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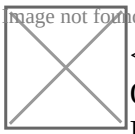

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Publisher:<!--BEGIN-OF-PUBLISHER--><!--END-OF-PUBLISHER--><!--END-OF-FILE-LIST--> This article appeared in the 2010 edition of The International Comparative Legal Guide to: Pharmaceutical Advertising 2010; published and reproduced with kind permission by Global Legal Group Ltd, London. Advertising of medicinal products in Romania is specifically regulated under Title XVII (Pharmaceutical Products), Chapter VIII (Advertising) of Law No. 95/2006 on the health sector reform (“Law 95/2006”, the “Law”), implementing Directive 2001/83/EC on the Community Code relating to medicinal products for human use. Other general enactments regarding advertising apply also the medicinal products.

 Advertising of medicinal products is also regulated under the Code of Ethics issued by the Romanian Association of International Medicines Manufacturers (“ARPIM”). The Code of Ethics is only mandatory for ARPIM members.

 The Law defines the advertising of medicinal products as any form of door-to-door information and any advertising activity aimed at incentivising the prescription activity, distribution, sale or consumption of medicinal products including, in particular: the advertising of medicinal products to the general public or to healthcare professionals; visits by medical sales representatives to persons qualified to prescribe medicinal products; supply of samples; sponsorship of promotional meetings attended by healthcare professionals or scientific congresses, etc.

 The marketing authorisation holder must keep available or provide the National Medicines Agency (“NMA”) with a sample of any advertising materials prepared and a statement regarding the addressees, dissemination method and release date of the advertisement. The compliance with the advertising rules must be insured by the scientific department of the marketing authorisation holder who is in charge with the relevant public data on the pharmaceutical products released on the market. Neither the Law nor the Code of Ethics requires companies to have SOPs governing advertising activities.

 Promotional activities targeting the general public (which could only be organised for non-prescription medicines) must be approved ex ante by the NMA. The authorisation is granted against a fee, upon submission of a standard application form available on the NMA website. Advertising materials addressed to the healthcare personnel are assessed by the NMA ex post (after dissemination) either randomly or further to a third party complaint. The pharmaceutical companies may, for legal certainty reasons, confirm with the NMA the compliance of the advertising materials, prior to release. To read the entire article, please download the .pdf attached.
