INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

ORGANISATION OF THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Recommended for Adoption

at Step 4 of the ICH Process

on 8 November 2000

by the ICH Steering Committee

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

ORGANISATION OF THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH Harmonised Tripartite Guideline

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 8 November 2000, this guideline is recommended for adoption to the three regulatory parties to ICH

OBJECTIVE OF THE GUIDELINE

This guideline presents the agreed upon common format for the preparation of a well-structured Common Technical Document for applications that will be submitted to regulatory authorities. A common format for the technical documentation will significantly reduce the time and resources needed to compile applications for registration of human pharmaceuticals and will ease the preparation of electronic submissions. Regulatory reviews and communication with the applicant will be facilitated by a standard document of common elements. In addition, exchange of regulatory information between Regulatory Authorities will be simplified.

BACKGROUND

Through the ICH process, considerable harmonisation has been achieved among the three regions in the technical requirements for the registration of pharmaceuticals for human use. However, until now, there has been no harmonisation of the organisation of the registration documents. Each region has its own requirements for the organisation of the technical reports in the submission and for the preparation of the summaries and tables. In Japan, the applicants must prepare the GAIYO, which organises and presents a summary of the technical information. In Europe, Expert Reports and tabulated summaries are required, and written summaries are recommended. The U.S. FDA has guidance regarding the format and content of the New Drug Application. To avoid the need to generate and compile different registration dossiers, this guideline describes a format for the Common Technical Document that will be acceptable in all three regions.

SCOPE OF THE GUIDELINE

This guideline primarily addresses the organisation of the information to be presented in registration applications for new pharmaceuticals (including biotechnology-derived products).

This guideline is not intended to indicate what studies are required. It merely indicates an appropriate format for the data that have been acquired. Applicants should not modify the overall organisation of the Common Technical Document as outlined in the guideline. However, in the Nonclinical and Clinical Summaries, applicants can modify individual formats if needed to provide the best possible presentation of the technical information, in order to facilitate the understanding and evaluation of the results.

GENERAL PRINCIPLES

Throughout the Common Technical Document, 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 both A4

paper (E.U. and Japan) and 8.5 x 11" paper (U.S.). The left-hand margin should be sufficiently large that information is not obscured by the method of binding. Font sizes for text and tables should be of a style and size that are large enough to be easily legible, even after photocopying. Times New Roman, 12-point font, is recommended for narrative text. Every page should be numbered, with the first page of each module designated as page 1. For a paper Common Technical Document that has multiple volumes in a module, each volume can be numbered beginning with page 1. Acronyms and abbreviations should be defined the first time they are used in each module. References should be cited in accordance with the 1979 Vancouver Declaration on Uniform requirements for Manuscripts Submitted to Biomedical Journals.

ORGANISATION OF THE COMMON TECHNICAL DOCUMENT

The Common Technical Document is organized into five modules. Module 1 is region specific. Modules 2, 3, 4, and 5 are intended to be common for all regions. Conformance with this guideline should ensure that these four modules are provided in a format acceptable to the regulatory authorities.

Module 1. Administrative Information and Prescribing Information

This module should contain documents specific to each region; for example, application forms or the proposed label for use in the region. The content and format of this module can be specified by the relevant regulatory authorities.

Module 2. Common Technical Document Summaries

Module 2 should begin with a general introduction to the pharmaceutical, including its pharmacologic class, mode of action, and proposed clinical use. In general, the Introduction should not exceed one page.

Module 2 should provide the Quality Overall Summary, the Nonclinical Overview, and the Clinical Overview. This should be followed by the Nonclinical Written Summaries and the Nonclinical Tabulated Summaries, and the Clinical Summary. The organisation of these summaries is described in Guidelines for M4Q, M4S, and M4E.

Module 3. Quality

Information on Quality should be presented in the structured format described in Guideline M4Q.

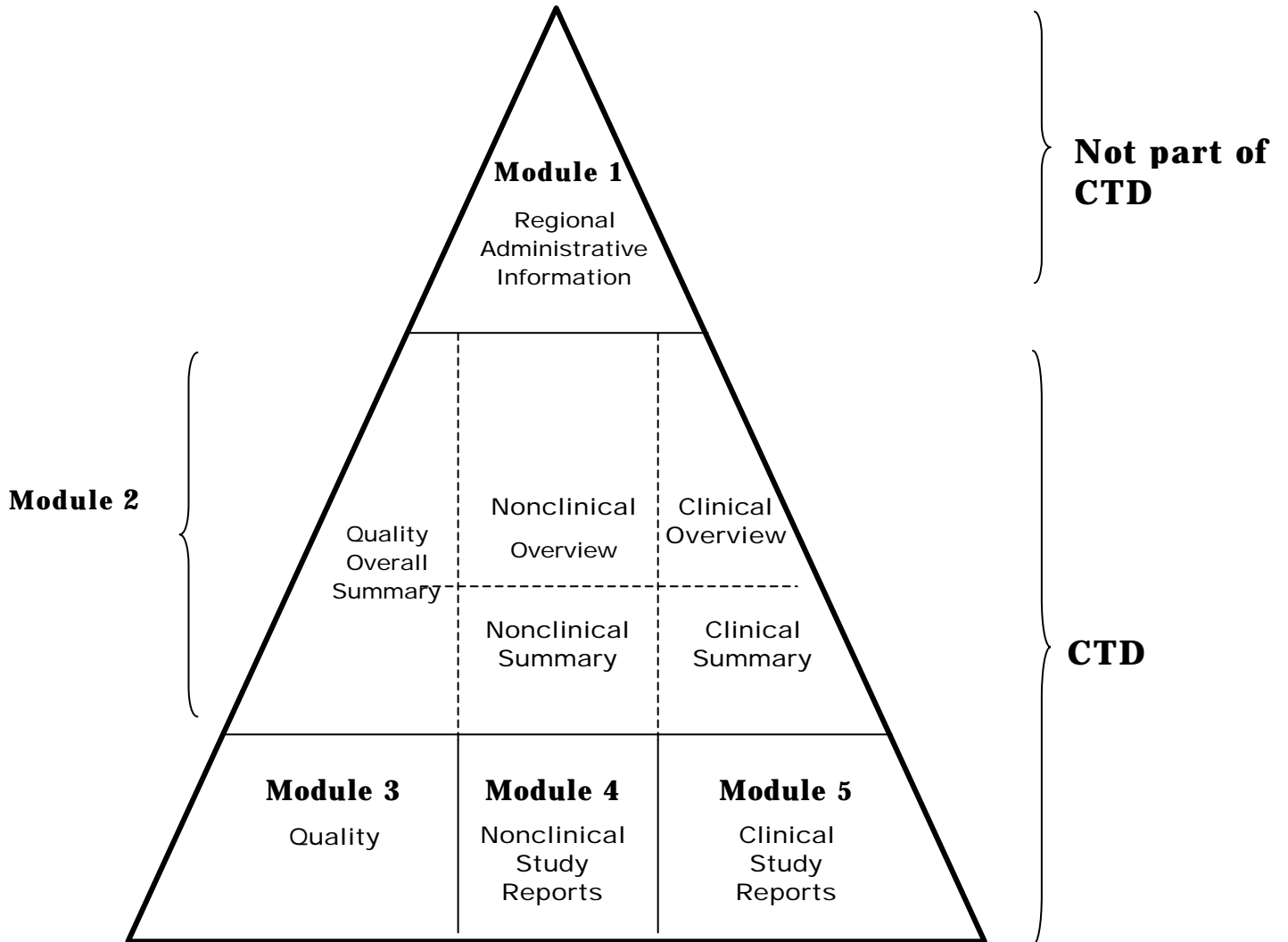### Module 4. Nonclinical Study Reports

The nonclinical study reports should be presented in the order described in Guideline M4S.

Module 5. Clinical Study Reports

The human study reports and related information should be presented in the order described in Guideline M4E.

The overall organisation of the Common Technical Document is presented on the following pages.

Diagrammatic Representation of the ICH Common Technical Document

	Module 1 Regional Administrative Information		Not part of CTD
Module 2	Quality Overall Summary	Nonclinical Overview	Clinical Overview	CTD
		Nonclinical Summary	Clinical Summary
	Module 3 Quality	**Module 4** Nonclinical Study Reports	**Module 5** Clinical Study Reports

ORGANISATION OF THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Module 1: Administrative Information and Prescribing Information

    A.   Module 1 Table of Contents

    B.   Documents Specific to Each Region (for example, application forms, prescribing information)

Module 2: Common Technical Document Summaries

    A.   Overall Common Technical Document Table of Contents

    B.   Introduction

    C.   Quality Overall Summary

    D.   Nonclinical Overview

    E.   Clinical Overview

    F.   Nonclinical Summary

        1.   Pharmacology

            a. Written Summary

            b. Tabulated Summary

        2.   Pharmacokinetics

            a. Written Summary

            b. Tabulated Summary

        3.   Toxicology

            a. Written Summary

            b. Tabulated Summary

    G.   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

Module 3: Quality

    A.   Table of Contents

    B.   Body of Data

    C.   Key Literature References

Module 4: Nonclinical Study Reports

    A.   Table of Contents

    B.   Study Reports

    C.   Literature References

Module 5: Clinical Study Reports

    A.   Table of Contents of Clinical Study Reports and Related Information

    B.   Tabular Listing of All Clinical Studies

    C.   Clinical Study Reports

    D.   Literature References