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Manufacturers of medicinal products are to follow the n common pharmaceutical market

7/4/2016

The rules regulating the emerging commonpharmaceutical market of the Eurasian not require an unconditional recognition of GMP (Good Manufacturing Practice) C that are non-members of the EAEU. To assure safety, quality and efficacy of medic countries, pharmaceutical manufactures will have to follow the new EAEU regulati

The news was announced by Arman Shakkaliev, the Director of the EEC Technica course of a working meeting with Luis Portero, the Head of the Department of Eco Representative Office of the European Union in Russia.

Mr. Shakkaliev informed his colleague from the European Union that the EAEU dru been developed with European standards in mind. For example, the draft Rules fo medical products for human use were developed based on EU Directive 2001/83/E Good Manufacturing Practice complies with the GMP EU revised in 2015.

As for GMP certification, a Drug Master File will have to contain a GMP Certificate Good Manufacturing Practice. Whereby, in the first three years after introduction o medicinal products registered in the member states of the Union may present a do the national standards instead of the EAEU GMP Certificate, and third countries' m compliance with national GMP requirements of the EAEU member states. If in the Drug Master File it is discovered that the documents mentioned above are missing manufacturing and carrying out quality control of the medicine will be subjected to

For a large-scale common pharmaceutical market to start operating in the Union, t EAEU member states has prepared 19 draft regulations of the "second level" regu set of drafts includes the Concept of Harmonisation of the Pharmacopoeias of the Economic Union; five documents focusing on the good laboratory, clinical, manufa distribution practices; Requirements to a patient information leaflet; Rules of analy Medicinal products labeling requirements; documents that regulate inspection proc

All the documents have been approved by the Board of the EEC. There is only on are being adopted as a "package" at the level of the EEC Council: there is a need Union to work out a common position as to the interchangeability of medicinal proc

Mr. Portero expressed his opinion that meetings of such nature had positive influe relations between the EAEU member states and the European Union.

The parties have agreed to continue their cooperation and reciprocal exchange of

Reference:

GMP (Good Manufacturing Practice) is a system of rules, regulations and guidanc drugs. It serves to ensure that drugs have consistent quality and allows timely dist into circulation of medicinal products deviating from the set standards in terms of c