IMPORTATION PROCEDURE OF THE CONTROLLED MEDICINES AS A PART OF HUMANITARIAN AID TO UKRAINE

(Draft date: 17 May 2022)

1. OVERVIEW OF UKRAINIAN AND INTERNATIONAL REGULATIONS RELATED TO CONTROLLED MEDICINES

As of today, there is no mention of importation procedures for controlled medicines to Ukraine for humanitarian aid purpose in any regulatory statements.

Ukrainian legislation, namely Resolution No.770* of the Cabinet of Ministers of Ukraine (the ‘CMU’) dated 6 May 2000(last revision on 11.04.2022, status-active), establishes the ‘List of Narcotic Drugs, Psychotropic Substances and Precursors’ (hereinafter – the ‘List of Narcotic Drugs’), which provides a list of narcotic substances, psychotropic substances and precursors, separated into 4 categories:

- Prohibited narcotic substances and psychotropic substances (Table I):
  - Especially dangerous narcotic substances which turnover is prohibited (Schedule 1);
  - Especially dangerous psychotropic substances which turnover is prohibited (Schedule 2);
  - Plants, containing narcotic and psychotropic substances, which turnover is allowed for manufacturing purposes (Schedule 3);

- Narcotic substances and psychotropic substances with limited turnover (Table II):
  - Narcotic substances with limited turnover (Schedule 1);
  - Psychotropic substances with limited turnover (Schedule 2);

- Narcotic substances and psychotropic substances with limited turnover and exclusion of certain control measures (Table III):
  - Narcotic substances with limited turnover and exclusion from certain control measures (Schedule 1);
  - Psychotropic substances with limited turnover and exclusion from certain control measures (Schedule 2);

- Precursors (Table IV):
  - Precursors with limited turnover subject to control measures (Schedule 1);
  - Precursors subject to control measures (Schedule 2).

The State Service of Ukraine on Medicinal Products and Drugs Control (hereinafter – the ‘SSM’) is a state body controlling the turnover of narcotic drugs, psychotropic substances and precursors, and combating its illegal trafficking. The SSM is responsible for the licensing of commercial activities connected with the production and import of medicinal products, wholesale and retail of medicinal products, and the turnover of narcotic drugs, psychotropic substances and precursors.

Pharmaceutical warehouses, pharmacies and their branches shall receive a special license for production, storage, transportation, purchase, sale, import, export, usage and utilization of narcotic drugs, psychotropic substances and precursors included in the List of Narcotic Drugs.

Under Ukrainian law, the illegal production, purchase, storage, transportation, transmission or turnover of narcotic drugs, psychotropic substances and their analogies as well as illegal cultivation of cannabis plants may entail administrative or criminal liability.

Ukraine also fulfills its international obligation in the field of control over narcotic and psychotropic drugs turnover. Notably, Ukraine is a participant of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which together set the framework for international drug control regulation.
Combating the illegal turnover of narcotic drugs, psychotropic substances and precursors is the responsibility of the National Police, the Security Service of Ukraine, the General Prosecutor’s Office, the State Fiscal Service, the State Border Service, and other bodies within their authority.

**Position and recommendations of the International Narcotics Control Board (INCB) regarding Ukraine**

On 1 March 2022, the INCB sent a circular letter Ref.: E/INCB/PSY/C.L. 8/2022 to all Governments, reminding them that in acute emergencies it is possible to apply simplified control procedures for the export, transportation and provision of medicines containing internationally controlled substances. This letter is focused on the Ukrainian emergency response.

Later, on 21 March 2022, the INCB together with the World Customs Organization (WCO), issued a joint letter, which was addressed to all WCO Members (184 Customs administrations). The letter highlights the simplified control procedures that can be applied in acute emergencies to the export, transportation and provision of medicines containing internationally controlled substances. Customs officers are encouraged to be aware of the simplified procedures for controlled medicines, while exercising the necessary control to expedite the cross-border movement of these goods to Ukraine and neighboring countries.

2. **DETAILED PROCESS**

2.1. **Forecast & validation**
   2.1.1. Need to have a formal request from MOH Ukraine (reference in the template 1).
   2.1.2. Need to identify the beneficiary(ies) who will receive the controlled medicines.

2.2. **Import license/permit (Ukraine side)**
   2.2.1. Even if the import license is automatic due to the context, it is better to ask for official letter from MoH. Please issue the official letter to the MOH of Ukraine (see template 1). Please include to the demand for import permit the two facilitation letters (INCB + WCO).
   2.2.2. Receiving the official response of MOH of Ukraine about recognition and obtaining a permit for the importation of controlled medicines is highly recommended due to the nature of imported items.
   According to the resolution of the Cabinet of Ministers of Ukraine of March 1, 2022 № 174 "Some issues of passage of humanitarian aid across the customs border of Ukraine under martial law" goods are recognized as humanitarian aid on a declarative basis without a decision of specially authorized state bodies on humanitarian aid.
   2.2.2. Need to ask supplier to share what are the necessary documents to obtain the exportation license. (to make sure that you asked for those in the letter to MoH UKR)
   2.2.3. The official response received from Ukraine MoH need to be shared with the suppliers, even if for EU countries there is a temporary exception (automated import license for Ukraine). This will help supplier to apply for the export license.

2.3. **Export license (could be from a supplier/manufacturer):**
   Export permit is delivered by the national regulatory authorities of the exporting country. Each country national rules/laws apply. Note that for EU rules are different from one country to another. Lead time varies from one country to another depending on the national rules / laws.
   Make sure that the consignee address is in Ukraine, controlled medicines need to be shipped directly to Ukraine, no transit to EU countries.

3. **VALIDITY OF UKRAINIAN EMERGENCY RESPONSE LEAD TIME**
Based to the resolution of the Cabinet of Ministers of Ukraine of March 1, 2022 № 174 "Some issues of passage of humanitarian aid across the customs border of Ukraine under martial law» and the facilitation letters from INCB and WCO are aiming to simplified export from territories of other countries and import of the controlled medicines during martial time into Ukraine for purpose of the emergency response.

Please be aware that situation is temporary, the simplified procedure of importation the controlled medicines as part of humanitarian aid can change at any time or be dropped. Please carefully monitor the CABINET OF MINISTERS OF UKRAINE RESOLUTION # 174 on the website https://zakon.rada.gov.ua/laws/show/174-2022-%D0%BF?lang=ukText.