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MALAYA AT MALUSOG NA PAMAYANAN

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BUREAU CIRCULAR
No. 2007 - 011

TO : **ALL CONCERNED DRUG ESTABLISHMENTS**

SUBJECT : **Adoption of the Association of Southeast Asian Nations Common Technical Documents (ACTD) and Common Technical Requirements (ACTR) on the Pharmaceutical Product Registration for Human Use**

I. BACKGROUND

The ASEAN Consultative Committee on Standards and Quality (ACCSQ) was formed by the ASEAN Economic Ministry in 1992 to facilitate and complement the objective of the ASEAN Free Trade Area (AFTA) particularly the elimination of technical barriers to trade. In the 4th Senior Economic Officials Meeting (SEOM) held in Indonesia, the SEOM approved the revised terms of reference of the ACCSQ, which among others, authorized them to involve regulatory bodies in the ACCSQ.

The Pharmaceutical Product Working Group (PPWG) was formed in 1999 through the ACCSQ to develop a harmonized scheme among ASEAN member countries and work on the standards and conformances of pharmaceutical products. Consequently, after a series of six meetings, the ASEAN Common Technical Dossier (ACTD) for quality, safety, efficacy, administrative data, and product information was established and adopted. Despite differences in the existing infrastructure capability and capacity of member countries, the PPWG has made considerable progress.

II. RATIONALE

With the advent of globalization, the need for efficiency in the implementation of regulations has compelled many national authorities to seek harmonized approaches to drug development and to enter bilateral mutual recognition agreements and other cooperative agreements, without interfering with each country's sovereign laws and directives. Efforts toward harmonization foster compatibility among structurally diverse regulatory systems. The convergence of these regulatory practices can help enhance public health protection by providing faster access to an improved availability of pharmaceutical products. Harmonization is seen as a means of streamlining regulatory approaches to ensure quality, safety, and efficacy, while reducing trade barriers and facilitating worldwide trade. It is also intended to provide the foundation for establishing partnership between countries and sectors and provide a means to leverage valuable resources.

The objectives of this Circular are:

1. To formally adopt and incorporate the ACTD and ACTR into the national regulations and registration requirements for pharmaceuticals, in so far as the same are not in conflict with existing national laws, in preparation for its full implementation in January 2009.
2. To allow a coordinated transition period for both BFAD and the Pharmaceutical Industry from the previous pharmaceutical regulation to the ACTD and ACTR

III. SCOPE

This Circular shall apply to all manufacturers, traders, exporters, and importers of pharmaceutical products. Manufacturers, traders, exporters and importers of vitamin-containing products, traditional and herbal medicines or products, veterinary products, and diagnostic reagents and kits are not covered by this Order.

IV. DETAILS/ DIRECTIVES:

The following ASEAN harmonized documents for the registration of pharmaceutical products for human use shall be incorporated into the national regulations in the registration of pharmaceutical products, in so far as they are not in conflict with existing national laws:

A. ASEAN Common Technical Documents (ACTD):

1. ASEAN Glossary
2. Organization of the Dossier
   - 2.1. Part I. Table of Contents, Administrative Data and Product Information
     - Section A: Introduction
     - Section B: Overall ASEAN Common Technical Dossier Table of Contents
     - Section C: Documents required for registration (for example, application forms, labeling, Product Data Sheet, Prescribing information)
   - 2.2. Part II. Quality Document
     - Section A: Table of Contents
     - Section B: Quality Overall Summary
     - Section C: Body of Data
   - 2.3. 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

2.4. 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

B. ASEAN Common Technical Requirement (ACTR)

1. ASEAN Guidelines on Stability Study of Drug Product
2. ASEAN Guidelines on Validation of Analytical Procedures
3. ASEAN Guidelines on Submission of Manufacturing Process Validation Data for Drug Registration
4. ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies
5. Guidelines on Nonclinical Documents
6. Guidelines on Clinical Documents

The BFAD shall make available the full text of these documents on the BFAD website for easy access and information of the pharmaceutical industries.

VI. REPEALING CLAUSE

All other issuances concerning pharmaceutical registration requirements inconsistent with this Circular are hereby repealed.

VI. SEPARABILITY CLAUSE

In case any provision of this Circular is declared contrary to law or unconstitutional, other provisions which are not affected thereby remain in force and effect.

IV. EFFECTIVITY

This Circular shall take effect immediately.

PROF. LETICIA-BARBARA B. GUTIERREZ, M.S.
Director IV