

International Trade Alert

January 3, 2017

OFAC Expands Iran-Related Authorizations for Medicine, Medical Devices and Agricultural Commodities

On December 23, 2016, the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) issued a Final Rule amending the Iranian Transactions and Sanctions Regulations, 31 C.F.R. Part 560 (ITSR) to expand the scope of permissible exports/re-exports of medicine, medical devices and agricultural commodities to Iran.

While helping improve Iran's access to medical devices and patient safety, these changes lower the regulatory barriers for U.S. agricultural, medical and pharmaceutical companies to export products and services to Iran. Specifically, the Final Rule makes the following changes:

- expands the scope of medical devices and agricultural commodities authorized for export or re-export to Iran
- provides new authorization for training related to the safe and effective use of medicine, medical devices and agricultural commodities
- expands the scope of authorization for replacement parts
- authorizes the export/re-export of software and services related to the operation, maintenance and repair of medical devices
- authorizes the importation into the United States of items that are broken or connected to product recalls or other safety concerns
- clarifies the definition of the terms "goods of Iranian origin" and "Iranian-origin goods."

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1. Additional Medical Devices and Agricultural Commodities

OFAC expanded the general license at ITSR 560.530(a)(3), which previously authorized the export or re-export to Iran of medicine and certain medical devices specifically listed on OFAC's "List of Medical Supplies." Following the amendment, the general license authorizes all items meeting the ITSR definition of "medical devices," except for those that are specifically excluded. The medical devices that are excluded from the general license can be found on OFAC's new "List of Medical Devices Requiring Specific Authorization."

OFAC has also updated the list of agricultural commodities excluded from the general license for the export/re-export of agricultural commodities at ITSR 560.530(a)(2). Shrimp and shrimp eggs, which had previously not been covered by the general license, will no longer require specific OFAC authorization.

2. Training “Necessary and Ordinarily Incident to” the Safe and Effective Use of Medicine, Medical Devices and Agricultural Commodities

OFAC also added a provision to authorize training “necessary and ordinarily incident to” the safe and effective use or operation of medicine, medical devices and agricultural commodities exported or re-exported under an Ag/Med general license. OFAC considers the following nonexhaustive list of training activities to be “necessary and ordinarily incident to” the safe and effective use or operation of medicine and medical devices (see FAQ 484):

- dissemination of product information on the intended use of the device
- comparisons of other devices and options
- manufacturer's instructions for use, labeling, warning, contraindications, storage, and maintenance of the medicine or device to be necessary and ordinarily incident to the safe and effective use of medicines and medical devices
- training of health care professionals to use medical devices safely in order to achieve the desired patient outcome
- training on procedures for cleaning and inspecting devices regularly to ensure that they are functioning correctly
- ongoing training and periodic testing to ensure that users stay competent
- training on procedures for adverse events or device failure.

3. Additional Replacement Parts for Certain Medical Devices

OFAC also expanded the general license at ITSR 560.530(a)(4), which previously authorized the export or re-export of replacement parts on a one-for-one basis of exchange. OFAC removed the one-for-one basis of exchange requirement and now authorizes the export or re-export of replacement parts for storage within Iran for future use, as long as:

- the replacement parts are intended to replace a broken or nonoperational component of a medical device previously exported or re-exported to Iran pursuant to an OFAC authorization, or the export/re-export of the replacement part is ordinarily incident and necessary to the proper preventative maintenance of the medical device
- the number of replacement parts that are exported or re-exported to and stored in Iran does not exceed the number of corresponding parts in use in relevant medical devices in Iran.

To be eligible for this general license, replacement parts must be designated EAR99 or, in the case of replacement parts that are not subject to the Export Administration Regulations (EAR), would be designated as EAR99 if located in the United States.

4. Software and Services Necessary for the Operation, Maintenance and Repair of Medical Devices

OFAC added a new general license at ITSR 560.530(a)(5) to authorize the export/re-export to Iran of software and services necessary for the operation, maintenance, and repair of medical devices and replacement parts. Specifically, the authorizations allow for the export/re-export of the following software and services:

- software for safety and service updates and the correction of system/operational errors in medical devices, replacement parts and associated software previously exported/re-exported pursuant to an OFAC authorization under the Ag/Med Program;
- software to maintain/repair medical devices previously exported/re-exported pursuant to an OFAC authorization under the ITSR, as well as related transactions subject to certain conditions repair services for medical devices authorized for export or re-export to Iran by OFAC under the Ag/Med Program, including inspection, testing, calibration, and diagnostic services to ensure patient safety or effective operation of such medical devices.

To be eligible for this general license, software must be designated EAR99 or, in the case of software that is not subject to the EAR, would be designated as EAR99 if located in the United States.

5. Importation of Items that Are Broken, Defective or Nonoperational

OFAC added a new general license at ITSR 560.530(a)(6) to authorize the importation into the United States of certain U.S.-origin agricultural commodities, medicine and medical devices that were previously exported to Iran under the Ag/Med Program and are:

- broken, defective or nonoperational connected to product recalls, adverse events or other safety concerns.

6. Definition of “Goods of Iranian Origin” and “Iranian-Origin Goods”

The revised rules also update the definition of the terms “goods of Iranian origin” and “Iranian-origin goods.” As long as goods are not grown, produced, manufactured, extracted or processed in Iran, “goods of Iranian origin” or “Iranian-origin goods” do not include the following categories:

- goods exported or re-exported to Iran under an ITSR authorization that are subsequently re-exported from and are located outside of Iran or
- goods transported on a vessel or aircraft that have not come into contact with Iran other than (1) passing through Iranian territorial waters or (2) stopping in Iran en route to another destination outside of Iran.

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