

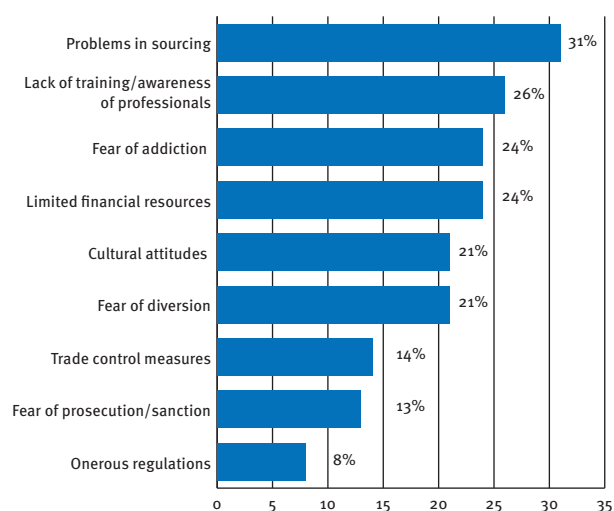
## II. Impediments to ensuring the adequate availability of controlled medicines

24. Over the years, INCB has reviewed and reported on the impediments to the availability of controlled substances. The questionnaire sent to competent national authorities in 2022 contained a general question, which had also appeared in previous surveys, about the factors that competent national authorities considered to be obstacles that unduly limited the availability of controlled substances for medical purposes. The analysis of the trend of the responses over the years (1995, 2010, 2014, 2018 and 2022) indicates a continuing decreasing trend in the mention of impediments associated with the requirements of the 1961 Convention and the 1971 Convention, such as onerous regulations and trade control measures. In 1995, more than 50 per cent of survey respondents cited onerous regulations as an obstacle to ensuring availability, while in 2022 fewer than 10 per cent of respondents did so. Similarly, trade control measures were first mentioned in 2014, in 22 per cent of the responses, but they were mentioned in only 14 per cent of responses in 2022. In 2022, more respondents cited limited financial resources and sourcing problems as an obstacle, and that increase is probably attributable to the COVID-19 pandemic, which resulted in varying degrees of social and economic difficulties on a global scale (see figures 1 and 2).

25. The obstacles to ensuring availability that are more closely related to cultural bias (cultural attitudes) and not necessarily based on evidence (fear of diversion, fear of

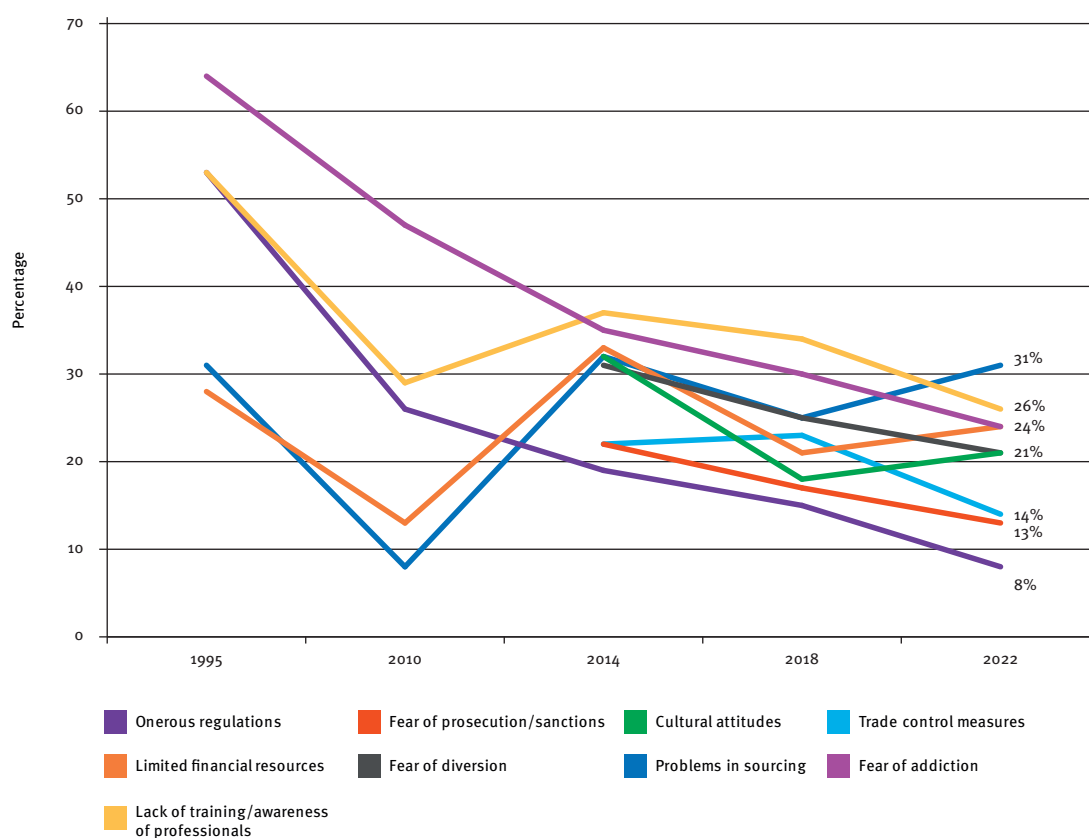
addiction, fear of prosecution) had different trends. Fear of diversion and fear of addiction increased slightly in comparison with 2018, while fear of prosecution and cultural attitudes continued to decrease. Lack of training or professional awareness remained a major obstacle (26 per cent of responses), although it was cited slightly less in 2022 than in 2018.

**Figure 1. Impediments to availability as mentioned by competent national authorities (2022)**



Source: INCB survey of Member States, 2022.

**Figure 2. Impediments to availability as mentioned by competent national authorities (1995, 2010, 2014, 2019 and 2022)**

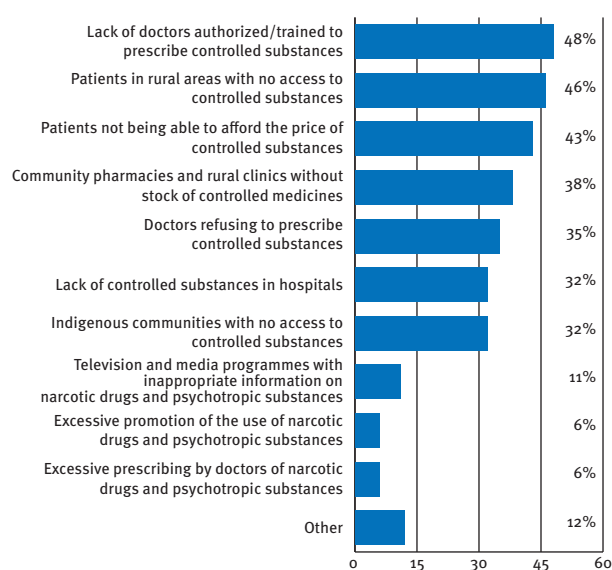


*Note:* The above figure has been developed to illustrate general trends. Data from questionnaires from different years are not directly comparable owing to variations in the number of countries that replied to the questionnaires and in which countries replied.

*Source:* INCB surveys of Member States of 1995, 2010, 2014, 2018 and 2022.

26. The Board, as it did in 2018, asked civil society organizations to provide their view on the progress made. The Board received responses from 65 civil society organizations based in 36 countries. Most of the civil society organizations that answered were from Asia (22), followed by Africa (16), Europe (13), Central and South America (10), North America (3) and Oceania (1). When asked, 65 per cent of civil society organizations reported that they had first-hand data and/or knowledge of a lack of availability of controlled substances for patients, and provided relevant information in that regard. Civil society organizations reported several factors that, in the context of their work, unduly limited the availability of narcotic drugs and psychotropic substances needed for medical or scientific purposes. Among the main barriers mentioned were the lack of authorized or trained doctors to prescribe controlled substances, lack of access for patients in rural areas and the unaffordable cost of medicines (see figure 3).

**Figure 3. Impediments in the availability of internationally controlled substances as reported by civil society organizations**



*Source:* INCB survey of civil society organizations, 2022.

## Implementation of recommendations

### 1. Member States

27. The outcome document of the thirtieth special session of the General Assembly, held in 2016, and the INCB supplementary report of 2015 on availability contain a series of operational recommendations relating to national legislation and regulatory systems, the health system, affordability, the training of health-care professionals, education and awareness-raising campaigns, and relating to estimates and the assessment of controlled substances. The questionnaire sent by INCB to countries in 2022 inquired about recent developments in those areas.

### Legislation and regulatory systems

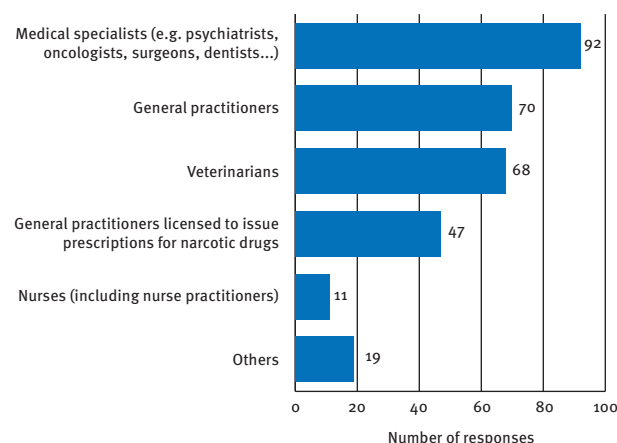
28. A total of 96 countries provided responses to the questionnaire of 2022. Of those, 60 per cent of countries reported that they had reviewed and/or changed their national legislation in the past five years, and 45 per cent had reviewed and/or changed their regulatory and administrative mechanisms in order to ensure accessibility of controlled substances and maintain adequate controls. One fifth of countries responding declared that the new or amended mechanisms affected availability of controlled substances. While competent national authorities of most countries referred to general changes, some countries referred to specific changes to measures related to cancer treatment and palliative care, electronic measures to facilitate prescription and the procurement of controlled substances or to allow the use of cannabis for medical purposes.

29. While nearly all countries do not allow for advertising of controlled substances to the general public (including on the Internet), a small number of countries stated that they had no legislation limiting advertising. In terms of sharing the promotion, information and advertising of controlled substances to the medical and pharmaceutical community, the majority of countries referred to regulatory systems in place to allow for information to be published in medical journals or other print media directed towards that community.

30. A small percentage of countries have in the past five years changed their regulations regarding the prescription

of controlled substances so that a larger base of health-care professionals can prescribe opioid analgesics and psychotropic substances. In 90 countries responding to the questionnaire only medical specialists may issue prescriptions for controlled substances, while in 68 countries general practitioners are allowed to do so without a special licence. In only 10 countries are nurses, including nurse practitioners, allowed to prescribe controlled substances (see figure 4). In addition, in 44 countries, the relevant legislation contains legal sanctions for doctors, pharmacists, nurses and other health personnel who make unintentional mistakes in the handling of opioids. Such legal sanctions are considered to be a major obstacle to rational and appropriate prescribing. Countries that have selected “others” specified practitioners such as midwives, paediatricians, anaesthesiologists and paramedics as well as dentists and dental surgeons and practitioners in private establishments requiring a special licence.

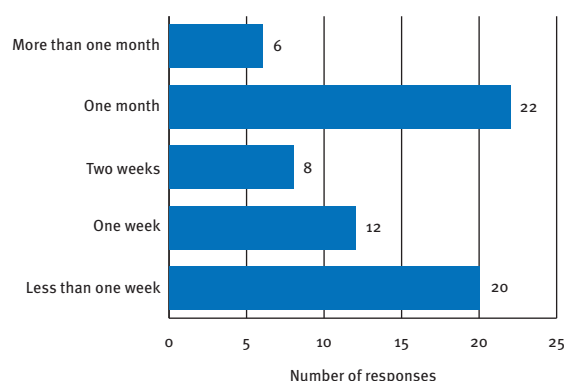
**Figure 4. Who can prescribe opioid analgesics and psychotropic substances**



Source: INCB survey of Member States, 2022.

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

31. In 90 per cent of the countries responding, medical prescriptions for narcotic drugs and psychotropic substances were subject to more stringent regulations than were other prescription medications, including a shorter period of validity and the prohibition of automatic renewals. Three countries reported that prescriptions for medicines containing controlled substances were issued in electronic form only.

**Figure 5. Validity of prescriptions for opioid analgesics**

Source: INCB survey of Member States, 2022.

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

32. With regard to the validity of prescriptions for opioid analgesics, of the 90 countries that responded to the question, 12 countries had changed the period of validity of prescriptions for opioid analgesics during the last five years. Further details were provided by 68 countries (see figure 5), out of which 22 countries had a validity of one month for prescriptions and six countries had a validity longer than one month. Two countries responded that opioid analgesics could be prescribed for up to one year, and 20 countries had a maximum validity of less than one week for such prescriptions. Additionally, 17 countries responded that the validity of prescriptions depended on numerous factors, such as the classification of the opioid analgesic in domestic legislation and the medical evaluation of the individual patient.

## Health system

33. The procurement of opioid analgesics and psychotropic substances alone will not solve the problem of the limited access experienced in many countries. Countries have been called upon to improve health systems to ensure that controlled substances were prescribed and administered in a rational and efficient manner. Specifically, in relation to opioid analgesics, it remains important for Governments to have a palliative care policy and an appropriate infrastructure in place. As in 2018, in the INCB questionnaire for 2022, countries were asked whether new palliative care policies had been introduced in response to resolution WHA67.19, adopted by the sixty-seventh World Health Assembly in 2014, entitled “Strengthening of palliative care as a component of comprehensive care throughout the life course”. Altogether, 53 per cent of countries responding in 2018 and 56 per cent of countries responding in 2022 indicated that palliative care measures and policies had been introduced in their countries.

34. The questionnaire also contained a question on whether countries have an appropriate and well-resourced health infrastructure and system that ensures the availability of opioid analgesics for the delivery of pain and palliative care. In this regard, 15 per cent of countries considered that their infrastructure and system were entirely appropriate and 38 per cent considered them to be appropriate. About 35 per cent of countries consider their infrastructure and system to be in need of some improvement and 12 per cent considered them to be in need of significant improvement.

35. Competent national authorities were also asked whether, to their knowledge, their Government had implemented low-cost, home-based palliative care services. In response, a slight majority (57 per cent) responded positively. In many countries, these services are partially or fully integrated in the national health-care system and/or funded (fully or partially) by the Government. Some countries indicated that while home-based palliative care services existed in their country, they were not covered by insurance schemes and needed to be fully covered by the patient.

36. In response to a question on what steps had been taken so that the distribution of opioid analgesics and psychotropic substances could reach all areas of the country, including rural areas, some countries indicated that distribution across their country was ensured through a centralized government agency responsible for distribution, while other countries had established local distribution channels. An important measure taken was to have enough hospitals and pharmacies strategically placed throughout the territory. Some countries indicated that the system for distribution required improvement.

## Affordability

37. An essential part of ensuring the availability of controlled substances for medical purposes was to make them affordable. In the past, INCB has recommended that countries improve access to essential drugs in general, and to opioid analgesics in particular, ensure funding for the purchase of opioid analgesics and develop and improve health insurance and reimbursement schemes that ensure access to such medications.

38. Overall, 73 countries responded to the question on affordability, naming the steps that had been taken to improve access to essential drugs in the past five years. Most countries referred to measures taken to improve the health insurance system and to amend guidelines and legislation. Some countries also indicated that opioid analgesics had

been included in the national list of essential medicines and steps had been taken for their procurement. Eight countries indicated that no steps in that regard had been taken in the past five years.

39. In addition, the majority of countries responding (75 per cent) reported they had sufficient resources and budget for the purchase of opioid analgesics. The remaining 25 per cent indicated that they did not have sufficient budget and resources for the purchase of opioid analgesics, most of them citing a limited or reduced budget and a general lack of resources to meet increased demand.

### Training of health-care professionals

40. The training of health-care professionals, which is a fundamental requirement for patients to have access to opioid medication, continues to be lacking in many Member States, and 26 per cent of responding countries cited lack of training as an impediment to availability. Lack of training and awareness among health professionals may be a result of gaps in the educational curricula of medical schools.

41. More than 70 per cent of countries responding, a large majority, reported that pain and palliative care were included in the educational curricula of medical schools and in the training of all health professionals, although it was not mandatory in some. In 75 per cent of countries responding, health-care professionals were provided with continued education, training and information on pain and palliative care, including on the rational use and the importance of reducing prescription drug abuse.

42. When it comes to updates of the educational curricula of medical schools and other mandatory and educational health-care training related to prescribing and dispensing controlled medicines, specifically on the rational prescribing and use of narcotic drugs and psychotropic substances, 51 per cent of countries responding reported no updates to training or curricula in the past years or not being aware of any such updates. Only 17.5 per cent of countries responding reported that curricula and training on prescribing and dispensing of controlled medicines was already in place.

43. Lack of training and updated knowledge may in effect lead doctors and other health-care professionals to assign low priority to pain management as they do not trust the patients' assessments of their pain and/or underestimate the degree of relief that can be attained through proper treatment, misjudging the need to use opioids such as morphine and overestimating the side effects of opioids, for example, the risk that a patient may become dependent.

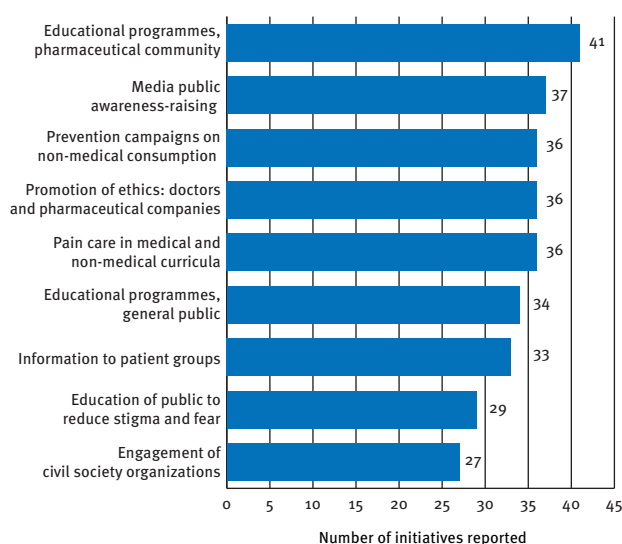
44. In the same manner, nurses and health workers that lack proper training in the rational use of controlled substances may act as an additional obstacle between patients and the pain treatment they need, whereas well-trained nurses and other health workers can play an important role in assisting patients and families with their concerns, helping them to learn to safely manage opioid analgesics that are prescribed by the responsible health professional and to administer the correct dosages that the patient requires.

### Education and awareness-raising

45. Also key to the issue of availability is ensuring that patients and communities are educated and aware of the importance of treating pain and mental health conditions, the advantages and risks of controlled substances, and the options that are available to patients.

46. Several countries have reported to the Board on the activities that have been promoted in their territories in the area of education and awareness-raising. These have benefited the general public, civil society organizations, patient groups, university students, the pharmaceutical community, doctors and pharmaceutical companies. Figure 6 shows all groups of initiatives that have been implemented by Member States in the last five years.

**Figure 6. Education and awareness-raising initiatives in the last five years (2017–2022)**



Source: INCB survey of Member States, 2022.

47. The largest number of activities (41 activities) reported were related to educational programmes for the pharmaceutical community involving community and

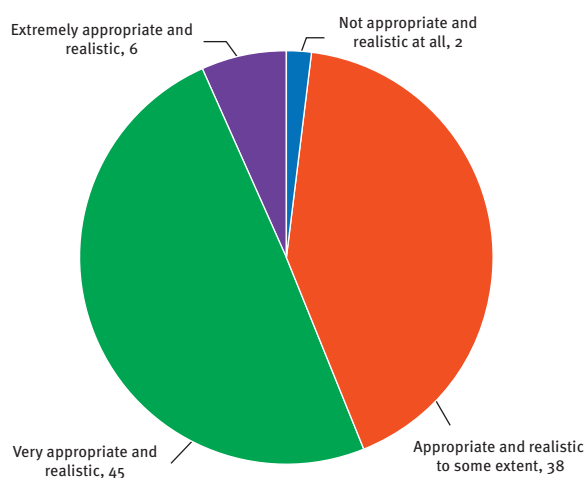


hospital pharmacists, followed by public awareness-raising through the media (37 activities). Responding countries also reported initiatives in the areas of support campaigns and efforts targeting the general public to prevent the non-medical consumption of controlled substances and encourage the active participation of the medical and pharmaceutical community in all measures related to the rational use of controlled medicines; the promotion of ethical attitudes among medical doctors and pharmaceutical companies, the provision of training and continued education for health-care professionals to encourage a better-justified and more rational use of psychotropic substances; and the inclusion of education on pain and palliative care in the curricula of medical and non-medical educational institutions.

## Estimates and assessments

48. Estimates and assessments are the core of the international drug control system established by the 1961 Convention and the 1971 Convention. Nevertheless, many countries struggle to produce estimates and assessments that reflect the real need of patients in their territories. Many countries, Governments and competent national authorities are not aware of the inadequacy of the level of consumption of controlled substances in their territory or that their estimates and assessments do not adequately reflect the needs of the population.

**Figure 7. Responses to the question “Are your country’s estimates of requirements of narcotic drugs and assessments of requirements of psychotropic substances appropriate and realistic in relation to the needs of patients?”**

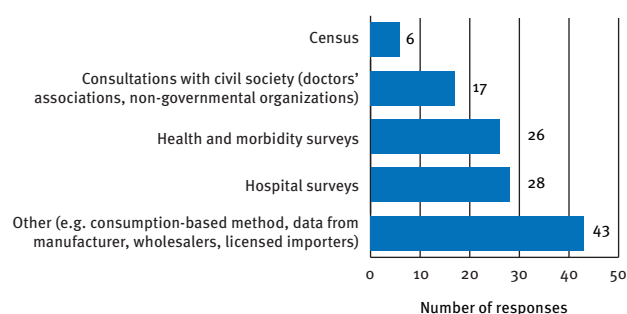


Source: INCB survey of Member States, 2022.

49. Almost all responding countries reported that their competent national authorities were aware of the *Guide on Estimating Requirements for Substances under International Control*, developed by INCB and WHO in 2012, and used it at least to some degree, and almost all of them (all except for two countries) considered that their estimates were, at the very least, “appropriate and realistic to some extent” (see figure 7). However, the low levels of consumption of opioid analgesics in many parts of the world, especially in low- and middle-income countries, is evidence that the needs of patients are not always appropriately reflected in the estimates of some Member States.

50. Although most countries are familiar with the *Guide on Estimating Requirements for Substances under International Control* and reported using it, only 28 countries reported preparing their estimates of requirements based on hospital surveys, and 26 countries based their estimates on health and morbidity surveys (with some possible overlaps in the methods employed) (see figure 8). Of those countries that indicated “Other” method used to estimate national needs for controlled substances, 26 countries specified that they used the consumption-based method, which uses recent years of consumption to estimate needs. Many of those countries also combine those data with statistics from manufacturers, wholesalers and licensed importers. Although estimates based on consumption provide the best data for decision makers and national competent authorities to define priorities and needs for controlled substances, they may often be resource-intensive, and some countries may find it difficult to conduct them often. The lack of surveys may be mitigated by periodic consultations with civil society, including non-governmental organizations supporting communities, including in rural areas, as well as patients and doctors associations.

**Figure 8. Instruments used by Member States to measure needs of patients for narcotic drugs and psychotropic substances**



Source: INCB survey of Member States, 2022.

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

## 2. Civil society organizations

### Legislation and regulatory systems

51. Sixty-five civil society organizations answered the questionnaire and reported on progress with respect to measures taken in their respective countries to implement the recommendations adopted in the outcome document of the thirtieth special session of the General Assembly, on the world drug problem, held in 2016. They reported positive changes in the area of legislation and regulations aimed at simplifying and streamlining processes in order to remove unduly restrictive regulations and thus ensure accessibility of controlled substances and maintain adequate control systems.

52. Approximately 25 per cent of the civil society organizations responding had observed an increase in the 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 in order to increase availability, in particular in remote or rural areas. Other measures to improve availability included the prescription of controlled medication using telecommunications technology. Two organizations reported that new legislation or regulations were being developed. Three organizations mentioned changes of regulation in the specific field of palliative care.

53. On the other hand, 52 per cent of civil society organizations reported no changes in their country regarding the prescription of controlled substances that would allow a larger base of health-care professionals to prescribe opioids and/or psychotropic substances in order to increase availability, in particular in remote or rural areas.

54. In the countries allowing the legal use of cannabis for medical and scientific purposes, civil society organizations reported highly restrictive regulations to control access to the substance. This has led patients to procure the cannabis they need from illicit sources. Another issue reported was the lack of knowledge among doctors about the use of cannabis for medical purposes.

55. Fifty per cent of civil society organizations (33 of 65) were of the view that in their country no changes had been made in terms of legislation due to the COVID-19 pandemic or other political challenges that occurred in the last years. Another, 30 per cent of the civil society organizations (20 out of 65) reported that their country had been implementing legislative and administrative changes with regard to the recommendations contained in the outcome document of the special session of the General Assembly

and in the supplement to the annual report of the Board for 2015 on the availability of internationally controlled substances.

56. Civil society organizations in seven countries reported new initiatives for training large numbers of health professional in the use of opioid analgesics for the treatment of pain. The development of national programmes focusing on or including palliative care was also mentioned.

57. Five civil society organizations stated that restrictive legislation and cumbersome administrative procedures still played an important role in limiting access to controlled substances, leading underresourced health-care services to avoid procuring and administering controlled substances to a preference to prescribe other medicines, such as tramadol and tapentadol, which are not internationally controlled and which civil society organizations consider to be easily accessible.

### Health systems

58. About half (34) of the civil society organizations that responded to the questionnaire reported that although availability may seem to be adequate when seen at the national level in some countries, in the rural areas, including in some high-income countries, inadequate availability remained a problem. It was also reported that inadequate availability affected particular population groups, such as indigenous people, children and people living on the street.

59. Approximately 50 per cent of the civil society organizations noted that it continued to be the case that only a limited number of physicians were able to prescribe. That situation, combined with issue of accessibility throughout the national territory, is considered a main obstacle in several countries.

60. Other challenges reported by civil society include the concern of some medical professionals, sometimes unfounded, about the risk of dependence related to opioid use. It is reported that some medical practitioners from various countries express hesitation to prescribe controlled substances despite demand from patients and the supporting scientific evidence from research about the proper and rational use of opioids.

61. Also, the prescription of cannabis for medical purposes has been a matter of concern because of differing views within the medical community, resulting in inconsistent prescription practices, with patients reporting dissatisfaction about the treatment options offered.

## Affordability

62. Approximately 30 per cent of civil society organizations (21 in total) reported the price of some medicines to be an impediment to accessibility. Two of them reported that there was lower utilization and adherence to prescribed medication regimens owing to the cost and financial barriers. They reported that patients frequently turned to the illicit market to procure their medications, often buying falsified products that posed considerable risk to their health. The loss of purchasing power due to the COVID-19 pandemic has led some families to reduce or suppress their purchases of medicines. Additionally, treatment and rehabilitation for drug dependence in prison settings, including the availability of controlled substances such as methadone and buprenorphine for medically assisted therapy, were further limited due to budgetary restrictions.

## Training of health-care professionals

63. About 52 per cent of the civil society organizations were directly engaged in education and training activities related to access to controlled substances. Also, about 75 per cent reported having undertaken educational and awareness-raising initiatives in that area. Seven of the responding civil society organizations mentioned educational and awareness-raising initiatives specifically in the area of palliative care. Most organizations reported that training was still much needed because while controlled medicines might in theory be available in many countries, some doctors were reluctant to prescribe in some of those

countries as a result of partial understanding of the risks and benefits of the substances.

64. With respect to the effects of the lack of knowledge among doctors, civil society organizations reported inappropriate prescribing of medicines containing controlled substances. The doctors' lack of knowledge also related to the possible legal use of cannabis and cannabis-derived substances for medical purposes.

## Role of civil society organizations

65. Civil society organizations were asked whether they were consulted in the process of preparing national estimates for the consumption of narcotic drugs and/or psychotropic substances. Only 35 per cent (23 out of 65) answered that they were part of the process. Some civil society organizations responding were not specialized in the area of ensuring availability of controlled substances for medical purposes and therefore could not legitimately be consulted by competent national authorities.

66. While 35 per cent of the responding organizations were aware of the simplified control measures in the import and export of controlled substances in emergency situations, only 3 civil society organizations (or 5 per cent) out of 65 in total provided narcotic drugs and/or psychotropic substances to countries with insufficient availability. Again, this may be a result of the limited number of civil society organizations directly involved in the specific area of ensuring availability.