Article Content

Title: Standards of Review Fees for the Registration of Western Medicines and Medical Devices Ch

Amended Date: 2015.05.13

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

Article 1 These standards are promulgated pursuant to the provisions of Paragraph 2 of Article 104-2 of the Pharmaceutical Affairs Act.

Article 2 Review fees that shall be submitted for each application of registration of western medicines and medical devices are as below:
I.New Drug
(I).Registration for products of new chemical entities (NCE): TWD 800,000.
(II).Registration for products of new therapeutic compound or new administration route: TWD 300,000.
(III).Registration for products of new dosage form, new dose unit, new unit strength or controlled release forms, new strength of the same therapeutic compound(s) and the same administration route: TWD 150,000.
II.Generic Drugs and Drugs for Export Only
(I).Registration for generic drug products under pharmacovigilance : TWD 80,000.
(II).Registration for generic drug products not under pharmacovigilance: TWD 50,000.
(III).Registration for products for export only: TWD 25,000.
III.Biological Drugs
(I).Registration for blood product, anti-toxin, or vaccine: TWD 800,000.
(II).Registration for gene-engineering biological product: TWD 800,000.
(III).Registration for approved biological drug with new dose package or new manufacturing site: TWD 150,000.
IV.Drug Clinical Trial
(I).Review of Investigational New drug (IND) application: TWD 30,000.
(II).Review of Investigational New drug (IND) Clinical trial report (CSR): TWD 20,000.
(III).Review of IND Amendments: TWD 5,000.
(IV).Review of bridging study: TWD 30,000.
V.Bioavailability (BA) and Bioequivalence (BE) Studies
(I).Review of a BA study protocol: TWD 15,000.
(II).Review of a BE study protocol: TWD 15,000.
(III).Review of a BA study report (including registration of products whose active ingredients are not under pharmacovigilance and changes of registered products): TWD 30,000.
(IV).Review or a BE study report (including registration of products whose active ingredients are not under pharmacovigilance and changes of registered products): TWD 30,000.
(V).Review of a dissolution profile comparison report (including registration of products whose active ingredients are not under pharmacovigilance and changes of registered products): TWD 20,000.
VI.Active Pharmaceutical Ingredients (API)
(I).Registration or technical documents review of API for drug manufacturing purpose: TWD 60,000.
(II).Submission for importing raw materials for their own use: TWD 3,000.
(III).Submission for importing raw materials for trial-production: TWD 3,000.
VII.Good Manufacturing Practice (GMP) Inspections for Western Medicines

(I).GMP inspections for Domestic pharmaceutical manufacturer
1.Inspection for new establishment, relocation, expansion, resumption of operation, or addition of a new active pharmaceutical ingredient, dosage form, process operation, medicinal product: TWD 120,000; Additional fee of TWD 20,000 will be charged whenever there is an additional dosage form, biological drug, or active pharmaceutical ingredient.
2.Follow-up inspection: TWD 120,000.
3.Review of a pharmaceutical manufacturer which produces both drugs and non-medical products: TWD 20,000; Additional fee of TWD 5,000 will be charged for a shared promise whenever there is an additional product.
4.Review of contract analysis application: TWD 10,000; Additional fee of TWD 20,000 will be charged whenever onsite inspection is needed.
5.Change of the medicament manufacturing license: TWD 10,000
(II).GMP inspections for Foreign pharmaceutical manufacturers
1.Review of a Plant Master File (PMF): TWD 120,000; Additional fee of TWD 20,000 will be charged when there is an additional dosage form, biological drug, active pharmaceutical ingredient or process operation.
2.Follow-up review: TWD 120,000.
3.Inspection on a site with a PMF approval: TWD 600,000; Inspection on a site without a PMF approval: TWD 700,000; the fee for Inspections listed above, inclusive of fee for documentation review (TWD 60,000) and on-site inspection (TWD 540,000 or 640,000).Additional fee will be charged as below when there is an additional dosage form, biological drug, or active pharmaceutical ingredient:
(1)Non-sterile products in the same premises, HVAC system and water system: TWD 35,000.
(2)Non-sterile products in the same premises, but with different HVAC system and water system: TWD 50,000.
(3)Sterile products in the same premises, but with different HVAC system or water system: TWD 88,000.
(4)Non-sterile products in the same premises, but with different HVAC system and water system: TWD 70,000.
(5)Sterile products in the same premises, but with different HVAC system and water system: TWD 105,000.
(6)Non-sterile products in different premises: TWD 105,000.
(7)Sterile products in different premises: TWD 105,000.
4.Follow-up inspection: TWD 600,000; Additional fee will be charged when there is an additional dosage form, biological drug, or active pharmaceutical ingredient shall apply mutatis mutandis the Item 2-3 of Subparagraph 7.
5.A change of Taiwan agent of GMP approval letter: TWD 20,000.
6.A change of GMP approval letter (shall be limited in items neither a change of Taiwan agent nor subjected to inspection, according to the Regulations of Medicament Manufacturer): TWD 10,000.
VIII.Medical Devices
(I).Registration for a medical device with new mechanism, new structure, new material, new function, or with no similar predicate: TWD 65,000.
(II).Registration for a class I medical device and for an export only medical device: TWD 10,000.
(III).Registration for a class II medical device: TWD 25,000.
(IV).Registration for a class III medical device : TWD 38,000.
(V).Consultation of the regulatory classification and applicable regulations of a medical device: TWD 2,000.
(VI).Initial or follow-up inspection of a domestic medical device manufacturer: TWD 38,000.
(VII).Initial or follow-up review of the quality system documentation (QSD) of a foreign medical device manufacturer: TWD 38,000.
(VIII).Inspection for addition of new product item(s) or site-relocation of a domestic medical device manufacturer: TWD 38,000.

(IX).Other change(s) of registered information of a medical device manufacturing license: TWD 8,000.
(X).Registration of a class III in vitro diagnostic medical device (new item): TWD 70,000.
(XI).Registration of a class III in vitro diagnostic medical device (similar item): TWD 40,000.
(XII).Application of medical device raw material for manufacturer' s own use: TWD 5,000.
IX.Medical Device Clinical Trials
(I).Review of a medical device clinical trial protocol: TWD 30,000.
(II).Inspection of a medical device clinical report: TWD 50,000.
(III).Evaluation of implementation of a medical device clinical trial: TWD 10,000.
(IV).Review of change(s) of a medical device clinical trial: TWD 5,000.
X.The post-approval change and extension or reissue due to damage or loss of drug licenses
(I).Site change or additional active pharmaceutical ingredient manufacturer of biologic drug, or biologic drug product manufacturing site change: TWD 150,000.
(II).Change in new indication, new administration dosage, new category or new excipient: TWD 100,000.
(III).Change in contract manufacturing, place of production or manufacturing-site relocation: TWD 30,000.
(IV).Change in transfer or merger: TWD 20,000.
(V).Changes other than previous 4 items: TWD 10,000.
(VI).Reissue of the license, approved label or package insert: TWD 8,000.
(VII).Extension of a drug license: TWD 8,000.
XI.The post-approval change and extension or reissue due to damage or loss of medical device licenses
(I).Change in intended use: TWD 30,000.
(II).Change in specification: TWD 25,000; change in specification without involving safety and effectiveness evaluation: TWD 15,000.
(III).Change in transfer, merger, place of production or manufacturing-site relocation: TWD 15,000.
(IV).Other changes or application for contract packaging: TWD 8,000.
(V).Reissue of a license, approved label or package insert: TWD 8,000.
(VI).Extension of a medical device license: TWD 6,000.
XII.Application of the authorization for import or export of drugs and medical devices: TWD 2,500.
XIII.Related certificates and reference letters of drug and medical devices
(I).Free Sale Certificate (FSC) in Chinese: TWD 1,500.
(II).FSC in English: TWD 1,500.
(III).GMP certificate in Chinese: TWD 1,500.
(IV).GMP certificate in English: TWD 1,500.
(V).Reference letter of clinical trial, BA and BE study in Chinese: TWD 1,500.
(VI).Reference letter of clinical trial, BA and BE study in English: TWD 1,500.
(VII).Reissue of medicament manufacturing license, reference letter and approval letter: TWD 1,500.
XIV.Collection of a medicament license (initial issuance, reissuance and replacement included): TWD 1,500.
XV.Letter of inquiry
(I).Inquiry about registration of drug (clinical trial included), medical device (clinical trial included) and quality inspection of medicament manufacturer: TWD 2,500.
(II).Inquiry about application of drug counseling project: TWD 15,000.

(III).Inquiry about retrieving data from national adverse drug/device reaction database: TWD 2,500.
XVI.Inspection of a foreign medical device manufacturer
(I).Initial or follow-up inspection: TWD 600,000.
(II).Inspection for addition of new product item(s): TWD 600,000.
(III).Inspection for site-relocation of manufacturer: TWD 600,000.
(IV).The fee for inspection listed above, inclusive of fee for documentation review (TWD 60,000) and fee for onsite inspection (TWD 540,000). Additional fee will be charged as below when there is an additional medical device item:
1.In the same-premise: TWD 35,000.
2.In different premise: TWD 105,000.
(V).Additional fee of TWD 105,000 will be charged when there is an additional sterilization process.
XVII.Good Clinical Practice (GCP) on-site inspection
(I).Clinical trial's (BA/BE study included) foreign GCP on-site inspection: TWD 500,000 for each country; this provision shall also apply to Mainland area
(II).Clinical trial's (BA/BE study included) domestic GCP on-site inspection: TWD 30,000 for each time.
Applications of the change listed in the Item 1 and 3 of Subparagraph 10 and Item 3 of Subparagraph 11 of preceding Paragraph are limited to one manufacturing site per application.
Applications of the certificates and reference letters listed in Subparagraph 13 of Paragraph 1 are limited to three copies per set for each application.
Applications of FSC listed in Item 1 and 2 of Subparagraph 13 of Paragraph 1 are limited to one license for each application.

Article 3 The cost of inspector(s) and experts when executing the jobs described in the Item 2 - 3、4 of Subparagraph 7, Subparagraph 16, and Item 1 of Subparagraph 17 of Paragraph 1 of Article 2 should be calculated based on the Guidance for Reimbursement for Overseas Traveling Expenses, and paid by the applicant to the central competent health authority.

Article 4 These standards shall be implemented from July 1st, 2015.