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U.S.-based life sciences companies considering transactions in Europe may easily become overwhelmed with the complexity of Europe's various jurisdictions. In this series, members of our European Life Sciences Transactions Team provide country-specific perspective and guidance to help you navigate the jurisdictional challenges and differences that you may run into when acquiring a European life sciences company.

In this edition, Oxana Balayan will discuss life sciences transactions in Russia.

M&A in Life Sciences: Top five challenges in Russia

The Russian pharmaceutical market continues to grow and presents huge opportunities for business expansion. Whilst the political situation in Russia remains unstable and the industry heavily regulated, that is no reason to hold back on targeted deals. Those investors who took the time to explore the challenges of the current Russian legal environment should be well prepared and doubtless should succeed in the market.

Share deal vs. asset deal: which to choose?

What is crucial in the life sciences business besides products, contracts and individuals? It is most certainly licenses (ie a state permit to conduct certain business activities such as the manufacture or sale of drugs) and other regulatory permits (eg marketing authorisations). Licenses are not transferrable in terms of Russian law.

Although it is possible to make an asset deal in Russia, it is not common to structure an M&A deal in this way. In practice, a Russian asset deal is structured via separate transfers of core elements of the business (fixed and intangible assets, contracts, employees). This means of transfer of a business is not suitable for licenses or for most other regulatory permits. They remain owned by the company. Consequently, if the target business relies on its regulatory permits, the transaction should be structured as a share transfer.

Beware strategic clearance

M&A transactions in life sciences sometimes require pre-transaction clearance by the applicable governmental commission (a "strategic clearance"). A strategic clearance is required for foreign investments in companies which are deemed to be strategic for reasons of state security. In particular, this includes companies that use agents of infection in their activities. Such activities are subject to state licensing (save for food production). Obtaining strategic clearance is a time-consuming process taking from 3 to 10 months in practice, which can significantly affect the overall timing of the transaction.

State regulation of prices

Every year the Russian Government adopts the so-called List of Essential Drugs, the prices for which are subject to state registration and mark-up regulation.

More than 76% of the drugs on this list are produced in Russia. The share of local manufacture is forecast to grow to 90% by 2020.

In the context of an M&A transaction, special attention should be paid to whether the drugs from the target's portfolio are, or would likely be, included in this list, since this could affect the profitability and volume of sales.

Localization: please establish a Russian manufacturing company

The localization of life sciences manufacturing remains one of the key priorities in Russian state policy.

In particular, public procurement rules provide incentives for domestic manufacture, for example 15% price preference for drugs produced in the Eurasian Economic Union. There are also restrictions on imported drugs manufactured outside of Russia in public procurement tenders (eg the 'odd man out' rule) as well as the possibility of various subsidies, tax benefits, etc.

Non-compliant provinces – a threat to every empire

Subsequent to the overall development of anti-corruption legislation in Russia, certain anti-corruption provisions have been introduced into Russian life sciences legislation. In particular, manufacturers and sellers of drugs are not allowed to offer, and healthcare professionals are forbidden to accept, gifts, payments and entertainment of any kind or value.

Given the importance of anti-corruption compliance for any foreign investor, the target's relations with public officials and health care practitioners should be thoroughly investigated.

Obviously, the five topics above are only the ‘tip of the iceberg’ of the relevant legal issues important to life sciences M&A in Russia. Our life sciences experts are always available to guide you through these and other important issues.

Oxana Balayan is a partner in Hogan Lovells’ Moscow office and is a modern dealmaker focusing on cross-border M&A and a full spectrum of corporate work. She is the ‘advisor of choice’ when it comes to complex domestic and international transactions or critical operational issues. Oxana has worked on more than 100 announced or completed M&A deals with a total transaction value exceeding U.S. \$50bn.

Our European Life Sciences Transactions Team

When the stakes are high, you want a partner who has the knowledge honed by decades of legal and industry experience on your side. A partner whose strategic advice is informed by a thorough examination of your business and your transaction. A partner who understands the challenges and opportunities you face and delivers solutions that achieve the best possible outcome. When faced with a difficult deal or a tough transaction, our European Life Sciences Transactions Team has you covered. [Learn More.](#)

Contacts



**Oxana
Balayan**

Office
Managing
Partner

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