Medicines (Licensing, Standard Provisions and Fees) (Amendment No. 2) Regulations 2010

Table of Contents

No. S 693

MEDICINES ACT
(CHAPTER 176)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) (AMENDMENT NO. 2) REGULATIONS 2010

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 No. 2) Regulations 2010 and shall come into operation on 1st January 2011.

Amendment of Fifth Schedule

2. Item 1 in Part I of the Fifth Schedule to the Medicines (Licensing, Standard Provisions and Fees) Regulations (Rg 6) is amended —

(*a*) by deleting sub-paragraphs (*a*) to (*d*) of paragraph (1) and substituting the following sub-paragraphs:

“

(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 by the licensing authority to undergo full evaluation, in respect of —	
(i) the initial screening#	$2,750
(ii) the evaluation*	$82,500
(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 by the licensing authority to undergo abridged evaluation, in respect of —	
(i) the initial screening#	$550
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$11,000
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,500
(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 by the licensing authority to undergo verification evaluation, in respect of —	
(i) the initial screening#	$550
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$16,500
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,500
(d) a generic drug product (i.e. essentially similar to another medicinal product which is currently registered with the licensing authority) which has been approved by at least one WHO-defined competent drug regulatory agency and which is allowed by the	