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No. S 489

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (FEES) (AMENDMENT) REGULATIONS 2024

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) (Amendment) Regulations 2024 and come into operation on 1 July 2024.

Amendment of First Schedule

2. In the Health Products (Fees) Regulations 2022 (G.N. No. S 450/2022) (called in these Regulations the principal Regulations), in the First Schedule, replace Part 1 with —

"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	$22,200
	(*b*) secondary packaging only	$10,800
2.	Application fee for renewal of a manufacturer's licence for —	
	(*a*) manufacture of any CTGT product	$13,600
	(*b*) secondary packaging only	$3,780
3.	Application fee for amending a manufacturer's licence —	
	(*a*) without technical assessment (for manufacture of any CTGT product)	$189

(*b*) without technical assessment (for secondary packaging only)	$189
(*c*) with technical assessment (for manufacture of any CTGT product)	$5,300
(*d*) with technical assessment (for secondary packaging only)	$2,840

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 healthcare service licensee)	$240
(ii) where the import is made in the circumstances described in regulation 9(*a*)(ii) of the CTGTP Regulations (import by healthcare service licensee or holder of pharmacy licence)	$240
(*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	$220
(ii) where the product is imported solely for export	$220
(*c*) where the CTGT product is authorised for import by a registrant of the CTGT product	$1,470

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	$220
	(ii) where the product is imported solely for export	$220
	(*b*) where the CTGT product is authorised for import by a registrant of the CTGT product	$550
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	$116 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	$270 per consignment
8.	Application fee for amending an importer's licence —	
	(*a*) without technical assessment	$126
	(*b*) with technical assessment	$1,160
9.	Application fee for a wholesaler's licence for any CTGT product	$1,470
10.	Application fee for renewal of a wholesaler's licence for any CTGT product	$550
11.	Application fee for amending a wholesaler's licence —	
	(*a*) without technical assessment	$126
	(*b*) with technical assessment	$1,160

12. Application fee for an importer's licence and a wholesaler's licence for any CTGT product	$2,630
13. Application fee for renewal of an importer's licence and a wholesaler's licence for any CTGT product	$990
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)	$95
(*b*) regulation 7(2)(*c*) of the CTGTP Regulations (import)	$95
(*c*) regulation 10(2)(*c*) of the CTGTP Regulations (wholesale)	$95
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	$3,050
(*b*) evaluation fee	$82,900
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)	$600
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$13,900
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,900
17. Submission of a notice relating to the supply of a Class 1 CTGT product under regulation 16(2) of the CTGTP Regulations	$95

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	$650
	(*b*) for on-site inspection	$31,700
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	$11,400
20.	Annual retention fee for the retention of the registration of a CTGT product	$330
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:	
	(i) application fee for the initial screening for a series of products of the same proprietary name	$2,730
	(ii) evaluation fee for a series of products of the same proprietary name	$51,400
	(*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)	$550
	(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$7,900
	(iii) evaluation fee for each subsequent product in a series of products of different strengths	$3,050
22.	Application fee for the Authority's approval to make any other variations to a registered CTGT product where such approval is required	$2,730

23.	Submission of a notice to the Authority to make any other variation to a registered CTGT product where such a submission is required	$400
24.	Application fee for the Authority's approval to change the registrant of a registered CTGT product	$158
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	$116
	(*b*) a GMP Certificate (with technical assessment)	$22,200
	(*c*) a GMP Certificate (without technical assessment)	$220
	(*d*) a GDP Certificate (with technical assessment)	$3,890
	(*e*) a GDP Certificate (without technical assessment)	$220

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Amendment of Second Schedule

3. In the principal Regulations, in the Second Schedule, replace Part 1 with —

"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	$111 per consignment
2.	Application fee for each of the following certificates or documents for a therapeutic product:	
	(*a*) a GMP Certificate	$6,570

(*b*)	each additional copy of a GMP Certificate	$220
(*c*)	a GDP Certificate	$3,900
(*d*)	each additional copy of a GDP Certificate	$220

3. Application fee for each of the following certificates or documents for a CTGT product or starting material used in the manufacture of a CTGT product:

(*a*)	a GMP Certificate (with technical assessment)	$22,200
(*b*)	a GMP Certificate (without technical assessment)	$220
(*c*)	a GDP Certificate (with technical assessment)	$3,890
(*d*)	a GDP Certificate (without technical assessment)	$220

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Amendment of Third Schedule

4. In the principal Regulations, in the Third Schedule, replace Part 1 with —

"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 —

(*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	$28

	(*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	$8
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	$13
	(*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	$8

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Amendment of Fourth Schedule

5. In the principal Regulations, in the Fourth Schedule, replace Part 1 with —

"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	$4,440
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	$220

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Amendment of Fifth Schedule

6. In the principal Regulations, in the Fifth Schedule, replace Part 1 with —

"PART 1

FEES FOR RETAIL PHARMACIES AND SUPPLY OF CERTAIN HEALTH PRODUCTS

1. Application fee for, or for renewal of, a pharmacy licence	$560
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	$330
3. Application fee for the Authority's approval under regulation 7(1) of the LRP Regulations —	
(*a*) with site inspection	$330
(*b*) without site inspection	$57

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Amendment of Sixth Schedule

7. In the principal Regulations, in the Sixth Schedule, replace Part 1 with —

"PART 1

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

1. Application fee for registration of —	
(*a*) a Class B medical device	$560
(*b*) a Class C medical device	$560
(*c*) a Class D medical device	$560
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	$2,010

(ii) which is immediately registered under regulation 26(4) of the MD Regulations	$1,000
(iii) which is immediately registered under regulation 26(4A) of the MD Regulations	$1,000
(iv) by evaluation under a full evaluation process	$3,900
(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3C) of the MD Regulations	$4,420
(vi) by evaluation under a priority full evaluation process mentioned in regulation 26(3D) of the MD Regulations	$5,660

(*b*) a Class C medical device —

(i) by evaluation under an abridged evaluation process mentioned in regulation 26(2) of the MD Regulations	$3,900
(ii) by evaluation under a full evaluation process	$6,250
(iii) by evaluation under an expedited abridged evaluation process mentioned in regulation 26(3) of the MD Regulations	$3,340
(iv) by evaluation under a priority full evaluation process mentioned in regulation 26(3C) of the MD Regulations	$7,000
(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3D) of the MD Regulations	$9,000

(*c*)	a Class C medical device that is a standalone mobile application which is immediately registered under regulation 26(4A) of the MD Regulations	$3,340
(*d*)	a Class D medical device —	
	(i) by evaluation under an abridged evaluation process mentioned in regulation 26(2) of the MD Regulations	$6,250
	(ii) by evaluation under a full evaluation process	$12,000
	(iii) by evaluation under an expedited abridged evaluation process mentioned in regulation 26(3A) of the MD Regulations	$5,930
	(iv) by evaluation under a priority full evaluation process mentioned in regulation 26(3C) of the MD Regulations	$13,600
	(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3D) of the MD Regulations	$17,500
(*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	$10,600
	(ii) by evaluation under a full evaluation process	$75,600
3. Annual retention fee for the retention of the registration of —		
(*a*)	a Class B registered medical device	$39
(*b*)	a Class C registered medical device	$67
(*c*)	a Class D registered medical device	$134

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	$560
(*c*) to make a change that may affect the safety, quality or efficacy of —	
(i) a registered Class B medical device	$560
(ii) a registered Class C medical device	$1,890
(iii) a registered Class D medical device	$3,120
5. Fee for application for, or application for renewal of —	
(*a*) a manufacturer's licence	$1,110
(*b*) an importer's licence (other than an importer's licence mentioned in item 8 or 9)	$1,110
(*c*) a wholesaler's licence (other than a wholesaler's licence mentioned in item 8 or 9)	$1,110
6. Notification fee under regulation 48(2) of the MD Regulations for changes in particulars in relation to —	
(*a*) a manufacturer's licence	$168
(*b*) an importer's licence, except an importer's licence mentioned in item 8	$168
(*c*) a wholesaler's licence, except a wholesaler's licence mentioned in item 8	$168
7. Fee for application to change registrant of a medical device	$880

8. Fee for application for an importer's licence or a wholesaler's licence relating to an unregistered medical device —		
	(*a*) 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	$390
	(*b*) 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	$168
	(*c*) where the unregistered medical device is to be used for a non-clinical purpose	$280
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)		$280
10. Fee for application for any certificate		$57
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	$57
	(*b*) for each additional medical device that is mentioned in the certificate	$57

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Amendment of Seventh Schedule

8. In the principal Regulations, in the Seventh Schedule, replace Part 1 with —

"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	$880
2.	Application fee for, or to renew, an importer's licence	$880
3.	Application fee for, or to renew, a wholesaler's licence	$880
4.	Application fee for, or to renew, an importer's licence and a wholesaler's licence	$1,110
5.	Application fee for registration of an oral dental gum	$18
6.	Registration fee for an oral dental gum	Nil
7.	Annual retention fee for the retention of the registration of an oral dental gum	$13
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	$18
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	$18
10.	Application fee for the Authority's approval of —	
	(*a*) an advertisement using light and sound projection	$220
	(*b*) any other advertisement that is not a sales promotion	$111
11.	Application fee for the Authority's approval of a sales promotion, in addition to the fee in item 10, if any	$111

12. Fee for the Authority's approval, for the first year, of —	
(*a*) an advertisement using light and sound projection	$111
(*b*) any other advertisement that is not a sales promotion	$111
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	$111
14. Fee for renewal of the Authority's approval, for each subsequent year, of —	
(*a*) an advertisement using light and sound projection	$331
(*b*) any other advertisement that is not a sales promotion	$222
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	$222
16. Application fee for variation of an approved advertisement or approved sales promotion	$57
17. Application fee for the transfer of approval from one person to another of one or more advertisements or sales promotions	$18

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Amendment of Eighth Schedule

9. In the principal Regulations, in the Eighth Schedule, replace Part 1 with —

"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	$1,670
(*b*) manufacture of oral preparations only	$1,670

(*c*) manufacture of external and oral preparations only	$2,230
(*d*) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in paragraphs (*a*), (*b*) and (*c*)	$3,340
(*e*) primary (with or without secondary) packaging	$1,110
(*f*) secondary packaging only	$660
2. Application fee for amending a manufacturer's licence —	
(*a*) without site inspection (administrative amendment)	$57
(*b*) without site inspection (for a manufacturer carrying out packaging only)	$57
(*c*) with site inspection (for a manufacturer carrying out packaging only)	$560
(*d*) with site inspection (for all other manufacturers)	$1,110
3. Application fee for, or for renewal of, an importer's licence for —	
(*a*) any therapeutic product	$560
(*b*) any therapeutic product imported under one of the following regulations:	$220
(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	$111 per consignment
5. Application fee for amending an importer's licence —	
(*a*) without site inspection (administrative amendment)	$57
(*b*) with site inspection	$330
6. Application fee for approval to import or export therapeutic products containing psychotropic substances	$111 per consignment
7. Application fee for approval to import registered therapeutic products under regulation 5(1)(*b*)(vii) of the TP Regulations	$280 per consignment
8. Application fee for, or for renewal of, a wholesaler's licence for any therapeutic product	$560
9. Application fee for amending a wholesaler's licence —	
(*a*) without site inspection (administrative amendment)	$57
(*b*) with site inspection	$330
10. Application fee for, or for renewal of, an importer's licence and a wholesaler's licence for any therapeutic product	$1,000
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	$3,060
(*b*) evaluation fee	$83,100

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) — $610

    (*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths — $11,600

    (*c*) evaluation fee for each subsequent product in a series of products of different strengths — $6,030

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) — $610

    (*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths — $17,100

    (*c*) evaluation fee for each subsequent product in a series of products of different strengths — $6,030

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) — $610

    (*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths — $4,280

    (*c*) evaluation fee for each subsequent product in a series of products of different strengths — $2,450

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)	$610
	(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,600
	(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,500
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)	$610
	(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,600
	(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,500
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	$660
	(*b*) evaluation fee for Quality System Dossier	$4,970
	(*c*) evaluation fee for on-site audit —	
	(i) in an ASEAN country	$18,600

(ii) in a non-ASEAN country in Asia	$20,600
(iii) outside Asia	$24,600
18. Registration fee for a therapeutic product	Nil
19. Annual retention fee for the retention of the registration of a therapeutic product	$330
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	$2,780
(ii) evaluation fee for a series of products of the same proprietary name	$51,600
(*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)	$560
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$6,030
(iii) evaluation fee for each subsequent product in a series of products of different strengths	$3,060
(*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)	$560

	(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$8,850
	(iii) evaluation fee for each subsequent product in a series of products of different strengths	$3,060
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)	$610
22.	Application fee for the following certificates or documents:	
	(*a*) a GMP Certificate	$6,570
	(*b*) each additional copy of a GMP Certificate	$220
	(*c*) a GDP Certificate	$3,900
	(*d*) each additional copy of a GDP Certificate	$220
	(*e*) certificate of registration or compliance under regulation 61 of the TP Regulations for a therapeutic product intended for export	$111
	(*f*) certificate of approval under regulation 64 of the TP Regulations for import of a therapeutic product into Singapore	$111

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[G.N. Nos. S 438/2023; S 833/2023]

Made on 30 May 2024.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

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