First published in the Government *Gazette*, Electronic Edition, on 15 February 2019 at 5 pm.

No. S 92

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