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No. S 732

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) (AMENDMENT) REGULATIONS 2021

In exercise of the powers conferred by section 72(1) of the Health Products Act, 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) Regulations 2021 and come into operation on 1 October 2021.

Amendment of regulation 2

2. Regulation 2(1) of the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016) (called in these Regulations the principal Regulations) is amended by inserting, immediately after the definition of "Authority's website", the following definition:

" "codeine cough preparation" means a therapeutic product that —

(*a*) is in liquid or solid form;

(*b*) contains codeine or its salts; and

(*c*) is intended for the treatment of coughs;".

Amendment of regulation 9

3. Regulation 9 of the principal Regulations is amended by deleting paragraph (1) and substituting the following paragraph:

"(1) Any person who intends to export a codeine cough preparation must obtain the Authority's prior approval for each

consignment of such codeine cough preparation to be exported.".

Deletion and substitution of regulation 14

4. Regulation 14 of the principal Regulations is deleted and the following regulation substituted therefor:

"**Restrictions on supply by retail sale of codeine cough preparations**

14.—(1) A qualified practitioner or qualified pharmacist who supplies by retail sale any codeine cough preparation must not supply more than the following to any individual within a period of 7 days:

(*a*) where codeine cough preparations are supplied to the individual in liquid form only — an aggregate amount of 240 ml of codeine cough preparations;

(*b*) where codeine cough preparations are supplied to the individual in solid form only or in both liquid and solid forms — an aggregate amount of 355 mg of codeine (calculated as codeine base) contained in the codeine cough preparations supplied.

(2) A qualified practitioner or qualified pharmacist who supplies by retail sale any codeine cough preparation must, on each occasion of the supply of the codeine cough preparation to an individual, provide professional counselling on the use of the codeine cough preparation.

(3) A qualified practitioner who supplies by retail sale any codeine cough preparation must, on each occasion of the supply of the codeine cough preparation to an individual, in addition to complying with regulation 16, record the purpose of the treatment for which the codeine cough preparation was supplied.".

Amendment of Seventh Schedule

5. Item 1 of the Seventh Schedule to the principal Regulations is amended by inserting, immediately after the word "Codeine" in the first column, the words "; its salts".

[G.N. Nos. S 219/2017; S 119/2018; S 92/2019; S 969/2020]

Made on 17 September 2021.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

[401:04/01-000; AG/LEGIS/SL/122D/2020/4 Vol. 1]

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