Lessons from countries and humanitarian aid organizations in facilitating the

Timely Supply of Controlled Substances during Emergency Situations

Over the past year with the global Covid situation, countries and humanitarian aid organizations were faced with considerable challenges in the timely supply of, and access to, controlled substances to emergency sites.

In response to these supply problems in emergency situations, WHO already in 1996 had developed the Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care (WHO Model Guidelines).

The International Narcotics Control Board (INCB), in line with its mandate under the international drug control conventions on the availability of controlled medicines, convened a meeting on 18 and 19 March 2021 to discuss and analyse the supply problems and identify best practices on how countries and the global community can facilitate the availability of controlled medicines during emergency situations by using these Model Guidelines. The meeting brought together the competent authorities of twenty-two countries and representatives from WHO, UNICEF, UNODC, ICRC and MSF with direct experience and involvement in these supply policies.
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Based on the experiences from the participants and the discussions, the meeting concluded that:

1. **It is critical to increase awareness among Governments and the international community of the rising need for pain and palliative care treatment, as well as treatment for mental health conditions, in emergency situations that require the use of internationally controlled substances.**

2. **Competent authorities in both the exporting and recipient countries are strongly encouraged to exercise the highest degree of flexibility and discretion in their application of control measures on the international trade of controlled substances during emergency situations.**

3. **Governments and the international community are encouraged to apply the simplified control measures as outlined in the WHO Model Guidelines, taking into consideration the following practical notes**

   - **Governments are strongly encouraged to review existing national legislation on controlled drugs and make amendment and/or adopt new provisions that allow for flexibility on the import and export of controlled substances during emergency situations, including for pharmaceutical products without prior registration in the country.**

   - **Depending on the urgency of the emergency situations, competent authorities of the exporting countries might wish to grant special permission to credible humanitarian organizations in applying the relevant control procedures (e.g., application of export authorizations and data reporting) a posteriori, i.e. after the actual shipment.**

   - **All Governments, United Nations agencies, international humanitarian organizations and any other non-governmental organizations, when using the model authorization form (as included in the WHO Model Guidelines) for the international trade in controlled substances for emergency humanitarian purposes, should clearly specify**
     - The nature of the emergency (brief description of the emergency)
     - Availability of, and action taken to contact the authorities in the receiving country

   - **Respecting the national sovereignty and the emergency situations faced by recipient countries, competent authorities in the exporting countries and responsible organizations supplying controlled substances to sites of emergency, are strongly encouraged to communicate to the competent authorities (or relevant authorities) in the recipient countries, to the extent possible,**
     - The purpose of the shipment (e.g., emergency humanitarian assistance/donations)
     - Relevant information concerning the controlled substances (e.g., names, types and quantities)
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The competent authorities are encouraged to ensure that the relevant front-
line workers in the supply chain (customs officers, staff of ports/airports/ 
border crossings, staff in distribution centres, warehouses and pharmacies, 
etc.) are aware of the emergency procedures and have been trained in using 
them, and have a mandate to apply the flexibility needed.

As a number of controlled substances (fentanyl, lorazepam, midazolam 
and morphine) have been included in table 1 (medicines used in the 
general management of hospitalized patients with COVID-19) and/or in 
table 3 (medicines which interrupted supply could result in serious 
health consequences) of the Custom Medicines Prioritization lists of 
WCO, customs officers are therefore advised to follow the guidelines 
outlined in the Secretariat Note of the Role of Customs in facilitating and 
securing the cross-border movement of situationally critical medicines 
and vaccines, especially to areas severely impacted by COVID-19.

Taking stock of the challenges faced by competent authorities during the 
COVID-19 pandemic and the lessons learnt so far, competent authorities are 
encouraged to set up or improve national monitoring systems on tracking 
the consumption of certain essential controlled substances, so as to 
formulate a better forecast of future needs and facilitate the timely 
submission of revised estimates/assessments to INCB.

To improve emergency preparedness, Governments are encouraged to build 
up buffer stocks and revise their estimates/assessments of some controlled 
substances, particularly those needed for the treatment of COVID-19 
patients and/or those listed in the WHO Model Lists of Essential Medicines.

To facilitate the availability of controlled substances during emergency 
situations, competent authorities are encouraged to

- Simplify their template for import and export authorizations, based on the 
template (import, export) established by the Commission on Narcotic Drugs, if needed
- Review their internal procedures on the issuance of import and export 
authorization (i.e., streamline the procedure without creating additional bottlenecks)
- Provide clear guidance to all stakeholders on the requirements and procedures 
for the application of import and export authorizations for controlled substances

To expedite the issuance and exchange of import and export authorizations 
in a secure manner, Governments are further encouraged to issue electronic 
import and export authorizations via the International Import and Export 
Authorization System (I2ES) and request relevant assistance from INCB, 
if needed.

Vienna, August 2021
For more information, visit the website of the Board  www.incb.org