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The Legal Basics of M&A Transactions in Russia's Healthcare Sector

The purpose of this note is to provide a general overview of various key aspects of planning and structuring an M&A transaction involving a target active in the Russian healthcare sector. In this briefing we address 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

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 healthcare 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 healthcare, 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 arrange-

ments 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 healthcare 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 healthcare 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 healthcare companies.

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.

The pharmaceutical industry has recently been subject to heightened scrutiny by the Russian competition authorities. 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 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 new price-regulation regime was introduced for pharmaceutical products that are on the list of so-called 'essential drugs', 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 on an annual basis. The registration of output prices is also a prerequisite for obtaining marketing authorisation for a new pharmaceutical product.

2012 regulatory developments in the pharmaceuticals sector

In late 2011 various legislative changes were adopted that significantly influence the pharmaceuticals industry. Among the most notable changes were:

- the elimination of the licensing requirement for the import of pharmaceuticals; and
- the introduction of restrictions on the marketing of pharmaceuticals with healthcare specialists. These restrictions took effect at the start of 2012 following the enactment of a long-debated framework law on healthcare. Gifts and hospitality have mostly been banned, and permitted communication between representatives of pharmaceuticals manufacturers and healthcare specialists is generally limited to

co-operation in clinical trials and professional development events.

Forthcoming legal changes and industry developments

The federal government has defined key priorities for the Russian healthcare sector over the next decade. These are summarised in the 'Pharma 2020' strategy which was announced in 2009. The main priorities include:

- localisation in Russia of state-of-the-art manufacturing technologies in the production of pharmaceuticals;
- better pharmaceuticals coverage for rare/orphan diseases;
- creation of incentives for the production in Russia of high-quality active ingredients (either chemical or biotechnological);
- introduction of Good Manufacturing Practice (GMP) standards for mandatory implementation.

Implementation of the priorities set out in the 'Pharma 2020' strategy will require substantial legislative amendments, as the current regulatory framework is in many respects underdeveloped. The anticipated amendments will affect both the production and sale of pharmaceuticals:

- the public procurement rules currently provide for incentives for pharmaceuticals of Russian origin, but the minimum requirements for localisation have yet to be established. Primary/ secondary packaging is unlikely to qualify as sufficient localisation of production;
- the new framework law on healthcare has introduced the concept of orphan diseases along with framework regulation on pharmaceutical coverage for such diseases to be provided at the regional and federal levels. The marketing authorisation and public procurement rules, however, are yet to be amended to allow for implementation of the new requirements for sufficient coverage of rare diseases.

It is expected that following Russia's accession to the WTO later in 2012 the Russian legislation will be amended to comply with TRIPS, which is expected to have an impact on the development of the production of generics in Russia. However, to date no parameters of potential changes have been officially announced.

Russia's Civil Code is in the process of being amended, which will have far-reaching consequences for any contractual arrangements. However, this reform is in the early stages and is unlikely be completed in 2012

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