WORLD TRADE ORGANIZATION

G/LIC/Q/RUS/5

8 April 2019

(19-2236)

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Committee on Import Licensing

Original: English

RUSSIAN FEDERATION IMPORT LICENSING PROCEDURES

REPLIES FROM THE RUSSIAN FEDERATION TO THE QUESTIONS FROM THE EUROPEAN UNION CONTAINED IN G/LIC/Q/RUS/4

The following communication, dated 4 April 2019, is being circulated at the request of the delegation of the Russian Federation.

EU question No 1: Could the Russian Federation explain why the procedures for obtaining the GMP certificate are not described under item 7 of its annual notification, describing the import licensing procedures for the importation of medicines and pharmaceutical products?

Reply: GMP is not covered by the notification on import licencing procedures (G/LIC/N/3/RUS/3) due to the fact that GMP is the requirement for registration of pharmaceuticals considered as conformity assessment procedure falling under the purview of the Agreement on Technical Barriers to Trade. In other words, GMP is not the requirement for imports of pharmaceuticals and is not covered by the Agreement on Import licensing procedures.

EU question No 2: Could the Russian Federation clarify what is the average time for obtaining the GMP? Could the Russian Federation share its statistics? In the notification (see page 22, reply to question 7.a), it is stated that the processing time should be between 5 days for obtaining a permit and 15 days for obtaining a license.

Reply: According to the information provided by the Ministry of Industry and Trade, the average time for obtaining the GMP-certificate is 113 days.

GMP is not the requirement for importation of pharmaceuticals. In this sense, it is not covered by the notification on import licensing procedures (G/LIC/N/3/RUS/3).

As for mentioned page 22, reply to question 7.a of the notification the indicated processing time is correct.

EU question No 3: Could the Russian Federation clarify to what permits and licenses the Russian Federation is referring to?

Reply: In the notification (section 7 of G/LIC/N/3/RUS/4) the Russian Federation refers to procedures of import licencing for pharmaceuticals. Initially, the importer is obliged to apply for permit to the Federal Service in Healthcare. After that, he should obtain import license in the Ministry of Industry and Trade. This procedure is the direct requirement for importation and falls under the purview of the Agreement on Import licensing procedures.

These requirements are applied to the registered medical products, while GMP is a part of registration procedures.

EU question No 4: Could the Russian Federation clarify whether the GMP is included in the definition of licence above?

Reply: GMP is not included in description of import licencing, because it is the inspection of production-sites. GMP is the requirement for registration of pharmaceuticals considered as conformity assessment procedure falling under the purview of the Agreement on Technical Barriers to Trade.

EU question No 5: Could the Russian Federation clarify the Russian Federation envisage any amendments to the current procedures and in what sense? Could they confirm that a bill of law was sent to the Duma early 2018 and inform about the current stage of this draft law?

Reply: The Federal Law № 140-FZ amended the Federal Law of 2010 № 61-FZ "On Circulation of pharmaceutical products" in order to simplify registration and significantly reduce its period. The Federal Law 140-FZ entered into force in summer of 2018.

In particular, these amendments provide for the following opportunities:

- to initiate a registration of a pharmaceutical on the basis of a copy of the decision of the Ministry of Industry and Trade of the Russian Federation to conduct a GMP inspection (not only on the basis of a copy of a GMP certificate, as it was previously);
- to provide registration in case of changes in the quality of a pharmaceutical and (or) in the methods of quality control of a pharmaceutical without re-inspection.