COMMON MARKET OF MEDICINES IN
THE EURASIAN ECONOMIC UNION: LAUNCHING

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On 26 April 2016, the Eurasian Economic Commission (EEC) notified on the receipt of the official notice of the completion by the Kyrgyz Republic of the domestic procedures required for the entry into force of the protocols on accession of the Republic of Armenia to the agreements on common principles and rules for circulation within the Eurasian Economic Union of medicines and medical devices.

The decisions of the EEC Collegium came into effect on 26 April 2017 (according to the announcement made by EEC Panel member (Minister) at the international scientific conference 'Development of Assessment of the Healthcare Technologies in the EEU' held in Astana on 27-28 April), in particular, those approving the Nomenclature of Dosage Forms, Rules for Maintaining the Nomenclature of Medical Products, Rules for Determining the Category of Medicines Sold with and without a Prescription, and Rules for Monitoring the Safety, Quality and Efficiency of Medical Products.

The principle acts of the Eurasian Economic Union (EEU) that regulate the functioning of common markets for medicines and medical products in the EEU came into force on 6 May 2017. Namely, 28 decisions of the EEC Council that approved, in particular:

- Rules for Registration and Examination of Medicines for Medical Use;
- EEU Good Laboratory Practice Rules in the area of Medicines Circulation;
- EEU Good Clinical Practice Rules;
- EEU Rules for Biological Medicines Testing;
- EEU Good Laboratory Practice Rules;
- EEU Good Distribution Practice Rules;
- Requirements for Labelling Medicines for Medical Use and Veterinary Medicines;
- Requirements for Patient Information and General Characteristics of Medicines for Medical Use.

Thus, starting from 6 May 2017, pharmaceutical companies (authorised representatives thereof) may form a registration dossier in accordance with the EEU rules and regulations and apply for registration of medicines with the national regulatory authority. (For more information regarding the EEU Registration and Examination Rules please see: http://www.gratanet.com/en/publications/details/eaeu_medicine_regeneration_dec2016.)

An obligatory document of the registration dossier is the EEU GMP certificate. During the transitional period until 31 December 2018, applicants may provide a national GMP certificate issued by a competent authority of the EEU member state, or an opinion (report) on the inspection of the production site instead of the EEU GMP certificate.

Besides, according to the Deputy Head of the Department for Coordination of Work in the Area of Medicines and Medical Products of the EEC Department of Technical Regulation and Accreditation, a decentralised procedure for registration of medicines will actually start operating after the launch of a single information system in the area of medicines circulation (as expected, in November 2017).

At the same time, as reported by the EEC press office, by 1 July 2017 the barrier to the functioning of the common market of medicines shall be eliminated in Kazakhstan: non-compliance of
the procedure for procurement of medicines, vaccines and other immunobiological products from the budget funds within the guaranteed free medical aid (under which national suppliers are given preferential conditions for participation in tender procedures) with the EEU rules.

A transition to quality control of medicines in accordance with the EEU Pharmacopoeia is expected during the next two-three years.

At the EEC meeting held on 27 April 2017, the EEU Pharmacopeial Committee approved draft 11 common pharmacopoeial articles of the EEU Pharmacopoeia - the basic set of requirements to the quality of medicines.

Common pharmacopoeial articles will be included in the first issue of Volume I of EEU Pharmacopoeia. Upon adoption of the EEU Pharmacopoeia these articles will set general requirements for quality control methods, equipment required for medicines quality testing, packaging materials, reagents, dosage forms, pharmaceutical substances, standard samples, auxiliary substances utilised for manufacturing of medicines intended for use within the EEU.

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Best Regards,

GRATA International Law Firm (Moscow)

Corporate and Commercial Law Department

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What we do:

– advising on the statutory requirements and restriction regarding the import and circulation in Russia and other EAEU member-states of medicines and medical products;
– advising and legal support in participating in public procurement;
– advising on legal compliance of advertising and marketing materials and activities, marking, packing, and labels;
– representing interests in the course of public discussions of draft regulatory legal acts, including acts of Eurasian Economic Commission.

Contacts:

Yana Dianova

Director of the Corporate and Commercial Law Department, GRATA International (Moscow)

Tel: +7 (495) 660 11 84

E-mail: ydianova@gratanet.com