No. S 000

HEALTH PRODUCTS ACT 2007
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) (AMENDMENT) REGULATIONS 2024

In exercise of the powers conferred by section 72(1) 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) Regulations 2024 and come into operation on 2024.

Amendment of regulation 23

2. In the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016) (called in these Regulations the principal Regulations), in regulation 23 —

(*a*) replace paragraph (1) with —

"(1) In dealing with an application for the registration of a therapeutic product, the Authority must consider the following:

(*a*) whether any of the following patents under the Patents Act 1994 is in force in respect of the therapeutic product to which the application for registration relates:

(i) a patent containing a claim for an active ingredient of that therapeutic product;

(ii) a patent containing a claim for a formulation or composition of that therapeutic product;

(iii) a patent containing a claim for the use of an active ingredient in the manufacture of that

therapeutic product for a specific therapeutic, preventive, palliative or diagnostic use;

(*b*) if one or more patents mentioned in sub-paragraph (*a*) is in force in respect of the therapeutic product to which the application for registration relates —

(i) whether the applicant for registration of the therapeutic product is the proprietor of the patent or patents;

(ii) if the applicant is not the proprietor of the patent or any of the patents —

(A) whether the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product to the applicant; or

(B) whether the patent or any of the patents is invalid or will not be infringed by the doing of the act for which the registration of the therapeutic product is sought.";

(*b*) in paragraph (2), replace sub-paragraph (*a*) with —

"(*a*) whether one or more patents under the Patents Act 1994 mentioned in paragraph (1)(*a*) are in force in respect of the therapeutic product; and";

(*c*) in paragraph (5), after "Patents Act 1994", insert "mentioned in paragraph (1)(*a*)";

(*d*) in paragraph (8), replace sub-paragraphs (*a*) and (*b*) with —

"(*a*) apply to a court for —

(i) an order restraining the act for which the registration of the therapeutic product is sought; or

(ii) a declaration that the patent is valid and will be infringed by the doing of the act for which the registration of the therapeutic product is sought; and

(*b*) furnish the following to the Authority:

(i) a written notice stating that an application under sub-paragraph (*a*) has been made;

(ii) evidence of the application made under sub-paragraph (*a*);

(iii) a declaration by the proprietor that the application made under sub-paragraph (*a*) relates to a patent mentioned in paragraph (1)(*a*) that is in force in respect of the therapeutic product that is the subject of an application for registration."; and

(*e*) after paragraph (10), insert —

"(11) To avoid doubt, this regulation does not apply to the following patents:

(*a*) a process patent, other than a process patent that contains a claim for the use of an active ingredient in the manufacture of a therapeutic product for a specific therapeutic, preventive, palliative or diagnostic use;

(*b*) a patent that contains only claims relating to packaging;

(*c*) a patent that contains only claims relating to metabolites;

(*d*) a patent that contains only claims relating to intermediates.".

Amendment of regulation 24

3. In the principal Regulations, in regulation 24(1)(*a*)(i), delete "or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act 1994".

Amendment of regulation 25

4. In the principal Regulations, in regulation 25 —

(*a*) in the regulation heading, replace "**patent declaration**" with "**declaration**"; and

(*b*) after "regulation 23(2)", insert "or (8)(*b*)(iii)".

[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]

Made on 2023.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

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