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Russian Healthcare Law

This overview summarises the key areas of Russian healthcare law with a focus on the pharmaceuticals sector. The first part focuses on the legal basics of M&A transactions in the Russian healthcare sector. The second part provides an overview of the regulatory landscape which is bound to be dramatically reshaped as a result of Russia's Pharma 2020 strategy. The third part deals with business compliance requirements for pharmaceuticals companies when operating in Russia.

The Legal Basics of M&A Transactions in the Russian Healthcare Sector

Introduction

The purpose of this section is to provide an overview of various key aspects of planning and structuring an M&A transaction involving a target active in the Russian healthcare sector. It addresses typical features and potential pitfalls of M&A transactions, essential rights of minority/majority shareholders, joint venture aspects, foreign investment restrictions, competition aspects, sector-specific requirements as well as recent legal changes and forthcoming developments.

Typical Features and Potential Pitfalls of M&A Transactions

Due to the complexity of the Russian statutory rules governing the sale of enterprises, the majority of Russian M&A transactions are done through share deals and only rarely by asset deals. It is a particularity of the pharmaceuticals sector that asset deals tend to be used more often than in other industry sectors. This is due to the fact that foreign healthcare groups wish to exclude the potential risks associated with the legal and compliance history of Russian targets. Asset deals can readily be implemented when the target has distribution and service operations, but they are much less feasible when the target has production facilities along with the necessary licences and permits, which are typically difficult to transfer.

Russian law is largely based on continental European law principles, and many Russian statutes are similar to those in Western Europe. That said, Russia continues to lack a judicial system that develops the interpretation of laws and offers legal certainty on the basis of settled case law. As a result, most M&A transactions in the Russian market are based on documentation that is governed by foreign law.

Recent market trends include a more cautious approach by M&A parties generally, which has led to increased due diligence by foreign investors and lending banks. This trend applies to M&A transactions in most Russian industry sectors, but holds particularly true in the healthcare sector, given the higher level of regulation and intensified scrutiny of this sector by Russian healthcare and competition regulators.

It is a general characteristic of the Russian market that local businesses are held through offshore holdings. It is not uncommon for foreign investors to encounter difficulties obtaining information about the holding structures used by their Russian counterparties. This can be especially relevant when it comes to structuring change-of-control clauses and ensuring post-completion protection in respect of warranties and representations given by a seller.

Because selling entities are often companies with little or no assets, their obligations under warranty and indemnity claims must typically be secured by other companies with substance and, more often, by personal guarantees of the ultimate beneficial owners of the selling entity, who may also be required to give non-compete and non-solicitation covenants. In the healthcare sector this is particularly relevant, as targets have often been set up and developed by one or more individuals who wish to dispose of their

business but do not own any significant assets other than the target.

Partial deferred payment of the purchase price, escrow structures and joint ventures with call option arrangements are some typical mechanisms investors use to protect themselves against risks that might not have been identified by due diligence or might not have been disclosed prior to signing.

The Russian takeover rules were introduced only a few years ago. The wording of many provisions is unclear, and the specific requirements continue to be debated. One key issue is whether takeover requirements only apply in the case of a direct Russian acquisition or if they also extend to indirect acquisitions at the offshore level. It is now widely assumed that the takeover regime does not apply where transactions are structured through indirect acquisitions.

Russian corporate law proceeds from the position that a company should always have two or more shareholders. While Russian law accepts the existence of companies with only a single shareholder, there is a prohibition on vertical chains of single-shareholder companies. This means that a single-shareholder company must at the next level have at least two shareholders (even if within the same group) in order to comply with the Russian legal requirements. While in practice this requirement is no more than a formal technicality, it nevertheless must be borne in mind and can increase the complexity of the transaction documentation.

The resolution of disputes arising out of Russian M&A transactions, including in the phama sector, is almost always referred to non-Russian international arbitration tribunals, whose decisions are generally enforceable in Russia. It is not common for disputes to be referred to foreign state courts, e.g. in the UK, USA or Germany, as their judgments cannot normally be enforced in Russia.

The Russian merger control thresholds are very low. As a result, almost any M&A transaction involving the acquisition of a Russian pharmaceuticals company by a foreign investor will require merger control clearance.

Essential Rights of Minority/Majority Shareholders in Case of Acquisition of Less than 100% in a Russian Target

Generally speaking, the scope of rights and level of protection afforded a shareholder by virtue of a minority or majority stake it holds are similar to those in other jurisdictions.

The Russian corporate governance rules are generally stricter than those in most Western European jurisdictions. It is often difficult to shift powers from one corporate body to another, particularly where a joint venture is structured through a Russian joint stock company.

Russian corporate law proceeds from the general position that a company should have 'one captain sailing the ship'. Accordingly, significant powers are referred to, and can only be exercised by, the general director of a company, and it is legally difficult to limit the general director's powers. As a result, the partner that appoints the general director is typically in a powerful position, irrespective of how the other corporate bodies in a joint venture are structured. At the same time, the level of personal responsibility/liability of a general director is higher than that of most other directors/officers.

Russian corporate law provides for specific minority protection rights which are generally felt to apply too broadly. In particular, there exist certain corporate approval requirements relating to so-called 'interested party transactions'. While these requirements are designed to prevent conflicts of interests, in practice they sometimes hinder majority shareholders from implementing important transactions, even if the latter are in the company's interest and even where the minority shareholder holds just a single share.

Arrangements between Shareholders, Joint Venture Aspects

Until recently there were no rules in Russian corporate law dealing with shareholders' arrangements. As a result, there is still significant uncertainty if and how shareholders' agreements relating to a Russian company can be structured in a legally enforceable manner. In practice it is therefore strongly advisable to structure joint ventures at the level of a non-Russian holding entity that holds 100% in the Russian company. This is common practice, although many Russian partners have a preference to structure the joint venture inside Russia, which often puts the foreign investor in a *de facto* weaker position.

In cases where joint ventures are implemented at the Russian level, it is open to debate whether or not it is preferable to structure the shareholders' agreement under foreign (usually English) or Russian law. English law

provides for greater flexibility and the use of up-to-date concepts for shareholders' arrangements. There is, however, Russian case law supporting the position that Russian law must be applied to such arrangements, meaning that parties have to accept limited flexibility and legal uncertainty as to how an arbitral tribunal may interpret the agreement.

Where joint ventures are structured at the Russian level, it is arguable whether the legal form of a limited liability or joint stock company provides greater legal comfort. A joint stock company allows the use of shares and avoids notarial form requirements for put/call option and exit arrangements under the shareholders' agreement (which requirements apply in the case of a limited liability company). At the same time, joint stock companies are regulated more strictly, meaning that there is even less flexibility to structure the joint venture according to the parties' preferences.

As noted above, the vast majority of joint ventures are structured through holding entities outside Russia, which then hold the Russian asset as single shareholder. The decision as to where to locate a joint venture is normally tax-driven. In practice, holding vehicles for Russian assets, including in the healthcare sector, are typically registered in Cyprus, the Netherlands or Luxembourg. There are, however, also numerous joint ventures registered in Germany, Austria and other jurisdictions.

The creation of a joint venture, whether full-function or non-full-function, does not in itself require merger clearance in Russia. But there does exist a voluntary procedure for clearance of agreements by Russia's Federal Antimonopoly Service. It is often advisable, depending on the specific circumstances, for a foreign partner to apply for voluntary clearance to obtain comfort that non-compete arrangements and exclusive supply/purchase arrangements, etc. are sanctioned by the authorities.

Foreign Investment Restrictions

There exists a special regime for foreign investment in Russian strategic sectors. The law lists some 42 such sectors, including the handling of infectious agents, meaning that the foreign investment regime also applies to many developers and manufacturers of pharmaceuticals.

Obtaining clearance under the foreign investment regime is time-consuming. In practice, the entire process, including preparation of the notification, takes 3 to 7 months.

Special foreign investment restrictions apply to state-controlled foreign investors in any Russian target, whether strategic or not, including pharmaceuticals companies.

The foreign investment regime can play a critical role for transactions in the Russian healthcare sector. In April 2013, the Governmental Commission responsible for implementing the regime blocked the proposed acquisition of Russian pharmaceuticals producer Petrovax by U.S.-based Abbott group. The Commission noted that Petrovax manufactures vaccines which may be of importance for the entire Russian population. The acquisition of such vaccine producer by a foreign investor was viewed to be in conflict with Russian security interests.

Competition Aspects

As a general rule, the merger control regime permits the blocking of acquisitions only on competition grounds, although in practice the regime has often been applied more broadly, with industrial, political and protectionist factors playing a role. That said, such factors are rarely of relevance in the healthcare sector. If relevant, they are typically addressed within the framework of the foreign investment regime.

Russia's Federal Antimonopoly Service tends to define product markets on the basis of INNs (international non-proprietary names) which can result in significant market shares and, in case of overlapping activities between the acquirer and the target, may lead to dominance concerns. In practice, approximately 10% of all transactions are cleared subject to conditions. Conditions are typically behavioural in nature and may include (i) regular reporting requirements on price and business developments, (ii) an obligation to draft and publish a commercial policy for the selection of distributors, (iii) non-discrimination requirements, (iv) rules for the application of bonuses, etc.).

The pharmaceutical industry has recently been subject to heightened scrutiny by the Federal Antimonopoly Service. A number of market assessments have been carried out and cases opened against manufacturers and distributors, including criminal cases relating to severe violations of the competition rules.

Licensing Requirements, Marketing Authorisation and Price Regulation

The manufacturing of pharmaceuticals is subject to mandatory licensing. Licences for products for human use

are granted by the Russian Ministry of Industry and Trade. There are separate licence requirements for wholesale and retail, storage and transportation of pharmaceuticals, as well as for handling narcotic and psychotropic agents. A significant number of safety permit and standardisation requirements apply to healthcare-related equipment.

In 2010 a price-regulation regime was introduced for pharmaceutical products that are on the list of so-called 'life-important pharmaceuticals', which includes several hundreds of international non-proprietary names (INNs). Producers are required to co-ordinate, justify and register maximum output prices for the relevant products. The registration of output prices is also a prerequisite for obtaining marketing authorisation for a new pharmaceutical product. For further detail on the requirements of the price-regulation regime please see page 7 below.

Recent years' regulatory developments in the pharmaceuticals sector and industry outlook

In recent years various legislative changes were adopted that significantly influence the pharmaceuticals industry (including pharmaceuticals regulatory, public procurement and anti-corruption compliance matters).

Among the most notable hot topics are:

- the Pharma 2020 strategy ("**Strategy**") which sets forth the priorities of governmental action in the Russian pharmaceuticals sector for the period until 2020;
- incentives for the localisation of pharmaceuticals production in Russia;
- introduction of an inter-changeability concept of pharmaceuticals which may affect the approach of Russian authorities under the public procurement regime; and
- introduction of stricter compliance requirements aimed at regulating the legal limits for cooperation and interaction between pharmaceuticals companies and healthcare specialists. Gifts and hospitality have mostly been banned, and restrictions on meetings have resulted in pharmaceutical companies more widely using online technologies for their communication with healthcare specialists instead of personal meetings.

In the below sections we provide an overview of the above topics with reference to the most recent developments and proposals considered by the Russian government.

Overview of Russia's Pharma 2020 Strategy

The Strategy is a state program for the development of the pharmaceutical industry. The Strategy was first approved by the Russian Ministry of Industry and Trade in October 2009. Since then it has been updated and amended various times. This section summarises the Strategy as adopted by the Russian Government in November 2012 under the name "*State Program for Development of the Pharmaceuticals and Medical Industry for 2013-2020*".

The Strategy has the characteristics of a framework document and sets forth the priorities of governmental action in the Russian pharmaceuticals sector which, in particular, are to support and develop local production of pharmaceuticals. To date, many of the basic principles set forth in the Strategy remain unsupported by any implementing legislative acts or other governmental initiatives.

Strategy Requirements

Targets

The Strategy states the following local production targets to be achieved by 2020:

- Local production of 90% of all pharmaceuticals which are included in the official Russian lists of "strategically-important pharmaceuticals" and "life-important pharmaceuticals" (see further details about these lists below); and
- Local production of 50% (based on value) of all pharmaceuticals consumed in Russia. This target is only considered to have been reached if the 50% threshold is exceeded with respect to the pharmaceuticals included in the lists of "strategically-important" and "life-important" pharmaceuticals (because these are considered the most significant pharmaceuticals for local production).

Measures

The Strategy defines the following key measures for achieving the above targets:

1. **Financial and organisational support** for local R&D initiatives and for manufacturing of generic and innovative pharmaceuticals inside Russia:

(a) A program to make state funding available for local R&D and manufacturing projects was approved in February 2011 (Governmental Decree No. 91); and

(b) Creating manufacturing clusters across Russia supported by subsidies coming from the federal budget. A framework to create clusters was developed during the course of 2013. Practical implementation is still to be seen, however, Russian and foreign manufacturers already tend to focus on these cluster regions because various academic institutions and existing pharmaceuticals centres are located there. The Moscow region, Saint Petersburg, Kaluga, Tomsk and Novosibirsk will be among the main clusters.

2. **Priority products for localisation have been identified.** According to the Strategy, priority products are those pharmaceuticals which are included in several official lists of pharmaceuticals maintained by the Russian Government. These lists are based on the international non-proprietary names of pharmaceutical substances (INNs), which is a classification system developed by the World Health Organisation. Generally, three official lists must be distinguished:

(a) **"List of strategically-important pharmaceuticals"**. This list includes 57 INNs relating to a broad range of diseases as well as products used in anaesthetics and diagnostics. Some of the main diseases targeted by this list are HIV, hepatitis C, cancer, haemophilia, cystic fibrosis, Gaucher's disease, multiple sclerosis and conditions which may occur after transplantation of organs.

(b) **"List of life-important pharmaceuticals"**. The list of life-important pharmaceuticals includes approximately 550 INNs, narrowed by reference to specific dosage forms for each INN. The list relates to Rx and OTC pharmaceuticals. It also covers all pharmaceuticals typically purchased by the state under public procurement programs, such as procurement of all vaccines included in an official state vaccination list and pharmaceuticals included in the '7 nosologies program' covering rare diseases with cost-intensive treatment, such as multiple sclerosis.

(c) **"Pharmaceuticals against diseases with social significance"**. This list of diseases with social significance includes cancer, diabetes, HIV, hepatitis B/C, tuberculosis, STDs, mental disorders and high blood pressure.

The three lists above are used in the context of various regulatory regimes (price regulation, public procurement, etc.) which refer to one or more of the lists depending on the circumstances. However, the three lists are not entirely separate from each other. Rather, there are many overlaps. For example, a pharmaceutical used to treat a certain disease may be considered strategically-important, life-important and also of social significance, e.g. to treat cancer. Also, for certain matters one list may fall into another one. For instance, for price regulation purposes, all INNs on the list of strategically-important pharmaceuticals are included in the list of life-important pharmaceuticals.

For the purposes of the Strategy, it is important that the pharmaceuticals included in the three lists are considered as priority products for localisation.

3. **The Strategy envisages legislative amendments** with respect to:

- requirements and procedures for manufacturing and marketing authorisations;
- pricing regulation;
- public procurement rules; and
- tax and customs incentives.

The Strategy does not set out an exhaustive list of regulatory amendments to be enacted; neither does it set specific deadlines by when the proposed amendments must be effective. Instead, the Strategy provides general guidance on the key areas in which the existing regulatory regimes must be improved to create stimuli for local production to develop.

Based on the content of the Strategy and the regulatory initiatives proposed to date, we summarise below the main legislative changes, which have already been enacted in connection with the Strategy or which are planned to be enacted.

Regulatory Measures to Support Implementation of the Strategy

1. Rules of Origin

The existing regimes and numerous legislative proposals distinguish between locally-manufactured and foreign-manufactured products in order to stimulate local production. It is, therefore, crucial to assess the rules of origin on the basis of which this distinction is made.

Current regime. Currently, there are no detailed rules defining the criteria for a product to be locally-manufactured. As of today, mere re-packaging is accepted by Russian authorities as being sufficient. This has led a number of international manufacturers to supply products to Russia in bulk and to enter into primary or secondary packaging arrangements with local partners.

Planned amendments. In January 2013, the Ministry of Industry and Trade published a draft decree which defines new criteria for a pharmaceutical to qualify as a local product. In brief, the proposed criteria require that the final dosage form and/or the active substance of a pharmaceutical must be manufactured in Russia in order to qualify as a local product.

The decree was intended to be in force starting from 1 January 2014, but has not been adopted so far. Earlier in 2013, the Ministry of Industry and Trade announced that the final version will be released shortly. It is now expected that the new rules of origin will enter into force during the course of 2014.

2. Public Procurement

A large number of pharmaceuticals are provided to patients by the state and are, therefore, purchased by the state within Russia's public procurement regime. The Strategy envisages that locally-manufactured products should enjoy a certain level of priority in public procurement.

Current regime. The current public procurement regime regulates price incentives for many locally-manufactured pharmaceuticals. In particular, there exists a 15% price adjustment mechanism, which is referred to as an incentive for local products, but *de facto* means a penalty of 15% on the purchase price of foreign-made pharmaceuticals. The background is as follows: public procurement is typically made through auctions based on price only. During an auction, local and foreign products can compete equally and the bidder with the lowest price wins the auction. The state has no influence over whether the winning bid is for a locally-manufactured or foreign product. However, a bidder winning with a locally-manufactured product[1] can sell the product at the winning bid price. In contrast, a bidder winning with a foreign-made product must accept a 15% price reduction on its winning bid price. In other words, if a foreign product wins, a 'penalty' of 15% is applied for the benefit of the state.

Planned amendments. The Russian public procurement regime is currently under reform. A new framework law will become effective in January 2014 and various implementing legislation will enter into force during the course of 2014, 2015 and 2016. In connection therewith, it is expected that additional regulations will be adopted to support locally-manufactured products in the procurement process.

3. Incentives based on level of localisation

The Government is considering the following measures to incentivise local manufacturers of generic products:

- A draft governmental decree was published in January 2013 suggesting a *de facto* ban of foreign pharmaceuticals in public procurement if pharmaceuticals are sufficiently available from local manufacturers. More specifically, where marketing authorisations have been granted to at least two locally-manufactured products, their foreign-manufactured equivalents will be excluded from the tender. The status of the decree is currently unclear. To our knowledge, no further action has been taken since January 2013.
- An additional preferential treatment of local pharmaceuticals has been proposed for tenders where local and foreign products compete with each other. The preferential treatment may vary depending on the level of localisation of the product in question. The proposals were lobbied by local manufacturers and suggested the following:
  - a 15% pricing advantage if packaging takes place in Russia; and
  - a 30% or 40% pricing advantage if the dosage form or active substance and dosage form are manufactured locally.

  However, the proposal remains at an early stage and no draft regulation is currently available.

4. Legislative amendments potentially beneficial for foreign manufacturers

Various legislative amendments have been enacted or have been proposed that may be beneficial for foreign-made pharmaceuticals. These amendments were proposed outside the scope of the Strategy, but must be considered

[1] Where a bidder offers a mix of products, such mix is deemed 'local' if more than half (in value) of the products are locally-manufactured.

in the broader context of the current developments in the Russian pharmaceuticals sector.

In exceptional cases, the existing public procurement rules permit procurement of certain pharmaceuticals on the basis of the brand name, i.e. not on INN basis. Such pharmaceuticals must be included in a special 'branded drugs list'. So far, this option is without practical relevance, because no branded drugs list has been adopted, and no criteria for including pharmaceuticals have been defined. However, draft rules have been prepared and were widely debated during the course of 2013. It is now expected that a branded drugs list will be adopted in 2014.

Draft amendments to the Pharmaceuticals Law have been prepared to introduce the concept of 'inter-changeability' and to define relevant criteria. Several versions were prepared by the Ministry of Health during the course of 2013 and resulted in an intense public debate. At this stage, it is unclear whether the concept will ultimately be beneficial for manufacturers of original or generic products. Approval by the Russian Parliament is pending and further revisions may be introduced before the amendments enter into force.

5. Pricing Regulation

Current regime. The current regime on price regulation for pharmaceuticals consists of two parts:

- registration of maximum output prices (which is the maximum price at which a product can be sold by a local or foreign manufacturer); and
- maximum resale margins for the distribution of pharmaceuticals, which apply at the wholesale and retail levels.

The regime on maximum resale margins does not distinguish between local and foreign products. However, the regime on registration of maximum output prices provides for significant differences between local and foreign products.

All pharmaceuticals on the list of 'life-important pharmaceuticals' (see clause 2 (b) of section "*Measures*" above) are subject to maximum output price registration. For this reason, the following aspects are important:

- The registration rules provide for different requirements for local and foreign manufacturers. Foreign manufacturers are required to justify their maximum output prices on the basis of their sales prices in the home market and in 20 reference countries.[2] Most of the reference countries are European states and some of them have strict pricing rules themselves, such as Turkey.
- Russian manufacturers are not subject to reference pricing requirements and can base their prices on local cost calculations.
- Local manufacturers are entitled to adjust their maximum output prices from time to time based on inflation rates; foreign manufacturers are not able to do so.

In practice, this has resulted in increasing pricing pressure for foreign manufacturers when registering maximum output prices. The Russian supervisory authorities have recently initiated various investigations into prices registered by foreign manufacturers since 2010. In addition, the antitrust authorities have recently announced action in areas where Russian price levels for pharmaceuticals are significantly higher than in Russia's neighbouring countries. In practice, this is expected to result in increasing scrutiny of foreign manufacturers.

Planned amendments. There have been various proposals to revise and amend the regime on pricing regulations in order to include further incentives for local manufacturers. However, to date, no specific measures have been announced.

6. GMP and Marketing Authorisations

In addition to the above-mentioned measures which specifically aim to support locally-manufactured products, the Strategy also envisages legislative amendments which aim to improve the pharmaceuticals sector generally. In particular, this relates to GMP compliance by all local manufacturers and changes in the procedure for granting marketing authorisations.

GMP. The Strategy envisages the adoption of local GMP rules. The adoption has been postponed several times during recent years, partly because many local manufacturers are yet to acquire the substantial

[2] Bulgaria, Germany, Greece, Spain, Turkey, Portugal, Denmark, Belgium, Netherlands, Ireland, Italy, Poland, Belarus, Kazakhstan, Romania, Slovakia, Ukraine, France, Czech Republic and Switzerland (Order N 961n/527-a of the Ministry of Health and the Federal Tariff Service of 3 November 2010).

investments necessary in order to be able to comply with the proposed standards.

Pursuant to the current version of the Pharmaceuticals Law, GMP compliance for local manufacturers became mandatory from 1 January 2014.

A decree setting out specific GMP rules to be observed by manufacturers was adopted by the Ministry of Industry and Trade in June 2013 (Order No. 916) and entered into force in late 2013. However, the practical implementation of GMP rules requires a number of various subordinate regulations. A number of procedural aspects currently remain unclear and, to our knowledge, in practice no GMP certificates have been issued so far.

Compliance Requirements for Pharmaceuticals Companies

This section provides an overview of compliance requirements related to the Russian pharmaceuticals industry. Focus is made on the industry-specific regulations relating to marketing and promotional practices in the pharmaceuticals sector, which have been subject to regulatory reforms in recent years.

Hospitality & Promotional Activity for Pharmaceuticals Companies

Restrictions on interaction with HCPs

1. **General Framework**

The Russian Federal Law "On Fundamental Principles of Healthcare of Individuals in the Russian Federation" and the Russian Federal Law "On circulation of Pharmaceuticals" (the "**Healthcare and Pharmaceuticals Law**"), set out a number of restrictions on healthcare professionals in the medical care ("**HCPs**") and pharmacy sectors when dealing with companies in the pharmaceuticals industry.

The restrictions set out in the Healthcare and Pharmaceuticals Law apply to:

- entities engaging in the development, production or distribution of pharmaceutical products;
- entities holding rights to use the trade name of a pharmaceutical product;
- wholesalers of pharmaceuticals and pharmacies, and
- their representatives.

This also means that the restrictions do not extend to companies in related business areas, apart from those specifically listed in the Healthcare and Pharmaceuticals Law. For example, producers of food additives are not considered pharmaceuticals companies for the purposes of the restrictions imposed by the Healthcare and Pharmaceuticals Law.

The Healthcare and Pharmaceuticals Law generally prohibits HCPs from meeting with representatives of pharmaceuticals companies during the HCP's surgery hours. During surgery hours, meetings are only allowed if they relate to clinical studies, pharmacovigilance or professional development events and have been approved by the medical institution at which the HCP is employed.

The Healthcare and Pharmaceuticals Law does not, however, ban HCPs from attending professional development events, including industry conferences, events for professional education, research seminars, etc.

2. **Open Issues and Risk Areas**

Due to the generality of the restrictions imposed by the Healthcare and Pharmaceuticals Law, there exists wide uncertainty as to how they apply in practice. For example, it remains unclear whether meetings with representatives of pharmaceuticals companies are permitted if held outside the HCP's surgery hours. It is also unclear whether or not meetings are permissible during surgery hours that are primarily devoted to pharmacovigilance or clinical trials, but also have other supplementary topics on their agenda. Similarly, it is not entirely clear whether the restriction only applies to meetings in person or also extends to contacts by other means of communication. So far, the rules are generally understood to refer to personal meetings only, which means that other types of correspondence, such as video conferences, online webinars, etc., appear to be outside the scope of restrictions imposed by the Healthcare and Pharmaceuticals Law.

Gifts and Hospitality

1. **Scope of Restrictions on Hospitality**

HCPs and pharmacy sector specialists are generally prohibited from accepting any money or gifts from pharmaceuticals companies. This ban also extends to participating in any entertainment event held at the expense of a pharmaceuticals company.

An exception from the ban only exists for remuneration provided to healthcare professionals in the medical care, and not in the pharmacy sectors, relating to:

- clinical studies of pharmaceuticals;
- scientific activities, such as research and consultancy services; and
- educational activities, such as lecturing.

These activities/ services are not deemed to be hospitality and can be remunerated. Also, in connection therewith, the Healthcare and Pharmaceuticals Law does not explicitly restrict payments made in order to compensate the relevant HCP for travel and accommodation costs.

Otherwise, offering of hospitality is generally prohibited, except where such hospitality cannot be viewed as being a gift or payment of money. As mentioned above, the Healthcare and Pharmaceuticals Law does not ban HCPs from attending professional development events. However, a cautious approach must be taken where pharmaceuticals companies organise or support such industry conferences, professional education, research seminars, etc.

As a matter of practical guidance, one may refer to the Code of Marketing Practices adopted by the Association of International Pharmaceutical Manufacturers ("**AIPM**"). Hospitality offered to HCPs participating in professional development events should remain modest and be provided in a way that avoids creating a conflict of interest on the HCPs' side.

Furthermore, the recently introduced restrictions on organising scientific conferences must be observed. In particular, companies in the pharmaceuticals sector organising/supporting scientific/educational events and conferences are required to ensure unrestricted access for competitors to also present at the relevant conferences.

There are no statutory requirements to obtain approval of the relevant hospitality from a regulatory or industry authority. However, under the new requirements on organising/supporting scientific conferences, pharmaceutical companies are required to notify the regulator in advance of the planned conferences. Such notification must be made two months in advance of the event and information must also be published online.

Apart from that, pursuant to the Healthcare and Pharmaceuticals Law, professional development events or pharmacovigilance-related meetings must be approved by the management of the relevant medical institution. The Healthcare and Pharmaceuticals Law does not, however, set out any procedural requirements for obtaining approval.

2. Scope of Restrictions on Gifts/Promotional Items

As stated above, the Healthcare and Pharmaceuticals Law prohibits HCPs from accepting any gifts or money from pharmaceuticals companies, save for exception made for remuneration under contracts for scientific activities, lecturing or clinical studies, which may include reimbursement of reasonable expenses for travel and accommodation in connection therewith.

The scope of application of the prohibition is not entirely clear. In the absence of guidance by the Healthcare and Pharmaceuticals Law it may be argued that any type of gift to HCPs is prohibited *per se*. Also, expenses that are reimbursed by pharmaceuticals companies to HCPs for scientific activities, lecturing or clinical studies, such as travel and accommodation costs, must be reasonable and properly documented. Otherwise such reimbursement may involve the risk of being considered as a gift.

In practice, providing small promotional items to HCPs is unlikely to raise concerns, in particular, where items are provided for informational purposes only.

In this context it is also worth pointing out that a draft bill aimed at introducing sanctions for non-compliance with the restrictions (the "**Draft Bill**") provides for a *de minimis* threshold of RUB 3,000 (approximately USD 100) for gifts below which no sanctions apply (see section "*Anti-Corruption / Conflicts of Interest*").

In certain cases, pharmaceuticals companies may specify that items are provided for educational purposes, but remain the property of the company. Cases where this appears workable include scientific books or special software programs.

In any event, the Healthcare and Pharmaceuticals Law prohibits HCPs from accepting samples of pharmaceuticals for use with patients.

Promotional Activities and Advertising Regulation

Under the current regulations, advertising of OTC products and food additives is generally permitted subject to certain requirements to its contents. Rx pharmaceuticals can be advertised only in professional periodicals or at professional conferences.

Proposals to tighten this regime were repeatedly submitted to the State Duma (Russia's lower chamber of parliament) recently. The proposals contain various potentially far-reaching measures. In particular, one of the legislative drafts submitted for consideration to the State Duma proposes a total ban on advertising of pharmaceuticals. However, none of these proposals have received substantial support so far. It is, therefore, unlikely that any of the proposals to restrict pharmaceuticals advertising will ultimately be adopted in the near future.

Sanctions for Non-compliance

At present, there exist no specific sanctions applicable to pharmaceuticals companies in case of violation of the rules on their interaction with HCPs. A notable exception relates to sanctions for failure to notify the regulator on a planned conference/scientific event for which administrative sanctions have recently been adopted (fines may amount up to RUB 70,000 (approximately USD 2,300).

In practice, compliance with the rules regulated by the Healthcare and Pharmaceuticals Law is, however, becoming increasingly important because of the anticipated introduction of severe sanctions for non-compliance, which has been long debated and, if adopted, will apply both to HCPs and pharmaceuticals companies. The Draft Bill for the introduction of sanctions was prepared by the Ministry of Economic Development in 2012 and has been widely debated since then. Although the Draft Bill has not been enacted so far, it may be expected that sanctions will be introduced in the short to medium term. A summary of the proposed sanctions is set out in section "Anti-Corruption / Conflicts of Interest" below.

In addition, the uncertain scope of application of the restrictions combined with a lack of official guidance mean that it is advisable for pharmaceuticals companies to carry out risk assessments on a case to case basis and to follow a cautious approach. Otherwise, pharmaceuticals companies may face risks of unexpected allegations of non-compliance by regulators, investigations as well as reputational consequences.

Anti-corruption / Conflicts of Interest

State Servants and Applicability to HCPs

The Russian civil service regime establishes certain restrictions applicable to public officials. However, the definition of public officials only includes government officials and officers of public authorities. As a rule, HCPs are not included, irrespective of whether or not they are employed by a state medical institution. The vast majority of HCP employees do not, therefore, qualify as public officials and are not subject to these restrictions.

Sanctions for Bribery: Criminal and Administrative Liability

In some cases the giving or accepting of gifts or benefits may be prohibited as bribery under the Russian Criminal Code. Thus, if the HCP accepting the gift or other benefit holds a management position in a state or private medical institution the act may be construed as bribery/ commercial bribery, as the case may be, if in exchange that HCP provides the giver with a benefit related to the performance of his/her managerial duties.

The criminal sanctions for bribe-giving include a fine proportionate to the amount of the bribe, imprisonment, compulsory work or disqualification from management positions. The maximum sanction for bribe-giving is imprisonment for up to 12 years combined with a fine equal to 70 times the value of the bribe.

The Russian Administrative Offences Code also sets out penalties that are applicable to legal entities in such cases. The maximum sanctions include a fine of up to 100 times of the amount of the bribe, but not less than RUB 100 mln (approx. USD 3 mln), as well as confiscation of the funds paid as the bribe.

Sanctions for Violation of Ethics Requirements

1. **Current Framework**

As stated above, Russian law does not presently establish sanctions for violations of the ethics requirements set out in the Healthcare and Pharmaceuticals Law and summarized in the above sections, except where the violation constitutes a criminal or administrative offence related to bribery or failure to provide information to the regulator.

Where a company is a member of the AIPM, non-compliance with the association's ethics code can lead to measures applied by the industry association. The industry association may publish a press release disclosing the member's violation of its ethics code and/or exclude the member from the association. Apart from the reputational risks resulting from such measures, the relevant company is likely to face increased scrutiny by Russian regulators.

2. **Proposed Sanctions Aimed at Pharmaceuticals Companies**

In 2012 the Russian Ministry of Economic Development published the Draft Bill, which proposes substantial fines for HCPs and pharmaceuticals companies for non-compliance with the restrictions set out in the Healthcare Law.

The Draft Bill envisaged the following sanctions for pharmaceuticals companies that fail to comply with the established regimes for the circulation of pharmaceutical products:

- general infringement: fine of up to 1% of the company's annual sales of the relevant pharmaceutical(s);
- infringement in connection with organizing conferences: fine of up to RUB 1 mln (approx. USD 33,000).

In addition to substantial fines for pharmaceuticals companies, the Draft Bill also proposed sanctions for officials of pharmaceuticals companies who can become subject to monetary fines or disqualification from their management position. It is worth pointing out that administrative liability imposed on a foreign citizen may also result in refusal or withdrawal of the Russian visa.

The Draft Bill is still at an early stage of consideration and little progress was made during the course of 2013. It is, therefore, not currently possible to predict the final form the Draft Bill by the time it gets adopted by the Russian Parliament. It is, however, expected that the Draft Bill will be further considered and enacted in one or the other form.

Conflicts of Interest

The Healthcare Law sets out conflict of interest rules for HCPs. A conflict of interest arises where an HCP has a personal interest in material gains or other benefits that conflicts with the interests of patients and affects (or could potentially affect) the HCP's professional performance.

An HCP is required to report any conflict of interest situations in writing to the head of the relevant medical institution/pharmacy. That person is in turn under an obligation to report the situation to the relevant regulator. Individual entrepreneurs are required to report directly to the regulator.

Sanctions for failure to report a conflict of interest by an HCP were introduced in late 2013, these include monetary fines ranging between RUB 3,000 and 20,000 (approximately USD 100 - 670) and also disqualification for an HCP breaching conflict of interest rules up to 6 months.

Finally, the AIPM Code of Marketing Practices requires pharmaceuticals companies to ensure that any cooperation with HCPs does not create a conflict of interest for the HCP.

FCPA and UK Anti-Bribery Act Compliance in Russia

The majority of international companies implement specific compliance programs that take account of the relevant requirements under the FCPA and UK Bribery Act when operating in Russia. These compliance programs typically consist of a standard set of rules and measures, including on compliance policy, training of employees and counterparties, compliance clauses in distribution agreements, 'Know Your Client' procedures, internal compliance audits, monitoring of distributors, etc.).

Anti-corruption Enforcement in Pharmaceuticals Sector

There are an increasing number of cases involving bribery in connection with public procurement of pharmaceuticals. In most of these cases, criminal charges were brought against public officials who engaged in bribery or fraud. Under the Criminal Code, a bribe-giver may avoid criminal liability if he/she actively contributes to the disclosure or investigation of the offence, and provided that the bribe-giver voluntarily reported the offence or was solicited to make the bribe.

Although the pharmaceuticals industry has been the focus of increasing attention from the Russian authorities in recent years, the fact that the relevant restrictions are relatively new means there is limited practice of their enforcement.

In particular, questionable practices used by some pharmaceuticals companies in Russia which were recently publicised in connection with FCPA investigations have not resulted in investigations and penalties. As was admitted by various Russian authorities, the activities in question did not formally constitute a violation under the legislation in force at the time. That said, all Russian regulators have recently been emphasising that any future cases of corrupt practices will be fully investigated and all available sanctions will be imposed.

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