SALE OF DRUGS ACT 1952

CONTROL OF DRUGS AND COSMETICS (AMENDMENT)

REGULATIONS 2007

IN exercise of powers conferred by subsection 26(1) of the Sale of Drugs Act 1952 [*Act 368*], the Minister makes the following regulations:

Citation and commencement

1. (1) These regulations may be cited as the Control of Drugs and Cosmetics (Amendment) Regulations 2007.

(2) These Regulations come into operation on 2007

Amendment of regulation 2

2. The Control of Drugs and Cosmetics Regulations 1984 [*P.U. (A) 223/1984*], which are referred to as the "principal Regulations" in these Regulations, are amended in regulation 2 –

(a) by inserting after the definition of "fully registered medical practitioner" the following definition:

'"health supplement " means any product which is used to supplement a diet and maintain, enhance and improve healthy function and contains one or more or a combination of the following –

(a) vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bahan bioaktive substances;

(b) substances derived from natural sources including animal, mineral and botanical materials in the the forms of extracts, isolates, concentrates, metabolites: or

(c) synthetic sources of ingredients mentioned in paragraph (a) or (b) if the safety of these has been proven."

Amendment of regulation 9

3. Regulation 9 of the principal Regulations is amended after subregulation (4) by inserting the following new regulations :

" (5) A certificate issued by the Director of Pharmaceutical Services or the officer who is responsible for the licensing, approval or notification shall be prima facie evidence of the facts stated .".

Amendment of regulation 29

4. Regulation 29 of the principal Regulations is amended –

(a) in subregulation (2) by substituting the words "Drug Control Authority " with the words "Director of Pharmaceutical Services".

(b) after subregulation (2) by inserting the following new regulations :

"29 A. Restrictions of application of Regulations

(1) Nothing in these Regulations except the provisions of regulations 2, 7(2)(b)(ii), 7(3), 7(4), 26, 29 and 30 shall apply to cosmetics.

to cosmetics

(2) No person shall possess, manufacture, sell, supply or import any cosmetics unless

(a) the cosmetic has been notified to the Director of Pharmaceutical Services,

(b) the person has an appropriate approval issued by the Director of Pharmaceutical Services.

(3) The Director of Pharmaceutical Services may issue approval for notification, manufacturer, importer and wholesaler of cosmetics.

(4) The Director of Pharmaceutical Services may charge any applicant such costs as it may incur for the purpose of issuing an approval for notification, manufacture, import and wholesale of any cosmetics.

(5) Every person who obtains any approval for the notification, manufacture, import and wholesale of any cosmetics, shall maintain proper records as determined by the Director of Pharmaceutical Services.

(6) The Director of Pharmaceutical Services may, at any time and without assigning any reason, cancel any approval for the notification, manufacture, import and wholesale of any cosmetics.

(7) No person shall possess, publish, broadcast or advertise any label, information, pictorial representation, statement or document which describes the indication or use of the cosmetics other than that as determined in the directives or guidelines issued by the Director of Pharmaceutical Services.

(8) Any cosmetic which has been registered under the principal regulations immediately before the date of coming into operation of these regulations, shall be deemed to be given the notification until such registration expires.

(9) Any person who has been licensed to import, manufacture or wholesale any cosmetics under the principal regulations immediately before the date of coming into operation of these regulations, shall be deemed to be given the approval to import, manufacture or wholesale until such licence expires.".

29 B. Promotion of unregistered products

(1) No person shall issue or promote a medicinal purpose which relates to any unregistered products whether in any printing, writing, internet, television, radio or other electronic media.

(2) No person shall possess any document which relates to the promotion of any medicinal purpose of any unregistered product."

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Minister of Health