

Update on proposed restrictions for foreign pharmaceuticals in Russian public procurement

On 8 October 2014 the Russian Ministry of Industry and Trade ("**MoIT**") published a revised draft government decree that significantly amends the version initially released in September 2014. The revised draft clarifies a number of provisions relating to the mechanics of proposed restrictions which had raised concerns. At the same time, the draft contains contradictory and unclear provisions on localisation requirements, including on conducting primary/secondary packaging operations in Russia.

The amended draft decree ("**Decree**") is available on the official Russian government website for public consultations¹ and will be further considered by the Russian government. It is currently expected that it will be finalised and approved by the end of 2014.

Mechanics of the proposed ban

The Decree has retained a key provision stipulating that foreign-made products must be excluded from an auction if sufficient local products are offered for the auction.

With respect to the mechanics of the new regulation, the Decree has been clarified as to the circumstances in which it will apply:

- **Single-INN lots only.** According to the Decree, the ban will apply to tenders for pharmaceuticals with a single international non-proprietary name (INN). The provisions related to mixed lots (i.e. where pharmaceuticals under several INNs are purchased in a single tender/lot) have been deleted.
- **At least two different local products must be offered at auction.** The revised Decree specifies that there must be a minimum of two tender applications offering two different local products manufactured by

two different producers in order for the foreign product to be ineligible for the auction.

- **Mixed offers.** The Decree does not set out any rules as to whether applications containing a mix of foreign and local products under a single INN ('mixed offers') should be treated as local or foreign. However it appears that a tender application will only be regarded as offering local products if it does not include any foreign products whatsoever.

Rules of origin and incentives for further localisation

The rules of origin/localisation criteria set out in the Decree have been revised. Essentially, the Decree now combines two regimes, namely:

- the customs rules of origin, based on which foreign products can be excluded from auctions; and
- a new industry-specific regime, yet to be elaborated (the regime should establish additional incentives for local products proportionate to the level of localisation).

Under the current wording of the Decree the two regimes are not integrated with one another and appear to conflict with respect to primary/secondary packaging operations done locally.

¹ http://regulation.gov.ru/project/18147.html?point=view_project&stage=3&stage_id=12923

Foreign products: rules of origin

As is the case with current localisation incentives, the Decree states that the country of origin must be determined based on the relevant customs rules (set out by the treaty between Russia, Belarus and Kazakhstan "On Unified Rules for Determining the Country of Origin of Goods" of 2008).

This regime is not linked to technological steps typical for the pharmaceuticals industry, such as API manufacturing, manufacturing of the final dosage form and primary/secondary packaging. Under the customs rules of origin:

- neither primary nor secondary packaging operations are generally treated as sufficient localisation;
- the question of whether the level of localisation is sufficient to change the country of origin primarily depends on whether the customs classification code of the final product differs from the code assigned to the raw materials/semi-finished products imported to Russia prior to the local operations.

Status of packaging operations remains unclear

The Decree contains a new rule that aims to support those manufacturers whose localisation goes beyond primary/secondary packaging. This rule is to come into effect on 1 January 2016.

The Decree stipulates that products in relation to which primary and/or secondary packaging is the only operation conducted in Russia, Belarus or Kazakhstan should be ineligible for public procurement tenders if at least two local products, manufactured in final form in Russia, Belarus or Kazakhstan, are being offered.

This provision clearly contradicts the customs rules of origin described above, which expressly state that neither primary nor secondary packaging operations are to be treated as sufficient localisation (if taken alone) and, consequently, such products should be ineligible for tenders if two or more local products are offered.

Against this background, it is likely that this part of the Decree will be revised further before it is approved by the

Russian government. In particular, we expect that wording will be added to eliminate the contradiction and to provide clearly that until 1 January 2016 products packed locally should not be excluded from auctions. For this purpose a carve-out is expected to be added to the wording relating to the rules of origin.

Incentives for local manufacturing: further localisation requirements

The Decree states that additional localisation criteria and corresponding incentives will be introduced in 2015:

- by 1 June 2015 the MoIT is to elaborate the procedure for confirming the local status of stages of manufacturing; and
- by 1 January 2016 the MoIT and the Ministry of Economic Development are to pass a regulation on additional incentives proportionate to different localisation levels.

Contacts

Torsten Syrbe
Partner
E: torsten.syrbe
@cliffordchance.com

Ivan Pavlovich
Associate
E: ivan.pavlovich
@cliffordchance.com

Maria Chivragova
Lawyer
E: maria.chivragova
@cliffordchance.com

Outlook

The Decree reflects some of the comments provided by the business community in response to the initial version.

Importantly, it clarifies that foreign products will only be banned if two different local products are offered in the framework of the same tender. It also stipulates that further incentives for higher levels of localisation may be expected in 2016.

Unfortunately, the Decree introduces some further ambiguity as to the treatment of primary and secondary packaging as a localisation step. That said, it is clear that whatever interpretation of the current rules may be correct, primary and secondary packaging will certainly not be sufficient to localise a product starting from January 2016.

This publication does not necessarily deal with every important topic or cover every aspect of the topics with which it deals. It is not designed to provide legal or other advice.

www.cliffordchance.com

Clifford Chance, Ul. Gasheka 6, 125047 Moscow, Russia
© Clifford Chance 2014
Clifford Chance CIS Limited

Abu Dhabi ■ Amsterdam ■ Bangkok ■ Barcelona ■ Beijing ■ Brussels ■ Bucharest ■ Casablanca ■ Doha ■ Dubai ■ Düsseldorf ■ Frankfurt ■ Hong Kong ■ Istanbul ■ Jakarta* ■ Kyiv ■ London ■ Luxembourg ■ Madrid ■ Milan ■ Moscow ■ Munich ■ New York ■ Paris ■ Perth ■ Prague ■ Riyadh ■ Rome ■ São Paulo ■ Seoul ■ Shanghai ■ Singapore ■ Sydney ■ Tokyo ■ Warsaw ■ Washington, D.C.

*Linda Widjati & Partners in association with Clifford Chance.