HEALTH SCIENCES AUTHORITY
PRESS RELEASE
29 FEBRUARY 2024

HSA INVITES FEEDBACK ON PROPOSED AMENDMENTS TO REGULATION 23 OF THE HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) REGULATIONS

The Health Sciences Authority (HSA) invites public feedback on proposed amendments to Regulation 23 of the Health Products (Therapeutic Products) Regulations ["TPR"] on patent declaration. The public consultation will run from 1 March 2024 to 31 March 2024. The public consultation document and draft legislation are available on the HSA website (https://go.gov.sg/hptp-reg-amend).

Background

2 Under Regulation 23 of the TPR, HSA must consider whether a patent under the Patents Act 1994 is in force in respect of the therapeutic product undergoing registration application. The applicant seeking to register a therapeutic product is required to make and furnish a patent declaration to HSA, and notify the patent proprietor if a registration application for a therapeutic product that is subject to a patent is made during the patent term without the consent or acquiescence of the proprietor.

3 The legislative mechanism was implemented to fulfil Singapore's obligation under the US-Singapore Free Trade Agreement. It seeks to facilitate timely resolution of any potential patent disputes prior to HSA's granting of registration for a therapeutic product.

Objectives

4 The proposed amendments aim to:

i. Provide clarity to industry stakeholders on the types of patents that must be considered when making a registration application for a therapeutic product, and for which the provisions under regulation 23 apply.
ii. Ensure a system that facilitates all industry stakeholders in making registration applications and minimise any potential indiscriminate use of the mechanism under regulation 23.

Key proposed legislative changes

5 Regulation 23 will be amended to apply to the following categories of patents that are in force in respect of the therapeutic product undergoing registration application:

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.

Patents that are in force in respect of the therapeutic product but do not fall under the abovementioned categories are not subject to the requirements under regulation 23.

6 Regulations 24 and 25 will be updated to reflect the jurisdiction under which patent infringement matters reside and clarify the offences related to making a false declaration, respectively.

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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood

Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.