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Turkish Medicines and Medical Devices Agency Published an Announcement on Brexit Process for Medical Device Companies

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European Commission has published a memorandum ("**Memorandum**") regarding the leaving of the United Kingdom ("**UK**") from the European Union ("**EU**") without any agreements ("**No-deal Brexit**") and impact of such on industrial products including medical devices. Therefore, Turkish Medicines and Medical Devices Agency ("**TMMDA**") published an announcement ("**the Announcement**") for the firms that are active and will be affected by the no deal Brexit in Turkey.

In the Announcement, TMMDA stated that the steps to be taken to keep the product in the market depends on the issue whether a product has entered the market before Brexit.

In the case of No-Deal Brexit, the UK will be considered a third-party country outside the EU as of the date Brexit, authorized representatives' resident in the UK will lose their status in terms of EU. Therefore, for a medical device to enter the market from the UK or via the UK, an authorized representative should be appointed in Turkey or EU. Also, in this context, since Notified Bodies ("**NB**") in the UK will lose their status under EU legislation, to import medical devices from the UK, firms should obtain a CE certificate from an authorized NB.

Also, medical devices or in vitro medical diagnostic devices must be registered in the national registration system to be present in the EU or Turkish market together with the authorized representative of the EU or Turkey.

In the light of these information TMMDA suggested below mentioned preparations to be made:

- For health care service providers, research institutes and health insurance companies, an inventory should be created regarding trade volumes within the UK in the field of medical devices, for the devices are required to obtain an EC certificate from an NB located in the UK or which devices are marketed by a UK-based manufacturer.
- As to the manufacturers, authorized representatives and distributors:
    - Manufacturers of devices that have received a conformity assessment service from an established NB company in the United Kingdom must be prepared to transfer the product files from another country to the EU or another accredited NB.
    - An addressee who wishes to get delivery messages regarding the manufacturers of third countries that place their products in the UK or EU through a representative or importer in the UK must also appoint an authorized representative in the member states or Turkey. The label of the product should also be reprinted accordingly.
    - Manufacturers transferring the certification of their products from an NB to an EU / Turkey in the UK should reorganize the EU declaration of conformity and the notified body certificates accordingly. The documents in question must show that the responsibility is in the new NB and should contain both the old and new NB's info and numbers.
    - It is the duty of suppliers, wholesalers and medical device purchasers to inform healthcare providers and other users of medical devices about potential alternatives and problems that may be encountered in supply and presentation to the market. The best information on medical devices or

devices that are subject to a resident NB inspection in the UK that are put into EU market from the United Kingdom or third countries via the UK should be found in suppliers, wholesalers, and medical device purchasers.

ADDITIONAL ANNOUNCEMENT

In accordance with the 10 April 2019 dated decision of the European Council Brexit date has been postponed to 31 October 2019.

TMMDA published an additional announcement stating that:

- If certified by the 0086 numbered British Standard Institute (BSI) Assurance UK Ltd, the EC certification will be transferred administratively to the 2797 numbered notified body BSI Group The Netherlands B.V.
- If certified by the notified body other than 0086 numbered British Standard Institute (BSI) Assurance UK Ltd, medical device companies will transfer their products to another notified body that is not resident in the UK.

A transition period of at least 1-2 years is foreseen for the issues related to:

- The processes of the notified body transfer,
- The re-certification of the products and the technical documentation such as the label,
- The declaration of conformity and the user manual to the new notified body.

TMMDA designated the conditions in order to implement this transition period with minimum public loss in Tukey.

You may reach to TMMDA's announcement and additional announcement here. (Only available in Turkish)

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