

# Russian legal alert

## Pitfalls and future restrictions of interaction with Russian health care professionals

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**I. INTRODUCTION**

The interaction between pharmaceutical companies and health care professionals ("HCPs") is vital to granting access to the latest, most accurate scientific information about new products and new treatments. It also helps supporting medical research and education and obtaining feedback about such new products and treatments. And ultimately, the patients of course benefit from it. Nevertheless, excessive practice in the past in the pharmaceutical industry has resulted in the criticism that the industry tried to influence the decisions of HCPs, particularly on prescribing certain medicines to patients. As a result, such interaction with HCPs has been increasingly regulated by a variety of restrictions and codices.

In Russia, there are various limitations which need to be observed in order to act in accordance with the applicable law and industry standards. The following example should help illustrating the complicated correlation of the diverse restrictions:

**CASE SCENARIO:** A Russian subsidiary (OOO) of the pharmaceutical company with headquarter in Germany PharmHead Ltd. ("PharmHead Ltd.") intends to invite a chief physician and a regular physician of a Russian state hospital to travel to Berlin and participate in an international symposium on a specific disease at which, inter alia, the latest prescription product of PharmHead Ltd. relating to that disease is introduced by PharmHead Ltd. Furthermore, the Russian subsidiary wishes to put an expensive music CD with the logo of the company in the hotel room of the Russian participants as a gift. Is this legally allowed?

## II. RUSSIAN BRIBERY LAW

In general, Russian law does not provide clear guidance as to which extent the interaction with HCPs is allowed. The restriction by the law depends on whether the HCP is employed by a state healthcare institution or a private/commercial institution.

1. Under Russian legislation state healthcare institutions have two types of employees: (1) officials who work under state (municipal) service agreements or perform organizational and regulative or administrative and economic functions; and (2) other professionals. Employees in private/commercial organizations can also be divided into two categories: (1) persons performing management functions (general directors, members of the board, head doctor etc.); and (2) other professionals. Restrictions are imposed mainly on officials and persons with management functions.
2. Sections 290 and 291 of the Russian Criminal Code penalize officials for receiving bribes (which include monetary and other benefits), and correspondingly any person for granting the aforementioned benefits to such officials for any action or inaction in favor of such person, or for any promotion of such action or inaction or for general patronage. Such action or inaction can even be lawful and within the competence of the official. A similar provision is contained in Section 204 regarding representatives of profit-making private/commercial organizations who perform management functions.
3. Furthermore, Section 575 of the Russian Civil Code prohibits any gifts for public officials or civil (municipal) servants, working under state (municipal) service agreements, save for simple gifts the value of which does not exceed 3,000 Rubles (70 Euro) , if such gifts are made “in connection with the execution of their duties”.
  - a) A literal interpretation of these provisions would result in the fact that any HCP who receives a benefit from a pharmaceutical company, such as an invitation to attend a medical conference or international seminar, and officially procures the products of the inviting pharmaceutical company subsequent to the attendance, might violate said provisions of the Criminal Code. Of course, a respective intent of the parties needs to be proven.
  - b) However, it should be assumed that the HCPs act in line with their business ethics, such as the Code of Medical Ethics of the Russian Federation, see Chapter 1.2. Usually, it should be assumed that any procurement of a product is motivated exclusively by the HCPs’ will to act for the patients’ benefit and wellbeing.
  - c) Furthermore, the provisions of the Russian Code of Marketing Practices of the Association of International Pharmaceuticals Manufacturers (“AIPM”) might serve as another counter argument against a literal interpretation of the law. Even though said Code is not an act of the Russian legislation, it might be understood as a common industry standard. It emphasizes the importance of proper interaction with HCPs as indispensable element in the pharmaceutical industry. The Code provides for regulations and restrictions of the interaction which are by far more detailed than the Russian law.
  - d) Hence, in light of the broad wording of the Criminal Code a reliable guarantee can hardly be offered. If a pharmaceutical company wishes to be on the safe side, it might restrict any invitations



only to such HCP who are neither officials nor performing management functions.

- e) Gifts from pharmaceutical companies, such as the aforementioned CD, are not per se prohibited, but fall within the restriction of the above stated provisions of the Criminal Code. A risk remains that such gifts could be seen as a benefit for an action or inaction in favor of the giver. This applies all the more, as the CD is a mere present without scientific benefit unlike the symposium. Furthermore, in order to easily comply with the restrictions of the section 575 of the Russian Civil Code, the gift should not exceed the value of 3,000 Rubles. Therefore, in practical terms the CD should only be given – if at all – to regular physicians who are neither officials nor perform management functions, and its value should be less then 3,000 Rubles. A “mass distribution” in hotel rooms is not advisable, as no distinction of recipients can be drawn.

**CASE:** In the aforementioned case the pharmaceutical company might decide to invite only the regular physician, but not the chief physician, in order to avoid an additional risk. Besides, the CD should have a value less then 3,000 Rubles and should only be given to the regular physician, but not to the chief physician, if at all.

## III. CODICES

In addition to the applicable Russian laws, in particular the laws covering bribery and commercial corruption, various national and international standards need to be observed to run the business in line with industry standards, provided that the pharmaceutical company is a member of the respective associations. Even if it is not a member, it might be advisable to comply with the provisions, as they



reflect common industry standard and best state-of-the-art practice. The latter might play a key role for maintaining its reputation in the market and vis-à-vis regulatory authorities.

**1. INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASSOCIATIONS (“IFPMA”):** The IFPMA has developed the IFPMA Code of Pharmaceutical Marketing Practices (“IFPMA Code”) which sets forth widely acknowledged industry standards of “dos and don’ts” regarding the interaction with HCPs. As numerous national pharmaceutical associations are member of the IFPMA, all companies of such national associations are bound by the IFPMA, even if they are not direct members of the IFPMA, see section 1.2.

**CASE:** Both the German Association of Research-Based Pharmaceutical Companies and the AIPM are member associations of the IFPMA. The IFPMA Code allows the sponsorship of a HCP by a pharmaceutical company to attend a scientific symposium in order to inform the HCPs about pharmaceutical products (sections 7.2). The symposium may take place outside of the HCP’s home country if it is justified from a logistical point of view. International scientific symposia that attract participants from many countries are explicitly justified. Thus, the HCPs can be invited to Germany. However, the sponsorship must be limited to the payment of travel, meals, accommodation and registration fees but should under no circumstances compensate for the time spent or for expenses of accompanying guests.

Regarding the CD, section 7.6 stipulates that gifts for the personal benefit of HCPs, such as music CDs, must not be offered. Placing it in the hotel room of the physicians as a gift would be a violation.

**2. RUSSIAN ASSOCIATION OF INTERNATIONAL PHARMACEUTICALS MANUFACTURERS (“AIPM”):** The Code of Marketing Practices of the AIPM (“AIPM Code”) establishes requirements which pharmaceutical AIPM member companies must observe when carrying out marketing activities in Russia.

**CASE:** If said Russian subsidiary wishing to invite the physicians to the symposium is a member of the AIPM, the AIPM Code needs to be observed, see I.1.1 of the Code. The AIPM Code has similar provisions as the IFPMA Code. Section III.3.3 allows the organization of a scientific symposium for HCPs under the same conditions as the IFPMA Code. Likewise, the music CD must not be placed in the hotel room as a gift for the participants, section III.3.8.2.

**3. EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS (“EFPIA”):** Furthermore, the EFPIA has developed the EFPIA Code on the Promotion of prescription-only medicines to, and interactions with, Healthcare Professionals (“EFPIA Code”). If Russian HCPs are hosted in European countries as specified by the EFPIA Code, the EFPIA Code needs also to be observed, on condition that the holding company of the acting Russian entity is a direct member of EFPIA. In this case, the applicability of the EFPIA Code is extended to its Russian subsidiaries for interactions with HCPs in Europe. This secures that pharmaceutical companies do not circumvent the EFPIA Code by shifting interaction activities with HCPs to its subsidiaries which are located outside of Europe. The same applies to a European holding company which is a member of a national member association so that observance of international standards, such as the EFPIA Code, is required.

**CASE:** If the German headquartered PharmHead Ltd. is a member of the EFPIA, the EFPIA Code applies also to activities of its Russian subsidiary, as the symposium takes place in Germany, a European country according to the definition set forth in the EFPIA Code. For the sake of clarity, even though the sponsoring company is the Russian subsidiary of PharmHead Ltd., the EFPIA Code applies to the Russian subsidiary. The same applies if PharmHead Ltd. is a member of a German national member association such as the Verband Forschender Arzneimittelhersteller e.V. which demands from its members compliance with international standards, such as the EFPIA Code.

The symposium may take place outside of the HCP's home country if it makes greater logistical sense, see Section 9.02. This is in line with the aforementioned codices. Thus, the HCPs can be invited to Germany. Furthermore, pursuant to Section 13.01 of the EFPIA Code the rules of jurisdiction of that country must be observed where the invited HCPs carry out their professions, which is Russia. Thus, the provisions mentioned in Section 1 apply. According to Section 10.04 of the EFPIA Code, personal gifts, such as a CD, should not be offered or provided.

- 4. NATIONAL MEMBER ASSOCIATION CODE:** Finally, also national member associations' codices must be complied with. This is the case if the interaction with the HCP takes place in a specific country of Europe and the interacting pharmaceutical company is subject to the EFPIA Code or is a member of the respective national member association of the country where the interaction takes place.

**CASE:** If the EFPIA Code needs to be observed, the national Code of Conduct on the Collaboration with Healthcare Professionals ("FSA Code") by the German association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." ("FSA") is applicable to the symposium in Berlin. Furthermore, the FSA Code requires also compliance with the code of the country where the inviting company is domiciled, Chapter 4, Section 20 (9), which is Russia. The invitation of the HCPs is legally allowed if the symposium is in the field of the medical expertise of the physicians.

Said music CDs in the hotel room are not intended for professional use and therefore forbidden, see Chapter 4, Section 21 (2) of the FSA Code.

#### **IV. INTERNAL CODICES AND CODES OF CONDUCT**

Most pharmaceutical companies have developed and published their own ethical standards which are usually called "Code of Conduct" or "Ethical Code". They have a self-binding effect and can serve as measurement of the management in case of non-compliance, in

particular in criminal investigations. In addition, there is a growing tendency to impose such internal standards on the contracting party in agreements, such as suppliers and contractors.

#### **V. ENVISAGED AMENDMENTS**

In line with political objectives, the pharmaceutical market will most likely undergo substantial changes. As a result, the Russian Federal Antimonopoly Service has introduced a draft Federal Law "On Introducing Amendments to Several Legislative Acts of the Russian Federation".

This draft aims at restricting the interaction of the pharmaceutical industry with HCPs. It provides for detailed stipulations of conflicting interests of HCPs, their duty to notify their superiors of such conflicts and the obligation of the superiors to properly solve the conflicts. The draft describes the potential risk of the patients' interest being impaired by a HCP unduly performing his duties due to his personal interest in receiving monetary benefits. Therefore, visits of sales reps during office hours are to be prohibited, as well as donations in form of providing samples. Also, post marketing trials would be restricted, in particular the number of participants.

The draft seeks to prohibit in general compensations in favor of HCPs by way of monetary aid, presents, payment for travel expenses and the like by pharmaceutical companies beyond 3,000 Rubles. It also explicitly aims at forbidding HCPs to participate in scientific seminars or conferences at the expense of a pharmaceutical company. The current draft acknowledges the sole exception that no mutual obligations between the HCP and the pharmaceutical company are created by such participation. Respectively, according to the draft it will be prohibited for pharmaceutical companies to organize such seminars and sponsor their attendance by HCPs who undertake to distribute the company's drugs.

In case a pharmaceutical company fails to observe the restrictions, it will have to pay administrative fines.

**CASE:** The participation of physicians is still possible, but sponsorship of this participation will be limited to 3,000 Rubles. To be able to invoke the exception to the general prohibition it should be clearly stated that the invitation and attendance does not create any obligation for the physician. Due to the emphasis of the general prohibition, it seems to be more critical to invite officials and persons with management functions, as the correlation of the general rule and the exception might even shift the burden of proof to the parties that there are no mutual obligations.

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