FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
15 DECEMBER 2015

HSA SEEKS VIEWS ON THE PROPOSED SUBSIDIARY LEGISLATION FOR THE TRANSFER OF CONTROLS OF PHARMACEUTICAL PRODUCTS TO THE HEALTH PRODUCTS ACT

1 The Health Sciences Authority (HSA) invites feedback on the proposed subsidiary legislation for the licensing of pharmaceutical products and related regulations, which will be transferred from the existing laws to the Health Products Act[1] (Cap. 122D). This public consultation is open from 15 December 2015 to 15 January 2016 and is the second in a series of consultations held by HSA. The first consultation was held from October to November last year.

2 HSA is proposing to streamline the existing regulatory controls for pharmaceutical products under the Medicines Act and Poisons Act, and bring them under a single legislation, the Health Products Act. The proposed regulatory controls for product registration, dealer licensing and clinical trials under the Health Products Act are largely similar to the controls under the Medicines Act and its regulations. Some changes are being introduced to strengthen the existing legislative framework, enhance regulatory efficiency, and provide clarity, while protecting public health and safety. The key proposed changes include:

- **Proposed definition of "therapeutic products**" based on their purpose and active ingredients;
- **Streamlining of licence application processes and the bundling of licence fees** to facilitate current business practices;
- **Enhancing the post-market surveillance of therapeutic products** in Singapore, including the implementation of risk management plans and submission of benefit-risk evaluation reports, maintaining of records and reporting of product defects, and refining the reporting timelines of serious adverse reactions;
- Changes to the licensing regime, including the need to apply for a separate Form A Poisons Licence under the Poisons Act for dealers of products. The relevant control will be subsumed under the Importer's Licence (IL) and Wholesaler's Licence (WL). Under the proposed regulations, the licence application requires the **Naming of a Responsible Person**, who should be a pharmacist or such a person as approved by HSA, when dealing with pharmacy-only medicines and prescription-only medicines;
- Introducing a **risk-based approach in regulation of clinical trials for therapeutic products** and refinements to existing legal provisions to enhance transparency and support global clinical development without compromising public health; and
- Introducing a notification system, in place of the existing import approval system for clinical trials materials (CTM), to facilitate CTM access **(**including therapeutic products and medical devices) **for use in clinical research.**

3 HSA welcomes feedback on the proposed definition and regulations for therapeutic products to ensure a smooth transition of the controls to the Health Products Act and to minimise any potential impact to stakeholders. HSA will take the feedback into consideration

[1] 医疗保健产品法令

when refining the proposed regulatory framework prior to finalisation for implementation in 2016.

4 More information on the public consultation and draft legislations are available on the HSA website (www.hsa.gov.sg) and REACH portal (www.reach.gov.sg). All feedback should be sent to HSA via email (hsa_feedback@hsa.gov.sg) from 15 December 2015 to 15 January 2016.

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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 drugs, 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.