ICLG

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2017

14th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

Allen & Gledhill LLP
ALRUD
Arnold & Porter Kaye Scholer LLP
Arthur Cox
Baker & McKenzie
Biolato Longo Ridola & Mori
Clayton Utz
Clifford Chance
Cuatrecasas
Deep & Far Attorneys-at-Law
Gorodissky & Partners (Ukraine)
Gün + Partners
Haavind
Herbst Kinsky Rechtsanwälte GmbH
Jones Day
Jusmedico Advokatanpartsselskab
Kyriakides Georgopoulos Law Firm
LCH Law Compliance Health
Life Sciences Legal
Mannheimer Swartling Advokatbyrå
Nishimura & Asahi
Norton Rose Fulbright Canada LLP
OLIVARES
Pestalozzi Attorneys at Law
Quinz
Roschier, Attorneys Ltd.
Sołtysiński Kawecki & Szlęzak
Subramaniam & Associates (SNA)

glg
global legal group

global legal group

Contributing Editor
Ian Dodds-Smith, Arnold & Porter Kaye Scholer LLP

Sales Director
Florjan Osmani

Account Director
Oliver Smith

Sales Support Manager
Paul Mochalski

Editor
Caroline Collingwood

Senior Editors
Suzie Levy, Rachel Williams

Chief Operating Officer
Dror Levy

Group Consulting Editor
Alan Falach

Publisher
Rory Smith

Published by
Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design
F&F Studio Design

GLG Cover Image Source
iStockphoto

Printed by
Stephens & George
Print Group
June 2017

ISBN 978-1-911367-61-1
ISSN 1743-3363

Strategic Partners

General Chapter:

Country Question and Answer Chapters:

EDITORIAL

Welcome to the fourteenth edition of *The International Comparative Legal Guide to: Pharmaceutical Advertising*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of pharmaceutical advertising.

It is divided into two main sections:

One general chapter. This chapter provides an overview of off-label use in the EU and U.S.

Country question and answer chapters. These provide a broad overview of common issues in pharmaceutical advertising laws and regulations in 29 jurisdictions.

All chapters are written by leading pharmaceutical lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editor Ian Dodds-Smith of Arnold & Porter Kaye Scholer LLP, for his invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.com.

Alan Falach LL.M.
Group Consulting Editor
Global Legal Group
Alan.Falach@glgroup.co.uk

PREFACE

It is a pleasure to have again been asked to provide the preface to *The International Comparative Legal Guide to: Pharmaceutical Advertising*, which is now in its fourteenth edition.

This year the guide contains one general chapter written by Arnold & Porter Kaye Scholer LLP and 29 individual chapters, the new ones of which are Russia, Singapore, Taiwan and Ukraine. The general chapter comprehensively covers the area of medicine off-label use in the EU and the U.S. Despite plenty of activity in the area, including a European Commission Report, the chapter suggests that little has been decided in either jurisdiction in this vexed area to provide certainty for manufacturers, and thereby patients, going forward.

As with other current editions in the ICLG series that I use as a reference point, this edition will be my first port of call when faced with thorny questions concerning pharmaceutical advertising.

Tom Spencer
Senior Counsel
Litigation
GlaxoSmithKline Plc.

Russia

Anton Dzhuplin

ALRUD

Maria Ostashenko

1 General – Medicinal Products

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

Basic law is the Federal Law On Advertising (No. 38-FZ dated March 13, 2006) ("Law on advertising"). Following this Law, there are official clarifications of competent authorities that clarify law provisions but do not alter them. In addition, AIPM Code of Conduct ("AIPM Code"), adopted by Association of International Pharmaceutical Association, provides additional rules for companies party to the said Association.

1.2 How is "advertising" defined?

Advertising is defined in article 3 of the Law on advertising as an information spread by any means, in any form and by any media, which is addressed to an indefinite circle of persons and aimed at drawing attention to advertised object, at creating or maintaining interest in it and at promoting it in the market.

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?

All items must be authorised prior to advertising them in Russia. Companies must also have all data, which are mentioned in advertising, confirmed documentarily, including respective researches and testing results. All advertising materials and any related documents must be stored within one year after the last distribution of advertisement.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no statutory requirements for companies, except for those regarding storing advertising materials. Additional guidance is provided under the AIMP Code, which requires its member to appoint an employee who will be authorised for prior approving of advertising materials. Such employee must have a suitable level of education and qualifications.

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?

There is no preliminary approval procedure provided under Russian law.

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?

The Federal Antimonopoly Service of the Russian Federation ("FAS"), the main state regulator of advertising market, is authorised to control advertising activity in Russia. The authority is entitled to demand ceasing violations of law and distribution of illegal materials under official decision when it comes to conclusion (as the result of considering the administrative case) under which the materials do not follow the law. The FAS is not competent to insist on the issuance of a corrective statement. Local and foreign companies have the right to appeal actions of the authority.

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? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Breaching law requirements in part of pharmaceutical advertising shall cause administrative liability in form of a fine in the amount up to 2,500 Roubles (approx. 40 Euro) for individuals, in the amount up to 20,000 Roubles (approx. 330 Euro) on officials, and in the amount up to 500,000 Roubles (approx. 8,280 Euro) on legal entities. Another risk can be blocking an information resource in Russia.

Within the scope of its authorities the FAS initiates and holds administrative proceedings on violations of advertising requirements. According to recent practice, the authority initiated several cases against major pharmaceutical companies, including Johnson & Johnson and Bayer. The costs of fines have not yet been defined.

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?

There are expert committees established by the FAS in its regional departments. The committees do not fully reflect the idea of a self-regulation institute although they do have some influence on decisions made by the FAS and the latter tend to rely on an opinion of the committee when assessing advertising materials in question.

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?

Russian law distinguishes liability for unfair competition and unfair advertising. Should an advertisement reflect the criteria of unfair competition, it will cause administrative liability provided for illegal advertising. E.g., a competitor who suffers damages or a negative effect on its business reputation may file a claim to the FAS or sue an infringer for damages in the court.

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)?

Discussing medicines at scientific events and meetings for healthcare professionals only is not prohibited under Russian law and can be initiated before the required authorisation is obtained. However, such discussion should not pursue the aim of promotion. Sponsorship of the meeting will be in question since it is a form of advertising under Russian law. Should such sponsor support the event with the only purpose to conduct discussing its product before authorisation, such sponsorship might be considered a veiled advertisement of an unauthorised product what is prohibited under Russian law. The position will be the same for off-label information.

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

Publishing information about medicines with a neutral nature of content (e.g. with no aim to promote the item) is permitted, in particular this can be analytical and scientific materials on recent developments in a disease's cure methods.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

Creating publications with respect to unauthorised products is prohibited, unless such publications have no aim to promote the respective item but only to keep the public informed of scientific or medical progress. As regards press releases, they are designed primarily for promoting the subject-matter focusing on a particular item, which is similar to the concept of an advertisement. Therefore, there will be a high risk of recognising such press releases as unlawful advertising.

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

Speaking about press releases, such materials are similar to the concept of an advertisement and thus distributing thereof is prohibited until authorisation is obtained. The remaining non-promotional materials are free to circulate between healthcare professionals and companies may distribute them. It should be also noted that healthcare professionals have a right to request such information, in which case a personalised reply to such request will not reflect advertising criteria anymore.

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?

The case did not have any direct influence either on legislation or on practice. However, it is likely that the same position as provided by the ECJ may be reflected in Russian disputes.

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?

In general, all prices are set when all formalities are completed and therefore any distribution of medicines or indications before obtaining authorisation will not work for procurement justification for Russian institutions. Therefore providing such medicines or indications will hardly be treated as aimed at planning the budgets and more likely be regarded as advertising.

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?

According to the Law on drug circulation (Federal law No. 61-FZ dated April 12, 2010), pharmaceutical companies may engage

healthcare professional in scientific and educational works. Thus it is possible to pay healthcare professionals for marketing research if their participation implies that material scientific work is done by such healthcare professionals. Such marketing studies cannot be used for the promotion or selling of any pharmaceutical products, managing the opinions of the participants of the study or pre-registration promotion for any pharmaceutical product in any instance.

3 Advertisements to Healthcare Professionals

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

There are no special requirements for this group. However, companies usually use a legal line in the marketing materials stating that the information is intended for healthcare professionals only.

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?

The following is generally prohibited for all advertisements:

- using foreign words and expressions that can lead to a distortion of the sense of information;
- referring to the fact that the object of advertising is approved by governmental bodies or local self-government bodies or by officials thereof;
- depicting the process of smoking or the consumption of an alcoholic product; images of medical and pharmaceutical personnel (except advertisement directed to healthcare professionals);
- referring to the fact that advertised goods are manufactured with human embryo tissues; and
- indicating curative qualities (except advertisement directed to healthcare professionals).

Moreover, information should be fair and truthful.

Describing properties and characteristics, including methods of application and use of medicines and medical articles, is permitted in advertisement only to the extent of indications contained in instructions (SmPC) for application and use of such objects of advertising that are approved in the established procedure.

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

Using endorsements by healthcare professionals is a limited tool for promoting medicines though not fully prohibited under Russian law. In any event, this should not contain images of such professionals since it is prohibited under Russian law, unless such advertisement is disseminated only during pharmaceutical events or in printed materials designed for professionals.

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 requirements to a particular number of "head to head" trials. The only requirement for comparison is that it shall be based on objective criteria.

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?

Comparisons between different brands are not prohibited for advertising provided that all data is correct and proved documentarily. However, referrals to non-authorised products should be avoided due to general prohibition on their advertising.

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

The main requirement is that participation of pharmaceutical companies, other than the organiser of the event, shall not be restricted or be of discriminatory nature. In addition, no participation fees shall be established in a manner leading to an unreasonable restriction on participation. Information about date, time and place of such event shall be published on the official website of the organiser no earlier than two months prior to its beginning. In addition, information on such event shall be submitted to an authorised governmental body for further official publication on its website.

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?

"Teaser" advertisements shall fall under general regulation prescribed for advertising in Russia. Depending on a type of medicines (prescription-only medicines or non-prescription ones) the terms of teasers distribution will differ.

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 Law on drug circulation prohibits provision of samples of medicinal products to healthcare professionals in case the samples are provided for subsequent transfer to patients with the exception of the provision of samples for the conduction of clinical trials. In case a pharmaceutical company complies with the AIPM Code, it shall not provide healthcare professionals with any samples of pharmaceutical products for personal use as well.

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

All gifts and donations are prohibited both by the Law on drug circulation and the AIPM Code. In practice, the provision of stationery of insignificant value free of charge during educational and scientific events is allowed.

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? If monetary limits apply, please specify.

If a healthcare organisation and a pharmaceutical company are registered as commercial companies in Russia, such gifts or donations of any kind are prohibited by tax legislation. If a healthcare organisation is a non-commercial company, the Law on advertising prohibits the donation of samples containing narcotic substances. Thus, all other gifts and donations are allowed in the absence of direct prohibition.

The additional requirements are described in the AIPM Code. *Inter alia*, respective gifts and donations to non-commercial organisations may be made only for publically beneficial purposes. Under no circumstance can the provision of a donation be made dependent on the purchase of pharmaceutical products.

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?

Subject to compliance with the restrictions indicated above, the provision of medical or educational goods and services to healthcare professionals which could lead to changes in prescribing patterns is allowed.

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?

In general, Russian legislation does not prohibit the provision of volume-related discount for the purchase of medicinal products by healthcare institutions. However, a respective discount should be commercially reasonable, otherwise it may be concerning for tax authorities.

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?

It depends on whether such offer is reflected in agreement between the pharmaceutical company and medical institution or respective services are provided unofficially to the executive officer of a medical institution in exchange for the purchase of a medicinal product. While Russian legislation does not prohibit the former, the latter is likely to be regarded as a bribe. Thus, in order to comply with Russian laws, the respective offer should be included in the agreement between a pharmaceutical company and medical institution for the purchase of medicinal products.

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?

Under consumers' rights protection laws consumers are entitled to refund and reimbursement of damages for products of substandard quality. In case information about the refund scheme is included in the promotional campaign such advertising may breach the Law on advertising, since it can be regarded as the assurance of the effectiveness and safety of a product.

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

Pharmaceutical companies are allowed to sponsor the scientific activities of healthcare professionals, which may include medical education.

4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

Russian legislation does not establish special anti-bribery rules applying to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations. According to the Criminal Code of Russia, the following actions are forbidden:

- the provision of money or other property as well as services or rights to the executive official of the company for certain actions or omission to act in the interests of a person or entity providing money, securities, etc. in case (i) the relevant actions are not based on law or agreement, and (ii) these actions or omission to act are included in his duties as the official of the company (as well as provision of these items to third party at the instruction of such executive official);
- receipt of money, securities, other property as well as services or property rights by executive official as described above; and
- actual transfer of money, securities, other property or property rights, as well as provision of services in the situations described above at the order to the person providing items listed above or any other assistance to these persons.

According to practice, Russian authorities can exchange information transferring matters to the relevant state body for its consideration. However, due to the limited scope of anti-bribery legislation, a situation where pharmaceutical company may breach both advertising and anti-bribery laws simultaneous is unlikely.

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?

According to Russian legislation, it is prohibited for pharmaceutical companies to pay healthcare professionals for entertainment, leisure, travel costs as well as engage them in entertainment events conducted at the expense of such pharmaceutical companies with the exception of scientific meetings.

Respective prohibition applies regardless of the place where such events take place and the cost of them. However, the AIPM Code states that pharmaceutical companies should not organise events for healthcare professionals outside their country of residence, unless it is justified in terms of logistics or security. The use of facilities associated with entertainment or luxury is prohibited.

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?

According to the Law on drug circulation, a pharmaceutical company may pay a healthcare professional for scientific and educational work. Thus, it is possible to pay in connection with attending a scientific meeting if the respective agreement between the pharmaceutical company and healthcare professional includes scientific or educational work done by such healthcare professionals (e.g., they may participate in scientific meeting as a speaker or use received information for further education of colleagues). The law does not establish restrictions on payments under such agreement.

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 Pharmaceutical company may be held liable for the breach of advertising legislation at these meetings in case it either organised such meeting or sponsored it in such way that allowed such pharmaceutical company to include breaching advertising in the content of meeting. However, the Russian legislation does not establish liability for the breach of restrictions on gifts or hospitality during such meetings. The compliance of Russian pharmaceutical companies with these requirements is dependent on them acting in good faith.

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

Pharmaceutical companies may pay healthcare professionals (except for pharmaceutical professionals and heads of pharmacy organisations) serving as experts for their work on the expert council, provided that the experts' work on the expert council is scientific in nature. However, requirements stated in question 5.2 should be observed.

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

The participation of healthcare professionals in clinical studies is allowed. Respective clinical studies should be done according to applicable legislation.

Please note that participation of healthcare professional should be structured in such a way that it does not lead to a conflict of interest.

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

According to the Law on drug circulation, a pharmaceutical company can pay a healthcare professional in connection with scientific and educational work. Thus, we believe it is possible to pay healthcare professionals for marketing research in case their participation implies material scientific work done by such healthcare professionals.

Additional requirements ensuring the independence of the opinion of healthcare professional are established in the AIPM Code (e.g., the healthcare professional is not informed on, and it is unclear from the materials of the study, which pharmaceutical company has ordered/sponsored the study). The requirements stated in the question 4.7 should be observed as well.

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?

Non-prescription medicines are permitted to be advertised to the general public. The basic requirement is that the advertisements should be fair and true.

The following actions are generally prohibited:

- advertising certain objects and products (e.g., human organs and tissues for sales purposes; those manufactured with the use of human embryo tissues);
- advertising of narcotic or psychotropic substances and their precursors;
- advertising of non-authorised items;
- advertising of prescription medicines, treatment methods, medical products and equipment that require special training for their use to general public; and
- depicting healthcare workers.

According to additional rules advertising of non-prescription medicines must not:

- be addressed to minors;
- contain references to specific cases of recovery from disease or improvement of health as a result of using advertised item;
- contain expressions of gratitude from individuals in connection with the use of the advertised item;
- create an impression of the advantages of the advertised item by reference to the fact that the trials required for its state registration have been conducted;

- contain statements or assumptions that consumers have certain diseases or impairments of health;
- facilitate the impression that a healthy person needs to use the advertised item (this prohibition does not apply to medicines used for prevention of diseases);
- create an impression that one does not need to consult a physician;
- guarantee the positive effect of the advertised object, its safety, effectiveness and absence of side effects;
- represent the advertised object as being a dietary supplement (or bio-active supplement) or other product that is not a medicine; and
- contain statements that the safety and/or effectiveness of the advertised item are guaranteed by its natural origin.

Very important to note that advertising of medicines, medical services and equipment must be accompanied by a warning regarding contraindications against their use and application, the necessity to read the instructions on their use or the necessity to consult a specialist.

All information placed in advertising materials must correspond to instructions.

Medicines containing permitted narcotic or psychotropic substances are prohibited for advertising to the general public.

Russia has set forth a specific regulation for biologically active additives (BAA).

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

The Law on advertising prohibits advertisement of prescription-only medicines and treatment methods, medical products and equipment that require special training for their use, except for printed materials targeting professionals or during professional events.

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?

Once conducted, campaigns do not include any product names, they will not draw attention to any items and thus advertising regulations will not apply. However, according to advertising laws, specific restrictions set for promoting certain goods will apply, *inter alia*, to any means of individualisation used to manufacturers or sellers of such goods, in particular names thereof. This can give rise to certain risks for campaigns, where medical conditions have a strong association with particular prescription-only medicines. Therefore running any campaigns by manufacturers or sellers specialised on prescription-only medicines can be recognised as veiled advertising even though no particular names of such items is in place in advertising. If so, such actions must be in strict compliance with advertising rules prescribed for prescription-only medicines.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Referring to prescription-only medicines is prohibited in publications made in printed materials if they are available to the general public, unless they have no aim other than to keep the public informed of scientific or medical progress. Thus, information and analytical materials (scientific research and testing results) are excluded explicitly from advertising regulation. However, press releases are closer to advertisement concept, since they are focused on a particular item. Therefore, there will be high risk that it shall be considered advertising which means an advertiser must comply with general and specific requirements provided for prescription-only medicines. Similar to aforementioned, unauthorised medicines or indications is only permitted for information purposes.

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

It is a general requirement that information must be true and accurate. However, a general description of goods manufactured/distributed by a legal entity or either description of its activity will not be deemed advertising. Therefore advertising regulation will not apply to such materials.

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

There is no official regulation in Russia and therefore general advertising rules will apply to this group, if communication with them is related to promoting medicines. Any meetings with and the funding of such organisation are allowed, provided they comply with the law. In case funding is part of the sponsorship campaign it will be recognised as advertising and thus is only permitted with respect to non-prescription medicines.

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?

Russian law provides for specific prohibition to distributing samples of medicines containing narcotic or psychotropic substances. This rule should be extended to providing prescription-only medicines as well, since this activity has a promoting nature and thus is restricted to the general public.

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 Rules of Good Clinical Practice approved by the Ministry of Health provide detailed instruction regarding the exchange of information between the participants of clinical trials such as medical organisation, patients, state bodies, etc. However, information about clinical trials is not disclosed to the public.

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 (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

Russian legislation does not provide for such requirement.

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 (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Respective requirements are reflected in the AIPM code. It is applicable to all companies, which voluntarily endeavour to comply with the AIPM code.

Each pharmaceutical company shall document and disclose the following transfers of value it makes, directly or indirectly, to or for the benefit of any healthcare professional or healthcare organisation being a recipient:

- donations and grants;
- contribution to costs related to events; and
- fees for service and consultancy.

Without limitation, transfers of value that: (i) are solely related to over-the-counter pharmaceutical products; (ii) are not listed above and are not restricted by applicable legislation and the AIPM Code; or (iii) are part of ordinary course purchases and sales of pharmaceutical products do not fall within the scope of the disclosure obligation.

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. Disclosures shall be made by each pharmaceutical company within six months after the end of the relevant reporting period and the information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed with some exception.

Disclosures are made on the relevant pharmaceutical company's website, provided that it is publicly available.

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 AIPM code does not directly regulate such situation. Since the respective transfers of value can be disclosed in a summarised and depersonalised way, we believe that the transfers of value to such individual healthcare professional may be disclosed by the company in a depersonalised way.

8 The Internet

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

Russian law does not provide for specific regulation of digital pharmaceutical advertising. Therefore the same requirements will apply to such information source as if respective materials was distributed in other forms.

It is allowed to have information resources for the purposes of providing information about a company or/and its products, etc. Consequently, it is allowed, *inter alia*, to place the description of items, prices details, etc. although this should not imply promoting purposes. Should this criteria be met, the information resource will not be subject to advertising regulation. Otherwise all promoting materials placed on the Internet must comply with general requirements set by advertising laws.

FAS is authorised to control, *inter alia*, online advertising. Information sources targeting Russian consumers, in particular available in Russian or either served on Russian domain names (.ru, .рф etc.) fall under its control.

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?

No online advertisement is allowed for such items as prescription medicines, treatment methods, medical products and equipment that require special training. For the rest of medicines an advertiser may place respective materials on the Internet without restricting access.

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?

Website content is treated as the property of its owner and any usage thereof is subject to consent of the right holder. Having sponsorship relations with an independent website owner does not authorise the company automatically to refer to such website. Therefore respective formalities should be settled with independent websites prior to placing a link thereto. The same principle will be relevant to reverse linking as well.

A party which places information should comply with the applicable law requirements. Therefore, a company will not be responsible for content of independent websites when placing the link. Nevertheless, it might be responsible for any description of such independent website.

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

According to Russian law, any information aimed at promoting prescription medicines, treatment methods, medical products and equipment that requires special training for use is not allowed to be addressed to the general public and such information must not be placed on a pharmaceutical company's website.

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

Russian law provides a common approach to regulation of advertising placed on any information resources whether it is a website or a page in a social network. Therefore the same requirements will apply to a page on a social network.

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?

No significant changes in pharmaceutical advertising regulation has been made over the last year.

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

There are different approaches currently under discussion which might give rise to developments of advertising regulation in future. For example, the Russian Parliament discussed an initiative to prohibit advertising of immunity improvement medicines. However, this topic has not gone further.

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

According to recent cases, authorities tend to focus on the description of the effect of a particular medicine provided by an advertiser. It appears from the practice that any statements promising an immediate or quick recovery are not acceptable.

Anton Dzhuplin
ALRUD
17 Skakovaya Street, building 2
6th Floor
125040 Moscow
Russia

Tel: +7 495 926 1648, ext.: +163
Email: ADzhuplin@alrud.com
URL: www.alrud.com

Anton Dzhuplin is a Partner at ALRUD Law Firm. Anton's diverse corporate practice includes M&A, domestic and international corporate finance, IPOs, private equity, joint ventures, public takeovers, corporate governance, restructuring and insolvency. He has an exceptional track record in many industries and he leads the firm's work in the pharmaceutical and infrastructure industry.

Anton joined ALRUD Law Firm in 2007. He became a Partner in 2014. Anton has broad industry experience and is always admired by his clients and business partners for his sharp advice and business intelligence.

Anton graduated from the State University Higher School of Economics, Faculty of Tax and Financial Law. He is a member of the International Bar Association.

Maria Ostashenko
ALRUD
17 Skakovaya Street, building 2
6th Floor
125040 Moscow
Russia

Tel: +7 495 926 1648, ext.: +190
Email: MOstashenko@alrud.com
URL: www.alrud.com

Maria Ostashenko is a Partner at ALRUD Law Firm, heading Commercial, Intellectual Property and Data Protection practice areas. Maria supports Russian and foreign clients providing her expertise in areas including pharmaceuticals and healthcare, FMCG, banks and financial institutions, retail trade, telecommunications, media and technology. Maria possesses vast experience in advising clients from pharma sector, including advice on distribution, marketing activities, relations with HCPs and medical institutions; regulatory rules applicable to the market players and to the products in the sector.

Maria graduated from the Moscow State University in 2004 and was awarded a LL.M. degree in private law by the Russian Private Law School by the President of the RF in 2006. Maria joined ALRUD team the same year. She became a Partner in 2016. She is a member of the International Bar Association and International Association of Privacy Professionals.

A·L·R·U·D 25 YEARS
LAW FIRM SINCE 1991

ALRUD is a leading independent law firm in Russia and is a recognised market leader. ALRUD offers a full range of legal and tax services for clients and advises in all legal spheres. We provide complete solutions of complex cases by analysing all the nuances and problems that may arise.

Currently, the company has more than 100 employees, 80 of whom are professional lawyers, advocates and tax specialists who speak one or more foreign languages. Our lawyers specialise in several areas of law simultaneously, providing comprehensive analysis of all relevant issues and a high quality of service.

Current titles in the ICLG series include:

- Alternative Investment Funds
- Aviation Law
- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Competition Litigation
- Construction & Engineering Law
- Copyright
- Corporate Governance
- Corporate Immigration
- Corporate Investigations
- Corporate Recovery & Insolvency
- Corporate Tax
- Cybersecurity
- Data Protection
- Employment & Labour Law
- Enforcement of Foreign Judgments
- Environment & Climate Change Law
- Family Law
- Fintech
- Franchise
- Gambling
- Insurance & Reinsurance
- International Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Outsourcing
- Patents
- Pharmaceutical Advertising
- Private Client
- Private Equity
- Product Liability
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks
- Vertical Agreements and Dominant Firms

glg global legal group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: info@glgroup.co.uk

www.iclg.com