The Effect of ASEAN Harmonization on Pharmaceutical Registration

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After two years of postponement, the Thai Food and Drug Administration (FDA) has announced the implementation of ASEAN Harmonization on Pharmaceutical Registration effective January 1, 2009. This represents a significant change in the Thai FDA's history of the registration of pharmaceutical products.

The ASEAN members have implemented, through their Pharmaceutical Product Working Group, the ASEAN Common Technical Requirements and Dossier (ACTR/ACTD) on Quality, Safety and Efficacy, which provide guidelines on analytical and process validation, stability studies, and bioavailability/bioequivalence (BA/BE). The ACTR is a set of written materials that serves as a guide for applicants when preparing their application dossiers. The ACTD is a part of the marketing authorization application dossier, which is common to all ASEAN member countries. These guidelines are compliant with the minimum standards set forth within the ICH guidelines. The ACTD includes a Common Technical Document, which is organized into four main parts:

Part 1: Administrative Data and Product Information;

Part 2: Quality (Overall Summary and Reports);

Part 3: Nonclinical/Safety (Summary and Study Reports);

Part 4: Clinical/Efficacy (Overview, Summary, Assessment Reports, and Study Reports).

The first part of the document shall include the administrative data and general product information, such as application forms, labels, package inserts, modes of action, and side effects.

The Quality Document will contain the quality control information on both the drug substance and the drug product (e.g., the general information, characterization, control, stability, container, etc., of the drug substance; the description, composition, and manufacture of the drug product; the control of the finished product; the interchangeability/equivalence evidence of the product; etc.).

The Nonclinical Document will include the data on pharmacology, toxicology, pharmacokinetics, local tolerance, other toxicity studies, and the list of the key literature references.

Finally, the Clinical Documents will consist of the clinical overview and the clinical summary. More specifically, it will contain the BA/BE and other pertinent studies, efficacy and safety, post-marketing data (if available), and references.

The new ASEAN Harmonization rules will have a substantial impact on those who register pharmaceutical products at the Thai FDA. Local manufacturers and generic drug companies will be the most affected by ASEAN Harmonization because their dossiers/documents have not been prepared in accordance with ICH guidelines. They will now have to prepare more new forms, request from their customers more details for every part specified in the ASEAN Harmonization guidelines, and conduct more searches from websites and pharmacopoeia for all the new information which is now required.

Multinational companies, in contrast, will be less affected by the implementation of ASEAN Harmonization because they are already accustomed to preparing their dossiers/documents in compliance with ICH guidelines.

Since ASEAN Harmonization is new to all concerned with regulatory work, FDA officers, and even the experts who read the files, a longer lead time will now be required in obtaining the approval of the registration of pharmaceutical products. Due to these new requirements, Regulatory Affairs specialists will need to ensure that all files are thoroughly prepared prior to submission to the FDA. ◆