Chapter Law Content

Title: Regulation of Bioavailability and Bioequivalence Studies CH

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Category: Ministry of Health and Welfare（衛生福利部）

Chapter I General Provisions

Article 1 The Regulation is set according to the Second Paragraph of Article 42 of the Pharmaceutical Affairs Act.

Article 2 The execution of bioavailability and bioequivalence and their related studies shall comply with the provisions of the Regulation. Matters not provided for herein should be governed by the Guidelines of Good Clinical Practice, the Regulation for Registration of Medicinal Products, and other relevant laws and regulations.

Article 3 The terms used in the Regulation defined as follows:
1.Bioavailability means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are no intended to be absorbed into the blood stream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.
2.Pharmaceutical equivalents means drug products in identical dosage forms that contain identical amounts of the identical active drug ingredient, and meets either the identical compendial or other applicable quality standards provided by the central competent health authority.
3.Pharmaceutical alternatives means drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Testing specifications of the drug product should meets either the identical compendial or other applicable quality standards provided by the central competent health authority.
Bioequivalence means the absence of a significant difference in the bioavailability between two pharmaceutical equivalents or pharmaceutical alternatives when administered at the same molar dose under similar conditions in an appropriately designed study.

Article 4 Pharmaceutical manufacturers must apply for the approval of the protocol from the central competent health authority before conducting bioavailability and bioequivalence studies. The content of studies should comply with the Guideline of Good Clinical Practices. However, the application of protocol for conducting bioavailability and bioequivalence studies of generic drugs can be waived.

Article 5 Application fees for applying any protocols and reports following the Regulation should be paid, and the completed application forms together with all required dossiers should be submitted to the central health competent authority for assessment.
The above-mentioned application forms and documents include the form of bioavailability study protocol, the form of bioequivalence study protocol, the form of bioavailability study report, the form of bioequivalence study report, the form of dissolution profile comparison report, and/or other forms and documents in relation to the application procedure.

Article 6 Reports should be written in the format required by the central competent health authority, and a complete report with any relevant study results should be submitted for assessment.
Applicants should provide a written statement that test drugs are indeed the registered drugs. Applicants have the ultimate responsibility for the quality and integrity of study results.

Article 7 Bioavailability and bioequivalence studies should be performed for non-intravenous administrated drug products that cause systemic action under any of the following circumstance:
1.Studies should be performed if requested by new drug application or the Regulation for Registration of Medicinal Products. However, studies can be waived with the approval of central competent health authority if the applicants have submitted relevant information for assessment.
2.Studies should be performed for drugs not under pharmacovigilance that requested by the central competent health authority.
All generic drugs with active ingredients under pharmacovigilance (include those pharmacovigilance period has expired) should submit bioequivalence study reports when applying for registration. However, submission of the study results could be waived with the approval of central competent health authority.

Article 8 Bioequivalent study can be waived if the drug product meet any of the following circumstance:
1.Intravenous administrated injection product.
2.Oral administrated generic drug with excipients that do not affect absorption of the active ingredient.
3.Extravascular administrated injection product, i.e. the injectable solution of generic drug that have same pH value as compendia or brand products. Except for the preservatives and buffers, its formulation should be the same as the brand drugs.
4.Drug products as inhaled gases or vapors.
5.Generic drugs with topical uses that are not subcutaneously or intradermally absorbed.
6.Ophthalmic and otic generic drugs.
7.For same oral solid drug products with different strength applying for registration, or drug products with approved bioequivalence reports submitting for post-approval changes, the bioequivalence study can be replaced by dissolution profile comparisons if approved by the central competent health

authority.
8.Others that are approved by the central competent health authority according to information provided by the applicants.