

## VI. Ensuring the availability of internationally controlled drugs in emergency situations

### A. Background on simplified control measures during emergency situations

139. Defined as “a disaster requiring international support (humanitarian assistance) to meet the basic needs of the affected population”, an international humanitarian emergency may be caused by a natural disaster or a human-made event and can occur suddenly or gradually. According to the estimates of the Office for the Coordination of Humanitarian Affairs of the United Nations Secretariat, 274 million people are facing hunger, armed conflict, displacement and the impacts of climate change and the COVID-19 pandemic in 2022, and require immediate humanitarian assistance.

140. A number of internationally controlled substances, for instance, morphine, diazepam and phenobarbital, which are listed by WHO as essential medicines and often included in emergency health kits, are vital for pain management, palliative care, surgical care and anaesthesia, and the treatment of mental health and some neurological conditions. Others, such as fentanyl and midazolam, are also used in many countries to treat patients with COVID-19 admitted to intensive care units. Additionally, ketamine, although not under international control but often subject to national control, is also commonly found in the emergency kits dispatched by non-governmental organizations to countries that require emergency humanitarian assistances.

141. Ensuring the availability of these controlled substances during emergency situations is critical to satisfy the sudden and acute needs of the receiving countries, in particular at the onset of emergencies.

142. Humanitarian relief agencies have found it difficult to rapidly obtain controlled substances for medical care in

emergency situations, partly because of the additional administrative requirements for their international movement. Some of these controlled medicines were even taken out of emergency health kits in order to minimize the possible delays that their presence might cause to the provision of humanitarian assistance. This problem is compounded if competent national authorities in the importing countries are no longer functioning.

143. The international community has long noted the urgent need for a practical solution to this obstacle. The Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care, published by WHO in 1996, represented the concerted effort to expedite the supply of controlled substances during emergency situations through simplified control measures.

144. During emergency situations such as the humanitarian crisis in Afghanistan starting in 2021 and that in Ukraine in 2022, the earthquake in Haiti in 2021 and the explosion in Beirut in 2020, competent national authorities may permit the export of controlled substances in the absence of the corresponding import authorizations and/or estimates. Furthermore, estimates for controlled substances in urgent deliveries may be submitted by the exporting country instead of by the recipient country.

145. In responding to these humanitarian emergencies, the Board has taken active steps to remind all countries that, in accordance with article 21 of the 1961 Convention, simplified control procedures are permissible in exceptional cases where the Government of the exporting country is of the view that the export of the controlled substances is essential for the treatment of the sick. The Board also facilitates communication between exporting and receiving countries and informs providers of humanitarian assistance about the simplified regulations, to hasten the supply of controlled medicines.

## B. Impact of COVID-19 on the availability of controlled substances

146. Since the beginning of 2020, the COVID-19 pandemic has created unprecedented challenges for the economies and public health systems of all countries. The lockdowns, border closures and social distancing measures adopted by most countries have put to the test the ability of the international community to ensure adequate access to and availability of internationally controlled drugs for those in need.

147. The global supply chain of medicines has been adversely affected as a result of both the disruption in the manufacturing of key starting materials and active pharmaceutical ingredients in some major manufacturing countries. Logistical challenges arising from border closures and other social distancing policies adopted by a number of countries also prolonged delays.

148. On top of challenges in sourcing active pharmaceutical ingredients and generic medicines, the surge in demand for the treatment of patients with COVID-19 further reduced the availability of some medicines containing controlled substances. In particular, the Board was aware of and concerned about news regarding shortages of substances such as fentanyl and midazolam in some countries, largely driven by significant increases in the need to provide pain relief and sedation for patients with COVID-19 admitted into intensive care units.

149. In the face of lower supply and greater demand, a number of contingency measures have been put in place by some countries, including increasing stocks to provide a greater buffer, resorting to alternative medicines, implementing temporary export bans (which have in turn led to shortages of certain medicines in other countries), and importing medicines containing controlled substances that in other countries are registered. The heightened demand for certain substances is partly due to a number of requests by Governments to increase their estimates and assessments and to a greater number of countries deciding to switch to issuing electronic import and export authorizations instead of hard copies since March 2020.

150. To facilitate the international movement of controlled substances during such emergencies, not only were the increased number of supplementary estimates for narcotic drugs and modifications to assessments for psychotropic substances processed expeditiously, the INCB secretariat also facilitated communication between importing and exporting countries and assisted in the verification of the legitimacy of import and export authorizations.

151. Meanwhile, the Board has repeatedly expressed its commitment to supporting Governments in using the International Import and Export Authorization System (I2ES) and enhancing their knowledge of the international drug control framework through INCB Learning. Such activities have taken on heightened importance during the COVID-19 crisis, as paperless trade and online training have become the norm.

152. Governments have been encouraged to share, through the I2ES forum, updates on contingency measures taken as a result of the COVID-19 pandemic so that trading partners are informed in a timely manner in order to minimize disruptions to trade. Furthermore, the INCB secretariat conducted several webinars to strengthen the operational capacity of the I2ES community.

153. Alongside the difficulties faced by most countries in the procurement and sourcing of controlled substances, disruption in the treatment and service delivery for people with mental health problems and substance use disorders since the onset of COVID-19 warrants specific attention. Based on the rapid assessment of WHO, more than 40 countries experienced disruption in their services for people with mental health problems and substance use disorders, including those related to life-saving emergencies. Community-based outpatient services, services to raise awareness of and prevent mental health problems, and services for older adults and children were among the most adversely affected. The lack of access to such essential treatment services as a result of the COVID-19 pandemic were extremely worrisome, as prolonged social distancing and the associated social isolation placed greater emotional strain on people with mental health problems and substance use disorders and may have further increased the number of people suffering from such conditions.

154. Research from UNODC has further confirmed the impact and health consequences of the COVID-19 pandemic on people who use drugs. Specifically, the mobility restrictions imposed by most Governments caused considerable disruption to access to drug treatment services, clean drug-using equipment and substitution therapy. The lack of access to treatment services and safe practices increased the risk of aggravating drug use disorders, as well as risks related to the health and survival of drug users. For instance, heroin users who could not access opioid-assisted therapy were reported to have suffered severe withdrawal symptoms. Meanwhile, shortages in the supply of drugs also led to the use of alternative means of administration (e.g. injection) by some users, incurring additional risks such as the spread of blood-borne diseases (e.g. HIV/AIDS and hepatitis C).

### The impact of COVID-19 on availability of controlled substances in Brazil

#### *Special times call for special measures*

In Brazil, a state of public health emergency was declared on 3 February 2020, after the identification of the first case of COVID-19. The subsequent rise in the number of COVID-19 patients, especially those admitted into the intensive care unit, generated considerable demand and pressure on the timely supply of controlled medicines.

Resolution RDC 483/2021, introduced in March 2021 and which remained in effect until 12 November 2021, outlined some extraordinary and temporary requirements related to the import of controlled substances used in the treatment of COVID-19, for example, alfentanil, diazepam, fentanyl, midazolam, morphine, remifentanil and sufentanil. For instance, hospitals could directly import those controlled substances, including those not registered in other countries. In addition, the Brazilian National Health Regulatory Agency (ANVISA), the competent national authority of Brazil, was requested to prioritize the processing of import requests of these substances and authorize their imports in the absence of the corresponding estimates.

Other temporary legislative measures, including the opening of additional entry and exit points for substances subject to special control due to the health emergency related to COVID-19 (resolution RDC No. 402/2020) and permission for home delivery of drugs subject to special control (resolution RDC No. 357/2020) also aimed to increase availability of and access to controlled drugs during the pandemic.

On 29 April 2021, INCB sent a circular letter to all competent national authorities to encourage them to implement simplified control measures for urgent deliveries to Brazil. Governments may permit the export of controlled substances to Brazil, even in the absence of corresponding import authorizations and/or estimates.

## C. Implementation of simplified control measures during emergency situations

155. A review and discussion of the lessons learned in the implementation of the simplified control measures during emergency situations, held among competent authorities, international humanitarian organizations and related United Nations agencies were conducted by INCB during two online meetings held in March 2021. The outcome document of those meetings, entitled “Lessons from countries and humanitarian aid organizations in facilitating the timely supply of controlled substances during emergency situations”, contains important actions that Governments can take to improve their emergency preparedness and sets out procedures that they can follow during emergency situations.

### Simplified control measures to facilitate export in the legislation of Belgium

#### *A small legislative change that yields great help during an emergency*

The competent national authorities of Belgium, the Federal Agency for Medicines and Health Products (FAMHP) has a long experience in the implementation of simplified control measures on controlled medicines during emergency situations.

A legislative change on the export of controlled substances was introduced in the narcotics law of Belgium in September 2017. The amendment was aimed at enhancing the implementation of simplified control measures during emergency situations, and providing better support to the Médecins sans frontières European supply centre, which is responsible for ensuring the supply of quality drugs and medical devices to 30 humanitarian missions of Médecins sans frontières around the world.

As outlined in article 34, section 5, of the royal decree of 06.09.2017 on regulating narcotic and psychotropic substances, in the case of emergency, no foreign import authorization or prior Belgian export authorization is required for the export of controlled substances, as defined in the WHO Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care by a wholesaler with a humanitarian purpose. The wholesaler, however, must inform FAMHP a posteriori as soon as possible using the notification form (in lieu of import authorization) contained in the Model Guidelines.

A posteriori export authorization, specifying the “WHO emergency procedure” was applied, and the date of the shipment is then registered in the FAMHP database, facilitating the monitoring by FAMHP. A copy of the export authorization is printed and sent to the competent authorities of the recipient country (if possible), who shall then be informed about the names and quantities of controlled substances shipped through the simplified control procedures.

Médecins sans frontières welcomed that legislative change and considered it to be of great help for their emergency operations, in particular in acute emergency phases when the competent authorities of receiving countries became temporarily unavailable or absent. MSF further noted that smooth implementation of the simplified control measures relies on transparency, that is, clear specification of (a) the nature of emergency and (b) the availability of control authorities in the receiving country, because that information is entered on the WHO model form, which is passed on to FAMHP after the urgent shipment took place.

156. Specifically, Governments are strongly encouraged to review existing national legislation on controlled substances and make amendments and/or adopt new provisions that allow for greater flexibility in the import and export of controlled substances during emergency situations, with clear specifications of the conditions under which such flexibility can be exercised. All relevant front-line workers responsible for the delivery of controlled substances should also be made aware of the emergency procedures and be trained in their use.

157. In an increasingly complex and uncertain world, for instance, the conflicts in Ukraine and the dire humanitarian situations in Afghanistan and many other countries, in which controlled substances remain vital in the provision of quality essential care to affected populations, the Board reminds all States that, under international humanitarian law, parties to armed conflicts have an obligation not to impede the provision of medical care to civilian populations located in territories under their effective control. This includes access to necessary narcotic drugs and psychotropic substances.

### Receiving donations in times of crises

#### *Communication and flexibility are key*

On 4 August 2020, a huge explosion occurred at the port of Beirut in Lebanon, causing at least 200 deaths and 6,000 injuries, and extensive infrastructure damage up to 8 km away. The explosion also resulted in considerable loss of medications and significant damage to several port entries, which further complicated the logistical situation faced by the authorities in receiving international assistance.

A national emergency of two weeks was immediately declared by the Government, after which the Ministry of Public Health swiftly drew up a corresponding emergency plan to overcome the logistical challenges and address the pressing medical needs of the injured. As the first step of the emergency plan, the Ministry conducted an analysis of the situation to lay out immediate actions. It then strived to save as many medications, including controlled substances, as possible. Meanwhile, alternative entry sites (the port of Tripoli, the Beirut airport and the intact, functional parts of the port of Beirut) were also designated for receiving humanitarian assistances.

As several exporting countries that implemented simplified control measures during emergency situations had not informed the competent national authorities of Lebanon about their shipments, the simultaneous influx of donations from different parts of the world within a short time, although they were a strong sign of goodwill and support from the international community, posed additional challenges to the receiving authorities. A delicate balance between expediting the movement of controlled substances for urgent medical needs and preventing their diversion became particularly hard to achieve amid the chaos and competing priorities.

As all activities concerning controlled substances in Lebanon are governed by Narcotics Law 673/98, the Narcotics Department of the Ministry of Public Health continued to issue import authorizations for all imports of controlled substances. Exemption for such issuance, however, had been granted to donations containing controlled substances, in order to expediate their supply to the injured.

To ensure that only credible operators handled controlled substances – a legal requirement for controlled substances in Lebanon – all donations were delivered only to the Lebanese military or eligible non-governmental organizations, for further distribution to the hospitals. Furthermore, all donations were checked by the Pharmaceutical Inspection Department before entering the country. Medications past their expiry dates or with other quality issues that failed to comply with national standards were also rejected in order to safeguard the health of the injured.

158. The Board invites Governments and humanitarian relief agencies to bring to its attention any problems encountered in exporting and/or receiving controlled substances during emergency situations. Together with the help of international humanitarian organizations and other United Nations agencies, INCB will continue to monitor and assist in the implementation of the simplified control measures during emergency situations, so as to ensure the timely supply of controlled substances to alleviate the pain and suffering of the most vulnerable.