GÜN + PARTNERS
AVUKATLIK BÜROSU

Kore Şehitleri Cad. 17
Zincirlikuyu 34394
İstanbul, Turkey

T: +90 (212) 354 00 00
F: +90 (212) 274 20 95
E: gun@gun.av.tr

www.gun.av.tr

The Regulation on Sales, Advertisement and Promotion of Medical Devices Has Been Amended

The regulation amending The Regulation on Sales, Advertisement and Promotion of Medical Devices was published in the Official Gazette No. 31232 dated 02.09.2020.

The most important amendments made to the Regulation on Sales, Advertisement and Promotion of Medical Devices ("Regulation") related to the restrictions imposed on medical device sales and advertising activities and regulations on notices to be made in personnel changes.

1. New Regulations Imposed on Sales of Medical Devices

By amending article 26 of the Regulation, the supply or offer of medical devices to the market through sale via newspapers, radio, television and telephone or direct sale addressed to the consumer is prohibited. However, the products that fall outside the two categories are allowed to be sold via internet to the consumer. These two categories are;

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

In case it is determined that an internet sale violates the provisions of the Regulation, the medical device sales center will be warned to eliminate the relevant impropriety. If the impropriety is not resolved within three business days from the date of notification of the warning, the sales activity of the medical device sales center will be temporarily ceased for 15 days.

In addition, sales centers are required to register medical devices that they have put on the market or have on the market, and to make individual movement notifications through the Product Tracking System to ensure the traceability of these devices. In addition, taking the pandemic into account, the Ministry of Health has been authorized to make exceptions for the places of sale of medical devices for protection in cases of epidemics, pandemics and similar cases affecting public health.

2. New Regulations on Advertising of Medical Devices

Devices covered by the advertising ban are re-arranged.

Advertising of

i. Devices that are sold, adapted or implemented only in hearing aid centers, tailored prosthetics and orthosis centers, opticians or dental prosthetics laboratories,

ii. 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.

Advertising of

iii. Devices other than these devices, only in the internet environment where the device is sold, addressed to the consumer,

iv. Devices included in Annex-3, without limitation,

is allowed.

Therefore, the regulation indicating that devices should be subject to an advertising ban if they are reimbursed by the Social Security Institution has been removed.

It has been stated that in case it is determined that an advertisement violates the provisions of the Regulation, the medical device sales center will be warned to eliminate the relevant impropriety, and if the impropriety is not resolved within three business days from the date of notification of the warning, the sales activity of the medical device sales center will be temporarily ceased for 15 days.

3. New Regulations Regarding the Change of Responsible Manager and Sales Promotion Representative

In the event that the responsible manager or sales and promotion representative loses his or her position in any way, and the responsible manager or sales and promotion representative dies, the periods for the obligation to notify the provincial directorate of health are arranged as ten working days and twenty working days, respectively.

In addition, a new responsible manager must be appointed no later than thirty business days after the determination of this situation, or a new sales and promotion representative must be appointed within sixty business days. If assignments are not made during these periods, the medical device sales activity of this center will be temporarily ceased until assignments are made at the end of the given period.

Evaluations

In the regulation on advertising of medical devices, the provision that devices should be subject to the advertising ban if they are reimbursed is removed, and now it is regulated that advertising of medical devices can be only done in accordance with the criteria set out above and the “internet environment” has been pointed out as the only platform in which advertising can be done. In the Annex-3 List, which includes devices that are kept free of any restrictions in terms of advertising, no amendments have been made.

However, the term “internet environment” is not defined in the Regulation in the article regulating advertising. For this reason, it is not clear whether the advertisement can only be made from the website where the sale is made or from the page where it is located, or whether it can be made by redirecting the advertisement to the site where the sale is made with another website. In this case, it can be interpreted that there are no other restrictions, provided that the sale is made via the internet.

Finally, there is no sanction to be applied to the entities who do not qualified as sales centers and perform advertising activities in violation of the Regulation. In the case of such violation, in accordance with the Regulation, the contradictory ads will be reported to the Ministry of Commerce and related organizations, as well as to the Advertising Board. However, before determining who the advertiser is, it is not clear whether the sales center has any responsibility or whether its defense will be taken.