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

No. S 537

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (EXEMPTION FROM GOOD DISTRIBUTION PRACTICE REQUIREMENTS) ORDER 2016

ARRANGEMENT OF PARAGRAPHS

In exercise of the powers conferred by section 70 of the Health Products Act, the Health Sciences Authority makes the following Order:

Citation

1. This Order is the Health Products (Exemption from Good Distribution Practice Requirements) Order 2016.

Definitions

2. In this Order —

"exemption period" means the period from 1 November 2016 to 31 October 2019 (both dates inclusive);

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

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

Exemption from good distribution practice requirements

3.—(1) Regulation 5(1)(*c*) of the Therapeutic Products Regulations does not apply to an applicant who applies, during the exemption period, for an importer's licence to import therapeutic products if —

(*a*) the applicant holds one or more product licences granted under section 5(1) of the Medicines Act (Cap. 176) for one or more of those products;

(*b*) the applicant does not hold an import licence mentioned in section 5(2) of the Medicines Act; and

(*c*) the application is only for the import of —

(i) therapeutic products under regulation 5(1)(*b*)(vi) of the Therapeutic Products Regulations; and

(ii) therapeutic products that are registered or deemed to be registered by the applicant under the Act.

(2) Regulation 5(1)(*c*) of the Therapeutic Products Regulations does not apply to an applicant who applies, during the exemption period, for an importer's licence to import therapeutic products under regulation 5(1)(*b*)(i) of those Regulations.

(3) Regulation 18(*b*) of the Therapeutic Products Regulations does not apply to an applicant who applies, during the exemption period, for a wholesaler's licence to supply by wholesale therapeutic products if —

(*a*) the applicant holds one or more product licences granted under section 5(1) of the Medicines Act for one or more of those products;

(*b*) the applicant does not hold a wholesale dealer's licence granted under section 6(3) of the Medicines Act; and

(*c*) the application is only for the supply by wholesale of therapeutic products that are registered or deemed to be registered by the applicant under the Act.

(4) Regulation 18(*b*) of the Therapeutic Products Regulations does not apply to an applicant who applies, during the exemption period, for a wholesaler's licence to supply by wholesale therapeutic products under regulation 58(1)(*f*) of those Regulations.

Made on 28 October 2016.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
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[HSA/LPPD/711:12/75-000; AG/LEGIS/SL/122D/2015/11 Vol. 1]