Amendments Introduced to the Regulation on Medical Devices and Regulation on Medical Devices for In Vitro Diagnostic Purposes

28 Oct 2022

- The Regulation Amending the Regulation on Medical Devices prepared by the Turkish Medicines and Medical Devices Agency ("**Agency**") and the Regulation on Amending the Regulation on Medical Devices for In Vitro Diagnostic Purposes were published in Official Gazette dated 29 July 2022 and numbered 31907 and entered into force on the same day. The amendments aim harmonization with the European Union legislation.

The important amendments regarding the Medical Device Regulation are as follows:

- Manufacturers shall ensure that the information is in the official language(s) of the European Union determined by the European Union member country where the information about the device is presented to the user or the patient.
- Disposable devices that were placed on the market before 26 May 2021 in accordance with the previous legislation may be reprocessed.
- Manufacturers and others who will use the European Database for Medical Devices ("**EUDAMED**") should use terminology provided by the European Commission.
- Clinical applications will be subject to ethical review by an ethics committee to be established by the Agency.
- The Agency may make its own evaluations regarding adverse effects and take measures against them. The coordinating country and the European Commission shall be informed about these issues.
- Health professionals, users and patients shall report serious adverse events related to devices on the market to the Agency. The Agency shall record these reports and take appropriate measures.
- Devices manufactured using derivatives of human-derived tissues or cells placed on the market in accordance with the legislation in force before 26 May 2021 may continue to be placed on the market.
- Obligations regarding EUDAMED will enter into force 6 months after a notice that EUDAMED is fully functional is published in the Official Journal Gazette of the European Union.
- Obligations regarding registration and notice of certificate will be in effect for another 18 months from the date specified above.
- Apart from these obligations, the obligations in article 78 regarding the evaluation procedure for clinical trials, which are not related to EUDAMED, will enter into force on 26 May 2027.
- The provisions of the Regulation will be executed by the President of the Agency.

The amendments regarding the Regulation on In Vitro Diagnostic Medical Devices are as follows:

- Manufacturers shall ensure that the information is in the official language(s) of the European Union determined by the European Union member country where the information about the device is presented to the user or the patient.
- Manufacturers and others who will use EUDAMED should use terminology provided by the European Commission.
- The Agency may make its own evaluations regarding adverse effects and take measures against them. The coordinating country and the European Commission shall be informed about these issues.
- Health professionals, users and patients shall report serious adverse events related to devices on the market to the Agency. The Agency shall record these reports and take appropriate measures.

- In cases where one of the European Union member countries is the coordinating country, the final evaluation report will be taken into account by the Agency when deciding on the sponsor's application.
- The validity period of the devices within the scope of the Regulation has been regulated in detail.
- The provisions of the Regulation will be executed by the President of the Agency.

Please see this link for the full text of the Regulation Amending the Medical Device Regulation (only available in Turkish).

Please see this link for the full text of the Regulation Amending the Regulation on In Vitro Diagnostic Medical Devices (only available in Turkish).

Related Practices

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- IP Litigation

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