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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2016

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A practical cross-border insight into pharmaceutical advertising

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Country Question and Answer Chapters:

Albania

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

There is no specific regulation on the advertising of medicinal products in Albania. The current legal framework governing this field is fragmented and still under development.

However, some provisions on the advertising of medicinal products are mainly found in Law no. 105/2014, dated 31.07.2014 "On Medicinal Products and Pharmaceutical Service", as amended (replacing the former Law no. 9323 dated 25.11.2004 "On Medicinal Products and Pharmaceutical Service), the Decision of Council of Ministers no. 299, dated 08.04.2015 "On the Approval of Regulation for Granting of Authorizations of the Trading of Medicinal Products in the Republic of Albania", as amended and Law no. 9902, dated 17.04.2008 "On the Protection of the Consumers", as amended.

It should be noted that, subject to provisions of the Law no. 105/2014, dated 31.07.2014 "On Medicinal Products and Pharmaceutical Service", it is the Minister of Health that approves the rules and procedures for the advertising of medicinal products in Albania. However, to date such document is not available.

1.2 How is "advertising" defined?

"Advertising" is defined as any type of presentation of commercial activities, businesses, vocations and professions, to promote the supply of goods and services, including rights and obligations.

"Advertising" is also defined as any form of publication or broadcast upon payment or other benefits by a public or private enterprise or by a person for self-advertising purposes, associated with its own trading and profitable activities, professional or expertise as well as support on the supply with goods or services, including immovable property.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The Albanian legislation is silent on this matter.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

There are no explicit requirements for companies to have in place SOPs on such advertising activities.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Based on Article 55/2 of Law no. 105/2014, the advertising of medicinal products is approved by the National Agency for Medicinal Products and Medical Devices, which is a specialised institution operating under the umbrella of the Ministry of Health charged with the analysis control of medicinal products, the granting of authorisations for trade, and the inspection of activities in the pharmaceutical field, including the administration of the standards for medical devices.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

There are no specific provisions that regulate this issue. However, general provisions of the Albanian Civil Code would apply. In this context, subject to these provisions, a remedy would be requested to the court that, upon request of the interested party, it orders the immediate cessation of the publication and the obligation of the responsible entity to conduct a public disproof, including payment of any damages relief.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The National Agency for Medicinal Products and Medical Devices is *inter alia* responsible for monitoring the advertisement of medicinal products.

Whenever the breach of law does not constitute a criminal offence but remains an administrative violation, the sanctions for pharmaceutical entities are as follows:

Based on Article 63/1(ll) of Law no. 105/2014, dated 31.07.2014, as amended, the advertising of medicinal products in breach of the rules on advertising and promotion is sanctioned by a fine of ALL 500,000 (five hundred thousand Albanian Lek) and, in case of repetition, by the revocation of the licence.

In addition, based on Article 63/1(m) of the same law, the advertising of OTC medicinal products without the appropriate approval and/or contrary to the rules on advertising and promotion is sanctioned by a fine of ALL 200,000 (two hundred thousand Albanian Lek) and, in case of repetition, by the revocation of the licence.

The National Agency for Medicinal Products and Medical Devices is the authority responsible for the enforcement of these rules.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The Albanian legislation does not specifically address this matter, but as mentioned above, the National Agency for Medicinal Products and Medical Devices is vested with the authority to inspect activities in the pharmaceutical field and enforce the rules covering this field.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Based on the provisions of the Albanian Civil Code, in all cases of unfair competition, upon the request of the interested party, the court decides on the necessary measures for the elimination of consequences. When actions of unfair competition have been performed upon misconduct, the entity responsible is obliged to compensate the damage.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Based on Article 3/64 of the Law no. 105/2014, dated 31.07.2014, 'the summary of the medicinal product's characteristics' is a comprehensive piece of information, approved under the authorisation procedure by the National Agency for Medicinal Products and Medical Devices, intended for use by healthcare professionals.

Also, based on Article 57/3 of the same law, healthcare professionals (doctors, dentists, pharmacists and nurses) and users of medicinal products must report any adverse effects associated with the medicinal products to the Centre of Pharmacovigilance.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

The Albanian legislation does not provide regulation for the publication of information on unauthorised medicinal products and/or off-label information.

The Law no. 105/2014, dated 31.07.2014 provides that the advertising of OTC medicinal products is possible only after its approval by the National Agency for Medicinal Products and Medical Devices.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

Please refer to our answer to question 2.2 above.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

The Albanian legislation is silent on this matter.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

To the best of our knowledge, the ECJ judgment in the Ludwigs case has not been reflected in the Albanian legislation as far as Albania is not a Member State of the EU.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

The Albanian legislation is silent on this matter.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The Albanian legislation is silent on this matter.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

As mentioned in our answer to question 2.1 above, the National Agency for Medicinal Products and Medical Devices issues a 'summary of the medicinal product's characteristics', which is comprehensive information, approved under the authorisation procedure by this agency, intended for use by healthcare professionals. (Article 3/64 of the Law no. 105/2014, dated 31.07.2014.)

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Upon the instruction of the National Agency for Medicinal Products and Medical Devices, the elements that an advertisement of medicinal products shall contain are determined, as well as the procedures to be followed for the evaluation of requests for approval of spots or advertising materials, and suggesting in any case, accuracy of information and data that are transmitted, as requested by the interested parties.

In this view, the National Agency for Medicinal Products and Medical Devices indicates that the following must accompany the request for approval of the advertisement presented by an interested party:

- a CD with the contents of the spot or advertising materials that will be used to advertise;
- a summary of the product characteristics (SmPC) of the medicinal products, for which the approval of the advertisement is requested;
- a leaflet; and
- a mock-up of the medicinal products.

The Albanian legislation does not provide any specification as to whether an advertisement may refer to studies not in the SmPC.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

There are no legal provisions that regulate this issue.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There are no legal provisions that regulate this issue.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Comparative advertisement is regulated by the provisions of Law no. 9902, dated 17.04.2008 "On the Protection of the Consumers". A comparative advertisement is permitted when in accordance with the following conditions:

a) it does not constitute a misleading practice or provides missing/misleading information according to the provisions of the applicable legislation;

b) it compares goods or services meeting the same needs or intended for the same purpose;

c) it objectively compares one or more important characteristics, verifiable and representative goods and services, in which the price may be included;

d) it does not discredit or denigrate the trademarks, trade names, other distinguishing marks, goods, services, activities, or circumstances of a competitor;

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

f) it does not unfairly benefit from the reputation of a trademark, trade name or other distinguishing marks of a competitor or of the denomination of origin of competing products;

g) it does not present goods or services as imitations or replicas of goods or services pertaining to a trade name or trademark protected; and

h) it does 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.

Regarding the possibility to refer to a competitor's product or indication which has not yet been authorised, there is no explicit determination in the Albanian legislation. From an overall interpretation of the law, it can be estimated that such reference is not allowed as long as advertising itself is only allowed for medicinal products that are already authorised and registered.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The Albanian legislation is silent on this matter.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

There are no specific rules regarding "teaser" advertisements.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

The Albanian legislation is silent on this matter.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

According to article 59 of the Code of Ethics and Medical Deontology, dated 11.11.2011, it is forbidden for a healthcare professional to demand or accept gifts or unsubstantiated and compromising funding from companies, firms or individuals marketing medicinal products, medical equipment or other medical materials, with the exception of those related to activities organised for the education of healthcare professionals and their vocational training.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

There are no provisions that govern this issue.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

The Albanian legislation is silent on this matter.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

The Albanian legislation does not regulate this matter.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

The Albanian legislation does not regulate this matter.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The Albanian legislation does not regulate this matter.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Yes, companies may sponsor continuing medical education, as this falls under the same provision as mentioned above in question 4.2. There are no other indications in the Albanian legislation specifying the rules that apply in this case.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Even though the Albanian legislation does not give an accurate definition of "hospitality", from article 59 of the Code of Ethics and Medical Deontology, mentioned in question 4.2 above, we understand that it is not possible for a healthcare professional to receive hospitality except when this is part of the funding for their education or vocational training.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Whenever the attendance of a scientific meeting is part of the education or vocational training of a healthcare professional, it falls under the same regulation provided by article 59 of the Code of Ethics and Medical Deontology.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

The Albanian legislation is silent on this matter.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

The Albanian legislation is silent on this matter.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

There are no specific legal provisions regulating this issue.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

The Albanian legislation is silent on this matter.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes, it is possible. Based on Article 55/3 of Law no. 105/2014, dated 31.07.2014, advertising of medicinal products includes, in particular, the advertising of non-prescription medicinal products, addressed to the general public, in accordance with the approved list of OTC medicinal products.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Law no. 105/2014, dated 31.07.2014, does not forbid the advertising of prescription-only medicines, but provides a few restrictions which are listed herein below.

Based on Article 55/4 of the Law no. 105/2014, dated 31.07.2014, advertising for medicinal products does not include:

a) the advertising of medicinal products addressed to qualified healthcare professionals;

b) healthcare representatives' visits to qualified healthcare professionals for the promotion of the medicinal products; healthcare representatives being informed of the scientific data on medicinal products;

c) the donation of diagnostic samples;

d) the sponsorship of promotional meetings/conferences attended by qualified healthcare professionals, organised under regular legal contracts between the parties;

e) the sponsorship of scientific congresses attended by qualified healthcare professionals, organised under regular legal contracts between the parties;

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

g) the labelling and leaflets of the medicinal product;

h) the correspondence, possibly not accompanied by non-promotional materials, needed to answer a specific question about a particular medicinal product;

i) the actual announcements, information and reference material, in connection with changes in packaging, warnings about adverse effects, as part of general precautions for medicinal products, trade catalogs and price lists, provided that they do not include claims for the medicinal products; and

j) statements with regard to human health or diseases, provided that there is no reference, even indirectly, to medicinal products.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Please refer to our answer to question 6.2 above.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

There are no specific provisions that would apply in case of press releases concerning prescription-only medicinal products to non-scientific journals.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

There are no specific provisions stipulated by the applicable law regarding this issue.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

The Albanian legislation is silent on this matter.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

The Albanian legislation is silent on this matter.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

The Albanian legislation is silent on this matter.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how?

The Albanian legislation is silent on this matter.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The Albanian legislation is silent on this matter.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

The Albanian legislation is silent on this matter.

8 The Internet

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet advertising in Albania is regulated as one of the forms of advertising mentioned above in question 1.2.

Further, the rules set forth in Law no. 9902, dated 17.04.2008 "On the Protection of the Consumers" regulating the types of illegal publicities and the responsibility held in such cases, also apply to internet advertising.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

There are no legal provisions regulating this issue.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

There are no legal provisions regulating this issue.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

There are no specific provisions regulating this issue. However, from an interpretation of Articles 55 and 56 of the Law no. 105/2014, dated 31.07.2014, companies are allowed to place on their websites advertisements about OTC medical products, as well as other medicinal products, if the advertising of which is approved by the National Agency for Medicinal Products and Medical Devices pursuant to the provisions/restrictions stipulated in Article 55/4 of the abovementioned Law.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There are no specific legal acts controlling the use of social media by companies.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The Albanian legal framework has had a few changes during the last year. However, such changes regulate matters like the authorisation and trading of medicinal products, and not pharmaceutical advertising.

The Minister of Health has not approved a regulation on the advertising of medicinal products yet. Such regulation is referred to in Article 66/2 of Law no. 105/2014, "On Medicinal Products and Pharmaceutical Service".

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

In order for the Albanian Law "On Medicinal Products and Pharmaceutical Service" to fully cover the pharmaceutical field in the country, it needs to be completed by additional secondary legislation, including the regulation on pharmaceutical advertising, to be approved by the relevant state authorities.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There are no general practice or enforcement trends that have become apparent over the last year or so.

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For years, Renata has been recognised as a "Leading Individual" in "Intellectual Property" in *Chambers and Partners*, and Chambers Europe – "Europe's Leading Lawyers for Business". According to Chambers Europe 2016, Renata Leka is a highly experienced IP lawyer, whose experience covers matters spanning all sectors, including energy, finance and consumer products. She also contributes to World Trademark Review magazine for the Albania jurisdiction.

Renata graduated in Law at the University of Tirana in 1996 and also holds a Practice Diploma in International Intellectual Property Law (2006) and a Practice Diploma in Anti-Trust Law (2009) from the College of Law of England and Wales, UK.

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Elona joined Boga & Associates in 2013. As part of the firm's professional team, she has been involved in several matters relating to intellectual property, employment and corporate law.

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