# ASEAN COMMON TECHNICAL DOSSIER
## (ACTD)

The ASEAN Secretariat
Jakarta

**TABLE OF CONTENTS**

**THE ASEAN COMMON TECHNICAL DOSSIER (ACTD)
FOR THE REGISTRATION OF PHARMACEUTICALS
FOR HUMAN USE**

**ORGANIZATION OF THE DOSSIER**

**THE ASEAN COMMON TECHNICAL DOSSIER (ACTD) FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE**

**ORGANIZATION OF THE DOSSIER**


**PREAMBLE**

This ASEAN Common Technical Dossier (ACTD) is a guideline of the agreed upon common format for the preparation of a well-structured Common Technical Dossier (CTD) application that will be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals and biologics for human use. Although the current ASEAN Common Technical Requirements (ACTR) has not included specific requirements for biosimilar products, the ACTD format is also applicable for biosimilar products. This guideline describes a CTD format that will significantly reduce the time and resources needed to compile applications for registration and in the future, will ease the preparation of electronic documental submissions. Regulatory reviews and communication with the applicant will be facilitated by a standard document of common elements.

This guideline merely demonstrates an appropriate write-up format for acquired data. However, applicants can modify, if needed, to provide the best possible presentation of the technical information, in order to facilitate the understanding and evaluation of the results upon pharmaceutical registration.

Throughout the ACTD, the display of information should be unambiguous and transparent, in order to facilitate the review of the basic data and to help a reviewer become quickly oriented to the application contents. Text and tables should be prepared using margins that allow the document to be printed on either A4 or 8.5″ x 11″ paper. The left-hand margin should be sufficiently large that information is not obscured by the method of binding.

Font and size, (Times New Roman, 12-point font), for text and tables should be of a style and size that are large enough to be easily legible, even after photocopying. Every page should be numbered, with the first page of each part designated as page 1. For a paper, Common Technical Acronyms and abbreviations should be defined the first time they are used in each part. References should be cited in accordance with the 1979 Vancouver Declaration on Uniform requirements for Manuscripts Submitted to Biomedical Journals.

The Common Technical Document is organized into four parts as follows:

**Part I. Table of Contents, Administrative Data and Product Information**
Part I contains initially the overall Table of Contents of the whole ACTD to provide basically the information that could be looked through respectively. Secondly, the next content is the Administrative Data where required specific documentation in detail is put together such as application forms, label, package insert etc. The last section of this part is Product Information where necessary information includes prescribed information, mode of action, side effects etc. A general introduction to the pharmaceutical, including its pharmacologic class and mode of action should be included.

**Part II. Quality Document**

Part II should provide the Quality Overall Summary followed by the Body of Data. The quality control document should be described in detail as much as possible.

**Part III. Nonclinical[1] Document**

Part III should provide the **Nonclinical** Overview, followed by the Nonclinical Written Summaries and the Nonclinical Tabulated Summaries. The documentation of this part is not required for Generic Products, Minor Variation Products and some Major Variation Products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference Countries. Therefore, the authority who requires specific Study Reports should ask for the necessary documents.

[1]The word "Nonclinical" replaces "Pre-clinical"

**Part IV. Clinical Document**

Part IV should provide the Clinical Overview and the Clinical Summary. The documentation of this part is not required for Generic Products, Minor Variation Products and some Major Variation Products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference Countries. Therefore, the authority who requires specific Study Reports should ask for the necessary documents.

The overall organisation of the Common Technical Dossier is presented on the following in Parts:

**Part I: Table of Content Administrative Information and Prescribing Information**
        Section A: Introduction
        Section B: Overall ASEAN Common Technical Dossier Table of Contents
        Section C: Documents required for registration (for example, application forms, labelling, Product Data Sheet, prescribing information)

**Part II: Quality Document**
        Section A: Table of Contents
        Section B: Quality Overall Summary
        Section C: Body of Data

**Part III: Nonclinical Document**
        Section A: Table of Contents
        Section B: Nonclinical Overview
        Section C: Nonclinical Written and Tabulated Summaries
                1. Table of Contents
                2. Pharmacology
                3. Pharmacokinetics
                4. Toxicology
        Section D: Nonclinical Study Reports
                1. Table of Contents
                2. Pharmacology
                3. Pharmacokinetics

4. Toxicology

**Part IV: Clinical Document**
Section A: Table of Contents
Section B: Clinical Overview
Section C: Clinical Summary
1. Summary of Biopharmaceutics and Associated Analytical Methods
2. Summary of Clinical Pharmacology Studies
3. Summary of Clinical Efficacy
4. Summary of Clinical Safety
5. Synopses of Individual Studies
Section D: Tabular Listing of All Clinical Studies
Section E: Clinical Study Reports
Section F: List of Key Literature References