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No. S 833

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (FEES) (AMENDMENT NO. 2) REGULATIONS 2023

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 No. 2) Regulations 2023 and come into operation on 18 December 2023.

Amendment of regulation 2

2. In the Health Products (Fees) Regulations 2022 (G.N. No. S 450/2022) (called in these Regulations the principal Regulations), in regulation 2, before the definition of "clinical research material", insert —

> "‘‘AI Regulations" means the Health Products (Active Ingredients) Regulations 2023 (G.N. No. S 831/2023);".

Amendment of regulation 3

3. In the principal Regulations, in regulation 3, after paragraph (8), insert —

> "(9) The fees specified in the Ninth Schedule are payable to the Authority for the manufacture, import and supply of active ingredients under the AI Regulations.".

Amendment of First Schedule

4. In the principal Regulations, in the First Schedule —

(*a*) in Part 1, in item 4(*a*)(i), delete "nursing home licensee or";

(*b*) in Part 1, in item 4(*a*)(ii), delete "nursing home licensee,"; and

(*c*) in Part 2, delete the definition of "nursing home licensee".

Amendment of Second Schedule

5. In the principal Regulations, in the Second Schedule —

(*a*) in Part 1, in item 3, delete ", or an active substance"; and

(*b*) in Part 2, delete the definition of "active substance".

Amendment of Sixth Schedule

6. In the principal Regulations, in the Sixth Schedule, in Part 1, in item 8, delete paragraph (*a*).

New Ninth Schedule

7. In the principal Regulations, after the Eighth Schedule, insert —

"NINTH SCHEDULE

Regulation 3(9)

PART 1

FEES FOR MANUFACTURE, IMPORT AND SUPPLY OF ACTIVE INGREDIENTS

1. Except where item 2 applies, application fee for a manufacturer's licence for —		
	(*a*) manufacture of any active ingredient	$31,790
	(*b*) primary (with or without secondary) packaging	$18,290
	(*c*) secondary packaging only	$9,290
2. Where an existing manufacturer applies for the first time, application fee for a manufacturer's licence for —		

	(*a*) manufacture of any active ingredient	$12,720
	(*b*) primary (with or without secondary) packaging	$6,100
	(*c*) secondary packaging only	$3,470
3.	Application fee for renewal of a manufacturer's licence for —	
	(*a*) manufacture of any active ingredient	$12,720
	(*b*) primary (with or without secondary) packaging	$6,100
	(*c*) secondary packaging only	$3,470
4.	Application fee for amending a manufacturer's licence —	
	(*a*) without technical assessment (for manufacture of any active ingredient)	$450
	(*b*) without technical assessment (for primary or secondary packaging only)	$450
	(*c*) with technical assessment (for manufacture of any active ingredient)	$15,230
	(*d*) with technical assessment (for primary or secondary packaging only)	$8,720
5.	Except where item 6 applies, application fee for an importer's licence for —	
	(*a*) import of any active ingredient intended for manufacture of a relevant health product in Singapore for application on or use by humans	$2,680
	(*b*) import of any active ingredient intended for a purpose not described in paragraph (*a*)	$400
6.	Where an existing dealer applies for the first time, application fee for an importer's licence for —	
	(*a*) import of any active ingredient intended for manufacture of a relevant health product in Singapore for application on or use by humans	$930

(*b*) import of any active ingredient intended for a purpose not described in paragraph (*a*)	$220
7. Application fee for renewal of an importer's licence for —	
(*a*) import of any active ingredient intended for manufacture of a relevant health product in Singapore for application on or use by humans	$930
(*b*) import of any active ingredient intended for a purpose not described in paragraph (*a*)	$220
8. Application fee for amending an importer's licence —	
(*a*) without technical assessment	$400
(*b*) with technical assessment	$2,250
9. Application fee for approval to import or export an active ingredient containing psychotropic substances under regulation 17 or 18 of the AI Regulations	$220 per consignment
10. Except where item 11 applies, application fee for wholesaler's licence for any active ingredient	$2,680
11. Where an existing dealer applies for the first time, application fee for wholesaler's licence for any active ingredient	$930
12. Application fee for renewal of wholesaler's licence for any active ingredient	$930
13. Application fee for amending a wholesaler's licence —	
(*a*) without technical assessment	$400
(*b*) with technical assessment	$2,250
14. Application fee for the following certificates or documents:	
(*a*) a GMP Certificate (with technical assessment)	$31,790

(*b*)	a GMP Certificate (without technical assessment)	$220
(*c*)	a GDP Certificate (with technical assessment)	$5,410
(*d*)	a GDP Certificate (without technical assessment)	$220
(*e*)	a Certificate of a Pharmaceutical Product under regulation 32(2) of the AI Regulations	$220

PART 2

DEFINITIONS

In this Schedule —

"container", in relation to an active ingredient, means an article or packaging immediately covering the active ingredient, but does not include an outer package or other packaging in which the container is further enclosed;

"existing dealer" means a person who, immediately before 18 December 2023, holds a valid licence issued under the Poisons Act 1938 for importing, storing and selling by wholesale any poison in the Poisons List in the Schedule to that Act (as set out in Form A of the Eighth Schedule to the Poisons Rules (R 1)) that is —

(*a*) specified as an active ingredient in the Schedule to the AI Regulations; and

(*b*) usable in the manufacture of any relevant health product;

"existing manufacturer" means a person who —

(*a*) before 18 December 2023, engaged in any of the following activities:

(i) the manufacture of an active ingredient;

(ii) the primary packaging of an active ingredient;

(iii) the secondary packaging of an active ingredient; and

(*b*) immediately before 18 December 2023, holds a valid —

(i) manufacturer's licence issued under the Act for the manufacture of a therapeutic product or a CTGT product; or

(ii) GMP certificate for an active pharmaceutical ingredient issued under the Medicines Act 1975;

"GDP Certificate" has the meaning given by regulation 34(1) of the AI Regulations;

"GMP Certificate" has the meaning given by regulation 33(1) of the AI Regulations;

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

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

"relevant health product" has the meaning given by regulation 2(1) of the AI Regulations;

"secondary packaging", in relation to an active ingredient 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; or

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

[G.N. No. S 438/2023]

Made on 24 November 2023.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

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