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No. S 834

POISONS ACT 1938

POISONS (AMENDMENT) RULES 2023

In exercise of the powers conferred by section 20 of the Poisons Act 1938, the Minister for Health makes the following Rules:

Citation and commencement

1.—(1) These Rules are the Poisons (Amendment) Rules 2023.

(2) Rules 2, 3, 4 and 5 come into operation on 18 December 2023.

(3) Rule 6 is deemed to have come into operation on 31 December 2021.

Amendment of rule 2

2. In the Poisons Rules (R 1) (called in these Rules the principal Rules), in rule 2(1) —

(*a*) before the definition of "animal", insert —

"“active ingredient” means any substance or compound that —

(*a*) is usable in the manufacture of a health product under the Health Products Act 2007 as a pharmacologically active constituent; and

(*b*) is specified as an active ingredient in the Schedule to the Health Products (Active Ingredients) Regulations 2023 (G.N. No. S 831/2023);"; and

(*b*) after the definitions of "British Pharmacopoeia" and "Pharmaceutical Codex", insert —

" "cell, tissue and gene therapy product" means a health product under the Health Products Act 2007 which is categorised as a cell, tissue or gene therapy product in the First Schedule to that Act;".

Amendment of rule 14

3. In the principal Rules, in rule 14 —

(*a*) renumber rule 14 as paragraph (1) of that rule;

(*b*) in paragraph (1)(*b*), delete "or" at the end;

(*c*) in paragraph (1)(*c*), replace the full-stop at the end with "; or";

(*d*) in paragraph (1), after sub-paragraph (*c*), insert —

"(*d*) a holder of a manufacturer's licence for an active ingredient who imports a substance specified in the First Schedule, if that substance is required for the manufacture of the active ingredient."; and

(*e*) after paragraph (1), insert —

"(2) In paragraph (1) —

"active ingredient" means any substance or compound that is usable in the manufacture of a health product under the Health Products Act 2007 as a pharmacologically active constituent;

"manufacturer's licence for an active ingredient" means a licence authorising the holder of the licence to manufacture any active ingredient under the Health Products (Active Ingredients) Regulations 2023.".

Amendment of rule 15

4. In the principal Rules, in rule 15(6), replace "published in pursuance of section 14(1) of the Dentists Act (Cap. 76)" with "maintained and kept under section 13(1)(*a*) of the Dental Registration Act 1999".

Amendment of Second Schedule

5. In the principal Rules, in the Second Schedule, in Group I, replace "Adhesives" with "Active ingredients other than substances and compounds adulterated with active ingredients; adhesives".

Miscellaneous amendments

6. In the principal Rules, in rule 2(1) —

(*a*) in the definition of "Chinese proprietary medicine", replace "(Cap. 176, O 6)" with "(O 6)";

(*b*) in the definition of "medical device", replace "(Cap. 122D)" with "2007";

(*c*) in the definition of "registered nurse", replace "(Cap. 209)" with "1999"; and

(*d*) in the definition of "therapeutic product", after "Health Products Act", insert "2007".

[G.N. Nos. S 632/1998; S 51/1999; S 177/1999; S 279/1999; S 68/2000; S 238/2001; S 473/2002; S 189/2004; S 299/2005; S 688/2007; S 539/2008; S 304/2009; S 714/2012; S 62/2016; S 555/2016; S 216/2018; S 100/2019; S 112/2021; S 463/2022; S 562/2022]

Made on 20 November 2023.

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(To be presented to Parliament under section 20(2) of the Poisons Act 1938).