Federal Ministry of Health

Promulgation

of the General Administrative Act concerning the export of medicinal products, which are also narcotic drugs, to Ukraine and the countries neighbouring Ukraine that are also Member States of the European Union for the benefit of the Ukrainian civilian population

of 7 March 2022

The war in Ukraine endangers the life and health of the affected population. Among other things, the supply of certain medicinal products is precarious. By issuing this General Administrative Act, the Federal Ministry of Health creates the prerequisites for enabling aid organisations to export these medicinal products to Ukraine and the countries neighbouring Ukraine that are also Member States of the European Union for the purpose of putting them to therapeutic use there.

In respect of sections 3 (1) and 11 (1) and (2) of the Narcotic Drugs Act (BtMG) in conjunction with section 15 of the Ordinance on the Foreign Trade in Narcotic Drugs (*Betäubungsmittelaußenhandelsverordnung – BtMAHV*), the Federal Ministry of Health, as the superordinate authority, issues the following Order:

1. Regulations on the export of narcotic drugs

1.1 This General Administrative Act covers narcotic drugs contained in Annex III to section 1 (1) of the Narcotic Drugs Act that are authorised as finished medicinal products.

1.2 Any person who intends to export narcotic drugs as specified in number 1.1. to Ukraine, and the countries neighbouring Ukraine that are Member States of the European Union, for therapeutic use in accordance with the emergency provisions stipulated in section 15 of the BtMAHV, to help those affected by the war in Ukraine, is considered to have been granted a licence to trade in narcotic drugs pursuant to section 3 (1) of the Narcotic Drugs Act and an export licence pursuant to section 11 (1) of the Narcotic Drugs Act for these purposes.

1.3 Entitled under number 1.2 are the humanitarian organisations that are part of the Humanitarian Assistance Coordinating Committee (https://www.auswaertiges-

amt.de/de/aussenpolitik/themen/humanitaere-hilfe/koordinierungsauss-chuss/238814).
Entitled under number 1.2 are also all hospitals in Germany.

1.4 Prior to export, anyone exporting narcotic drugs on the basis of this General Administrative Act must provide the Federal Opium Agency at the Federal Institute for Drugs and Medical Devices (BfArM) with the necessary information on the type, quantity and origin of the narcotic drugs. The information is to be sent by email to the following email address: btm-einfuhr-ausfuhr@bfarm.de.

1.5. For the customs declaration the legally binding declaration that the notification pursuant to number 1.4 has been transmitted, must be submitted to the competent export customs office. To this end, the following declaration must be made under Section 31 of the customs declaration "Description of goods": "This is a legally binding declaration that I have provided the Federal Opium Agency at the Federal Institute for Drugs and Medical Devices with the necessary information on the type, quantity and origin of the narcotic drugs registered for export, prior to such export. I am aware that false declarations in this respect will be penalised."

2. Clarification regarding medicinal products that are not narcotic drugs, and medical devices

The export of medicinal products that are not narcotic drugs does not require an export licence. The same applies to the export of medical devices.

3. Promulgation

This General Administrative Act is considered promulgated on the day following its publication on the website of the Federal Ministry of Health. It will cease to have effect on repeal.

4. Information regarding appeals

This General Administrative Act can be appealed, within one month of publication, at the Cologne Administrative Court (Verwaltungsgericht Köln), Appellhofplatz, 50667 Köln.

Bonn, 7 March 2022

The Federal Ministry

of Health

For the Federal Minister of Health

Müller