# THE COMMON MARKET FOR MEDICINES AND MEDICAL DEVICES WILL START FUNCTIONING IN THE NEAR FUTURE

*For the attention of Russian and foreign developers, manufacturers, holders of registration certificates, distributors, and other persons involved in the circulation of medicines and medical devices.*

**Pepeliaev Group advises that the Kyrgyz Republic has ratified the protocols of accession of the Republic of Armenia[1] to the Agreement on common principles and rules of circulation of medicines in the Eurasian Economic Union (EAEU)[2] and the Agreement on common principles and rules of circulation of medical products (medical devices and medical equipment) in the EAEU[3].**

To build the Common market of medicines and medical devices within the EAEU (the "Common Market"), the member-states had to introduce a number of domestic procedures.

Initially the construction of the Common Market and entry into effect of the Agreements was planned for 2016 but in view of accession of Armenia to the agreements, the process was paused as all the EAEU member states had to sign ratification protocols.

Please be reminded that one of the key tasks for the EAEU is to pursue a coordinated policy for the circulation of medicines and medical devices[4]. The "first level" regulations aimed at creating the single regulatory base of the Common Market were the Agreement on Common Principles and Rules for the Circulation of Medicines in the Eurasian Economic Union (EAEU) and the Agreement on common principles and rules for the circulation of medical products (medical devices and medical equipment) in the EAEU (jointly, the "Agreements"). These were entered into on 23 December 2014.

At present, 38 "second level" regulations have been adopted; these are decisions of the Eurasian Economic Commission (EEC) regulating the functioning of the Common market. These decisions will enter into effect 10 days after the agreements become effective or on the effective date of the protocols.

Therefore, ratification by the Kyrgyz Republic of the protocols (the protocols have previously been ratified by the remaining member states) means that the agreements and the 38 EEC decisions regulating the industry may come into effect as early as this April.

It is important to note that there is still no official confirmation of when the Common market will start to operate. Taking into account that the protocols and agreements come into effect on the date when the custodian, through diplomatic channels, receives the last written notice of completion by the member states of their domestic procedures required to bring the documents into force, delays are possible.

However, the fact that all member states have ratified the protocols and the agreements confirms that all of them have completed their domestic procedures. Therefore, it can be concluded that the Common market will be launched soon.

[1] The Protocol on the Accession of Armenia to the Agreement on the common principles and rules of circulation of medicines in the Eurasian Economic Union dated 23 December 2014 and The Protocol on the Accession of Armenia to the Agreement on the common principles and rules of circulation of medical devices in the Eurasian Economic Union dated 23 December 2014 (signed in Moscow on 2 December 2015) (jointly, the "protocols").

[2] The Agreement on the common principles and rules of circulation of medicines in the EAEU dated 23 December 2014.

[3] The Agreement on the common principles and rules of circulation of medical devices in the EAEU dated 23 December 2014.

[4] Articles 30 and 31 of the Treaty on the Eurasian European Union dated 29 May 2014 (the "treaty").

### What does the launch of the Common market mean?

First of all, the launch of the Common market means that common rules for regulation will be applied to all stages of the circulation of medicines and medical devices; and all market players should adjust their practices to comply with these regulations. Specifically, the following issues are regulated within the EAEU context: issues related to the registration of medical devices and medicines; regulations that have been approved concerning good practice, procedures for inspections, and certification of manufacturers' officials; rules for keeping a single EAEU register and EAEU databases;, a procedure for the application of measures preventing and prohibiting use of poor-quality, counterfeit, or falsified medicines and medical devices, etc.

### What to think about and what to do

Market participants, including developers, manufacturers, holders of registration certificates and distributors are advised to acquaint themselves with the Agreement and the EEC's decisions and consider them in their future operations. It is important to note that the EEC regulations are directly applicable in Russia.

### Help from your adviser

Pepeliaev Group's lawyers provide comprehensive legal support with respect to issues related to the new regulations of the EAEU Common market.

At the moment our law firm is finishing a review of all the regulations adopted by the EAEU and affecting the operation of the Common market. A review of the EAEU's medicines regulations is being readied for publication and will be followed by a review of the regulations concerning medical devices.

It is impossible to cover all regulatory updates by this alert, but once the reviews are ready we will send them to our clients.

We also inform you that we are planning to hold seminars dedicated the EAEU markets of medicines and medical devices. In these seminars, we will be discussing the key aspects of the markets starting to operate as well as the implications of the introduction of the new regulation.

We will keep you informed by email of the dates of the forthcoming seminars and registration details for them. All information will also be available on our official website.

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