

The most crucial changes brought with the Guidelines are in relation to the promotion, advertisement and sale activities of the medical device. New rules were also introduced in the Guidelines.

The Guidelines mentions that the manufacturer and the importer can conduct the informing activity. Pursuant to the Regulation, the medical device sales center is defined as places where the devices are sold. Therefore, the informing activity cannot be made by other medical device sales centers such as distributors.

- c) Devices other than these devices, is allowed only in the internet environment where the device is sold, addressed to the consumer.
- d) Devices included in Annex-3 of the Regulation, is allowed without any limitation.

iii. Online Sale

Pursuant to the Guidelines, for the sales from social media accounts, the social media account should belong to the sales center and a hyperlink to the website on which the online sales made should be included. Sale from social media accounts which do not belong to the medical devices sales center is prohibited.

As per Article 24/8 of the Regulation; “The manufacturers and the importers, can give free of charge application contact lenses, devices and their accessories that are essential in the use of drugs such as infusion pumps, insulin pens, needle tips, catheters, adapters, transfer sets and similar peritoneal dialysis auxiliary materials, self-blood glucose measurement systems.” It is stipulated that the products, listed in the Guidelines, can only be given free of charge, provided that they are approved within the scope of the patient support program.

Although the Guidelines is not as much as legally binding as the Regulation, since it is a provision that shows how the Agency interprets the Regulation's provisions, it must be taken into consideration in practice.