First published in the Government *Gazette*, Electronic Edition, on 13th September 2010 at 5:00 pm.

**No. S 510**

MEDICINES ACT
(CHAPTER 176)

MEDICINES
(LICENSING, STANDARD PROVISIONS AND FEES)
(AMENDMENT) 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) Regulations 2010 and shall come into operation on 15th September 2010.

## 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 inserting, immediately after sub-paragraph (*d*) of paragraph (1) of item 1, the following sub-paragraph:

| | | |
|---|---|---|
| "(*e*) 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 any reference drug regulatory agency specified by the licensing authority and which is allowed by the licensing authority to undergo verification evaluation under the "Special Scheme for Registration of Generic Medicinal Products from India" established pursuant to Chapter 5 of the India-Singapore Comprehensive Economic Cooperation Agreement, 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 | $10,000 |

(iii) the evaluation* for each subsequent product in a series of products of different strengths $5,000".

*[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]*

Made this 3rd day of September 2010.

YONG YING-I
*Permanent Secretary,*
*Ministry of Health,*
*Singapore.*

[HSA 401:04/03-000; AG/LLRD/SL/176/2010/1 Vol. 1]