

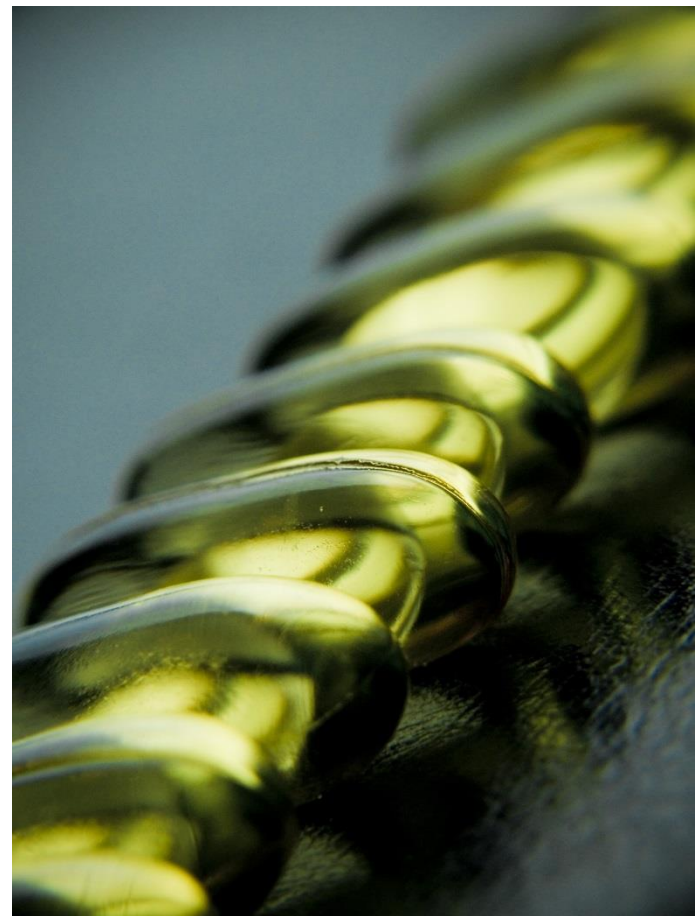
To keep you up-to-date with the latest economic and financial developments, this newsletter prepared by our Team provides information that may affect the operation of your business in Albania.

Instruction no. 25, dated 17.1.2019 “On approval of the Regulation on Pharmaceutical Advertising”

On 17.1.2019 the Minister of Health and Social Protection based on Law no. 105, dated 31.7.2014 “*On Medicinal Products and Pharmaceutical Service*” approved Instruction no. 25, dated 17.1.2019 “*On approval of the Regulation on Pharmaceutical Advertising*”, (the “**Regulation**”), which was published in the Official Journal on 12.2.2019.

The Regulation aims to define rules for the advertising of medicinal products addressed to the general public and provides that the Authority responsible for implementing the Regulation is the National Agency for Medicinal Products and Medicinal Devices.

One of the main principles of advertising of the medicinal products, consists in providing true information, which is scientifically proven and complies with ethical criteria to ensure an adequate and rational treatment of the patient.



Advertising to General Public

Advertising to general public is only allowed for medicinal products that are part of the list of OTC medicines. Advertising to the general public of medicinal products which are only available on medical prescription is normally, prohibited except for awareness raising campaigns or activities of public health institutions which are conducted in line with the programs adopted by the Ministry of Health.

Internet Advertising

The Regulation also permits Internet pharmaceutical advertising; however, the respective website shall have separate sections dedicated to the general public and to the health care professionals (in which case the access shall be granted via login in credentials).

The website should provide for the identity of the owners/clients of the said website and sources of the information which is available in the website.

The advertising of medicinal products to the general public shall contain the following information:

- Name of medical product followed by the common name where the product contains only one active substance;
- Instructions on the proper use of the medicinal products;
- Instructions regarding careful reading of the labeling and package leaflet.



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BOGA & ASSOCIATES

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Chambers Global 2019: Ranked in Band 1 in General Business Law

Chambers Europe 2019: Top Ranked in 5 practice areas

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Boga & Associates

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The firm’s particularity is linked to the multidisciplinary services it provides to its clients, through an uncompromising commitment to excellence. Apart from the widely consolidated legal practice, the firm also offers the highest standards of expertise in tax and accounting services, with keen sensitivity to the rapid changes in the Albanian and Kosovo business environment. The firm delivers services to leading clients in major industries, banks and financial institutions, as well as to companies engaged in insurance, construction, energy and utilities, entertainment and media, mining, oil and gas, professional services, real estate, technology, telecommunications, tourism, transport, infrastructure and consumer goods.