

Promotion of medicinal products: New requirements by EOF regarding vaccines and information campaigns (Circ.16427/2017)

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A new guideline has just been issued by EOF through its Circular Nr. 16427, which abolished EOF's previous relevant Circulars Nr. 43631/14-6-2012, 49392/7-7-2011 and 49393/7-7-201. The new circular interprets the applicable EU legislation for pharmaceutical products in relation to advertising and promotion. The most critical changes, established through the above mentioned circular are those related to public campaigns relating to vaccines and disease awareness.

General

EOF's **Circular Nr. 16427**, published on 24-2-2017 adds certain interpretative input with regard to EOF's procedure for the monitoring of the adherence of pharma companies to the terms and conditions for the promotion of medicinal products.

EOF's control of advertisements and promotional material, as amended through this new Circular, remains on the ex-post basis it used to be, except of the vaccines case. According to this Circular, the notification of all advertisements to the public, both of no prescription (OTC's) and of prescription only medicines, as well as the notification of the promotion of prescription-only medicinal products to the HealthCare Professionals, should be filed to EOF's Directorate for the Control of Production and Circulation (EPKP), by the Marketing Authorization Holders. The notification should include all necessary information of the promoting activity.

The provisions

It is explicitly mentioned in the Circular, that the above procedure does not constitute an approval procedure. Thus,

in case that EOF does not stipulate an opposition to a notification filed, this cannot by itself be perceived as a tacit approval, as it has been recently confirmed by the judgment of the First-Instant Committee of SFEE Code.

First of all, according to the new Circular, any advertisement including information with regard to the human health or diseases does not constitute advertising/promotion, provided that there is no direct or indirect reference to pharmaceutical products. On the other hand, even **any reference to the company's name can lead to the information being considered as disguised promotion.**

Furthermore, the above mentioned Circular, includes provisions regarding:

- i) General guidelines and obligations on information related to advertising medical-pharmaceutical products (OTC's) to the public and to the promotion of non-approved medicinal products on scientific events.
- ii) Medical information on substantially similar medicines (prearrangements of the documents shared, obligatory mentioning of the studies

- conducted with the innovative on-patent medicines).
- iii) Reminder cards, scientific event bags, calendars and posters
 - iv) Foreign documents on medical information (when the document is directed to Greek HCPs it must be in the Greek language) and
 - v) Placebos (which are permitted only for educational reasons)

Additionally, the Circular clarifies that its provisions shall not be applied to vaccine campaigns of prescription-only medicines, approved by EOF. The above campaigns, conducted by the Industry should be supported in order to increase public awareness and vaccination, which is one of the State's Public Health Policy purpose. However, vaccine campaigns must also follow certain rules. Sixty days before the campaign the duration of the campaign, its potential repetition and the inclusion of the vaccine to the National Vaccination System, should be declared to EOF.

All in all, there are serious sanctions imposed to infringers of the Circular, according to art. 19 of the Legislative Decree 96/1973 and Joint Ministerial Decision DYG3a G.P. 32221/2013.

Summary

To sum up, the most important changes stemming from the Circular, besides repeating the already known rules are related with two main domains of the advertising campaigns, the vaccines and the information on public health and diseases. More particularly, the vaccine public campaigns, from now on:

- i) Are subject to pre-approval 60 days before, instead of 30 that was provided according to the previous system.
- ii) Are oriented to the awareness and persuasion of the public to be vaccinated and not to advertise a specific pharmaceutical product.

While, at the same time, disease awareness campaigns to the public, from now on:

- i) Are not subject to pre-approval.
- ii) Contain information regarding health, diseases.
- iii) Must include no direct or indirect mentioning to specific medicines or companies.



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