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Some Medical Devices and Protective Equipments were Added among Products Subject to Prior Authorization, as per the Communiqué numbered 2020/4

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As per the Communiqué Amending the Communiqué Regarding Prohibited Goods and Subject to Prior Authorization ("**Communiqué numbered 2020/4**") published in the Official Gazette dated 4 March 2020 and numbered 31058;

- Export of the following goods placed on the market in line with the Regulation on Personal Protective Equipment;
    - Protective masks (gas, dust and radioactive dust filtered masks)
    - Jumpsuits as protective work-clothes
    - Waterproof aprons (protective aprons used against chemicals)
    - Protective glasses
- Export of the following goods placed on the market in line with the Regulation on Medical Devices;
    - Medical and surgical masks,
    - Sterilized/non-sterilized medical gloves

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

Classification of the Concerning Goods

- 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) control of conception, and 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 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;

- As per the Communiqué Amending the Communiqué Regarding Prohibited Goods and Subject to Prior Authorization published in the Official Gazette number 31080 dated 26 March 2020, no prior authorization shall be required for the goods that have been declared in the customs declaration which has been registered prior to 26 March 2020. Whereas, the export of goods declared in the customs declaration which has not been registered before such a date shall be subject to prior authorization of the Agency.
- Applications are free of charge and may only be made by the companys' 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 concerning 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.

Please see this link for the full text of the Communiqué numbered 2020/4 (only available in Turkish).