

Local Development of Drug as a Tool for Drug Sustainability: How to Verify the Acceptability - Summary of Some Researches from Thailand

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Abstract

Drug is the necessary substance for everyone for curing of illness. The production of drug is very important and needs good quality control. The manufacturing of drug has been developed in several countries. In Indochina, due to the poor pharmaceutical knowledge, the drug development is usually not qualified. Nevertheless, many drugs are locally produced and circulated for local use in local medical centers. Here, the authors discuss on local development of drug as a tool for drug sustainability. The way of pharmaceutical research to verify the quality of the locally made drugs is also mentioned.

Keywords: Food Product, Quality, Control.

Introduction

Drug is the necessary substance for everyone for curing of illness. The production of drug is very important and needs good quality control. The manufacturing of drug has been developed in several countries. In Indochina, due to the poor pharmaceutical knowledge, the drug development is usually not qualified. Nevertheless, many drugs are locally produced and circulated for local use in local medical centers. Here, the authors discuss on local development of drug as a tool for drug sustainability. The way of pharmaceutical research to verify the quality of the locally made drugs is also mentioned.

Case Study

In Thailand, as a developing country, the limitation of technology is still the big problem. Lack of good medical scientist is common. Nevertheless, the local Thai production of locally used drug already existed. The governmental pharmaceutical organization (GPO) mainly takes responsibility for local drug development and production. Some local pharmaceutical companies also produce some local drugs. The way to control the quality of the locally made drugs is very interesting. In fact, there are several steps before the locally made drugs can be accepted for local use. The standard clinical trials are usually required. However, the quality of the trials is still a controversial issue. Whether there is any conflict of interest on trials performing, research results

publication and registration problem is a big question. As an evidence, there are very few acceptable publications on locally developed drug in Thailand and this should be the point for further management by local public health agency.

Table 1. Summary of some important publications on study of the locally made drugs in Thailand (in international index, PubMed)

Authors	Drug	Details
Wiwanitkit et al [1].	Simvastatin	Wiwanitkit et al performed a -- a randomized crossover study to assess LDL-cholesterol lowering effect of a generic product of simvastatin compared to simvastatin (Zocor) in Thai hypercholesterolemic subjects [1].
Assawawitoontip and Wiwanitkit [2]	Simvastatin	Assawawitoontip and Wiwanitkit performed a randomized crossover study to evaluate LDL-cholesterol lowering effect of a generic product of simvastatin (Unison Company) compared to simvastatin (Zocor) in hypercholesterolemic subjects [2].
Wittayalerpanya et al [3].	Rosiglitazone	Wittayalerpanya et al studied on pharmacokinetic and bioequivalence study of an oral 8 mg dose of rosiglitazone tablets in Thai healthy volunteers [3].
Puavilai et al [4].	Corticosteroid	Puavilai et al. performed a comparative study of the efficacy of topical corticosteroid: five locally made and one brand name creams [4].

Discussion

To assure the quality of the locally produced drug is important in pharmaceutical process. In resource limited setting such as Thailand, it is usually difficult to perform a good trial on newly developed drug. In fact, based on clinical pharmacology principle, the new drugs have to be tested for several aspects including bioavailability and pharmacodynamics. The clinical studies to confirm the laboratory or clinical bioequivalence is needed. The main problem is there is no good clinical pharmacologist in Thailand and the local expert in medicine is not too good to perform a world class clinical trial. The problem exists and calls for attention to develop new knowledge before the generalization of local drug production in the country.

Conflict of Interest: None

References

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