COMPARATIVE ANALYSIS OF THE REGISTRATION DOSSIER STRUCTURE FOR EUROPEAN AND ASIAN COUNTRIES

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Introduction. One of the goals facing drug product (DP) manufacturers in Ukraine is to expand sales markets and enter a new international level. To sell products in foreign countries, it is necessary to first confirm the safety and efficacy of medicines, which is achieved by passing an examination in the regulatory bodies of foreign countries with subsequent receipt of approved registration documents. Pharmaceutical legislation in Ukraine is harmonized with EU legislation, which allows free registration of domestic drugs in European countries. Despite the fact that registration in Asian countries is of considerable interest to drug manufacturers in Ukraine, due to specific pharmaceutical legislation in Asian countries and the lack of an accessible information base, the documents preparation for registration is difficult.

Aim. The aim of the study is to compare the Registration Dossier (RD) structure for European countries and Asian countries, identify common features and differences, which will facilitate the transposition of RDs for registration in Asian countries.

Materials and methods. In the process of the study, the analysis of the Ukraine and the countries of Asia legislative bases in the drug registration system were used. As the result of the analysis, the table of the main differences in the contents of the RD is drawn up, using which it is possible to carry out work on adapting RDs to the requirements of Asian countries.

Results and discussion. The format of RD in Ukraine is CTD (Common Technical Documentation). RD in this format consists of 5 modules: Module 1. Administrative & Prescribing Information, Module 2. Summaries CTD, Module 3. Quality, Module 4. Non-Clinical Reports, Module 5. Clinical Reports. In its turn, the ASEAN Common Technical Documentation format consists of 4 parts: Part I - Administrative Data and Product Information, Part II - Quality Documents, Part III - Non Clinical Documents, Part IV - Clinical Documents.

The list of documents included in the administrative data, as well as the requirements for them are different, reflecting the specifics of drug registration in different countries.

The results of the comparative analysis and the main differences in the structure of the RD for the implementation of medicines abroad are presented in the table.

Comparative table of RD structures CTD-format and ACTD-format.

Comparison parameters	Ukraine (CTD-format)	Asian countries (ACTD-format)
Certificate of Pharmaceutical Product (CPP)	Not applicable	Requires a legalized CPP in the embassy of the country in which the drug will be registered
Summary and reviews of clinical and preclinical data, general quality report	Applicable	Only need to provide the general quality report
Certificates of Suitability to the Monographs of the European Pharmacopoeia (CEP)	Does not required legalized CEP	It is mandatory to have a legalized and authorized CEP in the country of the producer of the active pharmaceutical ingredient
Specification and quality analytical methods of FMP(finished medicinal product)	In accordance with the State Pharmacopoeia of Ukraine, the European Pharmacopoeia	In accordance with the European Pharmacopoeia, the United States Pharmacopeia
Certificate of compliance with the standard ISO 15378 “Primary packaging materials for medicinal products”	Not necessarily	Obligatory availability of the certificate of conformity to standard ISO 15378 from the manufacturer of primary packing materials
Conditions for carrying out long-term stability tests	Climatic zone II (Subtropical climate with possible high humidity) t^o = 25 ºC, relative humidity - 60%	For climatic zone IV A (Hot and humid climate) t^o = 30 ºC, relative humidity - 65% For climatic zone IV B (Hot and very humid climate) t^o = 30 ºC, relative humidity - 75%

Conclusions. Thus, a comparison of the RD structure for European countries and Asian countries, the identification of common features and differences, will facilitate and accelerate the transposition of RDs for registration in Asian countries.