Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2007

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No. S 28

MEDICINES ACT
(CHAPTER 176)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) (AMENDMENT) REGULATIONS 2007

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

Citation and commencement

1. These Regulations may be cited as the Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2007 and shall come into operation on 1st February 2007.

Amendment of Fifth Schedule

2. Part I of the Fifth Schedule to the Medicines (Licensing, Standard Provisions and Fees) Regulations (Rg 6) is amended by deleting item 1 and substituting the following item:

1. PRODUCT LICENCE

(1) Application for a licence for —

(a) an innovator product (i.e. containing any new chemical or biological entity, new combination, new dosage form or new route of administration) which has not yet been approved by any WHO-defined competent drug regulatory agency and which is required to undergo full evaluation by the licensing authority, in respect of —	
(i) the initial screening#	$2,500
(ii) the evaluation*	$75,000
(b) an innovator product (i.e. containing any new chemical or biological entity, new combination, new dosage form or new route of administration) which has been approved by at least one WHO-defined competent drug regulatory agency and which is allowed to undergo abridged evaluation by the licensing authority, in respect of —	
(i) the initial screening#	$500
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$10,000
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,000
(c) an innovator product (i.e. containing any new chemical or biological entity, new combination, new dosage form or new route of administration) which has been approved by any reference drug regulatory agency specified by the licensing authority and which is allowed to undergo verification evaluation by the licensing authority, in respect of —	
(i) the initial screening#	$500
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$15,000
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,000
(d) a generic drug product (i.e. essentially similar to another medicinal product which is currently registered with the licensing authority), in respect of —	
(i) the initial screening#	$500
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$3,500
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$2,000