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**No. S 547**

MEDICINES ACT
(CHAPTER 176)

MEDICINES
(LICENSING, STANDARD PROVISIONS AND FEES)
(AMENDMENT) REGULATIONS 2016

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 2016 and come into operation on 1 November 2016.

## Deletion and substitution of regulation 2

**2.** Regulation 2 of the Medicines (Licensing, Standard Provisions and Fees) Regulations (Rg 6) (called in these Regulations the principal Regulations) is deleted and the following regulation substituted therefor:

"**Definitions**

**2.** In these Regulations —

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

"Chinese proprietary medicine" has the same meaning as in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6);

"competent drug regulatory agency" means a national regulatory authority participating in the World Health Organization's Certification Scheme on the Quality of Pharmaceutical Products Moving in International

Commerce, and listed as such on the World Health Organization's website;

"licensing authority" means the Chief Executive of the Authority;

"major variation", in relation to a medicinal product, means any change to the product specifications of the medicinal product that relate to any of the following:

(*a*) the indications of the medicinal product;

(*b*) the dosage recommendations of the medicinal product;

(*c*) the patient groups for the medicinal product;

(*d*) clinical trial information on the medicinal product;

"psychotropic substance" has the same meaning as in the Medicines (Export Licence for Psychotropic Substances) Regulations (Rg 9);

"reference drug regulatory agency" means a national regulatory authority, specified by the Authority on the Authority's website, from whose regulatory decisions the Authority takes reference.".

**Deletion of regulation 5B**

**3.** Regulation 5B of the principal Regulations is deleted.

**Amendment of First Schedule**

**4.** Paragraph 4 of the First Schedule to the principal Regulations is amended by deleting the words "or animals".

**Amendment of Second Schedule**

**5.** Paragraph 7 of the Second Schedule to the principal Regulations is amended by deleting the words "or animals".

## Amendment of Fourth Schedule

**6.** Paragraph 13 of the Fourth Schedule to the principal Regulations is amended by deleting the words "or animals".

## Deletion and substitution of Fifth Schedule

**7.** The Fifth Schedule to the principal Regulations is deleted and the following Schedule substituted therefor:

"FIFTH SCHEDULE

Regulation 5

FEES

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| 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[#] | $2,750 |
| (ii) evaluation fee* | $82,500 |
| (*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[#] | $550 |
| (ii) evaluation fee* for a single-strength product or the first product in a series of products of different strengths | $11,000 |
| (iii) evaluation fee* for each subsequent product in a series of products of different strengths | $5,500 |
| (*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[#] | $550 |

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| (ii) evaluation fee* for a single-strength product or the first product in a series of products of different strengths | $16,500 |
| (iii) evaluation fee* for each subsequent product in a series of products of different strengths | $5,500 |
| (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 | $300 |
| (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# | $2,500 |
| (ii) evaluation fee* | $51,000 |
| (*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# | $500 |
| (ii) evaluation fee* for a single-strength product or the first product in a series of products of different strengths | $5,500 |
| (iii) evaluation fee* for each subsequent product in a series of products of different strengths | $2,750 |
| (*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# | $500 |
| (ii) evaluation fee* for a single-strength product or the first product in a series of products of different strengths | $8,250 |
| (iii) evaluation fee* for each subsequent product in a series of products of different strengths | $2,750 |

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| (*d*) to make any other variations to the product specifications of a medicinal product: | |
| (i) application fee[#] | $550 |
| (ii) evaluation fee | Nil |
| 2. IMPORT LICENCE (INCLUDING FOR CHINESE PROPRIETARY MEDICINES) | |
| (1) Application fee for an import licence | $500 |
| (2) Licence fee for — | |
| (*a*) the first year of the term of an import licence | Nil |
| (*b*) each subsequent year of the term of an import licence | $500 |
| (3) Application fee to amend an import licence — | |
| (*a*) with site inspection^ | $300 |
| (*b*) without site inspection^ | $50 |
| 3. WHOLESALE DEALER'S LICENCE (INCLUDING FOR CHINESE PROPRIETARY MEDICINES) | |
| (1) Application fee for a wholesale dealer's licence | $500 |
| (2) Licence fee for — | |
| (*a*) the first year of the term of a wholesale dealer's licence | Nil |
| (*b*) each subsequent year of the term of a wholesale dealer's licence | $500 |
| (3) Application fee to amend a wholesale dealer's licence — | |
| (*a*) with site inspection^ | $300 |
| (*b*) without site inspection^ | $50 |
| 4. MANUFACTURER'S LICENCE (INCLUDING FOR CHINESE PROPRIETARY MEDICINES) | |
| (1) Application fee for a manufacturer's licence for — | |
| (*a*) manufacture of external preparations only | $1,500 |
| (*b*) manufacture of oral preparations only | $1,500 |

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| (*c*) manufacture of external and oral preparations only | $2,000 |
| (*d*) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in sub-paragraphs (*a*), (*b*) and (*c*), if the medicinal product is not a Chinese proprietary medicine | $3,000 |
| (*e*) primary assembly of a medicinal product | $1,000 |
| (*f*) secondary assembly of a medicinal product | $600 |
| (2) Licence fee for — | |
| (*a*) the first year of the term of a manufacturer's licence | Nil |
| (*b*) each subsequent year of the term of a manufacturer's licence for — | |
| (i) manufacture of external preparations only | $1,500 |
| (ii) manufacture of oral preparations only | $1,500 |
| (iii) manufacture of external and oral preparations only | $2,000 |
| (iv) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in sub-paragraphs (i), (ii) and (iii), if the medicinal product is not a Chinese proprietary medicine | $3,000 |
| (v) primary assembly of a medicinal product | $1,000 |
| (vi) secondary assembly of a medicinal product | $600 |
| (3) Application fee to amend a manufacturer's licence — | |
| (*a*) with site inspection^ (for a licence to manufacture a medicinal product) | $1,000 |
| (*b*) with site inspection^ (for a licence to assemble a medicinal product) | $500 |
| (*c*) without site inspection^ | $50 |

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| 5. | CERTIFICATES AND DOCUMENTS (NON-MANDATORY) | |
| | (1) Application fee for a Certificate to Export a Medicinal Product | $100 |
| | (2) Application fee for a Certificate to Export a Chinese Proprietary Medicine | $100 |
| | (3) Application fee for a Confirmation of Authorisation to Import a Psychotropic Substance | $100 |
| | (4) Application fee for a Confirmation of Authorisation to Import a Restricted Substance | $100 |

# Fee is payable upon submission of application.

* Fee is payable upon acceptance of application.

^ Refer to the Authority's guidance notes on amendment applications for licences (available at the Authority's website) to find out if a site inspection is required.

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## Deletion of Sixth Schedule

**8.** The Sixth Schedule to the principal Regulations is deleted.

*[G.N. Nos. S 309/2001; S 641/2002; S 621/2003; S 384/2004; S 416/2005; S 499/2005; S 558/2005; S 681/2005; S 821/2005; S 648/2006; S 28/2007; S 510/2010; S 693/2010]*

Made on 25 October 2016.

CHAN HENG KEE
*Permanent Secretary,*
*Ministry of Health,*
*Singapore.*

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