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The Turkish Medicines and Medical Devices Agency Has Published an Announcement Regarding Products That Fall Outside the Scope of the Medical Devices Regulations.

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The Turkish Medicines and Medical Devices Agency ("**T?TCK**") published the "Announcement on Products Not Evaluated under Medical Device Regulations" ("**Announcement**") prepared by the Medical Devices Approved Organization and Clinical Research Department on October 30, 2023.

The Announcement provides information regarding products that have not been evaluated under the medical device regulations. It includes definitions for medical devices and in vitro diagnostic devices according to the relevant regulations. Additionally, the Announcement offers details about the registration of medical devices and in vitro diagnostic devices.

Furthermore, the Announcement includes a list of products that are not within the scope of the medical device regulations, and therefore, there is no requirement for their registration in the Product Tracking System. The Announcement also explains the characteristics and categories of these products.

The Announcement also clarifies the definitions and intended uses of medical devices as regulated by the EU's Regulations 2017/745 and 2017/746.

In summary, the explanations within the Announcement cover the following points:

- Medical devices are products designed for medical purposes that do not work pharmacologically, immunologically, or metabolically within the human body.
- In vitro diagnostic devices refer to products used to examine samples obtained from outside the human body to provide medical information.
- Registration in the Product Tracking System (ÜTS) is mandatory for medical devices.
- Whether products fall within or outside the scope of medical device regulations depends on their design, intended use, and form. Products with the same design but different uses, methods, or locations may be subject to different regulations.
- Manufacturers must include products intended for medical use under the Medical Device Regulations. However, products designed for general use without any medical purposes will not be evaluated within the scope of these regulations. The product's design and statements given on the same will determine its classification.
- For example, latex gloves designed for general use may not fall under medical device regulations. However, when latex gloves with the same design are marketed as surgical gloves, they may become subject to medical device regulations.
- Registration notifications relating to products that do not fit the definitions in medical device regulations should not be submitted to the Product Tracking System.
- These products can be reached from the mentioned announcement.

The full text of the Announcement can be reached via this link. (Only available in Turkish)

Related Attorneys

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