NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

REGULATION OF CLINICAL TRIALS IN MALAYSIA

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DEFINITION OF CLINICAL TRIALS

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), to identify any adverse reactions to an investigational product(s), to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the objective of ascertaining its safety and efficacy.

CLINICAL TRIAL IMPORT LICENCE (CTIL)

In A licence in Form 4 in the Schedule of the Control of Drugs and Cosmetics Regulations 1984, issued by Director of Pharmaceutical Services under regulation 12(1)(c) of the same Regulations which authorises the licensee to import any product for purposes of clinical trials, notwithstanding that the product is not a registered product.

CLINICAL TRIAL EXEMPTION (CTX)

An exemption issued under regulation 15 (5), Control of Drugs and Cosmetics Regulations 1984 by Director of Pharmaceutical Services which exempts a person who wishes to manufacture product(s) solely for the purpose of producing samples for clinical trials from the provisions of regulation 7 (1) or regulation 18A of Control of Drugs and Cosmetics Regulations 1984.

PRODUCTS THAT REQUIRE CTIL/CTX

Before commencing any clinical trials involving product(s) that requires CTIL/CTX prior to importation/local manufacturing of products for the study, the investigator/sponsor shall submit application for CTIL/CTX to NPRA. The following products will require a CTIL/CTX:

- A product including placebo which is not registered with the DCA and is intended to be imported for clinical trial purpose.
- A product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, and when used for unapproved indication and/or used to gain further information about an approved use for clinical trial purpose.
- A traditional product with a marketing authorisation with indication for "traditionally used" when used for unapproved indication / therapeutic claims for clinical trial purpose.
- An unregistered product including placebo manufactured locally for the purpose of clinical trial.