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Albania

PHARMACEUTICAL ADVERTISING

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Albania.

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ALBANIA
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

The regulatory framework governing medicinal advertising in Albania consists primarily of Law no. 105 date 31.07.2014 "*On medicines and pharmaceutical services*", as amended ("**Law 105/2014**"), which is partially aligned with European Directive 2001/83/EC and Directive 2001/20/EC, Decision of Council of Ministers no. 299, dated 08.04.2015 "*On the approval of regulation for the granting of authorizations for medicine trading and their classification in the Republic of Albania*", as amended ("**DCM 299**"), Order of the Minister of Health and Social Protection no. 25, dated 17.01.2019 "*On the approval of the regulation on the publicity of medicines and homeopathic medicines*", as amended ("**Order 25**") and Law no. 9902, dated 17.04.2008 "*On the Protection of the Consumers*", as amended ("**Consumer Protection Law**").

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

There is currently a lack of specific self-regulatory pertaining to the advertising of medicines. However, professional associations of doctors, dentists, pharmacists, and nurses have established ethical and deontological codes that inter alia provide some regulations regarding medicinal advertising.

According to the Code of Medical Ethics and Deontology, doctors are strictly prohibited from participating in any form of advertising or publicity, unless such activities serve a scientific or educational objective. The doctor is obligated to ensure that the advertising is impartial and consistent with the rules of medical deontology. The doctor is not allowed to make any advertising in favour of his personal activity or a certain institution.

These self-regulatory codes exclusively apply to individuals who are members of professional associations. Failure to adhere to the rules outlined in ethics and deontology codes leads to the implementation of disciplinary measures.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

The law on audiovisual media (*Law no. 97/2013 "On audiovisual media in the Republic of Albania", as amended*) provides a comprehensive and detailed definition of "advertising".

According to this definition, advertising is any type of publication disseminated by a public or private enterprise, an individual, or an organization for the purpose of self-promotion, in connection with their own trading and profitable, professional, or expertise-based endeavours, or in support of the supply with goods or services, real estate, or other obligations and rights, in exchange for payment.

Consumer Protection Law defines advertising as any type of presentation of commercial activities, businesses, vocations and professions to promote the supply of goods and services, including rights and obligations.

a) Specific definition on medicinal advertising is provided by Law 105/2014 which defines medicinal advertising as any form of information, support or inducement activity

that aims to raise awareness regarding the use of a medicine. Additionally, Order 25 defines medicine and homeopathic medicine advertising as any information pertaining to the medicine that is intended to promote its prescription, supply, sale, and consumption, irrespective of the medium via which it is transmitted.

Medicinal advertising for products does not include:

a) advertising addressed to qualified healthcare professionals;

b) medical representatives visiting certified health professionals to promote drugs;

c) the supply of sample;

d) sponsorship of legally contracted promotional meetings/conferences for qualified healthcare professionals;

e) sponsorship of legally contracted scientific congresses attended by certified health professionals;

f) sponsorship of participants in scientific congresses attended by qualified healthcare professionals;

g) labelling and accompanying package leaflets;

h) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicine;

i) factual, informative announcements and reference material relating to packaging changes, adverse-reaction warnings as part of general medicine precautions, trade catalogues and price lists, provided they include no product claims, and

j) statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products

b) As stated above, the definition and rules issued in this regard solely apply to the advertising of medicinal products directed at the general public.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Albanian legislation is silent on this matter.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Albanian legislation is silent on this matter.

6. Do companies have to have material approved by regulatory bodies prior to release?

Law no. 105/2014 stipulates that the advertising of medicinal products is approved by National Agency for Medicinal Products and Medical Devices/Agjencia Kombëtare e Barnave dhe Pajisjeve Mjekësore (the "**Agency**").

There is no specific procedure established for obtaining the medicinal advertising. Order 25, however, mandates that all information included in medicinal advertising must align with the most recent version of the leaflet and summary of product characteristics that the Agency has authorized in line with DCM 299.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Order 25 forbids medical advertising directed at the general public from (i) insinuating that one medicine is manifestly better to another and (ii) implying that a particular prescription medicine can be substituted for another.

The Consumer Protection Law stipulates specific regulations pertaining to comparative advertising. Under these regulations, a comparative advertisement is deemed permissible if it adheres to the following conditions:

a) cannot be misleading;

b) should compare similar products;

c) should compare one or more essential, relevant, verifiable and representative elements of the product (e.g., the price);

d) should not create confusion between the advertiser and the competitor or between their brands, trade names or other distinguishing marks;

e) in the case of products with denomination of origin, it connects in each case to products with the same designation;

f) should refrain from discrediting or disparaging the

other company and its products/activities;

g) should not represent the products as being an imitation or counterfeit of products with a protected brand or trade name; and

h) should not create confusion among traders, between the entity that promotes its goods or services and a competitor or between the trademarks, trade names, other distinguishing marks, goods or services of an entity that promotes its goods or services and those of a competitor.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

In Albania, the current legislation permits the advertising of pharmaceutical products and homeopathic medicines that are included in the list of over the counter (OTC) medicines and have received proper authorization from the Agency.

The provision of information on either unauthorised/authorized medicines or indications during a scientific conference directed at healthcare professionals, or providing of information to healthcare professionals, does not fall under the definition of medicinal advertising. There are no additional specific regulations in this regard.

Order 25 sets out (in addition to Q.3/b) that the following does not qualify as medicinal advertising:

a. Labelling of medicines and homeopathic medicines, summary of product characteristics and leaflet.

b. The correspondence between health care personnel, representatives of pharmaceutical companies and marketing authorization holders, which has attached material that does not serve promotional purposes, and which contains an answer to a specific question about the drug.

c. Informative notices and professional materials, which, for example, relate to changes in packaging, warnings regarding unwanted effects and other additional information related to safety, trade catalogues or price lists, provided that they do not contain advertising content for the drug.

d. All objective and unbiased information related to diseases, with possible methods of treatment and prevention including the pharmacological measures taken, which is not allowed to single out any specific medical product.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

The obligation for ensuring compliance with the following regulations regarding medicinal advertising lies with the holder of the marketing authorization in the Republic of Albania, or a representative thereof and the publicity agency.

Order 25 prohibits medicinal advertising directed at the general public regarding (i) prescribed medicines and prescribed homeopathic medicines, (ii) narcotic medicines, and (iii) psychotropic substances.

Medicinal advertising must include at least (i) the name of the medicine and in cases where the medicine contains a single active substance, the common name of international active substance (ii) the necessary instructions for correct medicine usage and (iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

The promotion of a pharmaceutical product to the general public is prohibited from including any content that:

– falsely asserts the absence of side effects, non-toxicity, or addiction risk associated with the drug;

– minimizes or hides the significance or occurrence of side effects;

– creates the belief that the medication ensures efficacy in treating the illness;

– asserts unequivocally that one medication is superior to another;

– asserts that the medicine can be administered even in the absence of symptoms, i.e., that it improves health;

– suggest that the subject’s health could be affected by not taking the medicine;

– asserts that the drug’s safety and efficacy are solely

attributable to the nature of its origin;

– asserts that the medicine is a widely used cosmetic, dietary, or other product;

– uses medical histories or diagnostic procedure stimulation that may encourage incorrect self-diagnosis or self-treatment;

– suggests that one prescribed medicine can be substituted for another;

– develops advertising specifically for children, wherein it is demonstrated that children can self-administer the medication or obtain it without adult supervision;

– includes the recommendation of health professionals or scientific researchers, or includes in the publicity persons whose celebrity may stimulate the use of the medicine;

– cites the announcement of the drug's inclusion in the list of reimbursable homeopathic medicines and drugs in the primary, secondary, and tertiary health care system;

– uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.;

– refers, in improper, alarming or misleading terms, to claims of recovery.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Order 25 explicitly prohibits the direct or indirect distribution of medicines and homeopathic medicines to the public for promotional reasons.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

As stated in Q.8, information directed at healthcare professionals, such as journal copies and clinical trial materials, does not qualify as medicinal advertising. No additional regulations are established in this regard.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Healthcare professionals are strictly prohibited by the Code of Ethics and Medical Deontology from soliciting or accepting unsubstantiated and compromising funding, or gifts from organizations, firms, or individuals marketing medicinal products, medical equipment, or other medical materials.

Further, pharmacists are strictly forbidden by the Code of Ethics of Pharmacists from accepting monetary value-added gifts, rewards, favours, loans, or anything else from persons or entities that have an interest in securing benefits in contractual relationships, administrative procedures, or any other relationship.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

The provision of samples to healthcare personnel does not fall under the definition of medicinal advertising as outlined in Law 105/2014, which does not provide further requirements on the subject. Nevertheless, it is stipulated that entities engaged in sample provisioning are obligated to submit an annual report to the Agency pertaining to such activity.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

The definition of medicinal advertising does not include sponsorship or attendance of scientific meetings or congresses by healthcare professionals, and Albanian legislation is silent on the subject. However, it is mandatory for entities involved in such operations to provide the Agency with an annual report.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Albanian legislation is silent on this matter.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Yes, as a general rule healthcare professionals receive payments for the services rendered. According to the Code of Medical Ethics and Deontology doctors must exercise caution and prudence when establishing their fees, considering factors such as the financial circumstances of their patients, the scope of the services they provide, and other relevant factors.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

The Code of Ethics and Medical Deontology allows lawful funding only for accredited activities organized in the context of doctor education and professional training. Further regulations are not specified in this regard.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Albanian legislation is silent on this matter.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

According to Order 25 natural persons or legal entities authorized to distribute medicinal products at distance are the holders of the marketing authorization or their authorized representatives in the Republic of Albania.

The website should be divided into two sections: one for the general public and one for health care professionals. Pages designated for health care professionals should be password-protected. The website is required to comply with all specific regulations pertaining to the safeguarding of information confidentiality and the protection of personal data.

Prescription medicinal products, apart from OTC medications, may be made available for public sale via the website, on the condition that such products include the following details: (i) the medicine trade name and/or the common name of international active substance and (ii) the approved method of use.

Both the general public and healthcare professionals have the possibility to submit inquiries via email in order to obtain further details regarding homeopathic medicines and other pharmaceutical products. When inquiries are posed by the general public, it is imperative to refrain from discussing personal health conditions and instead direct patients to consult with their healthcare providers.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

The anti-bribery rules that govern interactions between pharmaceutical companies, healthcare professionals, or healthcare organizations are outlined in the Albanian Criminal Code (*Law no. 7895, dated 27.01.1995, as amended*).

The Criminal Code stipulates that a person who promises, offers, gives, whether directly or indirectly, of any type of irregular advantage or irregular promise, for the benefit of oneself or for other persons, or the acceptance of an offer or a promise deriving from an irregular advantage, in order to perform, or not to perform, an action which is related to a person's duty/position or capacity may be held responsible for active bribery. The receiving person may be held responsible for passive bribery.

These regulations are applicable to both natural and legal persons in the public and private sectors. Companies can be held liable when an offense is committed on their behalf, or for their benefit by their bodies or representatives.

21. What are the rules (whether statutory

or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

With the exception of the information provided in Q.12, there are no additional regulations pertaining to this matter.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The Agency is the key enforcement entity in terms of pharmaceutical advertising rules. In addition, it is the responsibility of the Commission for the Protection of Consumers to safeguard rules against misleading advertising and unfair trade practices. While the Audiovisual Media Authority oversees medicinal advertising in television. Companies or individuals may bring legal actions in civil courts to seek remedies for damages resulting from false advertising.

Regarding the inducement regulations outlined in Q.12, disciplinary action may be imposed by the professional association. Moreover, in cases where the conduct in question violates the Criminal Code, the court is the enforcement authority.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Companies have the option to initiate legal proceedings against competitors for advertising infringements, citing various legal grounds that encompass medicinal advertising violations, trademark infringements, unfair competition, and violations of consumer protection laws. These proceedings can be brought before different regulatory bodies and courts such as the Agency, the Commission for the Protection of Consumers, the General Directorate for Industrial Property, or the Albanian Competition Authority, depending on the specific nature of the alleged infringement.

In addition to resorting to these regulatory bodies, competitors also retain the alternative of directly initiating legal actions before civil courts, although this course of action is less commonly employed.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

In instances where a legal violation does not amount to a criminal offense but instead constitutes an administrative breach, the penalties are as follows:

– Non-compliance with the advertising and promotional regulations specified in Law 105/2014 and Order 25 for medicinal products may incur a penalty of ALL 500,000 and potential license revocation upon recurrence,

– Violation of the regulations governing OTC as per Law 105/2014 and Order 25 is subject to a penalty of ALL 200,000 and potential license revocation upon recurrence.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The self-regulatory process operates independently and is distinct from the enforcement mechanisms overseen by the Agency. The Agency is responsible to monitor compliance with the specific rules outlined in Law 105/2014 and Order 25, whilst the self-regulatory bodies are tasked with ensuring adherence to ethical and deontological principles.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

As of November 2023, no enforcement trends have been observed in Albania with regard to medicinal advertising and there are no significant publicly known enforcement actions reported in the past two years.

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