[BG] CEM Position on Sponsorship from Manufacturers or Traders of Medicinal Products Available on Prescription

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On 18 January 2013, after having consulted with the Bulgarian Drug Agency (BDA), the media authority *Съвет за електронни медии* (Council for Electronic Media - CEM) published a position on the sponsorship of media services by manufacturers or sellers of medicinal products. The CEM asked the BDA for an interpretation of a relevant provision of the Medicinal Products in Human Medicine Act (MPHMA).

According to Article 244 para. (1) MPHMA, an advertisement of medicinal products is any form of information, presentation, promotion or offer with the aim of encouraging the prescription, sale or use of the medicinal product.

On the other hand, Article 244 para. (2) MPHMA provides an exhaustive list of the cases that are not considered advertising. This list does not include the so-called sponsored messages which contain information about a medicinal product.

Consequently, the BDA and the CEM consider that the broadcasting of trade names of medicinal products, showing their packaging and providing information about them is to be treated as advertising aimed at the public under the MPHMA. It is therefore subject to an authorisation regime even though it might be part of a sponsorship deal.

On the other hand, when the purpose of an advertisement is only to remind the public of an already known medicinal product, it may contain only its brand name and an international non-patent name of the active substance. This is specified in Article 5 para. (5) of Regulation No. 1/25.01.2012 on the requirements for the advertising of medicinal products. The Regulation is the basis for the authorisation of advertising for medicinal products. Its requirements relate to packaging as well as to the content of articles, broadcasts and films.

Neither the MPHMA nor the Regulation talk about sponsorship as defined in the Radio and Television Act (RTA). The BDA therefore considers that sponsorship messages should be treated as advertising and concludes that sponsorship of medicinal products available only upon prescription cannot be allowed.

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