

Russia, Belarus, and Occupied/Covered Regions of Ukraine

Best Practices for License Applications for Medical-related Items

The following guidance was prepared for exporters' use in submitting export license applications involving medical-related items destined to Russia, Belarus, and the Occupied/Covered Regions of Ukraine. Consistent with licensing policies set forth in Sections 746.5, 746.6, 746.8, and 746.10 of the Export Administration Regulations (15 CFR Parts 730-774, "EAR"), license applications for health and safety, medical, and humanitarian applications are generally reviewed on a case-by-case basis. This review policy reflects the U.S. Government's position that the Russian and Belarusian people are not the target of export controls imposed on Russia in response to its invasion and continuing aggression in Ukraine, as well as on Belarus, which has substantially enabled Russia's actions. However, the U.S. Government reviews all export license applications to evaluate whether approving the application would benefit the Russian or Belarusian government or defense sector, particularly with regard to the usefulness of the items for the treatment of battlefield casualties or the production of chemical and biological weapons and biotechnological (including biopharmaceutical) products.

You are encouraged to follow these guidelines to assist the reviewing agencies in processing your application more efficiently and expeditiously. We recommend that you provide all the necessary information when the application is first submitted so that the Bureau of Industry and Security (BIS) can promptly analyze the proposed scope of the transactions before referring the application for interagency review consistent with Executive Order 12981, as amended.

End-Use/User Statements

A statement certifying that due diligence has been exercised to ensure the medical facilities listed as ultimate consignees or end-users on the application are civilian facilities providing direct patient care facilitates a determination that the application will meet the humanitarian needs of the Russian or Belarusian people, rather than contribute to military or government resources in support of the war effort. The Ministries of Defence of both the Russian Federation and Belarus, including the national armed services (army, navy, marine, air force, or coast guard), are "military end-users" on the BIS Entity List in Supp. No. 4 to part 744 of the EAR, and exports to hospitals owned or operated by the Ministries will be reviewed consistent with the policy of denial that applies to the Ministries in general, with the exception of food and medicine designated as EAR99, which will be reviewed on a case-by-case basis.

License Scope

When licenses for exports (along with reexports and transfers in-country) to Russia, Belarus, and the Occupied/Covered Regions of Ukraine are approved, it is typically with a one-year validity period in order to limit the risk of diversion in a dynamic and fluid wartime environment.

License applications with a relatively narrow transaction scope can more quickly be evaluated by the reviewing agencies for risk of diversion, and thus tend to move through the interagency review process more efficiently than applications with many parties and large quantities of items.

As a best practice, consider narrowing your license application scope to a single consignee/distributor, no more than 100 end users (preferably fewer), and a 1-year supply of item quantities. When item quantities are correlated to demonstrable civilian demand, such as by referring to historical patient volume at the proposed end-users, interagency reviewers will often be able to resolve concerns over the risk of diversion more quickly.

Export Item Grouping

For license applications with varying categories of items (*e.g.*, several different types of items that could all be categorized as “consumables”), list the items individually but group them into like categories which clearly describe to interagency reviewers what items are being exported. License applications that include general item descriptions without specifics that can be evaluated by reviewing agencies (*e.g.*, “consumables” with no further description), or applications that only refer to an attachment often create inefficiency in consideration of diversion risk, including necessitating the need to request follow-up information. Providing a reference to specific Harmonized System (HS) Codes, where applicable, helps to reduce classification confusion and facilitate timely review, as does citation to relevant regulatory provisions in the EAR that apply to export of the item at issue (*e.g.*, after an item description, add “HS 902511, controlled under Section 746.5 and Supp. No. 4 to part 746 of the EAR”).

Direct Patient Care

License applications for medical-related items (*e.g.*, medicine, medical devices, medical equipment) move through the interagency review process more efficiently if they clearly demonstrate that the end users will use the items to provide direct patient care to civilian patients in a civilian treatment facility. Parties that clearly do not provide direct patient care to civilians or who are not purchasers or consignees/distributors may be removed from license applications to facilitate the processing of applications that focus on providing direct patient care to the Russian or Belarusian people.

The Centers for Disease Control and Prevention define “[direct patient care](#)” as “Hands on, face-to-face contact with patients for the purpose of diagnosis, treatment and monitoring.”

HS Codes

HS Codes are used globally to classify goods (commodities or physical products) for export and are used by customs authorities when assessing duties and gathering statistics. The HS is administered by the World Customs Organization and is updated every five years. It serves as the foundation for the import and export classification systems used in the United States and by many trading partners. The HS assigns specific six-digit codes for varying classifications and commodities. Countries are allowed to add longer codes to the first six digits for further classification. The United States uses a 10-digit code to classify products for export, known as a Schedule B number, with the first six digits being the HS number. There is a Schedule B number for every physical product. The Schedule B is administered by the U.S. Census Bureau's [Foreign Trade Division](#).

BIS is not able to classify goods by HS code in connection with a license application. Exporters may generally use the same HS code for BIS license applications as they use for other purposes, such as reporting shipments in the Automated Export System (AES), determining import tariff (duty) rates, or determining whether a product qualifies for preferential tariff treatment under a free trade agreement. For additional information, including on HS Code classification, *see* International Trade Administration, U.S. Department of Commerce, [Harmonized System \(HS\) Codes](#). To obtain a formal determination of an item's HS code, you may request a ruling letter from U.S. Customs and Border Protection (CBP); *see* CBP, [What are Ruling Letters?](#) License applications issued by BIS only authorize transactions involving the HS codes described on the license. If you misclassify your item, the BIS license may not authorize your proposed transaction.

The guidance in this document is intended to help exporters draft applications that can be reviewed efficiently. It does not impose or otherwise create additional requirements for license applications. All license applications received by BIS will be reviewed consistent with the provisions of Executive Order 12981 and the relevant provisions of the EAR, even if they do not contain the level of detail recommended in this guidance.

Best Practices Checklist

- Have you provided a statement certifying that the medical facilities on the application are civilian facilities providing direct patient care only to civilian patients?
- Are the item quantities scoped to what would be used over the period of 1 year?
- Do the items for export have an identifying description in the Technical Description Block?
- Did you scope the license to minimize the risk of diversion to unauthorized end users/end uses?
- For items controlled by HS code, have you included the HS code that covers your items and the section of the EAR where that HS code is referenced?
- Did you provide a description of how the items would be used for direct patient care?

- Have you explained the role of any parties that do not provide direct patient care?