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No. S 450

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (FEES) REGULATIONS 2022

ARRANGEMENT OF REGULATIONS

In exercise of the powers conferred by section 71 of the Health Products Act 2007, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Fees) Regulations 2022 and come into operation on 1 July 2022.

Definitions

2. In these Regulations, unless the context otherwise requires —

"clinical research material" has the meaning given by regulation 2(1) of the CRM Regulations;

"CP-ACD Regulations" means the Health Products (Cosmetic Products — ASEAN Cosmetic Directive) Regulations 2007 (G.N. No. S 683/2007);

"CRM Regulations" means the Health Products (Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016);

"CTGT product" means a health product categorised as a cell, tissue or gene therapy product in the First Schedule to the Act;

"CTGTP Regulations" means the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021);

"GMPC-CP Regulations" means the Health Products (Good Manufacturing Practice Certificate — Cosmetic Products) Regulations 2011 (G.N. No. S 543/2011);

"LRP Regulations" means the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

"MD Regulations" means the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010);

"medical device" means a health product categorised as a medical device in the First Schedule to the Act;

"ODG Regulations" means the Health Products (Oral Dental Gums) Regulations 2016 (G.N. No. S 539/2016);

"oral dental gum" means a health product categorised as an oral dental gum in the First Schedule to the Act;

"retail pharmacy" has the meaning given by regulation 2 of the LRP Regulations;

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act;

"TP Regulations" means the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016).

Fees payable to Authority

3.—(1) The fees specified in the First Schedule are payable to the Authority for the manufacture, import, supply and registration of CTGT products under the CTGTP Regulations.

(2) The fees specified in the Second Schedule are payable to the Authority for the manufacture, import and supply of clinical research material under the CRM Regulations.

(3) The fees specified in the Third Schedule are payable to the Authority for the submission of a notification under regulation 4 of the CP-ACD Regulations.

(4) The fees specified in the Fourth Schedule are payable to the Authority for an application for a certificate under regulation 3 of the GMPC-CP Regulations.

(5) The fees specified in the Fifth Schedule are payable to the Authority in relation to retail pharmacies and the supply of certain health products under the LRP Regulations.

(6) The fees specified in the Sixth Schedule are payable to the Authority for the manufacture, import, supply and registration of medical devices under the MD Regulations.

(7) The fees specified in the Seventh Schedule are payable to the Authority for the manufacture, import, supply, registration and advertisement of oral dental gums under the ODG Regulations.

(8) The fees specified in the Eighth Schedule are payable to the Authority for the manufacture, import, supply and registration of therapeutic products under the TP Regulations.

Time for payment of fees

4.—(1) An application fee mentioned in any of the Schedules must be paid when the application is submitted to the Authority.

(2) An approval fee in respect of any advertisement, including any variation of an approved advertisement or transfer of approval of an advertisement, specified in the Seventh Schedule must be paid when the application for the advertisement is submitted to the Authority.

(3) An evaluation fee for the registration of a health product specified in the First, Sixth or Eighth Schedule is payable upon the Authority's acceptance of the respective health product for evaluation after the Authority has conducted an initial screening.

(4) For the purposes of section 31(*a*) of the Act, the prescribed retention fee is specified in the First, Sixth, Seventh and Eighth Schedules and is payable on or before each anniversary of the date of registration of the respective health product.

Waiver or refund of fees

5. The Authority may, in any particular case or class of cases, waive or refund the whole or any part of any fee payable or paid under any of the Schedules.

FIRST SCHEDULE

Regulations 3(1) and 4(3) and (4)

PART 1

FEES FOR MANUFACTURE, IMPORT, SUPPLY AND REGISTRATION OF CTGT PRODUCTS

1.	Application fee for a manufacturer's licence for —	
	(*a*) manufacture of any CTGT product	$22,000
	(*b*) secondary packaging only	$10,600
2.	Application fee for renewal of a manufacturer's licence for —	
	(*a*) manufacture of any CTGT product	$13,400
	(*b*) secondary packaging only	$3,600
3.	Application fee for amending a manufacturer's licence —	
	(*a*) without technical assessment (for manufacture of any CTGT product)	$180
	(*b*) without technical assessment (for secondary packaging only)	$180
	(*c*) with technical assessment (for manufacture of any CTGT product)	$5,100
	(*d*) with technical assessment (for secondary packaging only)	$2,700

FIRST SCHEDULE — *continued*

4. Application fee for an importer's licence —	
(*a*) for any unregistered CTGT product imported for a named patient —	
(i) where the import is made in the circumstances described in regulation 9(*a*)(i) of the CTGTP Regulations (import on behalf of nursing home licensee or healthcare service licensee)	$230
(ii) where the import is made in the circumstances described in regulation 9(*a*)(ii) of the CTGTP Regulations (import by nursing home licensee, healthcare service licensee or holder of pharmacy licence)	$230
(*b*) for any CTGT product imported —	
(i) where the product is intended to be supplied solely for scientific education or research and development, or for a non-clinical purpose	$210
(ii) where the product is imported solely for export	$210
(*c*) where the CTGT product is authorised for import by a registrant of the CTGT product	$1,400
5. Application fee for renewal of an importer's licence —	
(*a*) for any CTGT product imported —	
(i) where the product is intended to be supplied solely for scientific education or research and development, or for a non-clinical purpose	$210
(ii) where the product is imported solely for export	$210
(*b*) where the CTGT product is authorised for import by a registrant of the CTGT product	$520

FIRST SCHEDULE — *continued*

6. Application fee for an importer's licence for a consignment of any CTGT product imported, where the product is intended to be supplied solely for scientific education or research and development, or for a non-clinical purpose, or solely for export	$110 per consignment
7. Application fee for an importer's licence for a consignment of any CTGT product imported, where the product is in all respects the same as a registered CTGT product and the registrant of which has not authorised the applicant to import that CTGT product	$260 per consignment
8. Application fee for amending an importer's licence —	
(*a*) without technical assessment	$120
(*b*) with technical assessment	$1,100
9. Application fee for a wholesaler's licence for any CTGT product	$1,400
10. Application fee for renewal of a wholesaler's licence for any CTGT product	$520
11. Application fee for amending a wholesaler's licence —	
(*a*) without technical assessment	$120
(*b*) with technical assessment	$1,100
12. Application fee for an importer's licence and a wholesaler's licence for any CTGT product	$2,500
13. Application fee for renewal of an importer's licence and a wholesaler's licence for any CTGT product	$940
14. Submission of a notice relating to activities involving a CTGT product that is a result of only minimal manipulation under one of the following regulations:	
(*a*) regulation 4(2)(*c*) of the CTGTP Regulations (manufacture)	$90
(*b*) regulation 7(2)(*c*) of the CTGTP Regulations (import)	$90
(*c*) regulation 10(2)(*c*) of the CTGTP Regulations (wholesale)	$90

FIRST SCHEDULE — *continued*

15. Registering one or more CTGT products which have not yet been approved by any competent drug regulatory agency and for which the Authority will conduct a full evaluation:	
(*a*) application fee for the initial screening	$2,900
(*b*) evaluation fee	$82,700
16. Registering a CTGT product which is approved by at least one comparable overseas regulator and for which the Authority will conduct an abridged evaluation:	
(*a*) application fee for the initial screening (for each product)	$570
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$13,700
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,700
17. Submission of a notice relating to the supply of a Class 1 CTGT product under regulation 16(2) of the CTGTP Regulations	$90
18. Application fees, in addition to the fees in items 15 and 16 (as the case may be), for overseas manufacturers:	
(*a*) for verification of compliance with Good Manufacturing Practice Standard	$620
(*b*) for on-site inspection	$31,500
19. Application fees, in addition to the fees in items 15 and 16, for verification of compliance with principles of good clinical practice and inspection overseas	$11,200
20. Annual retention fee for the retention of the registration of a CTGT product	$310
21. For the Authority's approval —	
(*a*) to make a major variation to a registered CTGT product, for which the Authority will conduct a full evaluation:	

FIRST SCHEDULE — *continued*

(i) application fee for the initial screening for a series of products of the same proprietary name	$2,600
(ii) evaluation fee for a series of products of the same proprietary name	$51,200
(*b*) to make a major variation to a registered CTGT product, for which the Authority will conduct an abridged evaluation:	
(i) application fee for the initial screening (for each product)	$520
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$7,700
(iii) evaluation fee for each subsequent product in a series of products of different strengths	$2,900
22. Application fee for the Authority's approval to make any other variations to a registered CTGT product where such approval is required	$2,600
23. Submission of a notice to the Authority to make any other variation to a registered CTGT product where such a submission is required	$380
24. Application fee for the Authority's approval to change the registrant of a registered CTGT product	$150
25. Application fee for the following certificates or documents:	
(*a*) certificate of registration or compliance under regulation 52 of the CTGTP Regulations for a CTGT product intended for export	$110
(*b*) a GMP Certificate (with technical assessment)	$22,000
(*c*) a GMP Certificate (without technical assessment)	$210
(*d*) a GDP Certificate (with technical assessment)	$3,700
(*e*) a GDP Certificate (without technical assessment)	$210

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FIRST SCHEDULE — *continued*

PART 2

DEFINITIONS

In this Schedule —

"Authority's website" has the meaning given by regulation 2(1) of the CTGTP Regulations;

"Class 1 CTGT product" has the meaning given by regulation 2(1) of the CTGTP Regulations;

"comparable overseas regulator" means a national regulatory authority specified on the Authority's website;

"competent drug regulatory agency" means a national regulatory authority participating in the World Health Organization's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and listed as such on the World Health Organization's website;

"container" has the meaning given by regulation 2(1) of the CTGTP Regulations;

"GDP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Distribution Practice Standard;

"GMP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Manufacturing Practice Standard;

"Good Distribution Practice Standard" means the Authority's Guidance Notes on Good Distribution Practice and any other good distribution practice standard approved by the Authority;

"Good Manufacturing Practice Standard" has the meaning given by regulation 2(1) of the CTGTP Regulations;

[*Deleted by S 438/2023 wef 26/06/2023*]

"healthcare service licensee" has the meaning given by regulation 2(1) of the CTGTP Regulations;

[S 438/2023 wef 26/06/2023]

"major variation", in relation to a CTGT product, means any change relating to the intended purpose or recommended dosage of, patient groups for, or clinical trial information on, the CTGT product;

"minimal manipulation" has the meaning given by regulation 2(1) of the CTGTP Regulations;

FIRST SCHEDULE — *continued*

"non-clinical purpose" has the meaning given by regulation 2(1) of the CTGTP Regulations;

"nursing home licensee" has the meaning given by regulation 2(1) of the CTGTP Regulations;

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"principles of good clinical practice", in relation to a CTGT product, has the meaning given by the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016);

"proprietary name" has the meaning given by regulation 2(1) of the CTGTP Regulations;

"secondary packaging", in relation to a CTGT product that is already enclosed in the container in which it is to be sold or supplied, means —

(*a*) the labelling of the container, or enclosure of the container with other packaging material (including product informational inserts); or

(*b*) the labelling of the packaging material before the product is sold or supplied in it.

SECOND SCHEDULE

Regulation 3(2)

PART 1

FEES FOR MANUFACTURE, IMPORT AND SUPPLY OF CLINICAL RESEARCH MATERIAL

1.	Application fee for approval to import or export clinical research material containing psychotropic substances	$106 per consignment
2.	Application fee for each of the following certificates or documents for a therapeutic product:	
	(*a*) a GMP Certificate	$6,370
	(*b*) each additional copy of a GMP Certificate	$212
	(*c*) a GDP Certificate	$3,710
	(*d*) each additional copy of a GDP Certificate	$212
3.	Application fee for each of the following certificates or documents for a CTGT product, or an active substance or	

SECOND SCHEDULE — *continued*

starting material used in the manufacture of a CTGT product:

(*a*)	a GMP Certificate (with technical assessment)	$22,000
(*b*)	a GMP Certificate (without technical assessment)	$210
(*c*)	a GDP Certificate (with technical assessment)	$3,700
(*d*)	a GDP Certificate (without technical assessment)	$210

PART 2

DEFINITIONS

In this Schedule —

"active substance" has the meaning given by regulation 2(1) of the CRM Regulations;

"GDP Certificate" has the meaning given by regulation 22(4) of the CRM Regulations;

"GMP Certificate" has the meaning given by regulation 21(4) of the CRM Regulations;

"psychotropic substance" means a substance specified in the First Schedule to the TP Regulations.

THIRD SCHEDULE

Regulation 3(3)

PART 1

FEES FOR SUBMISSION OF NOTIFICATION UNDER HEALTH PRODUCTS (COSMETIC PRODUCTS — ASEAN COSMETIC DIRECTIVE) REGULATIONS 2007

1. In relation to —

(*a*) any product intended for application around the eyes or on the lips;

(*b*) any oral or dental care product; or

(*c*) any hair dye containing diamine compounds,

for —

THIRD SCHEDULE — *continued*

(*d*) a new notification or further notification under regulation 4(1)(*b*) of the CP-ACD Regulations for a single product or each of the first 3 variants of a product; or	$27
(*e*) a new notification or further notification under regulation 4(1)(*b*) of the CP-ACD Regulations for each of the fourth and subsequent variants of a product	$7

2. In relation to any product not mentioned in item 1 —

(*a*) for a new notification or further notification under regulation 4(1)(*b*) of the CP-ACD Regulations for a single product or each of the first 3 variants of a product; or	$12
(*b*) for a new notification or further notification under regulation 4(1)(*b*) of the CP-ACD Regulations for each of the fourth and subsequent variants of a product	$7

PART 2

DEFINITIONS

In this Schedule —

"base formulation" means a partial cosmetic formulation shared by 2 or more cosmetic preparations manufactured by the same manufacturer and intended for the same use;

"variant" means a cosmetic preparation that is largely similar in composition to another cosmetic preparation (usually having a common base formulation) but having a different colour, shade, flavour, fragrance or other inherent characteristic apart from the base formulation.

FOURTH SCHEDULE

Regulation 3(4)

PART 1

FEES FOR APPLICATION FOR CERTIFICATE UNDER HEALTH PRODUCTS (GOOD MANUFACTURING PRACTICE CERTIFICATE — COSMETIC PRODUCTS) REGULATIONS 2011

1.	Application fee for a GMP Certificate	$4,240
2.	Application fee for each additional copy of a GMP Certificate which does not require further assessment of conformity with any Good Manufacturing Practice Standard	$212

PART 2

DEFINITIONS

In this Schedule —

"Good Manufacturing Practice Standard" has the meaning given by regulation 2 of the GMPC-CP Regulations;

"GMP Certificate" has the meaning given by regulation 2 of the GMPC-CP Regulations.

FIFTH SCHEDULE

Regulation 3(5)

PART 1

FEES FOR RETAIL PHARMACIES AND SUPPLY OF CERTAIN HEALTH PRODUCTS

1.	Application fee for, or for renewal of, a pharmacy licence	$530
2.	Application fee for the Authority's approval under regulation 3(1)(*b*)(ii) or 4(1)(*b*) of the LRP Regulations 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

FIFTH SCHEDULE — *continued*

3. Application fee for the Authority's approval under regulation 7(1) of the LRP Regulations —	
(*a*) with site inspection	$318
(*b*) without site inspection	$54

PART 2

DEFINITION

In this Schedule, "pharmacy licence" has the meaning given by regulation 2 of the LRP Regulations.

SIXTH SCHEDULE

Regulations 3(6) and 4(3) and (4)

PART 1

FEES FOR MANUFACTURE, IMPORT, SUPPLY AND REGISTRATION OF MEDICAL DEVICES

1. Application fee for registration of —	
(*a*) a Class B medical device	$530
(*b*) a Class C medical device	$530
(*c*) a Class D medical device	$530
2. Application fee for evaluation of a medical device for registration, in a case where the medical device is proposed to be classified as —	
(*a*) a Class B medical device —	
(i) by evaluation under an abridged evaluation process mentioned in regulation 26(2) of the MD Regulations	$1,910
(ii) which is immediately registered under regulation 26(4) of the MD Regulations	$950
(iii) which is immediately registered under regulation 26(4A) of the MD Regulations	$950
(iv) by evaluation under a full evaluation process	$3,710

SIXTH SCHEDULE — *continued*

(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3C) of the MD Regulations	$4,220
(vi) by evaluation under a priority full evaluation process mentioned in regulation 26(3D) of the MD Regulations	$5,460
(*b*) a Class C medical device —	
(i) by evaluation under an abridged evaluation process mentioned in regulation 26(2) of the MD Regulations	$3,710
(ii) by evaluation under a full evaluation process	$6,050
(iii) by evaluation under an expedited abridged evaluation process mentioned in regulation 26(3) of the MD Regulations	$3,180
(iv) by evaluation under a priority full evaluation process mentioned in regulation 26(3C) of the MD Regulations	$6,800
(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3D) of the MD Regulations	$8,800
(*c*) a Class C medical device that is a standalone mobile application which is immediately registered under regulation 26(4A) of the MD Regulations	$3,180
(*d*) a Class D medical device —	
(i) by evaluation under an abridged evaluation process mentioned in regulation 26(2) of the MD Regulations	$6,050
(ii) by evaluation under a full evaluation process	$11,800
(iii) by evaluation under an expedited abridged evaluation process mentioned in regulation 26(3A) of the MD Regulations	$5,730
(iv) by evaluation under a priority full evaluation process mentioned in regulation 26(3C) of the MD Regulations	$13,400

SIXTH SCHEDULE — *continued*

(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3D) of the MD Regulations	$17,300
(*e*) a medical device that contains a therapeutic product or medicinal product —	
(i) by evaluation under an abridged evaluation process mentioned in regulation 26(2) of the MD Regulations	$10,400
(ii) by evaluation under a full evaluation process	$75,400
3. Annual retention fee for the retention of the registration of —	
(*a*) a Class B registered medical device	$37
(*b*) a Class C registered medical device	$64
(*c*) a Class D registered medical device	$128
4. Fee for application for the Authority's approval of an application made under regulation 49(2) of the MD Regulations —	
(*a*) to make a notification change	Nil
(*b*) to make an administrative change	$530
(*c*) to make a change that may affect the safety, quality or efficacy of —	
(i) a registered Class B medical device	$530
(ii) a registered Class C medical device	$1,800
(iii) a registered Class D medical device	$2,970
5. Fee for application for, or application for renewal of —	
(*a*) a manufacturer's licence	$1,060
(*b*) an importer's licence (other than an importer's licence mentioned in item 8 or 9)	$1,060
(*c*) a wholesaler's licence (other than a wholesaler's licence mentioned in item 8 or 9)	$1,060

SIXTH SCHEDULE — *continued*

6.	Notification fee under regulation 48(2) of the MD Regulations for changes in particulars in relation to —	
	(*a*) a manufacturer's licence	$160
	(*b*) an importer's licence, except an importer's licence mentioned in item 8	$160
	(*c*) a wholesaler's licence, except a wholesaler's licence mentioned in item 8	$160
7.	Fee for application to change registrant of a medical device	$840
8.	Fee for application for an importer's licence or a wholesaler's licence relating to an unregistered medical device —	
	(*a*) by a nursing home licensed under the Private Hospitals and Medical Clinics Act 1980, or a person acting on its behalf, where the unregistered medical device is to be used by a patient of the nursing home	$370
	(*b*) by a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service, or a person acting on the firstmentioned person's behalf, where the unregistered medical device is to be used by a patient of the firstmentioned person	$370
	(*c*) by a qualified practitioner, or a person acting on his or her behalf, where the unregistered medical device is to be used by a patient of the practitioner	$160
	(*d*) where the unregistered medical device is to be used for a non-clinical purpose	$266
9.	Fee for application for an importer's licence or a wholesaler's licence relating to an unregistered medical device solely for export or re-export (being a medical device manufactured solely for export or imported solely for re-export)	$266
10.	Fee for application for any certificate	$54

SIXTH SCHEDULE — *continued*

11. Processing fee in relation to a certificate under regulation 30(1) of the MD Regulations for a medical device intended for export —		
	(*a*) where the application is for a certificate in respect of one medical device and addressed to one country	$54
	(*b*) for each additional medical device that is mentioned in the certificate	$54

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PART 2

DEFINITIONS

In this Schedule —

"administrative change", for any information submitted to the Authority in relation to the registration of a medical device, means a change to (but not a deletion or removal of) such information that is entered in the Register of Health Products in respect of the medical device, where the change does not affect the safety, quality or efficacy of the medical device;

"medicinal product" has the meaning given by regulation 2 of the MD Regulations;

"non-clinical purpose" has the meaning given by regulation 10(2) of the MD Regulations;

"notification change" means —

(*a*) a deletion or removal of any information submitted to the Authority in relation to the registration of a medical device that is entered in the Register of Health Products in respect of the medical device, where the deletion or removal does not affect the safety, quality or efficacy of the medical device; or

(*b*) a change to any other information submitted to the Authority in relation to the registration of a medical device, where the change does not affect the safety, quality or efficacy of the medical device;

"qualified practitioner" has the meaning given by regulation 2 of the MD Regulations.

SEVENTH SCHEDULE

Regulations 3(7) and 4(2) and (4)

PART 1

FEES FOR MANUFACTURE, IMPORT, SUPPLY, REGISTRATION AND ADVERTISEMENT OF ORAL DENTAL GUMS

1.	Application fee for, or to renew, a manufacturer's licence	$840
2.	Application fee for, or to renew, an importer's licence	$840
3.	Application fee for, or to renew, a wholesaler's licence	$840
4.	Application fee for, or to renew, an importer's licence and a wholesaler's licence	$1,060
5.	Application fee for registration of an oral dental gum	$17
6.	Registration fee for an oral dental gum	Nil
7.	Annual retention fee for the retention of the registration of an oral dental gum	$12
8.	Application fee for the Authority's approval of any change affecting a licence mentioned in regulation 24(1) or (2) of the ODG Regulations	$17
9.	Application fee for the Authority's approval of any change concerning a registered oral dental gum mentioned in regulation 25(1) of the ODG Regulations	$17
10.	Application fee for the Authority's approval of —	
	(*a*) an advertisement using light and sound projection	$212
	(*b*) any other advertisement that is not a sales promotion	$106
11.	Application fee for the Authority's approval of a sales promotion, in addition to the fee in item 10, if any	$106
12.	Fee for the Authority's approval, for the first year, of —	
	(*a*) an advertisement using light and sound projection	$106
	(*b*) any other advertisement that is not a sales promotion	$106
13.	Fee for the Authority's approval, for the first year, of a sales promotion, in addition to the fee in item 12, if any	$106

SEVENTH SCHEDULE — *continued*

14.	Fee for renewal of the Authority's approval, for each subsequent year, of —	
	(*a*) an advertisement using light and sound projection	$318
	(*b*) any other advertisement that is not a sales promotion	$212
15.	Fee for renewal of the Authority's approval, for each subsequent year, of a sales promotion, in addition to the fee in item 14, if any	$212
16.	Application fee for variation of an approved advertisement or approved sales promotion	$54
17.	Application fee for the transfer of approval from one person to another of one or more advertisements or sales promotions	$17

PART 2

DEFINITION

In this Schedule, "sales promotion" has the meaning given by regulation 2 of the ODG Regulations.

EIGHTH SCHEDULE

Regulations 3(8) and 4(3) and (4)

PART 1

FEES FOR MANUFACTURE, IMPORT, SUPPLY AND REGISTRATION OF THERAPEUTIC PRODUCTS

1.	Application fee for, or for renewal of, a manufacturer's licence for —	
	(*a*) manufacture of external preparations only	$1,590
	(*b*) manufacture of oral preparations only	$1,590
	(*c*) manufacture of external and oral preparations only	$2,120
	(*d*) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in paragraphs (*a*), (*b*) and (*c*)	$3,180
	(*e*) primary (with or without secondary) packaging	$1,060

EIGHTH SCHEDULE — *continued*

(*f*) secondary packaging only	$630
2. Application fee for amending a manufacturer's licence —	
(*a*) without site inspection (administrative amendment)	$54
(*b*) without site inspection (for a manufacturer carrying out packaging only)	$54
(*c*) with site inspection (for a manufacturer carrying out packaging only)	$530
(*d*) with site inspection (for all other manufacturers)	$1,060
3. Application fee for, or for renewal of, an importer's licence for —	
(*a*) any therapeutic product	$530
(*b*) any therapeutic product imported under one of the following regulations:	$212
(i) regulation 5(1)(*b*)(ii) of the TP Regulations (for scientific education, etc.)	
(ii) regulation 5(1)(*b*)(iii) of the TP Regulations (for export only)	
(iii) regulation 5(1)(*b*)(iv) or (v) of the TP Regulations (for supply to a ship or an aircraft)	
4. Application fee for an importer's licence for a consignment of any therapeutic product imported under regulation 5(1)(*b*)(ii), (iii), (iv) or (v) of the TP Regulations	$106 per consignment
5. Application fee for amending an importer's licence —	
(*a*) without site inspection (administrative amendment)	$54
(*b*) with site inspection	$318
6. Application fee for approval to import or export therapeutic products containing psychotropic substances	$106 per consignment

EIGHTH SCHEDULE — *continued*

7. Application fee for approval to import registered therapeutic products under regulation 5(1)(*b*)(vii) of the TP Regulations	$266 per consignment
8. Application fee for, or for renewal of, a wholesaler's licence for any therapeutic product	$530
9. Application fee for amending a wholesaler's licence —	
(*a*) without site inspection (administrative amendment)	$54
(*b*) with site inspection	$318
10. Application fee for, or for renewal of, an importer's licence and a wholesaler's licence for any therapeutic product	$950
11. Registering one or more innovator products which have not yet been approved by any competent drug regulatory agency and for which the Authority will conduct a full evaluation:	
(*a*) application fee for the initial screening	$2,910
(*b*) evaluation fee	$82,900
12. Registering an innovator product which is approved by at least one competent drug regulatory agency and for which the Authority will conduct an abridged evaluation:	
(*a*) application fee for the initial screening (for each product)	$580
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$11,400
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,830
13. Registering an innovator product which is approved by any reference drug regulatory agency and for which the Authority will conduct a verification evaluation:	
(*a*) application fee for the initial screening (for each product)	$580

EIGHTH SCHEDULE — *continued*

(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$16,900
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,830
14. Registering a generic drug product which is approved by at least one competent drug regulatory agency and for which the Authority will conduct an abridged evaluation:	
(*a*) application fee for the initial screening (for each product)	$580
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$4,080
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$2,330
15. Registering a generic drug product which is approved by any reference drug regulatory agency and for which the Authority will conduct a verification evaluation under the Special Scheme for Registration of Generic Medicinal Products from India established pursuant to Chapter 5 of the India-Singapore Comprehensive Economic Cooperation Agreement:	
(*a*) application fee for the initial screening (for each product)	$580
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,400
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,300
16. Registering a generic drug product which is approved by any reference drug regulatory agency and for which the Authority will conduct a verification evaluation:	
(*a*) application fee for the initial screening (for each product)	$580

EIGHTH SCHEDULE — *continued*

(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,400
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,300
17. Fees, in addition to the fees in item 11, 12, 13, 14, 15 or 16 (as the case may be) for overseas manufacturers:	
(*a*) application fee for verification of Good Manufacturing Practice Standard	$630
(*b*) evaluation fee for Quality System Dossier	$4,770
(*c*) evaluation fee for on-site audit —	
(i) in an ASEAN country	$18,400
(ii) in a non-ASEAN country in Asia	$20,400
(iii) outside Asia	$24,400
18. Registration fee for a therapeutic product	Nil
19. Annual retention fee for the retention of the registration of a therapeutic product	$318
20. For the Authority's approval —	
(*a*) to make a major variation to a registered therapeutic product, for which the Authority will conduct a full evaluation —	
(i) application fee for the initial screening for a series of products of the same proprietary name	$2,650
(ii) evaluation fee for a series of products of the same proprietary name	$51,400
(*b*) to make a major variation to a registered therapeutic product, for which the Authority will conduct an abridged evaluation —	
(i) application fee for the initial screening (for each product)	$530
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$5,830

EIGHTH SCHEDULE — *continued*

(iii) evaluation fee for each subsequent product in a series of products of different strengths	$2,910
(*c*) to make a major variation to a registered therapeutic product, for which the Authority will conduct a verification evaluation —	
(i) application fee for the initial screening (for each product)	$530
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$8,650
(iii) evaluation fee for each subsequent product in a series of products of different strengths	$2,910
21. Application fee for the Authority's approval to make any other variations to a registered therapeutic product where such approval is required (excluding applications to change the forensic classification of the product)	$580
22. Application fee for the following certificates or documents:	
(*a*) a GMP Certificate	$6,370
(*b*) each additional copy of a GMP Certificate	$212
(*c*) a GDP Certificate	$3,710
(*d*) each additional copy of a GDP Certificate	$212
(*e*) certificate of registration or compliance under regulation 61 of the TP Regulations for a therapeutic product intended for export	$106
(*f*) certificate of approval under regulation 64 of the TP Regulations for import of a therapeutic product into Singapore	$106

EIGHTH SCHEDULE — *continued*

PART 2

DEFINITIONS

In this Schedule —

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

"competent drug regulatory agency" means a national regulatory authority participating in the World Health Organization's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and listed as such on the World Health Organization's website;

"container" has the meaning given by regulation 2(1) of the TP Regulations;

"forensic classification" means the classification of a therapeutic product as "prescription-only medicine", "pharmacy-only medicine" or "general sale list medicine";

"GDP Certificate" has the meaning given by regulation 63(4) of the TP Regulations;

"generic drug product" means a therapeutic product containing a chemical entity or a combination of chemical entities that is essentially similar to a registered therapeutic product;

"GMP Certificate" has the meaning given by regulation 62(4) of the TP Regulations;

"Good Manufacturing Practice Standard" has the meaning given by regulation 62(4) of the TP Regulations;

"innovator product" means a therapeutic product containing any new chemical or biological entity, new combination of chemical or biological entities, new dosage form or new route of administration;

"major variation", in relation to a therapeutic product, means any change relating to the intended purpose or recommended dosage of, patient groups for, or clinical trial information on, the therapeutic product;

"primary packaging", in relation to a therapeutic product, means the enclosure of the product in a container which is labelled before the product is sold or supplied;

"psychotropic substance" means a substance specified in the First Schedule to the TP Regulations;

EIGHTH SCHEDULE — *continued*

"reference drug regulatory agency" means a national regulatory authority specified by the Authority on the Authority's website from whose regulatory decisions the Authority takes reference;

"secondary packaging", in relation to a therapeutic product that is already enclosed in the container in which it is to be sold or supplied, means —

(*a*) the labelling of the container, or enclosure of the container with other packaging material (including product informational inserts); or

(*b*) the labelling of the packaging material before the product is sold or supplied in it.

Made on 25 May 2022.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

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