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IMPORTANT POINTS IN THE DRUG REGISTRATION PROCESS AND NAMING NEW MEDICATIONS IN THE REPUBLIC OF UZBEKISTAN

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Abstract: Because of development of pharmaceutical industry, it has already been common to seen medications with similar names in the market in the world. Uzbekistan is not exception in this trend and there are hundreds of medications in our market with similar names came from different countries. In this article I am going to discuss how to register new medications with new brand names in the Republic of Uzbekistan.

Key words: Uzbekistan, Pharmaceuticals, Medical Devices, bacterial infections, Law, antibiotics, resistance, State Committee, infections

Introduction

The drug registration process is an essential aspect of the pharmaceutical industry that ensures the safety and efficacy of new medications before they are marketed to the public. In Uzbekistan, the regulatory body responsible for drug registration is the State Committee for the Control of Pharmaceuticals, Medical Devices, and Medical Equipment. The process involves several stages, including pre-clinical testing, clinical trials, and post-marketing surveillance. Additionally, naming new

medications is a crucial part of the drug registration process, as it helps to identify and differentiate the drug from other products in the market. This article highlights the important points in the drug registration process and the naming of new medications in Uzbekistan.

Drug Registration Process in Uzbekistan

The drug registration process in Uzbekistan is governed by the Law on Medicines and Pharmaceutical Activities, which sets out the requirements for the quality, safety, and efficacy of medications. The process begins with pre-clinical testing, which involves laboratory studies to assess the drug's toxicity, pharmacokinetics, and pharmacodynamics. If the results of pre-clinical testing are positive, the drug moves to the next stage, which is clinical trials.

The clinical trial stage involves three phases: phase I, phase II, and phase III. Phase I trials involve a small number of healthy volunteers to assess the drug's safety and pharmacokinetics. Phase II trials involve a larger group of patients to evaluate the drug's efficacy and safety, while phase III trials involve a more extensive patient population to confirm the drug's efficacy and safety compared to existing treatments.

After successful completion of the clinical trials, the drug registration applicant submits a registration dossier to the State Committee for the Control of Pharmaceuticals, Medical Devices, and Medical Equipment. The dossier includes data on the drug's quality, safety, and efficacy, as well as information on the manufacturing process, labeling, and packaging.

The State Committee reviews the dossier to determine whether the drug meets the regulatory requirements. If the drug is approved, the applicant receives a registration certificate, and the drug can be marketed in Uzbekistan. However, the process does

not end there. The State Committee conducts post-marketing surveillance to monitor the drug's safety and efficacy in the real-world setting.

Naming New Medications in Uzbekistan

In Uzbekistan, the naming of new medications is regulated by the Law on Medicines and Pharmaceutical Activities. The law requires that drug names be unique, easy to pronounce, and not misleading to the public. The naming process involves two stages: the international non-proprietary name (INN) and the trade name.

The INN is a generic name assigned to a drug by the World Health Organization. It is a unique name that identifies the drug's active ingredient and its pharmacological properties. The INN is used globally and is essential for the identification and differentiation of drugs.

The trade name, on the other hand, is the proprietary name assigned to a drug by the manufacturer. The trade name is unique to the manufacturer and is used for marketing purposes. The trade name should be distinct from other drug names to avoid confusion among healthcare professionals and the public.

Conclusion

The drug registration process and the naming of new medications are critical aspects of the pharmaceutical industry in Uzbekistan. The process involves several stages, including pre-clinical testing, clinical trials, and post-marketing surveillance, to ensure the safety and efficacy of new medications. Naming new medications involves assigning an INN and a trade name that are unique, easy to pronounce, and not misleading. Adherence to these regulations ensures that medications are safe and effective and that the public can access quality healthcare.

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