioid analgesics and/or psychotropic substances to increase availability, particularly in remote or rural areas. Other measures to improve availability included the provision of opioid-substitution treatment in prisons and the prescription of controlled medication through telecommunications technology.

83. According to the civil society organizations that responded to the questionnaire, public policies on the availability of controlled substances, including national plans on palliative care, were lacking in some countries. In other countries, there are no departments or focal points appointed under national health institutions (e.g., the ministry of health) to oversee the adequacy of consumption levels together with competent national authorities. In some cases, it was reported that legislation had become more restrictive regarding access to controlled substances.

84. The responding organizations stated that legislation and punitive sanctions for accidental breaches could be so strict that they virtually prohibited the provision of care, including pain treatment and opioid-substitution treatment. The absence of clear guidelines and medical protocols created a situation of legal uncertainty that could prevent health professionals from prescribing.

85. The restrictions imposed by national legislation and regulations also affected research on the uses of controlled substances. The high prices of licences and punitive sentences for accidental breaches of regulations by researchers and universities were said to be among the elements that may be hindering research on the medical use of such substances. Those restrictions affected all controlled substances, but especially the ones for which the efficacy of medical use was still the subject of further research, such as cannabis, fentanyl analogues and ketamine analogues.

Health systems

86. Civil society organizations reported that, although, overall, national availability seemed to be adequate, in some areas, in particular rural ones, inadequate availability remained a problem, including in high-income countries. Inadequate availability was also reported to affect particular population groups, such as indigenous and rural communities, children and people living on the street.

87. Civil society organizations noted that the limited number of physicians able to prescribe, combined with geographical accessibility, was an obstacle in many countries. In such a context, the prescription of controlled medication through so-called e-prescribing might contribute to ameliorating the situation. It had already been put into practice in some countries where, for example, physicians used telecommunications technology to prescribe to patients receiving opioid-substitution treatment.

88. Other challenges reported by civil society included the relatively low number of qualified physicians to deal with the demand for palliative care and with overdose and suicide.

Affordability

89. Civil society organizations reported that, in some countries, a stronger financial commitment from Governments and donors was needed to overcome the availability gap. The recognition of the problem of a lack of awareness by authorities was often not followed up with sufficient resources to expand the provision of health services, including controlled substances, beyond pilot schemes. In many settings, patients relied solely on non-governmental organizations to access the medication they needed. Even in high-income countries, people not covered by health-care systems encountered difficulties in accessing the medications that they needed, as a result of their high costs.

90. It was reported that countries in Africa were focusing on the possibility of formulating oral morphine from morphine powder for use by patients.

Training of health-care professionals

91. About 37 per cent of the civil society organizations that responded to the questionnaire were directly engaged in education and training activities. Moreover, about 64 per cent of the organizations reported having knowledge of country-provided continued education, training and information on palliative care for health-care professionals, including on rational use and the importance of reducing prescription drug abuse.

92. However, the organizations reported that training was still much needed in various parts of the world: while controlled medicines might be available in many countries, doctors were reluctant to prescribe in some of them as a result of limited understanding of the risks and benefits of the substances. The issue of the quality of training provided, which is key to ensuring successful treatment, was also mentioned by respondents.

93. Another important factor mentioned by organizations in their replies was the training provided to health professionals by private pharmaceutical companies. It was reported that some pharmaceutical companies imparted erroneous or misleading information to doctors without being held accountable for it. Without additional training or reversal of that situation, doctors might carry on prescribing on the basis of erroneous information.

Education and awareness-raising

94. Civil society organizations reported being particularly active in the area of education and awareness-raising at the local, national, regional and international levels: about 37 per cent of organizations that responded to the questionnaire were working on advocacy and public policy areas and about 27 per cent were working with academia and in the area of research. Those were described as key areas where civil society organizations had the opportunity to mobilize decision makers with regard to availability and, in the case of research, develop and disseminate more science-based information to contribute to the debate.

95. Civil society organizations reported conducting their work on education and awareness-raising through

multi-stakeholder workshops, in which recommendations and guidelines could be developed, as well as working-level and high-level meetings, including inter-ministerial ones. Organizations reported focusing on the delivery of lectures, courses and manuals, the organization of congresses and conferences and the publication of technical reports and academic journals. They had contributed to the inclusion of palliative care and pain relief in medical and nursing curricula and were developing clinical studies on new uses of controlled substances. The launch of information campaigns and the promotion of networks were also mentioned among their main activities.

96. It was reported that the African Palliative Care Association (APCA) had developed the *APCA Atlas of Palliative Care in Africa,* which provided Africa-focused indicators for measuring progress in the provision of palliative care in the continent, as well as up-to-date country-specific information, including the availability of opioids for pain management. Africa is the continent with the lowest levels of consumption of opioid analgesics in the world.

C. International community

97. The international community has reached consensus on the need to improve availability and access to controlled substances for medical and scientific purposes, as reflected in the outcome document of the special session of the General Assembly on the world drug problem held in 2016. Although not exclusively driven by that consensus, global awareness of the need for pain management and palliative care has been steadily increasing. Specific steps in that direction include the publication by WHO of *Planning and Implementing Palliative Care Services: a Guide for Programme Managers*;[28] the addition, in 2017, of a basic palliative care package for cancer patients as a priority intervention under the WHO *Global Action Plan for the Prevention and Control of Non-Communicable Diseases 2013–2020*; and the preparation of new guidelines for the clinical management of cancer pain in adults,[29] all of which provide guidance on the appropriate use of controlled substances in pain management. Similarly, *Improving Access to and Appropriate Use of Medicines for Mental Disorders*[30] contains recommendations on the rational use of preparations containing controlled psychotropic substances.

98. Capacity-building and development support are being provided by Member States, international organizations and non-governmental organizations to countries and populations in need of support to tackle the access and availability gap. INCB, WHO and UNODC are among the organizations that have been implementing capacity-building initiatives, with the support of Member States. Those efforts need to be scaled up in order to provide sufficient and sustainable support to Governments to close the access and availability gaps in the shortest possible time span.

99. To supplement and increase the effectiveness of the support provided by INCB to Governments to ensure the availability of internationally controlled substances for medical and scientific purposes, INCB launched INCB Learning in 2016. The objective of INCB Learning is to support Governments in the implementation of the operational recommendations on ensuring access to controlled substances for medical and scientific purposes contained in the outcome document of the special session of the General Assembly held in 2016. In the period since its inception, INCB Learning has conducted regional training and awareness-raising activities in Africa, Asia, Europe, Central America and Oceania. INCB Learning has also developed a suite of e-learning courses to support the ongoing training of the staff of competent national authorities responsible for providing the estimates of and assessments for narcotic drugs and psychotropic substances needed at the national level for medical purposes, facilitating related international trade and fulfilling the reporting obligations under the drug control treaties.

100. INCB commends the international community, including Member States, international organizations and civil society, on their efforts to improve the lives of people worldwide through the facilitation of the provision of adequate treatment with appropriate medication, and encourages continued and strengthened action in that area.

[28] Geneva, 2016.

[29] WHO (forthcoming).

[30] WHO (Geneva, 2017).