NEWSLETTER

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Single Pharmaceutical Market in the Eurasian Economic Union

On January 31, 2016 the Russian President signed the Federal Law "On Ratifying the Agreement on Common Principles and Rules for the Circulation of Medical Devices (Medical Goods and Medical Equipment) within the Framework of the Eurasian Economic Union" and Federal Law "On Ratifying the Agreement on Common Principles and Rules for the Circulation of Pharmaceuticals within the Framework of the Eurasian Economic Union" (the "Agreements") that came into force on February 11, 2016.

The entry of the federal laws into force signals the launch of the single market for pharmaceuticals and medical devices, which has great international significance. It must be noted that the launch of the single market in the Eurasian Economic Union (EAEU), as announced by the Treaty on the Eurasian Economic Union of May 29, 2014 and then scheduled for January 01, 2016, was postponed due to the delayed ratification of the agreements by the Russian Federation – the last EAEU member to ratify.

Key changes on the EAEU pharmaceutical market are:

- The Agreements will provide a legal basis for common rules for circulation of pharmaceuticals and medical devices in the five member states;
- Bringing the rules for circulation of pharmaceuticals and medical devices to the single standard and the unification of the EAEU member states' laws will bring the EAEU legislation in line with the EU legislation, taking into account the EU and the OECD requirements;
- The EAEU Commission will adopt the best practice standards, most of which have already been approved in drafts. The practices will work directly on the territory the EAEU member states;
- The rules for registration of pharmaceuticals within the EAEU will enter into force;
- The need to duplicate preclinical and clinical drug trials will be eliminated (its results must be recognised);
- The rules for recognition of pharmaceutical inspections will be defined;
- The rules for mutual recognition of documents (issuance of unified documents) confirming that pharmaceuticals are in line with GMP rules will be defined;
- Control over the safety of pharmaceuticals will be ensured at all stages of treatment;
- The market will expand.

Most of the documents regulating the above issues have been agreed and submitted to the EEC for approval. According to the Ministry of Health, the procedure for identifying interchangeability of pharmaceuticals at the registration stage is still uncoordinated.

In addition, in May 2015, the EEC has received the status and powers of the new supranational antitrust authority. In accordance with the Treaty on the EAEU, the Commission monitors compliance with the general rules for competition in the cross-border markets. These powers include not only the conduct of antitrust investigations, but also field audits together with national regulators. The EEC will have a right to independently claim turnover-based fines on the revenue earned in all the EAEU states affected by a breach. We believe that the formation of a single pharmaceutical market in the EAEU might result in new antitrust risks that need appropriate assessment.

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