

The Guidelines For The Implementation of The Regulation on Sales, Advertisement And Promotion of Medical Devices Has Been Updated

Following the adoption of the substantial amendments to the Regulation on Sales, Advertisement and Promotion of Medical Devices ("Regulation") on 2 September 2020, the new Guidelines for the Implementation of the Regulation on Sales, Advertisement and Promotion of Medical Devices ("Guidelines") has been published on the Turkish Medicines and Medical Devices Agency's ("Agency") website on 12 February 2021.

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.

i. Informing

The informing activity was defined in Article 15/2 of the Regulation, as an activity which shall not be considered as an advertisement. However, the informing activity was not defined in the Regulation. Now, the "informing activity" and its scope is regulated for the first time.

The Guidelines regulates that the informing activity can only be conducted specifically for products registered to the Product Tracking System ("UTS") by the medical device company, on the official website or the social media accounts of the medical device company. It is stated that the informing activity can be made via social media accounts provided that the accounts are referred to the medical device company's official website. It is regulated that the domain name of the medical device company's websites can also be chosen as the product name.

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.



The Guidelines also regulates the limits of the information activity, in other words, it regulates when to evaluate the informing activity as sales activity and as advertising activity. The activity made on the social media accounts is regarded as sales activity when it is possible to access the websites on which the product is sold. If the price information is included and the activity conducted has an impact on the consumer's behavior, the activity is considered as an advertisement activity, not as an informing activity.

Finally, information that is not included in the technical documentation of the products and is obtained from the company's surveys, studies etc.; shall not considered as an informing activity.

It is understood that the scope of the informing activity is quite restricted and the maximum information pertaining to the product shall be indicated to be differentiated from the advertisement.

ii. Advertisement

The amendment to the Regulation adopted on 2 September 2020 regarding the advertisement activity, is also repeated in the Guidelines.

Advertisement of

- a) Devices that are sold, adapted or implemented only in hearing aid centers, tailored prosthetics and orthosis centers, opticians or dental prosthetics laboratories,
- b) Devices that are intended to be used or implemented exclusively by healthcare professionals or that require implementation in medical device sales centers,

addressed to the consumer, is prohibited.

Advertisement of

- 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.



The advertisement rules of the devices in the category (c) is detailed in the Guidelines.

The advertisement activity of the referred products via social media is permitted when the social media account belongs to the medical device sales center and the access is provided from the said social media account to the internet website where the online sale of the product is made.

Medical device advertisement made through social media accounts or websites belonging to different persons or institutions, pop-ups, banners, etc. is prohibited. For instance, the advertisement of the products from the social media account of celebrities and/or reputable institutions is now prohibited.

The activities that are deemed as covert advertising are also indicated in the Guidelines. Using the names, brands, logos or other distinctive shapes or expressions of the goods or services and trade names or business names for the purpose of advertisement and presenting them in an introductory manner in articles, news, broadcasts and programs without clearly indicating that they are advertisements are accepted as covert advertisement. The covert advertisement is explicitly prohibited.

Visuals, brochure, posters placed in internal spaces of the sales center are not considered as advertisement. The information on distributors can be shared via the manufacturer's or the importer's websites and this would not be considered as advertising or informing.

Lastly, advertisement activities cannot be carried out in a way that violates privacy or discloses personal data. It is also stated in the Guidelines that the advertisement cannot include personal data. The Guidelines does not bring an explanation on why the data of a person who has been informed and whose explicit consent was acquired, as per the Law on Protection of Personal Data, shall not be used in the advertisement. Although the ground of the provision regarding the advertisement containing personal data cannot be determined, it is important for the companies to be sensitive about this issue as it may affect the advertising activities in practice.

iii. Online Sale



The amendment to the Regulation adopted on September 02, 2020, paved the way for some products to be sold on the internet.

As per Article 26, the products which cannot be sold addressing the consumers, are categorized as follows:

- a) Devices that are sold, adapted or implemented only in hearing aid centers, tailored prosthetics and orthosis centers, opticians or dental prosthetics laboratories,
- b) Devices that are intended to be used or implemented exclusively by healthcare professionals or that require implementation in medical device sales centers,

It is provided that the rest of the products can be sold solely by the medical device sales center via internet. A sales center authorization certificate is not required for the online sales of products listed in Annex-3 of the Regulation. In addition, it is regulated that sales centers can only sell through websites owned by themselves.

The Guidelines also provides the dispositions regarding the medical device sales performed through the intermediary service providers. The definition of the intermediary service providers is given in the Law on the Regulation of Electronic Commerce, numbered 6563 ("Law no. 6563"). As per the Law no. 6563, the intermediary service provider is a natural or legal person that provides an electronic environment where others can conduct financial and commercial activities.

In this respect an intermediary service provider wishing to enable the sale of medical devices must be authorized in accordance with the Law no. 6563; but no medical device sales center authorization certificate is required to be obtained by intermediaries, if they do not directly sell medical devices.

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.



Medical devices that are forbidden to be sold addressing the consumer, are allowed to be sold on the internet to the healthcare professionals or medical device sales centers, through the platforms designed as a closed system that cannot be reached by the consumers.

Since contact lenses can only be sold through opticians, the online sale of these products should be indisputable. Nevertheless, a provision specifically explains that it is prohibited to sell online prescription glasses, spectacle frames specially manufactured for these glasses and prescribed contact lenses. No special provision is stipulated for any other products, other than these products.

iv. Promotion

The definition of demo device which is not defined in the Regulation but is listed among promotional materials, is defined in the Guidelines as medical devices provided to the health service providers and healthcare professionals so that healthcare professionals acquire experience with the product.

In addition, it is stipulated that demo devices and free samples must be registered to the information management system of the Agency.

Samples requested within the scope of medical device tenders shall not be considered as free samples but as demo devices. Similarly, application lenses are explicitly defined as demo devices. The advantages of a product being categorized as a demo device instead of a sample is that it shall not be subject to the limitations imposed on free samples such as adding a disclaimer on the outer packaging and quantity quota.

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.



The patient support program, which is regulated by the Circular dated 2016/4 of the Agency, is a program that is subject to the permission of the Agency, initiated by the companies who have a marketing authorization for a drug, in order to provide support for patients regarding the usage of the drug. Therefore, since this practice is only related to drugs, it is not clear how patient support programs will be implemented to medical devices.

Evaluation

Most of the amendments to the Regulation adopted on 2 September 2020 have been explained in detail in the Guidelines. However, it can be admitted that some new provisions are not clear enough.

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.