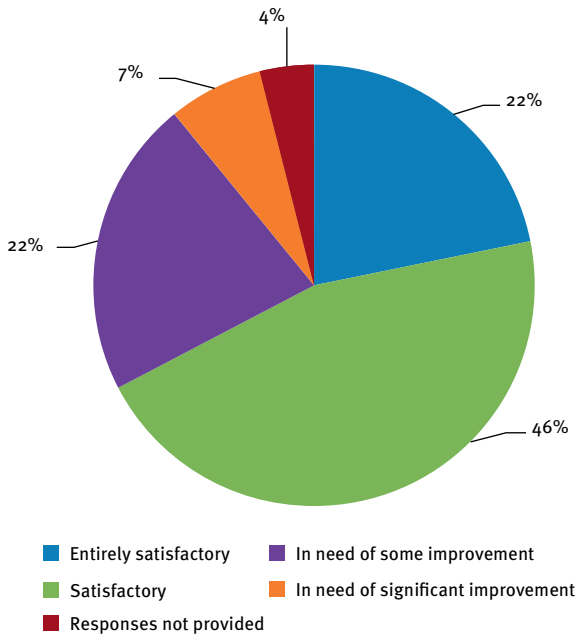
C. Impediments to the availability of narcotic drugs

107. In 2014, INCB carried out a survey asking countries to provide information on policies and practices at the national level to implement the provisions of the 1961 Convention to ensure the availability of narcotic drugs for medical and scientific purposes. The Board received responses from 107 countries. The following paragraphs are an analysis of those responses, with a particular focus on the impediments to availability identified by the competent national authorities.[47]

108. An analysis of the responses indicates that in recent years Member States have taken action to improve availability. This is likely to have contributed to the increase in the consumption of opioid analgesics, as expressed in S-DDD per million inhabitants per day, reported earlier. The answers to the survey show that a large number of countries that are paying attention to the issue of availability and have taken action to overcome legislative, administrative and other impediments have increased access to narcotic drugs for medical purposes and improved the quality of life of people in need of palliative care.

109. This conclusion emerges from an analysis of the consumption patterns examined in previous chapters, but it also derives from self-evaluations by countries of their performance in relation to the availability of narcotic drugs. As shown in figure 31, two thirds of countries consider their situation satisfactory or entirely satisfactory (46 and 22 per cent, respectively), while others indicated the need for some (22 per cent) or significant improvement (7 per cent). Obviously, these self-evaluations need to be checked against the real situation, but they provide an insight into how countries perceive their own performance and therefore whether they are considering taking action or not.

Figure 31. Availability of narcotic drugs, as evaluated by countries themselves, 2014

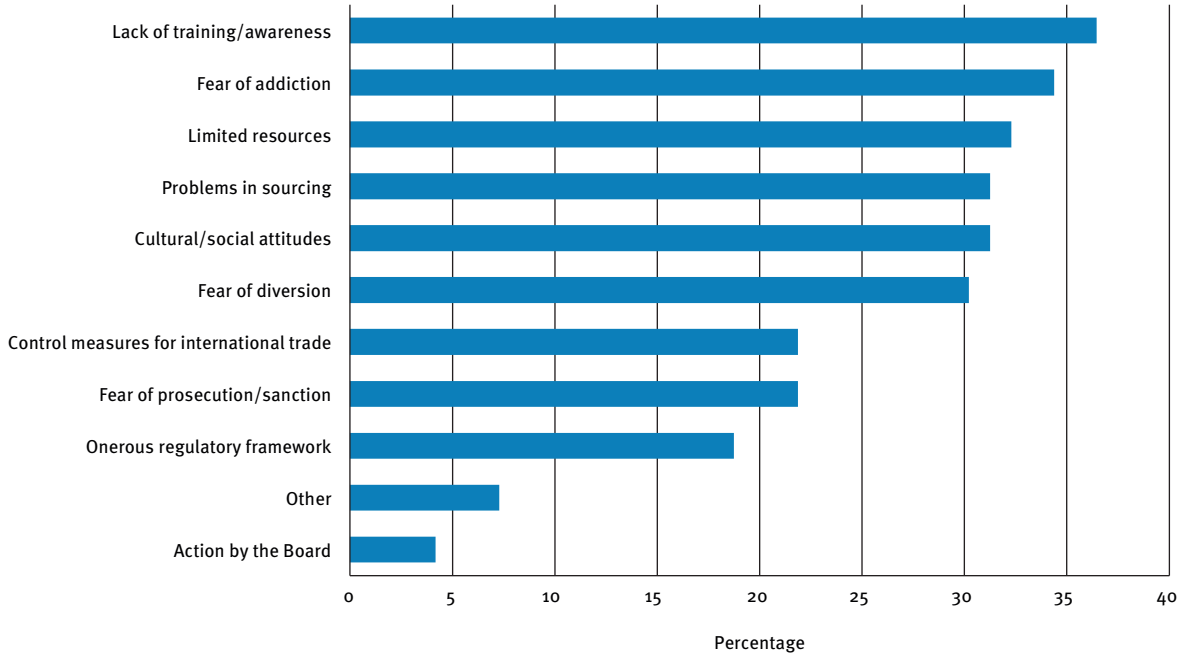


Source: International Narcotics Control Board survey 2014.

110. Member States have reported to the Board on the main factors that unduly limit the availability of narcotic drugs needed for medical or scientific purposes (see figure 32). Out of 96 valid responses to this specific question, 36 per cent of countries indicated as a major impediment a lack of training or awareness among members of the medical profession regarding the use of narcotic drugs. This was followed by fear of addiction (34 per cent) and limited financial resources (32 per cent).

[47] Results shown in the figures are based on replies submitted by Member States to the INCB questionnaire on availability. The number of responses taken into consideration for the calculation of percentages relates to the total number of valid responses for each of the questions, and therefore varies. The sum of all percentages may not amount to 100 in some figures, as countries are given the option of marking one or more options in multiple-choice questions.

Figure 32. Impediments to availability of narcotic drugs



Source: International Narcotics Control Board survey 2014.

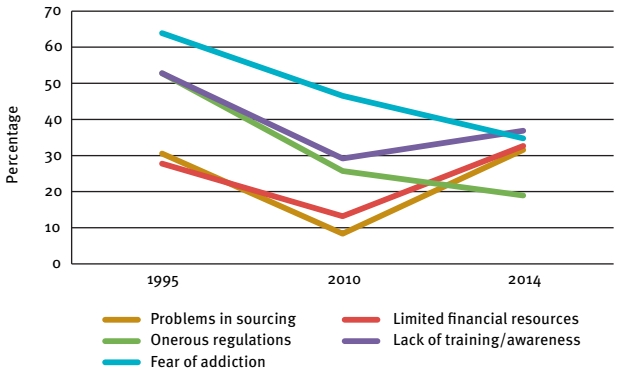
111. The Board also reviewed the impediments identified by researchers and civil society organizations involved in health and palliative care. Sometimes the impediments and their prioritization identified by these stakeholders did not match those identified by the competent national authorities. Civil society and academia often consider onerous regulations, strict trade control measures and problems in sourcing as being among the causes of limited access to pain relief medications. Countries responding to the questionnaire, however, highlighted lack of training/awareness and fear of addiction as the main problems.

112. For some of these factors, it is possible to make a comparison with information from the surveys carried out by the Board in 1995 and 2010. Fear of addiction, for example, was identified as an impediment by 64 per cent of countries in 1995, but only by 47 per cent in 2010; in the most recent survey, it declined even further, to 34 per cent. Similarly, the mention of onerous regulations and legislative restrictions decreased considerably, as shown in figure 33.

113. The mention of lack of training/awareness among medical professionals as an impediment declined between 1995 and 2010, but it has since increased. It was the most mentioned impediment in the 2014 survey, indicated by 36 per cent of countries. Problems in sourcing or insufficient supply followed a similar trajectory. From 31 per cent in 1995, they dropped to 8 per cent in 2010, and bounced back to 31 per cent in 2014.

114. Similar fluctuations can be seen in responses citing the cost of medicines or lack of financial resources: from 28 per cent in 1995 to 32 per cent in 2014, with a drop to 13 per cent in 2010.

Figure 33. Impediments to availability, 1995-2014



Source: International Narcotics Control Board surveys 1995, 2010 and 2014.

115. The paragraphs below provide an analysis of responses by countries to the 2014 survey. The identified impediments are discussed in descending order by number of mentions.

1. Lack of training or awareness among health professionals

116. Lack of training and awareness among health professionals was the most often mentioned impediment in the responses received from Member States. Several studies and analyses of the problem confirm this. In several countries, health professionals may not have sufficient professional knowledge about pain and pain management. There may be excessive concerns about the side effects of opioids and the possibility that patients may become dependent. Doctors may lack confidence in the patient's report of pain, or assign low priority to pain management. A possible reason for this situation may be the limited attention devoted to palliative care in the curricula of medical schools. In other cases, doctors may be reluctant to prescribe opioid analgesics because they do not trust the ability of the patients and their families to safely manage them.

117. Because of insufficient education and training on palliative care treatment, doctors sometimes underestimate the degree of relief that can be attained with proper treatment, and the extent to which pain is undermedicated. Physicians may also underestimate the need to use potent opioids, such as morphine, for severe pain, and instead prescribe less effective drugs. Also, some physicians may not be able to establish, or may not be used to establishing, an interpersonal relationship that would help to identify the adequate pharmacological therapy and allow for personalized prescriptions that take the patient's needs and current health status into account.

118. In addition, nurses in some countries may not be adequately trained to manage pain and support patients, and may have misconceptions and prejudices about opioid medications similar to those held by doctors, as described above. In some cases, nurses may administer lower dosages than required or none at all, or they may try to convince the patient to wait and endure the situation without adequate pain medication.

119. In the 2014 survey, 70 countries reported having an educational curriculum for medical practitioners that included content on the rational prescription and use of narcotic drugs. Of those, 73 per cent (51 countries) had registered an increased per capita consumption between the 2007-2009 and the 2011-2013 periods.

120. Out of 61 countries that reported implementing awareness-raising measures to foster a deeper understanding of responsible prescribing practices for narcotic drugs among health professionals, 45 countries (74 per cent) had observed an increase in S-DDD per million inhabitants per day. Such measures have included workshops, seminars, special training and supervision, and distribution of informative materials, as well as working groups with pharmacists, representatives of the pharmaceutical industry and medical associations.

2. Fear of addiction

121. Thirty-three countries (34 per cent) reported fear of addiction as an impediment to availability, the second most mentioned impediment in the 2014 survey. Out of those countries, 18 (55 per cent) remained below the minimum levels of consumption.

122. According to Human Rights Watch, the reluctance among health professionals to prescribe opioid analgesics may be related more to the fear of causing addiction or respiratory distress in patients than the fear of prosecution or sanction.[48] This emerges also from the 2014 survey, in which fear of addiction was identified as an impediment by 33 countries and fear of prosecution or sanction by 21 per cent.

123. It seems that fear of addiction is related to lack of awareness and training, as well as cultural attitudes. Both patients and medical professionals may be reluctant to prescribe and use narcotic drugs due to lack of knowledge about their properties and safe ways to prescribe them, as well as prejudices against the use of such substances.

3. Limited financial resources

124. Thirty-one countries (32 per cent) identified financial issues as an impediment to the availability of narcotic drugs. Lack of resources can be particularly prohibitive when narcotic drug prices are high. While some formulations, such as oral morphine, can be produced quite cheaply, prices of narcotic drugs may be driven up by government regulation, licensing and taxation, as well as poor distribution systems (e.g. ones that require expensive and lengthy travel to collect medicines), among other things.[49] For example, the Latin-American Association of Palliative Care reported that, in one country in Central America, the price of a one-month treatment with injectable morphine was more than double the national minimum monthly wage. In this context, availability is dependent on the ability of patients to afford narcotic drugs that are prescribed. Therefore, it is important to consider whether patients are

[48] Human Rights Watch, *Global State of Pain Treatment: Access to Palliative Care as a Human Right* (2011), chap. II.

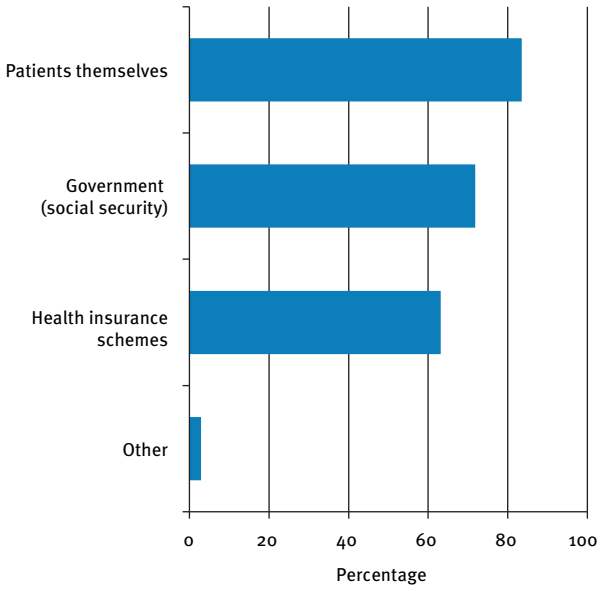
[49] Ibid.

expected to cover all or most costs for such drugs, or if there is financial support through social security or national health insurance schemes. In the responses to the question on who pays for narcotic drugs prescribed (see figure 34), patients were mentioned the most (83 per cent), followed by the government (72 per cent) and health insurance schemes (63 per cent).

125. A cross-sectional study carried out in 2014 suggests that, particularly in countries with limited resources for subsidy and reimbursement schemes for opioid analgesics, the additional costs arising from regulatory requirements might thus be transferred directly onto patients. The study also found that the price of oral solid immediate-release morphine was 5.8 times higher in lower-middle-income countries than in high-income countries. This difference in dispensing prices may be related to the artificial lowering of the price of other more expensive formulations (fentanyl) owing to heavy subsidies, which in turn creates a condition of economic disadvantage for oral solid immediate-release morphine.[50]

126. Thus, impediments to the affordability of narcotic drugs can derive from lack of resources, high prices created by restrictive national regulations and international trade control measures, and non-supportive policies, including lack of public health reimbursement schemes.

Figure 34. Who bears the cost of prescribed narcotic drugs, 2014



Source: International Narcotics Control Board survey 2014.

[50]Liliana De Lima and others, "Cross-sectional pilot study to monitor the availability, dispensed prices, and affordability of opioids around the globe", *Journal of Pain and Symptom Management*, vol. 48, No. 4 (October 2014).

4. Problems in sourcing from industry or imports

127. Many responses indicated problems in sourcing. Some formulations of narcotic drugs, such as oral morphine, may not be available in sufficient quantities, as manufacturers and importers/exporters, especially in the case of smaller populations and/or low market demand, may prefer to produce and trade only more expensive formulations. Marketing of such formulations, coupled with the subsidies granted for specific products (for example, fentanyl), may explain why an analysis of consumption data shows a much steeper increase in the consumption of fentanyl than of morphine.

128. In several countries, local pharmaceutical companies lack interest in manufacturing oral morphine, in part because the prescribing of opioids by physicians is too limited and the demand from hospitals insufficient to justify production. In some developing countries, morphine is only available through import from international pharmaceutical companies, with prices that are unaffordable both for the government and the population. Finally, some local pharmaceutical companies are not interested in producing opioid medications because of security costs and legal risks associated with this kind of product.

129. In addition to the lack of local production, another obstacle to the availability of narcotic drugs is the difficulty in sourcing through imports. Several countries indicated that there were shortages of medications as a result of delays in the supply chain due to lengthy and burdensome regulatory requirements (e.g. import/export licensing). The supply of narcotic drugs has also been found to be restricted by inadequate national estimates, time-consuming reporting requirements and difficulties in the management of narcotic drugs.

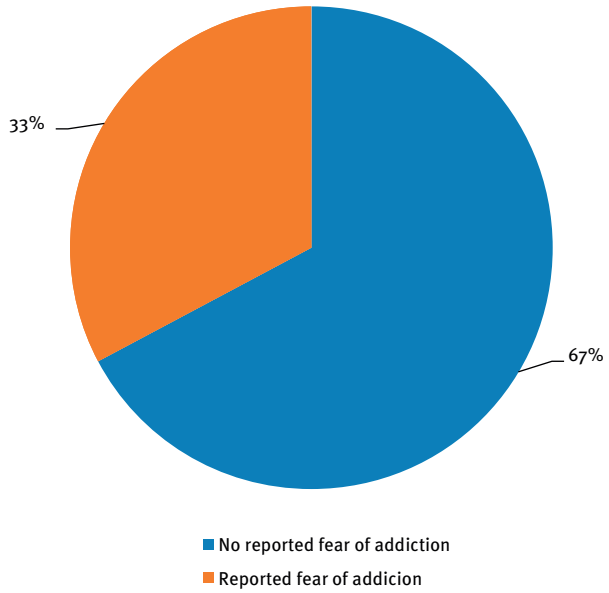
5. Cultural and social attitudes towards the treatment of pain

130. Impediments related to attitudes and knowledge, identified by 31 per cent of countries, included the beliefs of doctors, patients and their families, as well as policymakers. Patients may sometimes be the ones to refuse pain relief due to their reluctance to report pain or to accept the idea of taking opioids. Some patients and/or their family members may be concerned about the side effects of opioids and try to reduce the dosages. They may also worry about the stigma associated with the use of opiates or pain medication. Some patients may avoid taking opioids owing to their sedative effects, because they want to remain conscious, especially patients in the

terminal stages of a disease who may be afraid to lose the bond with their families.

131. Out of 61 countries that had implemented awareness-raising measures among health professionals, a large proportion (67 per cent) did not report fear of addiction as an impediment to availability (see figure 35). This may indicate that investing in fostering a deeper understanding of responsible prescribing practices for narcotic drugs among health professionals can contribute to overcoming the impediments created by the fear of addiction and other misconceptions regarding opioid analgesics and the management of pain.

Figure 35. Reports of fear of addiction among countries and territories that have implemented awareness-raising measures, 2014



Source: International Narcotics Control Board survey 2014.

6. Fear of diversion into illicit channels

132. Out of 96 responding countries, 29 (30 per cent) reported fear of diversion as an impediment to availability. Out of these, 20 countries (69 per cent) had levels of consumption below 200 S-DDD per million inhabitants per day, a level that is not considered to be adequate by the Board.

133. Reported fear of diversion can result from the experiences of countries with the emergence of unregulated parallel markets for narcotic drugs. Among the countries that reported fear of diversion as an impediment, 41 per cent also reported experiencing problems with parallel markets. One country mentioned that limited availability had been the result of stricter regulatory measures enacted in response to the use of the Internet to purchase and sell opioid analgesics without prescription.

7. Fear of prosecution or sanction

134. Out of 99 responding countries, 81 (82 per cent) reported the existence of penalties for inadequate record-keeping. Reported penalties ranged from monetary fines, to licence revocation, to prison sentences. Reports by the Access to Opioid Medication in Europe project[51] and Human Rights Watch[52] suggest that fear of sanction may arise in the context of unclear, often stigmatizing legislation, lack of legal knowledge among health professionals and harsh penalties, including penalties for unintentional violations. In the survey, out of 21 countries reporting fear of prosecution/sanction as an impediment, almost all indicated the existence of penalties, and three quarters of them showed inadequate S-DDD levels, i.e. below 200 per million inhabitants per day.

8. International trade control measures

135. Policies, rules and regulations to control the production, import and export of controlled substances have been established and are monitored at the international level by INCB. For some countries, the effort to estimate the amount of controlled medication needed may be beyond their capacities and existing resources, and therefore technical and logistical support may be required.

136. Countries have reported difficulties with the issuance of import/export permits, along with other international drug control measures that require lengthy procedures and thus may lead to delays and shortages.

9. Onerous regulations

137. Out of 53 countries that reported having taken legislative or regulatory action in the previous 10 years to

[51] Access to Opioid Medication in Europe, *Final Report and Recommendations to the Ministries of Health*, Lukas Radbruch and others, eds. (Bonn, Germany, Pallia Med Verlag, November 2014).

[52] *Global State of Pain Treatment*, chap. II.

increase the availability of narcotic drugs for medical purposes, 37 countries (70 per cent) had observed an increase in S-DDD rates since the 2007-2009 period. Among such legislative or regulatory actions, countries reported the following: facilitating the prescription and dispensing of narcotic drugs, which could include the elimination of obligatory prescription pads for doctors and the extension of prescription periods; allowing nurses and midwives to prescribe and administer narcotic drugs; facilitating accessibility of treatment for patients; simplifying record-keeping; and issuing informative leaflets on uses, side effects, warnings and precautions concerning narcotic medicines.

138. At the national level, some countries, out of fear of diversion and risk of addiction, have developed regulatory systems that go beyond the requirements provided in the drug control treaties, with unnecessary impediments that do not take into full account the WHO and INCB recommendations.

139. Regulations that restrict opioid prescription mechanisms include the following: requiring special patient permits; limiting the authority of physicians to prescribe opioids, even for cancer patients with strong pain; imposing dose limits that restrict the ability to adjust the dose to individual patient needs; imposing severe limits on the duration of prescriptions; restricting the dispensing of opioids, making it harder for patients to access such medication; increasing bureaucratic burdens through the use of complex or poorly accessible prescription forms or complex reporting requirements; and introducing disproportionate legal sanctions that result in the intimidation of health-care providers and pharmacists.

140. In some countries, regulations prevent doctors from prescribing appropriate substances and sufficient dosages, so that patients have to visit their physicians very frequently, for example, because they are not allowed to get a prescription for morphine for more than 7 or 10 days. Of the countries responding, only 21 per cent stated that they allowed refills under certain circumstances without requiring a new prescription.

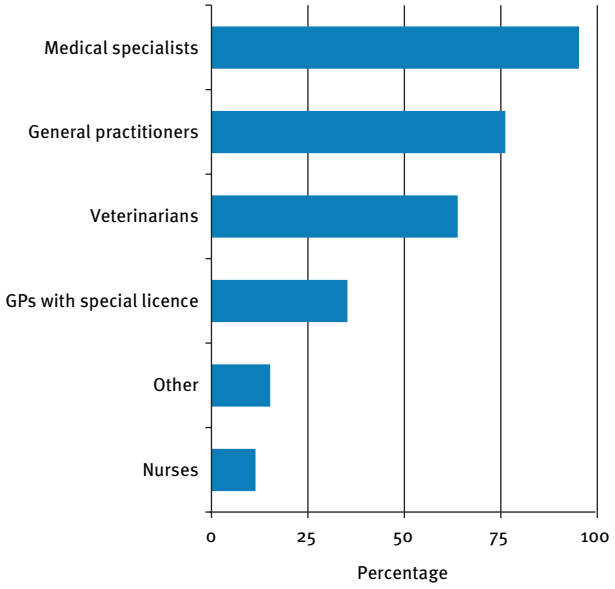
141. Particularly in low-income countries, the ability to prescribe morphine and other potent opioids is limited to a small number of physicians, who are required to undergo a special registration procedure. In some cases, not even specialists in diseases requiring palliative care have independent prescribing authority.

142. Another example of a regulatory impediment is the special triplicate forms doctors have to fill out, which can be difficult to obtain and for which in many cases doctors have to pay. According to WHO, special multiple-copy prescription requirements typically "reduce prescribing of covered drugs by 50 per cent or more".[53]

143. Of 102 responding countries, 75 per cent legally required prescribers to keep records of narcotic drug prescriptions. This may discourage the stocking of opioid analgesics owing to costs and time-consuming procedures, and possibly fear of prosecution and sanctions. It is certainly possible to find a way to ensure that records are kept while preventing this basic requirement from becoming too onerous for those who are doing the prescribing.

144. As illustrated in figure 36, nurses are seldom allowed to prescribe narcotic drugs. This may also be an impediment to availability, especially in countries facing challenges in their health-care systems and infrastructure.

Figure 36. Prescribers of narcotic drugs, 2014



Source: International Narcotics Control Board survey 2014.

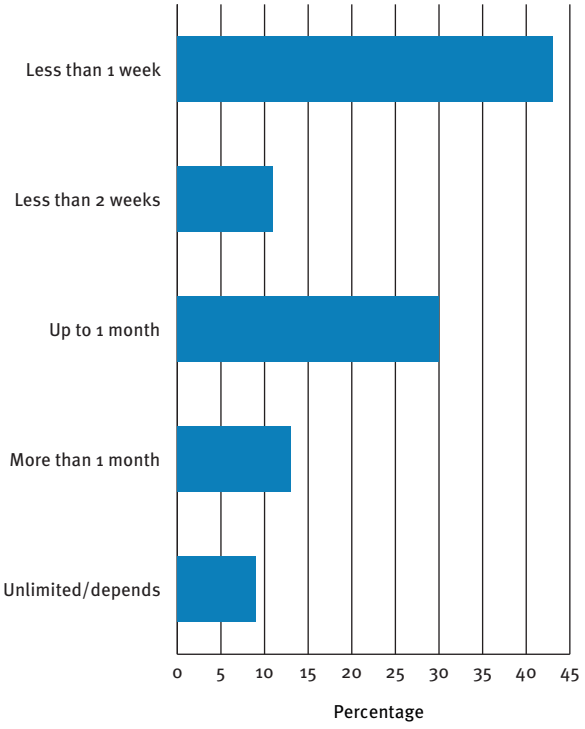
145. Some countries that have been able to considerably increase their levels of consumption in S-DDD per million inhabitants per day during the past two decades have reported that midwives are also allowed to prescribe narcotic drugs. The issue of pain during labour is mostly overlooked in the discussion, despite its ubiquity, which calls for measures to ensure its adequate management, including the use of narcotic drugs.

[53] World Health Organization, *Cancer Pain Relief, With a Guide to Opioid Availability*, second edition (1996), part 2.

146. There was a wide range of prescription validities among countries (see figure 37). Forty-three per cent of countries reported that prescriptions were valid for up to seven days. The second most often reported validity (30 per cent of countries) was between two weeks and a month.

147. Centralized systems can furthermore limit adequate distribution, because opioids are often only available in major cities and are not delivered to rural areas. Sometimes, doctors have to travel to major cities to get medications and even prescription forms; patients may have to do the same. In some countries, it can take more than a month for an opioid medication to be delivered from urban centres to provincial and rural areas.

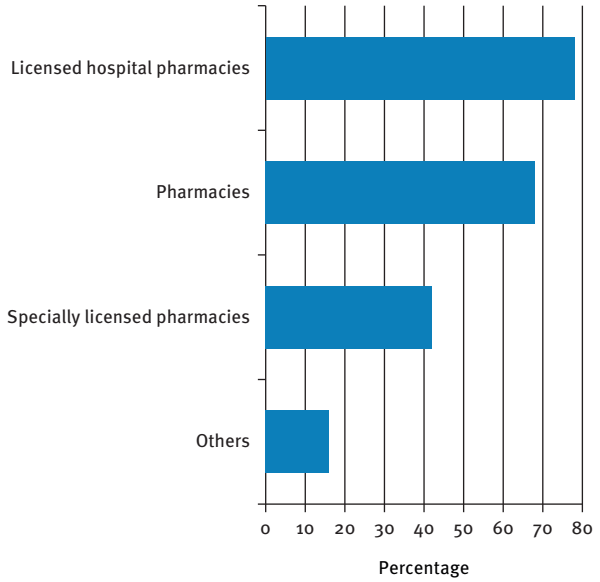
Figure 37. Maximum validity period of prescriptions that contain narcotic drugs, 2014



Source: International Narcotics Control Board survey 2014.

148. Member States reported that narcotics were dispensed mostly in licensed hospital pharmacies (75 per cent). Slightly more than half of responding countries (54 per cent) reported that narcotics could be dispensed in regular pharmacies (see figure 38).

Figure 38. Facilities where prescriptions for narcotic drugs can be dispensed, 2014



Source: International Narcotics Control Board survey 2014.

149. Restrictions on the number of pharmacies that are allowed to dispense controlled substances may also reduce availability. The administrative burden for pharmacies is an additional factor. In some countries, pharmacists must collect a standard set of information: patient name, address and date of birth; drug dispensed, as well as the date, quantity and dosage, the number of days' supply and the number of refills; and the patient's health-care provider. Pharmacies are also required to keep such information in a central database for several years. This necessitates the use of human resources, time and access to specific technology for monitoring and data collection. The existence of a legal requirement for dispensing agents to keep records was reported by 101 (98 per cent) of 103 responding countries.

150. In many countries, only one institution, or else a few pharmacies, are allowed to stock opioid medication. To do so, they have to seek permission from drug regulatory authorities through a lengthy process. Even in acute-care hospitals, morphine may not be included in the drug list for emergencies. In addition, some pharmacies located in unsafe areas are afraid to sell opioids because of the risk of being robbed.

10. Other impediments

151. Other impediments identified by a smaller number of countries (seven) point to insufficient supply due to a lack of certain opioid formulations, an unexpected increase in demand for a specific drug, or business

decisions by industry and importers of narcotic drugs. Also mentioned were a lack of awareness on the part of patients, inadequate estimates and reporting, and the existence of illegal markets.

11. Action by the Board

152. In the survey, countries could also indicate that actions taken by the Board had been an impediment. Only four countries did so.

153. In addition, countries were asked to suggest measures the Board could take to improve the availability of narcotic drugs for medical and scientific purposes. Most countries mentioned the provision of training and information to authorities and stakeholders on several issues: benefits, rational prescription and use of narcotic drugs; management, distribution and control of narcotic drugs; estimates and assessments; and awareness-raising programmes to address fears relating to prescribing or dispensing narcotics.

154. Other countries pointed to the need to facilitate the procurement of narcotic drugs through quick and flexible approval of estimates and supplementary estimates by the Board, as well as the introduction of online software for import and export licensing. In addition, INCB was requested to play a more active role by urging manufacturers to deliver the necessary medications on time, asking Governments to provide the necessary human and financial resources, and facilitating the availability of limited quantities for the purpose of test and reference standards. A few countries mentioned the need for more research on availability, the development of recommendations to increase access and the establishment of a laboratory for quality control of narcotic drugs.

155. Among responding countries, there was a high level of awareness of the procedures for submitting estimates and supplementary estimates (97 per cent), as well as knowledge of INCB training materials (82 per cent) and joint INCB/WHO guidelines (87 per cent) on the preparation of estimates.