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MEDICINES ACT
(CHAPTER 176)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) (AMENDMENT) REGULATIONS 2019

In exercise of the powers conferred by section 74 of the Medicines Act, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2019 and come into operation on 2 April 2019.

Deletion and substitution of Fifth Schedule

2. The Fifth Schedule to the Medicines (Licensing, Standard Provisions and Fees) Regulations (Rg 6) is deleted and the following Schedule substituted therefor:

"FIFTH SCHEDULE

Regulation 5

FEES

1. PRODUCT LICENCE	
(1) Application for a product licence for —	
(*a*) a medicinal product that has not yet been approved by any competent drug regulatory agency and is therefore required by the Authority to undergo full evaluation:	
(i) application fee for the initial screening[#]	$2,830
(ii) evaluation fee*	$82,700

(*b*) a medicinal product that has been approved by at least one competent drug regulatory agency and is therefore allowed by the Authority to undergo abridged evaluation:	
(i) application fee for the initial screening[#]	$565
(ii) evaluation fee* for a single-strength product or the first product in a series of products of different strengths	$11,200
(iii) evaluation fee* for each subsequent product in a series of products of different strengths	$5,665
(*c*) a medicinal product that has been approved by a reference drug regulatory agency and is therefore allowed by the Authority to undergo verification evaluation:	
(i) application fee for the initial screening[#]	$565
(ii) evaluation fee* for a single-strength product or the first product in a series of products of different strengths	$16,700
(iii) evaluation fee* for each subsequent product in a series of products of different strengths	$5,665
(2) Licence fee for —	
(*a*) the first year of the term of a product licence	Nil
(*b*) each subsequent year of the term of a product licence	$309

(3) Application to amend a product licence —

(*a*) to make a major variation, where the application is required to undergo full evaluation by the Authority:		
	(i) application fee for the initial screening[#]	$2,575
	(ii) evaluation fee*	$51,200
(*b*) to make a major variation, where the application can be reviewed by the Authority through abridged evaluation:		
	(i) application fee for the initial screening[#]	$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, where the application can be reviewed by the Authority through verification evaluation:		
	(i) application fee for the initial screening[#]	$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
(*d*) to make any other variations to the product specifications of a medicinal product:		
	(i) application fee[#]	$565
	(ii) evaluation fee	Nil