GUIDELINE ON NATURAL PRODUCTS WITH THERAPEUTIC CLAIM

Introduction

Current Situation

- Traditional medicines are based on an extensive history of use
- Abridge evaluation – safety, quality and claimed benefit
- General health claims

Introduction

MOVING FORWARD

Guideline of Natural Products with Therapeutic Claim

Scope of guideline

1. Type of evidence to support natural products with therapeutic claim for human consumption

2. Applicable to products containing plant/herbal medicinal ingredients

Requirement

Claims should primarily be based on evidence provided by well-designed human intervention studies on the end product.

The study must show a consistent association between the active ingredient/herbal ingredient(s) and the health effect.

Requirement

Manufactured in a Good Manufacturing Practice (GMP) Compliance premise which follows Pharmaceutical Inspection Co-Operation Scheme-Guide to Good Manufacturing Practice for Medicinal Products (PIC/S) guideline.

Requirement

Non-clinical safety study must be conducted in a facility which comply to Organisation for Economic Coorperation and Development (OECD) Good Laboratory Practice (GLP) requirement as mentioned in (40) dlm.BPFK/PPP/07/25 Bil. 9 Tahun 2016 Keperluan Good Laboratory Practice (GLP) bagi Kajian Keselamatan Bukan Klinikal Untuk Tujuan Pendaftaran Produk New Chemical Entity (NCE), Biologik dan Produk Herba Dengan Tuntutan Terapeutik Tinggi.

Requirement - QUALITY

- Finished product
- Standardisation and Specifications of Standardized Extract
- Information on the laboratory/ies
- Method of Identification and Analysis of Active Ingredient in the Standardised Extracts
- Manufacture of Product
- Finished Product Quality Control
- Validation of Analytical Method
- A stability studies carried out in accordance to ASEAN/ ICH Stability Studies Guidelines.
- Container/packaging

Requirement – NON CLINICAL

- Should present an integrated and critical assessment of the pharmacologic, pharmacokinetic and toxicological evaluation.
- GLP status for non-clinical studies
- Relevant scientific literature and related active ingredient(s) of product can be considered as an additional supporting document.

Requirement – CLINICAL

- Should describe and explain the overall approach to the clinical development of a herbal product.
- Assess the quality of the design and performance of the studies, and to include a statement regarding GCP compliance.
- Scientific evidence from human studies on end-product

Requirement – CLINICAL

Examples of supporting scientific literature evidence:

- Evidence obtained from at least one properly designed randomized controlled (preferably multi-centre) double blind trial. It is preferable to have data from at least two trials independent of each other, but in some cases, one large well-conducted trial may suffice.
- Evidence can be obtained from well-designed controlled trials with or without randomization.
- Evidence obtained from well-designed studies such as epidemiological cohort and case-control studies.
- Evidence obtained from multiple time series with or without intervention. including within country
- Systematic reviews of the clinical research relating to particular subject areas
- Peer reviewed scientific data or meta-analysis (these evidences must be product specific and published in reputable peer reviewed journals)

Requirement – CLINICAL

- Where there are differences between the ingredient and reported therapeutic benefit, a justification will be required in your evidence package to address the discrepancy.

- Non-clinical studies, cellular or pharmacological studies, these alone are not considered sufficient evidence to support a scientific indication. However, such studies can be used to provide secondary support to human data.

- Internationally recognised monographs and pharmacopoeias can also provide additional support to specific indications referring to health enhancement claims, but such items will need further evidentiary support from primary research articles and/or systematic reviews. The more specific the indication, the more evidence you need to support your indication.

Reference:

1. Drug Registration Guidance Document, DRGD
2. ASEAN Common Technical Dossier/ Requirements (ACTD/ ACTR)
3. Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption, Malaysian Guideline for Good Clinical Practice (GCP)
4. Pharmaceutical Inspection Co-Operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products

THANK YOU