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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) (AMENDMENT) REGULATIONS 2019

In exercise of the powers conferred by section 71 of the Health Products Act, 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 (Therapeutic Products) (Amendment) Regulations 2019 and come into operation on 2 April 2019.

Amendment of Sixth Schedule

2. The Sixth Schedule to the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016) is amended by deleting items 1 to 22 and substituting the following items:

" 1.	Application fee for, or for renewal of, a manufacturer's licence for —	
	(*a*) manufacture of external preparations only	$1,545
	(*b*) manufacture of oral preparations only	$1,545
	(*c*) manufacture of external and oral preparations only	$2,060
	(*d*) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in paragraphs (*a*), (*b*) and (*c*)	$3,090
	(*e*) primary (with or without secondary) packaging	$1,030
	(*f*) secondary packaging only	$615

2. Application fee for amending a manufacturer's licence —	
(*a*) without site inspection (administrative amendment)	$52
(*b*) without site inspection (for a manufacturer carrying out packaging only)	$52
(*c*) with site inspection (for a manufacturer carrying out packaging only)	$515
(*d*) with site inspection (for all other manufacturers)	$1,030
3. Application fee for, or for renewal of, an importer's licence for —	
(*a*) any therapeutic product	$515
(*b*) any therapeutic product imported under one of the following regulations:	$206
(i) regulation 5(1)(*b*)(ii) (for scientific education, etc.)	
(ii) regulation 5(1)(*b*)(iii) (for export only)	
(iii) regulation 5(1)(*b*)(iv) or (v) (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)	$103 per consignment
5. Application fee for amending an importer's licence —	
(*a*) without site inspection (administrative amendment)	$52
(*b*) with site inspection	$309
6. Application fee for approval to import or export therapeutic products containing psychotropic substances	$103 per consignment

7. Application fee for approval to import registered therapeutic products under regulation 5(1)(*b*)(vii)	$258 per consignment
8. Application fee for, or for renewal of, a wholesaler's licence for any therapeutic product	$515
9. Application fee for amending a wholesaler's licence —	
(*a*) without site inspection (administrative amendment)	$52
(*b*) with site inspection	$309
10. Application fee for, or for renewal of, an importer's licence and a wholesaler's licence for any therapeutic product	$925
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	$2,830
(*b*) evaluation fee	$82,700
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)	$565
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$11,200
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,665

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)	$565
	(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$16,700
	(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,665
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)	$565
	(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$3,965
	(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$2,265
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)	$565
	(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,200

(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,150
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)	$565
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,200
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,150
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	$615
(*b*) evaluation fee for Quality System Dossier	$4,635
(*c*) evaluation fee for on-site audit —	
(i) in an ASEAN country	$18,200
(ii) in a non-ASEAN country in Asia	$20,200
(iii) outside Asia	$24,200
18. Registration fee for a therapeutic product	Nil
19. Annual retention fee under regulation 68(4)	$309
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	$2,575

(ii) evaluation fee for a series of products of the same proprietary name	$51,200
(*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)	$515
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$5,665
(iii) evaluation fee for each subsequent product in a series of products of different strengths	$2,830
(*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)	$515
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$8,450
(iii) evaluation fee for each subsequent product in a series of products of different strengths	$2,830
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)	$565
22. Application fee for the following certificates or documents:	
(*a*) a GMP Certificate	$6,180
(*b*) each additional copy of a GMP Certificate	$206

(*c*)	a GDP Certificate	$3,605
(*d*)	each additional copy of a GDP Certificate	$206
(*e*)	certificate of registration or compliance under regulation 61 for a therapeutic product intended for export	$103
(*f*)	certificate of approval under regulation 64 for import of a therapeutic product into Singapore	$103

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[G.N. Nos. S 219/2017; S 119/2018]

Made on 13 February 2019.

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Chairman,
Health Sciences Authority,
Singapore.

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