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After all, three becomes a crowd. New restrictions on foreign pharmaceuticals in Russian public procurement

In recent years the Russian government has been continuously looking at various initiatives to support local pharmaceutical manufacturers and incentivise foreign players to localise their production in Russia. The framework for these developments was set by the "Pharma 2020 Strategy" initially adopted in 2009, which sets out priorities and goals for the Russian pharmaceutical sector.

The "three's a crowd" initiative, seeking to ban foreign products from state procurements in cases where at least two local products are available, has been at the heart of the debates involving industry players, various federal ministries and services, and the Russian government. Many widely differing drafts of the regulations were prepared by different stakeholders before ultimately the final version was approved by the Russian government on 30 November 2015 and published yesterday. This note addresses the key elements of the regulations ("**Regulations**") as now adopted.

1. Key Aspects

Scope of application. The Regulations apply to state procurements of pharmaceuticals included on the list of Vital Drugs (*перечень жизненно необходимых и важнейших лекарственных препаратов*) where a tender is held for a single international non-proprietary name (INN), i.e., to all the major procurements by the Russian state.

The Regulations are adopted within the framework of the Russian regime of procurement by public authorities for state needs as regulated by Federal Law No. 44. The Regulations do not extend to the broader procurement rules applicable to state enterprises, state-controlled companies and their respective sub-organisations as regulated by Federal Law No. 223, as this would conflict with Russia's obligations under the WTO framework.

Entry into force. All procurements for state needs announced from 10 December 2015 will be subject to the Regulations.

Key rule. The purchaser, e.g., the federal or a local Ministry of Health, must reject all applications from bidders offering a foreign product if it receives at least two applications which (i) satisfy the tender requirements, (ii) offer pharmaceuticals originating from the Eurasian Economic Union (Russia, Belarus, Kazakhstan, Armenia or Kyrgyzstan), and (iii) offer pharmaceuticals that are manufactured by companies belonging to different groups.

Two locals. The third condition, requiring that the products offered be manufactured by two different groups is critical. One of the industry's recommendations was to link the difference in products to different marketing authorisations (MAs). However, the government decided that it should be linked to manufacturers belonging to a different group of

companies as defined by Russian competition law. In most cases this distinction will be sufficient to ensure that there are indeed two different local products before the ban on foreign products is triggered. However, it remains unclear whether all stages of manufacturing must be performed by manufacturers belonging to different groups or not.

Rules of origin. It was expected that the Regulations would base the rules of origin on different stages of production, such as production of API, final product, primary packaging, secondary packaging and release. However, the Regulations refer to the existing rules of origin as used under the customs regime of the CIS. According to those rules, origin depends on 'sufficient processing requirements', which can be described as follows:

- a change of any of the first four digits in the customs classification code (this key criterion applies unless there are other criteria prescribed for specific goods);
- sufficient technological operations as defined for specific types of goods (not yet defined for pharmaceuticals); or
- *ad valorem* criterion defined for particular types of goods (not defined for pharmaceuticals in finished form).

The main criticism regarding these existing rules has been that they often do not fit pharmaceutical manufacturing processes. For a number of pharmaceuticals the first four digits of their customs classification would not change even if almost all production steps were to be localised in countries of the Eurasian Economic Union.

From a procedural perspective, the origin of a pharmaceutical will need to be evidenced by a Certificate of Origin, "CT-1". In Russia these certificates are issued by the Chamber of Commerce and Industry.

Repackaging. The Regulations will not apply to foreign products repacked in Russia (whether in primary or secondary packaging) until 31 December 2016. In other words, for another year secondary packaging will remain sufficient for a product to be deemed local. Starting from 2017 it will be necessary to increase the degree of localisation of a pharmaceutical production beyond mere packaging operations.

15% penalty. The existing 15% penalty for suppliers of foreign products competing against suppliers of Russian products remains in force. It will apply if, for example, only two suppliers participate in an auction – one offering a foreign product and the other one offering a Russian product. In such cases the foreign product will not be banned from the auction, but a 15% decrease in price will be applied if the foreign product wins the auction.

2. Outlook

The Regulations have been long expected and don't come as a surprise to most manufacturers. Most international players are in the process of localising production beyond mere packaging. That said, there remain numerous legal uncertainties that have hindered the process of localisation by several manufacturers. Looking forward, it will be critical to establish clearer rules of origin which take into account the specifics of pharmaceutical manufacturing as well as a timeline for potential future increases of the local content requirements.

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