MOROĞLU ARSEVEN

More Medical Devices and Protective Equipments are Included to Products Subject to Prior Authorization, as per the Communiqué numbered 2020/6

1 Apr 2020

As per the Communiqué Amending the Communiqué Regarding Prohibited Goods and Goods Subjected to Prior Authorization ("**Communiqué numbered 2020/6**") published in the Official Gazette number 31080 and dated 26 March 2020, the export of the following goods placed on the market in line with the Regulation of Medical Devices

- Ventilators
- Ecmos
- Oxygen concentrators
- Ventilation consumables (flow sensors, expiration valves, oxygen sensors, ventilator circuits)
- Anesthesia /ventilator circuits
- IV cannulas
- Intubation tubes
- Intensive care monitors

have been subjected to the prior authorization of Turkish Medicines and Medical Devices Agency ("**Agency**").

Previously, certain medical devices have been subjected to the same authorization with the Communiqué Amending the Communiqué Regarding Prohibited Goods and Subject to Prior Authorization ("Communiqué numbered 2020/4") published in the Official Gazette number 31058 and dated 4 March 2020.

Classification of the Concerned Goods

- The Regulation on Medical Devices defines medical devices as; "*Any instrument, apparatus, appliance, software, accessory or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for the device's proper application, manufactured to be used for human beings for the purpose of: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease diagnosis, (ii) monitoring, treatment, alleviation of or compensation for an injury or handicap, (iii) investigation, replacement or modification of the anatomy or of a physiological process, (iv) conception control, in which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means*".
- Regulation on Personal Protective Equipment defines personal protective equipment as; *"(i) equipment designed and manufactured to be worn or held by persons for the purpose of protection against one or more health and security risks, (ii) changeable parts required for the protective purposes and belonging to the equipment defined under item (i), (iii) connection systems that are not worn or held by persons, belonging to the equipment defined under item (i) designed to attach the equipment to an external device or a proper anchoring point and that are not permanently attached to a structure and not required to be fastened before use*."

Procedures and Principles Regarding the Prior Authorization Application

Procedure and principles pertaining to the authorization application that is to be made to the Agency for the export of the goods subjected to the prior authorization of the Agency are explained in the announcements made on the

Agency's website on 5 March 2020, 6 March 2020 and 26 March 2020.

Accordingly;

- According to the temporary article introduced in the Communiqué numbered 2020/6, no prior authorization shall be required regarding the goods declared in the customs declaration which have been registered prior to 26 March 2020. Whereas, the export of the goods declared in the customs declaration of which have not been registered before such date shall be subject to prior authorization of the Agency.
- Applications are free of charge and may only be made by the company's authority, on behalf of whom the customs declaration will be issued.
- Applications to the Agency must be made separately for each declaration of export, as the authorization shall be granted for the number of goods declared in the declaration of export. In addition, if the export destination countries are more than one, prior authorization application must be made separately for each declaration and country.
- As of 27 March 2020, prior authorization applications shall be solely made through the Electronic Information Management System by real and legal persons. The procedure to be followed with regards to the application and template petitions are provided in the announcement published on the Agency's website and the user manual provided.
- If the authorization application is approved, the Single-Window System number will be granted automatically and sent to the e-mail address provided in the application. The export processes will be carried out through such number

Please see this link for the full text of the Communiqué numbered 2020/6 (only available in Turkish).