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The Guide on The Implementation of the Regulation on the Sale, Advertising, and Promotion of Medical Devices Has Been Updated

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The Guide on the Implementation of the Regulation on the Sale, Advertising, and Promotion of Medical Devices ("**Guide**") has been updated by the Turkish Medicines and Medical Devices Agency ("**TMMD**"). This update, replacing Version 2, entered into force as of **September 27, 2024,** with Version 3 now published on TMMD's website.

With this update, TMMD has introduced new provisions regarding technical service activities for medical devices and the warranty certificates issued for medical devices.

The primary amendment is the addition of the fifth section titled "Provisions Regarding Technical Service and Warranty Certificates" to the guide, and new regulations have been made to the amendments made within the scope of the second revision which had taken effect on January 9, 2024.

Technical Service:

- Sales centers must fulfil their obligations regarding the technical service activities for medical devices and their accessories for which they act as the manufacturer or importer. The obligations have been outlined in the Regulation on Technical Service Activities for Medical Devices Used in Health Service Provision ("**Regulation**"), published in the Official Gazette on May 26, 2023, no. 32202.
- A commitment to provide technical service for the device and its accessories throughout their lifespan must be registered in the Product Tracking System ("**PTS**") by the sales centers, manufacturers, or importers in accordance with the relevant legislation, as stated in the annex of the Guide on the Implementation of the Regulation on Technical Service Activities for Medical Devices Used in the Scope of Health Service Provision ("**Implementation Guide**").
- Sales centers, manufacturers, or importers that do not submit their commitment in the **PTS** by January 1, 2025, will no longer be able to register the devices at issue in the system. Additionally, records of those failing to make such commitments will be removed after March 31, 2025.
- Sales centers, must fulfil spare parts requests from the technical service authorized by the **TMMD** within the scope of the **Regulation** or the health service provider to whom the device they are the manufacturer or importer of within 20 business days for domestic and 30 business days for international supply.
- When calculating the time for spare part supply, the period between the date the request is made and the date the part is delivered to the requester will be taken into account, excluding the time the requester will spend to receive approval for matters such as the price quote.
- The maximum time for international procurement will be 90 business days in cases where delays are caused by official procedures not under the sales center's responsibility. In force majeure situations, such as commercial restrictions, the timeframe may be extended by **TMMD** upon receiving the necessary documentation.

- Sales centers must supply, free of charge, all passwords and similar information required for technical service activities for devices they manufacture or import, for the entire lifespan of the device. This information must be provided within a maximum of 24 hours following a request from the healthcare provider where the device is in use.

Warranty:

- If healthcare providers opt to have a device replaced with an unused equivalent under their warranty rights, the standard forty-five-day period for fulfilling this request may be extended to 180 days if **TMMD** deems that this request places disproportionate hardship on the sales center.
- A separate warranty certificate will not be required for accessories covered by the device's warranty.
- The warranty certificate accepted by the healthcare provider through a permanent data storage device can be provided using various means, such as text message, email, internet, disk, CD, DVD, memory card, or similar formats. These methods must allow the information to be recorded, copied without alteration, and accessed in its exact form, enabling the healthcare provider to review the information for its intended purpose within a reasonable time.
- The warranty period will begin from the date the invoice is issued following the delivery of the device to the healthcare provider. However, if the invoice has to be issued before the delivery of the device due to commercial contracts or alternative financing models, the warranty period will start from the date of the actual delivery, irrespective of the invoice issuance date.
- The warranty certificates must also include the lifespan of the device as defined in Article 4, paragraph 1(cc) of the Regulation, under the section titled "Definitions."

The full text of the Guide can be accessed here.

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