List of Revised Fees for Health Products

Revised fees are applicable to applications submitted on and after 1 July 2022

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Medical Devices Registration, Manufacture, Import and Wholesale

Medical Devices Registration, Licences and Change Notification

PRODUCT REGISTRATION AND EVALUATION FEES FOR MEDICAL DEVICES	Revised Fees *(effective 1 July 2022)*
Class B	
(i) Application fee	$530
(ii) Immediate route fee	$950
(iii) Abridged route fee	$1,910
(iv) Full route fee	$3,710
Class C	
(i) Application fee	$530
(ii) Immediate route fee	$3,180
(iii) Expedited route fee	$3,180
(iv) Abridged route fee	$3,710
(v) Full route fee	$6,050
Class D	
(i) Application fee	$530
(ii) Expedited route fee	$5,730
(iii) Abridged route fee	$6,050
(iv) Full route fee	$11,800
Class D with a registrable drug	
(i) Application fee	$530
(ii) Abridged route fee	$10,400
(iii) Full route fee	$75,400

PRIORITY REVIEW SCHEME PRODUCT REGISTRATION	Revised Fees *(effective 1 July 2022)*
Class B	
Application fee	$530
Full route (Priority Review Scheme Route 1)	$4,220
Full route (Priority Review Scheme Route 2)	$5,460

List of Revised Fees for Health Products

Revised fees are applicable to applications submitted on and after 1 July 2022

PRIORITY REVIEW SCHEME PRODUCT REGISTRATION	**Revised Fees** *(effective 1 July 2022)*
Class C	
Application fee	$530
Full route (Priority Review Scheme Route 1)	$6,800
Full route (Priority Review Scheme Route 2)	$8,800
Class D	
Application fee	$530
Full route (Priority Review Scheme Route 1)	$13,400
Full route (Priority Review Scheme Route 2)	$17,300

ANNUAL RETENTION FEES FOR MEDICAL DEVICES LISTED ON SINGAPORE MEDICAL DEVICE REGISTER (SMDR)	**Revised Fees** *(effective 1 July 2022)*
Class B	$37
Class C	$64
Class D	$128
Class D with a registrable drug	$128

MANUFACTURER'S AND DEALER'S LICENCE APPLICATION AND AMENDMENT	**Revised Fees** *(effective 1 July 2022)*
New application for or annual renewal of manufacturer's and dealer's licence	
Manufacturer	$1,060
Importer	$1,060
Wholesaler	$1,060
Amendment application for manufacturer's and dealer's licence	
Manufacturer	$160
Importer	$160
Wholesaler	$160

CHANGE NOTIFICATION	Revised Fees *(effective 1 July 2022)*
Class B	
Administrative Changes	$530
Review Changes	$530
Class C	
Administrative Changes	$530
Technical Changes	$1,800
Class D (including devices with a registrable drug)	
Administrative Changes	$530
Technical Changes	$2,970

Other Medical Devices Applications

FREE SALE CERTIFICATES	Revised Fees *(effective 1 July 2022)*
Application fee	$54
Processing fee for one device and one country	$54
Processing fee for each additional device	$54
Processing fee for each additional country	$54

CHANGE OF REGISTRANT	Revised Fees *(effective 1 July 2022)*
Application fee for change of registrant	$840

SPECIAL ACCESS ROUTES	Revised Fees *(effective 1 July 2022)*
Unregistered devices requested by qualified practitioners	$160
Unregistered devices requested by a licensed PHMC	$370
Import for re-export of unregistered devices	$266
Unregistered devices for non-clinical purpose	$266

Therapeutic Products Registration and Post-approval Variation

PRODUCT REGISTRATION FOR NEW DRUG APPLICATION (NDA)	Revised Fees *(effective 1 July 2022)*
a) Screening Fee	
(i) Abridged/Verification Evaluation Route	$580
(ii) Full Evaluation Route	$2,910
b) Evaluation Fee	
(i) Abridged Evaluation Route	
- NDA-1 & NDA-2	$11,400
- NDA-3	$5,830
(ii) Verification Evaluation Route	
- NDA-1 & NDA-2	$16,900
- NDA-3	$5,830
(iii) Full Evaluation Route* - NDA-1, NDA-2 & NDA-3 **All fees for full evaluation route are charged per NDA submission package which can contain one or more NDA to register the product or product line.*	$82,900
c) Annual retention fee (per registered product)	$318

PRODUCT REGISTRATION FOR GENERIC DRUG APPLICATION (GDA)	Revised Fees *(effective 1 July 2022)*
a) Screening Fee	
(i) Abridged/Verification Evaluation Route	$580
b) Evaluation Fee	
(i) Abridged Evaluation Route	
- GDA-1	$4,080
- GDA-2	$2,330

PRODUCT REGISTRATION FOR GENERIC DRUG APPLICATION (GDA)	Revised Fees *(effective 1 July 2022)*
(ii) GDA Verification Evaluation Route	
- GDA-1	$10,400
- GDA-2	$5,300
(iii) GDA Verification Evaluation Route (CECA Scheme)	
- GDA-1	$10,400
- GDA-2	$5,300
c) Annual retention fee (per registered product)	$318

POST APPROVAL VARIATION APPLICATION	Revised Fees *(effective 1 July 2022)*
a) Major Variation Application (MAV-1)	
(i) Screening Fee	
- Abridged/Verification Evaluation Route	$530
- Full Evaluation Route	$2,650
(ii) Evaluation Fee	
- Abridged Evaluation Route	
- for first strength	$5,830
- for subsequent strength	$2,910
- Verification Evaluation Route	
- for first strength	$8,650
- for subsequent strength	$2,910
- Full Evaluation Route	$51,400
b) MIV-1	
- Abridged/ Verification Evaluation Route	$580

CONSIGNMENT APPROVAL	Revised Fees *(effective 1 July 2022)*
Import and supply of registered Therapeutic Product on consignment basis	$266 per consignment

Therapeutic Products Manufacture, Import and Wholesale

Manufacturer's Licence for Therapeutic Products

MANUFACTURER'S LICENCE FOR THERAPEUTIC PRODUCTS	Revised Fees *(effective 1 July 2022)*
Application Fee for, or for Renewal of, a Manufacturer's Licence for:	
(a) manufacture of external preparations only (non-sterile)	$1,590
(b) manufacture of oral preparations only (non-sterile)	$1,590
(c) manufacture of external and oral preparations only (non-sterile)	$2,120
(d) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in paragraphs (a), (b), (c)	$3,180
(e) primary packaging only (with or without secondary)	$1,060
(f) secondary packaging only	$630
Application Fee for Amending a Manufacturer's Licence:	
(a) without site inspection	$54
(b) with site inspection for a manufacturer carrying out packaging only	$530
(c) with site inspection for all other manufacturers	$1,060

Importer's and Wholesaler's Licence for Therapeutic Products

IMPORTER'S LICENCE FOR THERAPEUTIC PRODUCTS	Revised Fees *(effective 1 July 2022)*
Application fee for, or for renewal of, an importer's licence for:	
(a) any therapeutic product (full scope)	$530
(b) any therapeutic product imported under the following restricted activities only (limited scope); (i) for non-clinical purpose (ii) for export only (iii) for supply to a ship or an aircraft leaving Singapore	$212 (annual licence for multiple consignments) $106 (licence per consignment only)

IMPORTER'S LICENCE FOR THERAPEUTIC PRODUCTS	Revised Fees *(effective 1 July 2022)*
Application fee for amending an importer's licence:	
(a) without site inspection	$54
(b) with site inspection (full scope)	$318

WHOLESALER'S LICENCE FOR THERAPEUTIC PRODUCTS	Revised Fees *(effective 1 July 2022)*
Application fee for, or for renewal of, a wholesaler's licence for any therapeutic product	$530
Application fee for amending a wholesaler's licence:	
(a) without site inspection	$54
(b) with site inspection	$318

BUNDLED NEW AND RENEWAL FEE FOR IMPORTER'S LICENCE AND WHOLESALER'S LICENCE FOR THERAPEUTIC PRODUCTS	Revised Fees *(effective 1 July 2022)*
Bundled new and renewal fee of the importer's licence (full scope) and the wholesaler's licence	$950

GMP Conformity Assessment for Therapeutic Products

GOOD MANUFACTURING PRACTICE (GMP) CONFORMITY ASSESSMENT OF OVERSEAS MANUFACTURERS OF THERAPEUTIC PRODUCTS	Revised Fees *(effective 1 July 2022)*
GMP Evidence Evaluation (per manufacturing site)	$630
Quality System Dossier (QSD) Evaluation (per manufacturing site)	$4,770
On-site GMP audit of a manufacturer located in:	
(a) an ASEAN country (per manufacturing site)	$18,400
(b) an Asian country (outside of ASEAN) (per manufacturing site)	$20,400
(c) a country outside of Asia (per manufacturing site)	$24,400

Other Therapeutic Product / Medicinal Product / Active Pharmaceutical Ingredient Certificates (GMP / GDP Certificates, CPP etc)

GMP Certificate for Therapeutic Product / Medicinal Product / Active Pharmaceutical Ingredient

GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE	**Revised Fees** *(effective 1 July 2022)*
Application for GMP Certificate (valid for 3 years)	$6,370
Each additional GMP certificate not requiring further assessment	$212

GDP Certificate for Therapeutic Product / Medicinal Product / Active Pharmaceutical Ingredient

GOOD DISTRIBUTION PRACTICE (GDP) CERTIFICATE	**Revised Fees** *(effective 1 July 2022)*
Application for GDP certificate (valid for 3 years)	$3,710
Each additional GDP certificate not requiring further assessment	$212

Certificate of A Pharmaceutical Product (CPP)

CERTIFICATE OF A PHARMACEUTICAL PRODUCT	**Revised Fees** *(effective 1 July 2022)*
Application for Certificate for a Pharmaceutical Product (CPP)	$106

Statement of Licensing Status

STATEMENT OF LICENSING STATUS (SLS)	**Revised Fees** *(effective 1 July 2022)*
Application for Statement of Licensing Status (SLS)	$106

Controlled Drugs / Psychotropic Substances Licences and Authorisation

LICENCES AND AUTHORISATIONS FOR CONTROLLED DRUGS / PSYCHOTROPIC SUBSTANCES	Revised Fees *(effective 1 July 2022)*
Licence to Manufacture Controlled Drugs	
Application for a licence to manufacture controlled drugs	$530
Application to amend the licence (a) with site inspection (b) without site inspection	 $212 $54
Applications to Import and Export Restricted / Psychotropic Substances, Licence to Import / Export Controlled Drugs and Licence to Sell Controlled Drugs	
Application for licence to sell controlled drugs by wholesale	$530
Application to amend the licence to sell controlled drugs by wholesale (a) with site inspection (b) without site inspection	 $212 $54
Application for a licence to import controlled drugs	$106
Application for a licence to export controlled drugs	$106
Application for approval to import therapeutic products (including clinical research materials) containing psychotropic substances or confirmation of authorisation to import a psychotropic substance	$106
Application for approval to export therapeutic products (including clinical research materials) containing psychotropic or export licence for psychotropic substances	$106
Application for certificate of approval for import of a therapeutic product or confirmation of authorisation to import a restricted substance	$106

Form A Poisons Licence

FORM A POISONS LICENCE FOR NON-PHARMACISTS	Revised Fees *(effective 1 July 2022)*
Application for Form A Poisons Licence (FAPL)	$276
Form A Poisons Licence (1-year validity)	$106
Application to amend FAPL	$37

Note:

- *Application fee and licence fee for FAPL are both payable for each year of issue*
- *Currently, the chargeable fee for pharmacist applicants is waived*

Chinese Proprietary Medicines Dealer's Licences and Certificates

LICENCES AND CERTIFICATES OF CHINESE PROPRIETARY MEDICINES	Revised Fees *(effective 1 July 2022)*
Import Licence	
Application fee for a new licence	$530
Licence fee for each subsequent year	$530
Application to amend a licence	
(a) with site inspection	$318
(b) without site inspection	$54
Wholesale Dealer's Licence	
Application fee for a new licence	$530
Licence fee for each subsequent year	$530
Application to amend a licence	
(a) with site inspection	$318
(b) without site inspection	$54
Manufacturer's Licence	
Application fee for a new licence for	
(a) Manufacture of either an external preparation OR oral preparation	$1,590
(b) Manufacture of both an external preparation AND oral preparation	$2,120
(c) Primary assembly	$1,060
(d) Secondary assembly only	$630
Licence fee for	
(a) Each subsequent year for	
(i) A manufacturer of either an external preparation OR oral preparation	$1,590
(ii) A manufacturer of both an external preparation AND oral preparation	$2,120
(iii) A primary assembler	$1,060
(iv) A secondary assembler	$630
Application to amend a licence	
(a) with site inspection (for manufacturers)	$1,060
(b) with site inspection (for assemblers)	$530
(c) without site inspection (for manufacturers/ assemblers)	$54

LICENCES AND CERTIFICATES OF CHINESE PROPRIETARY MEDICINES	Revised Fees *(effective 1 July 2022)*
Certificate for Export	
Certificate for Exporter of Chinese Proprietary Medicines (Free Sale Certificate)	$106
Good Manufacturing Practice (GMP) Certificates	
GMP certificate (valid for 3 years)	$6,370
Each additional GMP certificate not requiring further assessment	$212

Cosmetic Products Notification and GMP Certificate

NOTIFICATION AND GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE FOR COSMETIC PRODUCTS	Revised Fees *(effective 1 July 2022)*
a) Notification and re-notification of cosmetic products for application around the eyes or on the lips, for oral or dental care or hair dyes containing diamine compounds	
(a) Single product or each of the first 3 variants of a product	$27
(b) Each of the 4th and subsequent variants of a product	$7
b) Notification and re-notification of other cosmetic products not described above in a)	
(a) Single product or each of the first 3 variants of a product	$12
(b) Each of the 4th and subsequent variants of a product	$7
Good Manufacturing Practice (GMP) Certificate	
(a) Application for a GMP Certificate	$4,240
(b) Application for each additional GMP Certificate which does not require further assessment of conformity with any Good Manufacturing Practice Standard	$212

Oral Dental Gum Registration, Manufacture, Import and Wholesale

REGISTRATION, MANUFACTURE, IMPORT AND WHOLESALE OF ORAL DENTAL GUM	Revised Fees *(effective 1 July 2022)*
Registration	
Application fee for registration of an oral dental gum	$17
Annual retention fee for registration of an oral dental gum	$12
Application fee for the Authority's approval of any change concerning a registered oral dental gum mentioned in regulation 25(1) of the Health Products (Oral Dental Gums) Regulations	$17
Manufacture, Import and Wholesale	
Application fee for, or to renew:	
- A manufacturer's licence	$840
- An importer's licence	$840
- A wholesaler's licence	$840
- An importer's licence and a wholesaler's licence	$1,060
Application fee for the Authority's approval of any change affecting a licence mentioned in regulation 24(1) or (2) of the Health Products (Oral Dental Gums) Regulations	$17

Retail Pharmacy Licence

RETAIL PHARMACY LICENCE	Revised Fees *(effective 1 July 2022)*
Application fee for, or for renewal of, a pharmacy licence	$530
Application fee for the Authority's approval under Regulation 3(1)(b)(ii) or 4(1)(b)* in respect of a retail pharmacy if made on a separate occasion from an application for a pharmacy licence in respect of that same retail pharmacy	$318
Amend retail pharmacy licence	
(a) With site inspection	$318
(b) Without site inspection	$54
* Note for the Health Products (Licensing of Retail Pharmacies) Regulations: Regulation 3(1)(b)(ii) indicates the supply by retail sale of any specified health products via special mode (e.g. secured box for self-collection) Regulation 4(1)(b) is for the regulation of telepharmacy services	

Medical Advertisements & Sales Promotion

PERMITS FOR MEDICAL ADVERTISEMENT & SALES PROMOTION	Revised Fees *(effective 1 July 2022)*
Application for a permit for:	
(a) a still media advertisement	$106
(b) a sound media advertisement	$106
(c) a light and sound media advertisement	$212
(d) a sales promotion	$106
Permit for:	
(i) the first year for	
(a) a still media advertisement	$106
(b) a sound media advertisement	$106
(c) a light and sound media advertisement	$106
(d) a sales promotion	$106
(ii) each subsequent year for	
(a) a still media advertisement	$212
(b) a sound media advertisement	$212
(c) a light and sound media advertisement	$318
(d) a sales promotion	$212
Application to amend a permit	$54
Transfer of medical advertisement/ sales promotion permit	$17