Comparison of the procedure for registration of medicines in the European Union and the Republic of Macedonia

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Abstract

Registration is a necessary step which follows every pharmaceutical preparation before being sent to the market and becoming available to patients. The approval follows two stages, the first clinical stage which provides security, safety and optimization of dosage integratively used in the four steps of clinical trials, and the second phase that provides marketing authorization. There are four agencies which operate with the procedure for approval and regulation of drugs: EU Legislation - Eudralex, European Directorate for the Quality of Medicines and Healthcare (EDQM), European Medicines Agency (EMA), Heads of Medicines Agencies (HMA) in the European Union.
Objectives – Literature review of drugs registration procedure in our country and its connection to the form and content in the available literature documentation for the medicines registration in the European Union.
Materials and methods - Comparative methods are used to compare the available literature data on the registration of medicines. Used data is from the guide on the form and content of the common technical document (Presentation and format of the dossier Common Technical Document (CTD) Volume 2B) and the Law on medicines and medical devices in the Republic of Macedonia.
Results - The main difference between the European and Macedonian legislation for the registration of medicines is that the European legislation through extensive guides, closely defines every part of the documentation. The entire documentation should be submitted in the format designated as common technical document, whose form and content is on the EMA website with a guide of 303 pages. Here, we explain each module in a detailed manner, ranging from font, text size, the length of the text, to the content of each section. Thus, each application takes the form of a standardized and uniform document. On the other hand, in the Republic of Macedonia there are no such guides, so the applications can exhibit significant variations in form and content.
Conclusion - Registered drugs in the country are registered under the national procedure for the registration of medicines in the country, according to the Law on medicines and medical devices. The national procedure is controlled by the Drug Bureau. The Republic of Macedonia needs to adopt guidelines as bylaws with exactly defined form and content of each part of the documentation.

Keywords:
Eudralex, EDQM, EMA, law, registration, drugs

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