Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2006

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No. S 648

MEDICINES ACT
(CHAPTER 176)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) (AMENDMENT) REGULATIONS 2006

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 2006 and shall come into operation on 1st December 2006.

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(1)

FEES FOR LICENCES AND CERTIFICATES

PART I

WESTERN MEDICINES

1. PRODUCT LICENCE

(1) Application for a licence, in respect of —

(a) the initial screening#	$250
(b) the evaluation* for —	
(i) an innovator product containing new chemical or biological entity, new combination, new dosage form or new route of administration — single-strength product or first product in a series of products of different strengths	$2,000
(ii) an innovator product containing new chemical or biological entity, new combination, new dosage form or new route of administration — subsequent product in a series of products of different strengths	$1,000
(iii) a generic drug product — single-strength product or first product in a series of products of different strengths	$500
(iv) a generic drug product — subsequent product in a series of products of different strengths	$300

(2) Licence for —

(a) the first year	No charge
(b) each subsequent year	$100

(3) Application to amend a licence —

(a) to make changes to product specifications relating to indications, dosage recommendations or patient groups, in respect of —	
(i) the initial screening#	$250
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$1,000
(iii) the evaluation* for a subsequent product in a series of products of different strengths	$200
(b) to make any other changes to product specifications	$100

2. IMPORT LICENCE

(1) Application for a licence for —	
(a) importation authorised by product licence holder	$500
(b) importation not authorised by product licence holder — per consignment imported	$250
(2) Licence for —	
(a) importation authorised by product licence holder for —	
(i) the first year	No charge
(ii) each subsequent year	$500
(b) importation not authorised by product licence holder — per consignment imported	No charge
(3) Application to amend a licence —	
(a) with site inspection	$300
(b) without site inspection	$50

3. WHOLESALE DEALER'S LICENCE

(1) Application for a licence	$500
(2) Licence for —	
(a) the first year	No charge
(b) each subsequent year	$500
(3) Application to amend a licence —	
(a) with site inspection	$300
(b) without site inspection	$50

4. MANUFACTURER'S LICENCE

(1) Application for a licence for —	
(a) manufacture of external preparations	$1,500
(b) manufacture of oral preparations	$1,500
(c) manufacture of contact lens solutions	$1,500
(d) manufacture of external and oral preparations	$2,000
(e) manufacture of sterile preparations or other types of dosage forms, or dosage form combinations other than the	$3,000