

Insights

MEDICAL INDUSTRY: CERTAIN CLINICAL TRIALS AUTHORIZED

Mar 28, 2022

On March 24, 2022, the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC") updated General License 6 of Executive Order ("EO") 14024 under the Russia Harmful Foreign Activities Sanctions Regulations. **General License 6A of EO 14024 now includes authorization for ongoing clinical trials and other medical research activities that were in effect prior to March 24, 2022.**

General License 6 of EO 14024 previously authorized U.S. persons to engage in activities ordinarily incident and necessary to the following activities:

- The export and re-export of medicines, medical devices, replacement parts and components for medical devices, and software updates for medical devices to, from, or transiting the Russian Federation; and
- The prevention, diagnosis, or treatment of COVID-19 (including research or clinical studies relating to COVID-19).

Now General License 6A of EO 14024 ("General License 6A") also authorizes U.S. persons to engage in ongoing clinical trials and other medical research activities that were in effect prior to March 24, 2022. This impacts those companies with a U.S. nexus to their clinical trials and other medical research activities, such that U.S. sanctions restrictions affected what could or could not be done going forward.

Given that the Russia-related sanctions do not prohibit all activities in Russia, not all parties with clinical trials or medical research in Russia need to rely on General License 6A for authorization to keep their activities going. Rather, this impacts activities that had been (or will be) affected by U.S. sanctions because the trials involved a Specially Designated National and Blocked Person ("SDN") designated under EO 14024 only. The SDN may be an entity or individual affiliated with the trials or research, or it may be a bank through which payments associated with the work passed. With the introduction of this updated general license, companies with clinical trials and other medical research activities already in existence in Russia prior to March 24, 2022, and affected by the

sanctions imposed under EO 14024 can continue those programs by relying on this General License.

Notably, the inclusion of clinical trials and other medical research activities in a general license focused on medicine and medical devices is unique to General License 6A. Companies cannot construe the authorization provided for clinical trials in General License 6A to apply to prohibited activities under any other sanctions programs, including those concerning Belarus or the so-called Donetsk People's Republic ("DNR") or Luhansk People's Republic ("LNR") regions of Ukraine.

Likewise, the scope of authorized activities with SDNs remains limited to those SDNs designated under EO 14024. Transactions with SDNs designated under other sanctions programs are not authorized by General License 6A of EO 14024. Hence, to the extent that any SDNs are identified, it is important to identify all program designations applicable to the SDN in order to verify whether this general license authorizes activities involving that SDN.

The authorization for activities ordinarily incident and necessary to ongoing clinical trials and other medical research activities includes interacting with banks designated as SDNs pursuant to EO 14024 in order to process transactions related to the activities described in the General License; however, General License 6A does not permit:

- opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity on the Correspondent Account or Payable-Through Account ("CAPTA") List (Directive 2 of EO 14024); or
- debits to accounts on the books of US financial institutions of the Russian Central Bank, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation.

In all cases where a general license is relied upon, companies must first ensure all requirements under the general license are met and the scope of the general license is not exceeded. BCLP's international trade team can assist you to answer any questions you have about whether the General License 6A will authorize your Company's specific activities.

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