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No. S 691

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) (AMENDMENT NO. 2) REGULATIONS 2024

In exercise of the powers conferred by section 72 of the Health Products Act 2007, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Therapeutic Products) (Amendment No. 2) Regulations 2024 and come into operation on 4 September 2024.

Amendment of regulation 11

2. In the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016) (called in these Regulations the principal Regulations), in regulation 11(d), after "the first column of", insert "item 1, 2, 2A or 2B of Part 1 of".

Amendment of regulation 12

3. In the principal Regulations, in regulation 12(b), after "the first column of", insert "item 3, 4 or 5 of Part 1 of".

Amendment of Third Schedule

- **4.** In the principal Regulations, in the Third Schedule
 - (a) after the Schedule reference, insert —

"PART 1";

(b) after item 2, insert —

"2A. The holder of a pharmacy licence that is issued in respect of an approved retail pharmacy

Influenza vaccine

2B. The holder of a pharmacy licence that is issued in respect of an approved retail pharmacy

Adrenaline administered using an autoinjector The supply must be made to a customer of the approved retail pharmacy for the purpose of administering the influenza vaccine to the customer at the approved retail pharmacy

The supply must be made to a customer of the approved retail pharmacy who, having been administered an influenza vaccine by an approved pharmacist at the approved retail pharmacy —

- (a) suffers an adverse reaction to the influenza vaccine; and
- (b) needs to be administered adrenaline to resolve or reduce the adverse reaction

"; and

(c) after item 3, insert —

"4. An approved pharmacist employed by the holder of a pharmacy licence in respect of an approved retail pharmacy

Influenza vaccine

- (a) The influenza vaccine must not be administered to any person other than a customer of the approved retail pharmacy
- (b) The influenza vaccine must be administered at the approved retail pharmacy
- (c) The influenza vaccine must have been supplied to the customer by the holder of the pharmacy licence to the customer

- 5. An approved pharmacist employed by the holder of a pharmacy licence in respect of an approved retail pharmacy
- Adrenaline administered using an autoinjector
- (a) The adrenaline must not be administered to any person other than a customer of the approved retail pharmacy
- (b) The adrenaline must be administered at the approved retail pharmacy
- (c) The adrenaline must have been supplied to the customer by the holder of the pharmacy licence to the customer

PART 2 DEFINITIONS

In this Schedule —

- "approved pharmacist", in relation to a holder of a pharmacy licence in respect of an approved retail pharmacy, means a qualified pharmacist who
 - (a) is employed by the holder of a pharmacy licence to administer the types of prescription-only medicines specified in the second column of items 4 and 5 of Part 1 of this Schedule at the approved retail pharmacy;
 - (b) has completed such training course or courses that are specified by the Chief Pharmacist relating to the administration of
 - (i) the prescription-only medicines mentioned in paragraph (a); and
 - (ii) essential life-saving measures to an individual; and
 - (c) is approved by the Chief Pharmacist to administer the types of prescription-only medicines mentioned in paragraph (a) at the approved retail pharmacy;
- "approved retail pharmacy" means a licensed retail pharmacy that is approved by the Director-General of Health to supply and administer the types of prescription-only medicines specified in the second column of items 2A, 2B, 4 and 5 of Part 1 of this Schedule;
- "Chief Pharmacist" has the meaning given by section 2 of the Pharmacists Registration Act 2007;
- "Director-General of Health" includes any individual who is, for the time being, discharging the duties of the Director-General of Health.".

[G.N. Nos. S 219/2017; S 119/2018; S 92/2019; S 969/2020; S 732/2021; S 1081/2021; S 458/2022; S 436/2023; S 681/2023; S 811/2023; S 610/2024]

Made on 29 August 2024.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

[401:04/01-000; AG/LEGIS/SL/122D/2020/4]

(To be presented to Parliament under section 72(5) of the Health Products Act 2007).