

ADOPTION OF THE ICH HARMONISED TRIPARTITE GUIDELINE, QUALITY OF BIOTECHNOLOGICAL PRODUCTS: STABILITY TESTING OF BIOTECHNOLOGICAL/BIOLOGICAL PRODUCTS Q5C

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I. BACKGROUND

Republic Act No. 3720, otherwise known as the “Food, Drugs, and Devices, and Cosmetics Act”, as amended, and further strengthened by Republic Act No. 9711, otherwise known as the “FDA Act of 2009”, declare it a policy of the State to ensure the safety, efficacy and quality of drugs, including biotechnological/ biological products and vaccines. In line with this, Administrative Order No. 47-a, series of 2001, “Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products” was promulgated for the regulation of such products.

However, with the recent advances in the regulatory science, the current guidance for the conduct of stability studies for these products prove to be insufficient and not at par with international standards, specifically, the International Conference on Harmonisation (ICH) Q5C. Thus, in order to ensure the safety, efficacy, and quality of such products, and to align with international standards, this Circular is hereby issued to adopt the aforementioned guideline document.

II. OBJECTIVE

The objective of this Circular is to formally adopt the “ICH Harmonised Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C” as a regulatory requirement for the conduct of stability studies for biotechnological products.

III. SCOPE

This Circular shall apply to all manufacturers, traders and distributors (e.g. exporters, importers and wholesalers) of biotechnological/biological products, including vaccines.

For purposes of this Circular, biological product shall mean any attenuated or inactivated virus or bacteria, or subcomponents attached to adjuvants, toxoids, hyperimmune serum, and analogous products applicable to diagnosis, prevention treatment or cure of disease or injuries to man, obtained or derived from living matter - animals, plants or microorganisms, or parts thereof. It includes preparations primarily designed to develop a type of immunity or preparations that are concerned with immunity.

In line with the Administrative Order No. 2013-0021, “Adoption of the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier (ACTD) and Common Technical Requirements (ACTR) for the Registration of Pharmaceutical Products for Human Use”, biological product may also mean any product of biological origin, prepared with biological processes, derived from human blood and plasma, or manufactured by biotechnology, consisting of substances of higher molecular weight whose purity, potency, and composition cannot readily and reliably be determined by chemical or physicochemical analysis. Examples of this group

include vaccines, blood products, modified animal tissues, high molecular weight hormones, allergens, and the products of genetic engineering or other newer biotechnological techniques. This definition does not include antibiotics and substances that, although of biological origin, are of low molecular weight and can be isolated as pure substances, such as purified steroids and alkaloids.

Biotechnological products, on the other hand, shall mean any product prepared with genetic engineering or other newer biotechnological techniques. All biotechnological products fall into the definition of biological products.

IV. IMPLEMENTING DETAILS

A. Stability Study Guidelines

The stability studies of all biotechnological/biological products shall be conducted following the adopted “ICH Harmonised Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C” - from the selection of batches, stability-indicating profile, storage conditions, testing frequency, specifications and up to the final labeling of the product.

B. Supplements and Revisions

All supplements and revisions related to the adopted ICH guideline shall be adopted automatically.

C. Accessibility

The adopted ICH guideline shall be made available in the FDA website.

V. TRANSITORY PROVISIONS

The revised stability requirements shall only apply to incoming applications; all pending applications and their compliances shall not be covered by this Circular.

VI. REPEALING CLAUSE/SEPARABILITY CLAUSE

Provisions on previous circulars and memoranda that are inconsistent with this issuance are hereby withdrawn, repealed, and/or revoked accordingly.

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions of this Circular shall not be affected.

VII. EFFECTIVITY

This Circular shall take effect on 11 November 2013.

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