First published in the Government *Gazette*, Electronic Edition, on 31st October 2016 at 5:00 pm.

No. S 541

MEDICINES ACT
(CHAPTER 176)

MEDICINES (CESSATION OF APPLICATION OF ACT TO THERAPEUTIC PRODUCTS) ORDER 2016

ARRANGEMENT OF PARAGRAPHS

In exercise of the powers conferred by section 77 of the Medicines Act, the Minister for Health makes the following Order:

Citation

1. This Order is the Medicines (Cessation of Application of Act to Therapeutic Products) Order 2016.

Definitions

2. In this Order, unless the context otherwise requires —

"health product" has the same meaning as in the Health Products Act (Cap. 122D);

"health product manufacturer's licence" means a manufacturer's licence mentioned in section 12 of the Health Products Act;

"import licence" means an import licence mentioned in section 5(2) of the Act;

"importer's licence" means an importer's licence mentioned in section 13 of the Health Products Act;

"licensed retail pharmacy" means premises specified in a pharmacy licence;

"medicinal product" means a medicinal product that falls within the category of a therapeutic product on or after 1 November 2016;

"medicine manufacturer's licence" means a manufacturer's licence mentioned in section 6(2) of the Act;

"Medicines Exemption Order" means the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6);

"pharmacy licence" means a licence issued under the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

"product licence" means a product licence mentioned in section 5(1) of the Act;

"Register of Health Products" has the same meaning as in the Health Products Act;

"registrant", in relation to a registered therapeutic product, means a person who has applied for and obtained the registration of the therapeutic product under the Health Products Act;

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Health Products Act;

"Therapeutic Products Regulations" means the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016);

"wholesale dealer's licence" means a wholesale dealer's licence mentioned in section 6(3) of the Act;

"wholesaler's licence" means a wholesaler's licence mentioned in section 14 of the Health Products Act.

Cessation of application of Act

3. The provisions of the Act cease to apply to any therapeutic product as from 1 November 2016.

Saving and transitional provisions

4.—(1) Every application that is pending immediately before 1 November 2016 in relation to a medicinal product specified in the first column of the First Schedule is treated, on or after that date, as an application in relation to a therapeutic product specified opposite in the second column.

(2) Every licence, certificate or permit that is valid immediately before 1 November 2016 in respect of a medicinal product and specified in the first column of the Second Schedule is treated, on or after that date and for so long as the licence, certificate or permit remains valid, as if it were a licence, certificate or other document issued in respect of a therapeutic product as specified opposite in the second column.

(3) Every medicinal product for which a product licence is valid immediately before 1 November 2016 is deemed, on or after that date and for so long as the product licence remains valid, to be registered as a therapeutic product under the Health Products Act (Cap. 122D), and the holder of the product licence is deemed —

(*a*) to be the registrant of the therapeutic product; and

(*b*) to be subject to the duties of a registrant under the Health Products Act and the Therapeutic Products Regulations.

(4) Every person holding a medicine manufacturer's licence, import licence or wholesale dealer's licence that is valid immediately before 1 November 2016 in respect of a medicinal product is deemed, on or after that date and for so long as the licence remains valid —

(*a*) to be the holder of a health product manufacturer's licence, an importer's licence or a wholesaler's licence, as the case may be; and

(*b*) to be subject to the duties of a holder of the relevant licence under the Health Products Act and the Therapeutic Products Regulations.

(5) Any declaration or notice made under section 12A(2) or (3)(*a*), respectively, of the Act in any application that is pending immediately before 1 November 2016 for a product licence in relation to a medicinal product is treated, on or after that date, as a declaration or notice made under regulation 23(2) or (5) of the Therapeutic Products Regulations, as the case may be.

(6) Any permit granted under paragraph 5 of the Medicines Exemption Order that is valid immediately before 1 November 2016 is deemed, on or after that date and for so long as the permit remains valid, to be an importer's licence under the Health Products Act.

(7) Every registered pharmacy from which a retail pharmacy business is conducted immediately before 1 November 2016 is deemed, on or after that date and for so long as the registration remains valid, to be a licensed retail pharmacy.

FIRST SCHEDULE

Paragraph 4(1)

SAVING AND TRANSITIONAL PROVISIONS FOR PENDING APPLICATIONS

First column	*Second column*
Type of application in relation to a medicinal product	*Type of application or notice in relation to a therapeutic product*
1. Application for a product licence	Application for registration under section 30 of the Health Products Act (Cap. 122D)
2. Application to renew a product licence	Retention of registration by payment of retention fee mentioned in section 31 of the Health Products Act
3. Application for, or to renew, a medicine manufacturer's licence	Application for, or to renew, a health product manufacturer's licence
4. Application for, or to renew, an import licence	Application for, or to renew, an importer's licence

FIRST SCHEDULE — *continued*

First column	*Second column*
Type of application in relation to a medicinal product	*Type of application or notice in relation to a therapeutic product*
5. Application for an import licence on a consignment basis under section 10(3) of the Act	Application for approval to import registered therapeutic products under regulation 5(2) of the Therapeutic Products Regulations
6. Application for, or to renew, a wholesale dealer's licence	Application for, or to renew, a wholesaler's licence
7. Application for an export licence under the Medicines (Export Licence for Psychotropic Substances) Regulations (Rg 9)	Application for approval to export a therapeutic product containing a psychotropic substance under regulation 8 of the Therapeutic Products Regulations
8. Application to amend a product licence	Application for approval to make changes concerning a registered therapeutic product under regulation 42 of the Therapeutic Products Regulations
9. Application to amend a medicine manufacturer's licence, an import licence or a wholesale dealer's licence	(*a*) Notice of change or proposed change under regulation 41(1) of the Therapeutic Products Regulations (*b*) In addition, if applicable, application for approval under regulation 41(3) of the Therapeutic Products Regulations for any change that significantly affects the activities of the licence holder
10. Application for a certificate under the Medicines (Good Manufacturing Practice Certificate) Regulations (Rg 16)	Application for a certificate under regulation 62 of the Therapeutic Products Regulations
11. Application for a certificate under section 22 of the Act, other than a certificate mentioned in item 10	Application for a certificate under regulation 61 of the Therapeutic Products Regulations

FIRST SCHEDULE — *continued*

First column	*Second column*
Type of application in relation to a medicinal product	*Type of application or notice in relation to a therapeutic product*
12. Application for a permit to import a medicinal product without a product licence or an import licence under paragraph 4(*b*) or (*c*) of the Medicines Exemption Order	Application for approval under regulation 51(3) of the Therapeutic Products Regulations
13. Application for authorisation to import psychotropic substances	Application for approval under regulation 6(3) of the Therapeutic Products Regulations
14. Application for authorisation to import restricted substances	Application for certificate issued under regulation 64 of the Therapeutic Products Regulations
15. Application for the registration of any premises as a pharmacy under section 37 of the Act	Application for a pharmacy licence under regulation 5 of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016)
16. Application for retention of name of pharmacy in register under regulation 7(2) of the Medicines (Registration of Pharmacies) Regulations (Rg 4)	Application for renewal of a pharmacy licence under regulation 5 of the Health Products (Licensing of Retail Pharmacies) Regulations 2016
17. Application to amend a certificate of registration under regulation 3(3) of the Medicines (Registration of Pharmacies) Regulations	Application for approval for changes affecting pharmacy licence under regulation 7(3) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016

SECOND SCHEDULE

Paragraph 4(2)

SAVING AND TRANSITIONAL PROVISIONS FOR DOCUMENTS ISSUED

First column	*Second column*
Documents issued under Medicines Act	*Documents issued under Health Products Act*
1. Product licence	Extract from the Register of Health Products for a registered therapeutic product
2. Medicine manufacturer's licence	Health product manufacturer's licence
3. Import licence	Importer's licence
4. Wholesale dealer's licence	Wholesaler's licence
5. Export licence granted under the Medicines (Export Licence for Psychotropic Substances) Regulations (Rg 9)	Notice of approval under regulation 8 of the Therapeutic Products Regulations to export a therapeutic product
6. Permit to import a medicinal product without a product licence or an import licence under paragraph 4(*b*) or (*c*) of the Medicines Exemption Order	Notice of approval under regulation 51(3) of the Therapeutic Products Regulations
7. Good Manufacturing Practice Certificate issued under the Medicines (Good Manufacturing Practice Certificate) Regulations (Rg 16)	GMP Certificate issued under regulation 62 of the Therapeutic Products Regulations
8. Certificate to Export a Medicinal Product	Certificate issued under regulation 61 of the Therapeutic Products Regulations
9. Confirmation of Authorisation to Import Psychotropic Substances	Notice of approval to import a therapeutic product containing a psychotropic substance under regulation 6(1) of the Therapeutic Products Regulations

SECOND SCHEDULE — *continued*

First column	*Second column*
Documents issued under Medicines Act	*Documents issued under Health Products Act*
10. Confirmation of Authorisation to Import Restricted Substances	Certificate issued under regulation 64 of the Therapeutic Products Regulations
11. Statement of Licensing Status of a Medicinal Product	Certificate issued under regulation 61 of the Therapeutic Products Regulations
12. Certificate of registration for a registered pharmacy	Pharmacy licence

Made on 31 October 2016.

AUBECK KAM
Permanent Secretary,
Ministry of Health,
Singapore.

[HSA/LPPD/711:12/72-006; AG/LLRD/SL/176/2010/5 Vol. 1]