**HEALTH SCIENCES AUTHORITY**
**PRESS RELEASE**
**17 JULY 2023**

# HSA INVITES FEEDBACK ON THE PROPOSED REGULATION FOR ACTIVE INGREDIENTS UNDER THE HEALTH PRODUCTS ACT

The Health Sciences Authority (HSA) invites public feedback on a new piece of legislation known as the proposed Health Products (Active Ingredients) Regulations 2023. The public consultation will run from 17 July 2023 to 17 August 2023, at https://go.gov.sg/airegpublicconsult2023. The public consultation document and draft legislation are available on the HSA website (www.hsa.gov.sg/active-ingredients) and REACH portal (https://go.gov.sg/feedbackaireg2023).

2 Active ingredients[1] are pharmacologically active substances that may be used to manufacture health products, including therapeutic products, cell tissue or gene therapy products, and medical devices. Active ingredients are currently regulated under two different Acts, namely the Poisons Act 1938 and the Medicines Act 1975.

3 With the increasing complexity in the manufacturing and supply chain of active ingredients, streamlined and risk-based regulatory controls will ensure that active ingredients consistently meet the appropriate quality standards. To achieve this, HSA will be consolidating and enhancing the regulatory controls for active ingredients under a single Act, the Health Products Act (HPA). When the proposed Health Products (Active Ingredients) Regulations 2023 is implemented, the regulatory controls of active ingredients under the Poisons Act 1938 and Medicines Act 1975 will no longer apply.

## Objectives

4 HSA's proposed new regulation of active ingredients aims to achieve the following objectives:

[1] "Active ingredients" under the Health Products Act is also commonly referred to as "Active Pharmaceutical Ingredients" in the industry.

i. To safeguard public health by ensuring that active ingredients are consistently manufactured, stored and distributed with the quality standards appropriate for their intended use.

ii. To provide a fit-for-purpose and risk-based licensing framework that aligns with international standards and enhances mutual confidence with overseas counterparts.

iii. To streamline the regulation of active ingredients under a single legislation through the HPA, providing greater clarity in legal requirements and regulatory controls for all active ingredient manufacturers, importers and wholesalers.

**Key proposed legislative changes and regulatory controls**

5 The key proposed legislative changes and regulatory controls include:

i. **The scope of Active Ingredients regulatory controls.** The Health Products (Active Ingredients) Regulations 2023 is proposed to regulate active ingredients that are specified in The Schedule of the Regulations. The scheduled active ingredients are those that are usable as pharmacologically active constituents in the manufacture of any of the following health products:

- Therapeutic Products
- Cell Tissue or Gene Therapy Products that are not a result of only minimal manipulation of cell or tissue
- Medical Devices

ii. **Adopting a risk-based regulatory approach** for activity-based licensing of manufacturers, importers and wholesalers of active ingredients:

- Inspection and licensing controls will apply to all manufacturers, importers and wholesalers of active ingredients used in health products for local clinical use. Such companies handling active ingredients will be inspected for compliance with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice (GMP) Guide or HSA Good Distribution Practice (GDP) standard.
- Importers and/or wholesalers performing lower risk activities such as supplying active ingredients for non-clinical use (e.g., scientific research,

use in animals and other applications not involving humans) will be subjected to less stringent requirements. HSA shall reserve the rights to inspect, as required.

- Licensed importers and wholesalers of active ingredients will no longer need to hold separate Form A Poisons Licences under the Poisons Act.

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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.