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New License Exception Authorizes Exports of Previously Restricted Medical Devices and Related Items to Russia, Belarus, Occupied Ukraine

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The US Department of Commerce's Bureau of Industry and Security (BIS) added a new License Exception for Medical Devices (License Exception MED), effective April 29, 2024, authorizing exports, reexports and transfers of certain medical devices and related parts, components, accessories, and attachments for use therein to Russia, Belarus, and the Crimea, Donetsk People's Republic, and Luhansk People's Republic regions of Ukraine (collectively, the subject countries). License Exception MED likely will be a welcome change for clinical research, pharmaceutical and other medical device exporters who remain active in the subject countries, and is anticipated to reduce licensing volume for BIS significantly.

In response to Russia's February 2022 invasion of Ukraine, BIS expanded license requirements for exports to the subject countries of items subject to the Export Administration Regulations (EAR). Notably, BIS's license requirements previously applied to a broad range of medical devices and related items classified for export control purposes as EAR99 – a classification that typically does not trigger a country-based license requirement for Russia or Belarus. License Exception MED effectively eliminates these licensing requirements, subject to certain conditions.

For purposes of License Exception MED, "medical devices" are defined with reference to section 201 of the Federal Food, Drug, and Cosmetic Act and include – without limitation – medical supplies, instruments and equipment. To reduce the risk of diversion to industrial or military end uses, only parts, components, accessories and attachments that are necessary for replacement or maintenance in or with EAR99 medical devices are authorized.

Importantly, License Exception MED does not authorize:

1. Exports of covered medical items to restricted parties, including Entity List parties or military end users.
2. Exports to a "production facility" with knowledge or reason to know that the device is intended to develop or produce items (for purposes of this restriction, the assembly in a hospital or other healthcare facility of a finished medical device produced entirely outside the subject countries for the sole purpose of using that medical device at the same hospital or healthcare facility does not constitute "production").

Further, parties relying on License Exception MED "must maintain a system of distribution" to ensure that covered items are not delivered to restricted parties or used in production. Compliance verifications may involve obtaining documentation and affirmations from consignees and conducting periodic onsite spot-checks. Parties must maintain records of verifications for a period of five years (in addition to the standard recordkeeping requirements of the EAR).

Although License Exception MED provides relief to medical device exporters, exports to and other dealings with the subject countries remain considerably restricted. Importantly, US persons are prohibited from "new investment" and providing various services – including management consulting, accounting, and trust and corporate formation services. Accordingly, all activities involving the subject countries should be closely evaluated to ensure compliance with applicable laws and regulations.

Cooley closely monitors enforcement-related and other regulatory developments. If you have any questions, please reach out to your Cooley contact or one of the lawyers listed below.

Cooley associate Shelby Saunders also contributed to this alert.

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