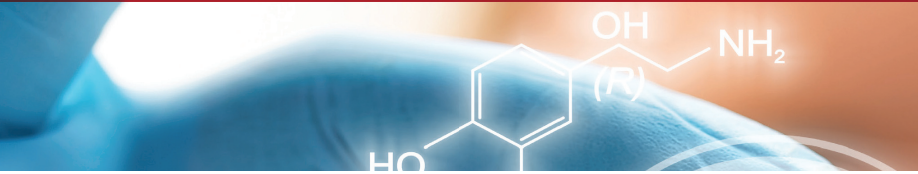


Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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Russia

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Introduction

Russian legislation regulating medicines and medical devices is undergoing substantial changes as part of the current reform of the Russian healthcare system. This process also affects the promotion and advertising of medicines and medical devices.

We would like to start out by explaining the terminology used in relation to the promotion of medical products in Russia, which due to constant legislative changes, may be rather confusing. First of all, Russian legislation does not use the term “medical products” to incorporate the terms “medicines” and “medical devices.” This term will nonetheless be used in this publication for convenience purposes. Furthermore, the Fundamentals (as defined below) dramatically changed the terminology used in the medical devices area, replacing the previously used term “products with medical purposes,” which included “products with medical purposes” and “medical equipment” as subcategories, with the unified term “medical devices” with no internal division to single out medical equipment. This new terminology was then implemented into the regulation of advertising and will be used herein.

In addition, Russian regulations in the relevant parts of legislation do not use the unified term “healthcare professionals,” but rather rely on the terms “medical professionals” and “heads of medical institutions” (together, “Medical Professionals”); and “pharmaceutical professionals” and “heads of pharmacies” (together, “Pharmaceutical Professionals”). In the discussion below, the term “Healthcare Professionals” will be used to refer to medical and pharmaceutical professionals, collectively.

The Regulatory Framework

The following are the main legislative acts that currently govern the advertising and promotion of medical products:

- Federal Law No. 61-FZ on the Circulation of Medicines dated 12 April 2010, as further amended (“Law on Circulation of Medicines”)
- Federal Law No. 323-FZ on Fundamentals of the Protection of Citizens’ Health in the Russian Federation dated 21 November 2011 (“Fundamentals”)
- Federal Law No. 38-FZ on Advertising dated 13 March 2006, as further amended (“Law on Advertising”)

Medicines are currently regulated by the Law on Circulation of Medicines. The healthcare system in general and medical devices are regulated by the Fundamentals. The latter document is intended to form the basis of all healthcare regulation in Russia, which should cover, *inter alia*, medical devices. The Fundamentals, however, do not address the regulation of medicines (fully covered by the Law on Circulation of Medicines), and its two articles governing medical devices at present serve as the only regulations concerning this topic at a legislative level. The draft of a separate law on the circulation of medical devices is in the process of being prepared and, according to the most recent information available, will be presented to the legislative body for review before the end of the 2015.

Notwithstanding the above, the regulation of promotion in Russia is rather uniform both for medicines and medical devices, despite the applicable rules being set in different legislative acts. Most importantly, the rules on the advertising of medicines and medical devices are grouped in the Law on Advertising. The Fundamentals establish specific rules governing interactions between pharmaceutical and medical device companies and medical and pharmaceutical professionals, while the Law on Circulation of Medicines almost mirrors (although with some modifications) provisions of the



Fundamentals in respect of the rules on interactions between pharmaceutical companies and medical and pharmaceutical professionals.

Permitted and Prohibited Practices

Until very recently, the only area related to the promotion of medical products that was specifically regulated by Russian law was simple advertising. However, with the enactment of the Fundamentals, Russian law has, for the first time, introduced specific regulations governing the interactions between pharmaceutical and medical device companies and Healthcare Professionals. These rules, however, are not always clear. The Russian market is currently in a transition period where the pharmaceutical and medical device industries are trying to adapt their practices to the new requirements with no official guidance on how the relevant rules should be applied.

Gifts, Seminars, Hospitality and Entertainment

The Fundamentals directly prohibit Healthcare Professionals from receiving any kind of gifts or monetary payments from pharmaceutical and medical device companies and their representatives. A gift under Russian regulations is understood rather widely as a gratuitous transfer or provision of something of material value, free of charge or without any other consideration in return. Therefore, technically, even the provision of a branded pen to a Medical Professional may qualify as a gift and hence be subject to the said restriction.

Furthermore, as a result of the above prohibition, Healthcare Professionals may not attend any conferences or other similar events at the expense of pharmaceutical or medical device companies. This is because any gratuitous sponsorship (e.g., reimbursement for attendance, transportation or lodging expenses) will qualify as a gift under Russian law.

Healthcare Professionals are not restricted from participation in non-entertainment events organized by pharmaceutical and medical device companies. However, their expenses related to such participation

should not be covered by the companies or the companies' representatives. Theoretically, any hospitality provided during events that Healthcare Professionals attend by themselves may also be viewed as a gift under Russian law. In our view, however, modest hospitality (e.g., water, tea or coffee) is unlikely to be prosecuted in practice.

The Fundamentals also directly prohibit Healthcare Professionals from attending any entertainment events organized by pharmaceutical or medical device companies.

It is important to note, however, that the Fundamentals contain an important exception from the above restriction regarding making monetary payments to Medical Professionals. Medical Professionals may receive remuneration under agreements for the conducting of clinical trials of medicinal products or clinical studies of medical devices, or for performing teaching and/or scientific activities. Please refer to the section on contracts with healthcare professionals and medical institutions below for a more detailed analysis in this regard.

The status of state or municipal servants, which in practice is rare among Healthcare Professionals (except for healthcare professionals in the military and law enforcement sectors, who are often military or law enforcement officers) should also be taken into account, as the rules applicable to those categories of individuals also contain restrictions on gifts, hospitality and entertainment. However, given the strictness of the rules set forth in the Fundamentals, this special status in our view may only further impede the ability to contract with the relevant Healthcare Professionals.

Please note that the above restrictions are only applicable to interactions with individual Healthcare Professionals and not with medical or pharmaceutical organizations.



Promotional Activities

The Fundamentals also contain further restrictions limiting certain promotional activities involving Healthcare Professionals. The Fundamentals prohibit Healthcare Professionals from:

- concluding agreements with companies or representatives of companies to prescribe or recommend certain medicines or medical devices to patients (except in the context of clinical trials of medicinal products or clinical studies of medical devices);
- prescribing medicines or medical devices on blank forms containing promotional information, as well as on prescription forms that already contain the name of medicines or medical devices; and
- meeting with representatives of pharmaceutical companies, manufacturers and sellers of medical products, except for cases related to the performance of clinical trials of medicinal products or clinical studies of medical devices, the participation in meetings of medical workers or other events related to their professional development, or the provision of pharmacovigilance or materiovigilance information in accordance with the procedure established by the management body of a medical organization (this restriction is not applicable to Pharmaceutical Professionals). This provision is slightly restated in the Law on Circulation of Medicines with respect to interactions between pharmaceutical companies and Medical Professionals and prohibits visits to Medical Professionals *during working hours at their workplaces* except for cases related to the performance of clinical trials of medicinal products or clinical studies of medical devices, the participation in meetings of medical workers or other events related to their professional development, or the provision of pharmacovigilance or materiovigilance information in

accordance with the procedure established by the head of a medical organization.

The only other type of promotional activity that is specifically regulated by Russian law is “advertising,” defined in Article 3 of the Law on Advertising as “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 the object advertised, at creating or maintaining interest in it and at promoting it in the market.”

The Law on Advertising specifically requires that prescription medicinal products, medicines containing narcotic or psychotropic substances approved for medical use, methods of prophylaxis, diagnostics, treatment and medical rehabilitation and medical devices that require special training for use can only be advertised in specialized printed publications intended for medical and pharmaceutical professionals and/or at medical or pharmaceutical events. This law sets out that only registered and certified medicines and medical devices are permitted to be advertised.

Furthermore, the Law on Advertising requires that the advertisement of medicinal products, medical services (including methods of prophylaxis, diagnostics, treatment and medical rehabilitation) and medical devices 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 if any problem arises. Such warning should last for a minimum of three seconds in radio advertisements and a minimum of five seconds in television, film and video advertisements (and not less than 7 percent of the frame area should be allocated to this warning); and not comprise less than 5 percent of the total area/volume in advertisements disseminated by other methods. This requirement, however, does not apply to advertisements distributed at medical or pharmaceutical events and/or contained in specialized printed publications for medical and pharmaceutical professionals, nor to other advertisements where the recipients are solely medical and pharmaceutical professionals.



The Law on Advertising further sets out other restrictions that apply to the advertising of medicines, specifically that the advertising of medicines should not:

- be addressed to minors;
- contain references to specific cases of recovery from disease or improvement of health resulting from the use of the advertised product (except in advertising exclusively aimed at medical and pharmaceutical professionals);
- contain expressions of gratitude from individuals in connection with the use of the advertised object (except in advertising exclusively aimed at medical and pharmaceutical professionals);
- create an impression of the advantages of the advertised object 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 object (this prohibition does not apply to medicines used for the 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, efficacy and absence of side effects;
- represent the advertised object as being a biologically active additive or a dietary supplement or other product that is not a medicine; and/or

- contain statements that the safety and/or effectiveness of the advertised object are guaranteed by its natural origin.

The restrictions in items 2 through 5 above are also applicable to the advertising of medical services, including methods of prophylaxis, diagnostics, treatment and medical rehabilitation, and the restrictions in items 1 through 8 above apply equally to the advertising of medical devices.

The Law on Advertising also contains an important general prohibition against using images of medical and pharmaceutical professionals in any advertisements, except for advertisements of medical services or personal care products and/or in advertising exclusively aimed at medical and pharmaceutical professionals.

The Law on Advertising contains general restrictions on advertising that are equally applicable to advertising medical products. One general requirement is that advertising should be fair and true.

Samples

With the adoption of the Fundamentals, the distribution of samples to Healthcare Professionals is now expressly prohibited by Russian law. Healthcare Professionals are not allowed to receive samples of medicinal products or medical devices for the purpose of giving them to patients. The only applicable exception to this rule relates to clinical trials of medicinal products and clinical studies of medical devices.

Furthermore, the provision of samples of medicinal products by wholesalers of medicinal products directly to Healthcare Professionals (except for privately practicing licensed Healthcare Professionals) will still violate rules of circulation of medicinal products and therefore will qualify as a violation of licensing terms and conditions by the involved wholesalers of such medicinal products.

Again, this prohibition does not apply to interactions with medical or pharmaceutical organizations. Pharmaceutical and medical device companies may make gifts or donations (generally beneficial purpose-



specific gifts) to these organizations, provided they are non-commercial organizations, which may receive such gifts or donations. When this activity is performed, all other rules governing the circulation of medicinal products need to be carefully observed.

Consequences of Breach

Civil Law Liability

There are two main types of civil law liability that may be imposed by Russian courts on individuals and companies carrying out promotional and similar activities in violation of the abovementioned legislative provisions:

- Invalidation of the relevant transaction; and
- Compensation for losses, which includes actual losses and/or lost profits.

According to a general principle of Russian civil law, as stipulated in the Russian Civil Code, a transaction that does not correspond to the requirements of the law is considered to be invalid. Based on this principle, the receipt of benefits by a Medical Professional in breach of the legislative restrictions would constitute an invalid transaction. As a consequence of any breach, an interested party may, through a court, demand “mutual restitution, “that is, the return to each of the parties of what they received as a result of the invalid transaction. In the case of such a gift, the doctor would be obliged by a court decision to return the gift or its value to the individual who provided it.

Similarly, the receipt of restricted benefits by a Healthcare Professional would also constitute an invalid transaction as it would be deemed a breach of the Fundamentals and/or the Law on Circulation of Medicines.

If a promotional activity is carried out in violation of the Law on Advertising or other applicable laws, an obligation to compensate may be imposed if such activity has caused losses to individuals or legal

entities. The Russian Civil Code provides for compensation of such losses, provided that a direct connection is established by the court between the unlawful activity and the losses caused by the activity. In cases involving promotional activity, especially advertising, the individuals or legal entities that would commonly seek to recover such compensation for losses before the Russian courts would be customers or competitors of the infringer.

Administrative Liability

Administrative liability may be imposed on individuals and legal entities carrying out promotional activities prohibited by the Law on Advertising. In most cases, administrative liability is imposed in the form of fines of various amounts to be paid to the state budget. In the case of an infringing advertising activity, a court or an authorized governmental agency, such as the Russian Federal Antimonopoly Service, may also demand the publication of corrective advertising and the removal/destruction of unlawful advertising, among other measures.

In addition to the above, it is planned that the restrictions imposed by the Fundamentals shall be supported through the establishment of specific administrative penalties for their violation. Such penalties shall be applicable to both the pharmaceutical and medical device companies and the Healthcare Professionals involved.

This has not yet been implemented, despite the draft amendments to the Code of Administrative Violations having been prepared some time ago.

Lastly, in relation to the below analysis of the potential anti-corruption aspect of promotional activities, please note that Russian legislation establishes administrative liability for legal entities involved in corrupt activities (Russian criminal law does not include the concept of corporate criminal liability).



Criminal Liability

There is a theoretical possibility that the receipt of benefits by a Healthcare Professional could give rise to criminal liability under Articles 204, 291 and 291.1 of the Criminal Code of the Russian Federation (the “Criminal Code”). These articles deal with different types of bribery, that is, the transfer of money or other assets or the rendering of services to an individual with the intent of obtaining certain benefits or inducing the recipient to either take certain actions in the interest of the giver or act as mediator by assisting the recipient and/or giver of the bribe in the achievement of their unlawful aim. Article 204 also imposes liability on the recipient of the commercial bribe, and Article 290 deals with the liability of a public official for the receipt of a bribe. A detailed analysis follows on the liability arising for the giver of a commercial bribe under Article 204 and the giver of a bribe under Article 291 of the Criminal Code.

For criminal liability to arise under Articles 204 and 291 of the Criminal Code, the recipient of the benefits would have to be either a person holding a managerial position in the medical institution concerned (Article 204) or a public official (Article 291), although in the case of a public official, liability could arise if he or she was the indirect recipient (e.g., the money was paid to a third person for onward transmission to the public official). Consequently, any benefits provided to professionals who are not public officials and who hold no managerial position in the institution concerned cannot give rise to liability under these articles.

A gratuitous benefit can only be deemed a bribe if the necessary intent on the part of the giver (as described above) can be proved. While it could always be argued that a pharmaceutical company would not provide a benefit if it were not in its commercial interest to do so, it would be extremely difficult to use a general intention – for example, familiarizing a Medical Professional with a company’s products – as a sufficient basis for criminal liability.

As of now, there is no concept of corporate criminal liability under Russian law, and so criminal liability may attach only to individuals. Criminal liability that could be imposed on individuals under the abovementioned articles of the Criminal Code are as follows:

- Article 204 (Commercial Bribery)

Liability for this violation can involve a fine varying from 10 to 50 times the amount of the commercial bribe, along with a prohibition on the right to hold specified offices or engage in specified activities for a term of up to two years, a restraint of liberty for a term of up to two years, compulsory labor for a term of up to three years, or imprisonment for the same term.

If the crime was committed by a group of persons in conspiracy or by an organized group or the commercial bribe was given for knowingly conducting illegal actions or omissions, it is punishable by a fine varying from 40 to 70 times the amount of the commercial bribe, along with a prohibition on the right to hold specified offices or engage in specified activities for a term of up to three years; compulsory labor for a term of up to four years; arrest for a term of three to six months; or imprisonment for a term of up to six years.

Under certain circumstances, such as active assistance in a criminal investigation or voluntary disclosure of information regarding the crime of commercial bribery to the relevant body empowered to initiate criminal proceedings, a bribe-giver is relieved from criminal liability.

- Article 291 (Bribery)

Liability for this violation can involve a fine in an amount of up to RUB500,000 or in the amount of one year's salary or wage, or any other form of income, of the convicted person; a fine varying from five to 30 times the amount of the bribe; correctional labor for a term of up to two years; prohibition from holding specified offices or engaging in specified activities for a term of up to three years; compulsory labor for a term of up to three years; or imprisonment for



up to two years accompanied by a fine varying from five to 10 times the amount of the bribe.

If the bribe was substantial (i.e., in excess of RUB25,000, which as of October 2015 is approximately USD390), the crime may be punishable by a fine in the amount up to RUB1 million or in the amount of two years' salary or wage, or other any other income, of the convicted person; a fine varying from 10 to 40 times the amount of the bribe; correctional labor for a term of one to two years, disqualification from holding specified offices or engaging in specified activities for a term of one to three years; or imprisonment for up to three years, accompanied by a fine varying from five to 15 times the amount of the bribe.

If the bribe was given for knowingly conducting illegal actions or deliberate oversights, the crime may be punishable by a fine varying from 30 to 60 times the amount of the bribe or by imprisonment for a term of up to eight years accompanied by a fine of 30 times the amount of the bribe.

If the crime was committed by a group of persons acting in conspiracy or by an organized group, or if the bribe qualified as large (i.e., in excess of RUB150,000, which as of October 2015 is approximately USD2,344), it may be punishable by a fine varying from 60 to 80 times the amount of the bribe, along with a prohibition on holding specified offices or engaging in specified activities for a term of up to three years, or by imprisonment for a term of five to 10 years accompanied by a fine of 60 times the amount of the bribe.

If the bribe was classed as extremely large (i.e., in excess of RUB1 million, which as of October 2015 is approximately USD15,625), it may be punishable by a fine varying from 70 to 90 times the amount of the bribe, or by imprisonment for a term of seven to 12 years accompanied by a fine of 70 times the amount of the bribe.

Please note that under certain circumstances, such as if active assistance is provided in a criminal investigation or if information is

voluntarily disclosed to the relevant body empowered to initiate criminal proceedings with respect to the crime of bribery, a bribe-giver may be relieved from criminal liability.

Article 291.1 of the Criminal Code also now establishes liability for mediation in bribery.

Professional Codes of Conduct

In 1994 a group of multinational research-based pharmaceutical manufacturers doing business in Russia formed the Association of International Pharmaceutical Manufacturers (AIPM). AIPM member companies currently represent approximately 80 percent of world production and sales of pharmaceuticals. AIPM has adopted its own Code of Practice (the “Code”), with which all AIPM member companies have agreed to comply.

The Code was revised during the second half of 2006 and subsequently in 2009. The Code was then substantially revised in 2013 when the current version was adopted to reflect recent changes in pharmaceutical and healthcare regulations, and in order to incorporate the requirements for detailed disclosure regarding the nature and scale of interactions between pharmaceutical companies and Healthcare Professionals and healthcare organizations pursuant to the Code of the European Federation of Pharmaceutical Industries and Associations, which the AIPM joined in 2012. It is understood that the Code now governs good practices in general and not just marketing practices.

The international medical devices industry also has a local association, that is, the International Medical Device Manufacturers Association (IMEDA). IMEDA adopted its Ethical Code for Medical Devices Manufacturers (the “IMEDA Code”) in 2008 and it was subsequently revised in 2013 when the current version was adopted to reflect recent changes in medical devices regulations. The members of IMEDA have voluntarily undertaken to follow the IMEDA Code, which does not apply to medical device companies that are not IMEDA members.



Contracts with Healthcare Professionals and Medical Institutions

The procedure for entering into agreements with Healthcare Professionals and institutions, and the regulations relating to such agreements, are subject to the general rules established by Russian contract law and the restrictions imposed by the Fundamentals and the Law on Circulation of Medicines.

Both Medical and Pharmaceutical Professionals are prohibited from receiving money from pharmaceutical and medical device companies and such companies' representatives. As mentioned above, in relation to Medical Professionals, the Fundamentals contain an important exception from this general prohibition. Medical Professionals may receive remuneration under agreements in the course of conducting clinical trials of medicinal products or clinical studies of medical devices, or in relation with their performance of teaching and/or scientific activities.

As a result, Medical Professionals who are duly engaged by pharmaceutical and medical device companies to conduct clinical trials or to perform teaching and/or scientific activities may be entitled not only to fair market compensation for their activities but also, under the relevant agreement, to reasonable compensation of their travel and living expenses incurred in connection with the performed activities.

No exceptions of this sort are established in relation to Pharmaceutical Professionals, and hence in accordance with the general prohibition set out in the Fundamentals, they may not receive money under any type of agreement with pharmaceutical and medical device companies.

Again, the restrictions imposed on Medical and Pharmaceutical Professionals do not extend to medical and pharmaceutical institutions.

We note that the contracting with Medical Professionals allowed by the Fundamentals and the Law on Circulation of Medicines is likely to be further restricted if the Medical Professionals involved simultaneously have the status of a state or municipal servant. The status of state or municipal servants is regulated by separate laws, including Federal Law No. 58-FZ on the System of State Service in the Russian Federation dated 27 May 2003, as amended; Federal Law No. 79-FZ on Civil State Service in the Russian Federation dated 27 July 2004, as amended; and Federal Law No. 25-FZ on Municipal Service in the Russian Federation dated 2 March 2007, as amended. By virtue of these laws, restrictions are imposed on persons falling under the category of a state or municipal servant. For instance, such persons may not receive any remuneration in the form of monetary compensation, gifts, loans, services, payment for entertainment, vacations, transportation expenses or other such remuneration related to the fulfilment of their duties as state or municipal servants, from legal entities or individuals; neither can they conduct any entrepreneurial activities or leave the state territory of the Russian Federation for the purpose of fulfilling their duties at the expense of legal entities or individuals. They also must observe all applicable rules on conflicts of interests. In this regard, state and municipal servants may engage in another paid activity, subject to the restrictions contained in the relevant laws regulating their status, provided that a prior notification is sent to the representative of the employer and no conflict of interest arises.

Federal Law No. 76-FZ on Military Service dated 27 May 1998, as amended, contains a list of prohibited activities for military servants, which is almost identical to the list of prohibited activities for municipal servants.

Restrictions placed on state and municipal servants effectively prohibit pharmaceutical companies from entering into, and making payments under, almost any type of contract with them aimed at the promotion of medical products.



Additionally, Russian law distinguishes, as a category that is separate from state and municipal servants, officials whose offices are established by the Russian Constitution, constitutions and charters of the subjects of the Russian Federation, and federal and regional laws for the direct exercise of federal and regional powers (the “Supreme Offices”). These offices are regulated by separate laws and/or regulations. For example, the office of the Minister of Health is governed by Federal Constitutional Law No. 2-FKZ on the Government of the Russian Federation dated 17 December 1997, as amended. Similar restrictions apply to Supreme Offices as to state and municipal servants.

Recommendations

In order to ensure compliance with Russian legislation governing the promotion of medical products, we recommend the following:

- Implement transparent internal policies on interactions with healthcare professionals, promotion and compliance matters.
- Appoint leaders responsible for monitoring compliance with the applicable rules.
- Refrain from giving any gifts, monetary payments or charitable donations, regardless of their value and purpose, to individual healthcare professionals.
- Analyze carefully every agreement that is intended to be concluded with a medical professional from the perspective of its compliance with the restrictions set out in the Fundamentals and applicable legislation governing the status of state and municipal servants and Supreme Officers.
- Organize training programs for employees in order to develop professional awareness and ensure law-abiding conduct while interacting with healthcare professionals.



This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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