Medicines (Cessation of Application of Act to Therapeutic Products) Order 2016

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No. S 541

MEDICINES ACT
(CHAPTER 176)

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

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.