FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
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HSA SEEKS VIEWS ON THE PROPOSED SUBSIDIARY LEGISLATION FOR THE TRANSFER OF CONTROLS OF PHARMACEUTICAL PRODUCTS ("THERAPEUTIC PRODUCTS") TO HEALTH PRODUCTS ACT

The Health Sciences Authority (HSA) invites feedback from the public and stakeholders from the pharmaceutical industry as well as healthcare professionals and institutions from 27 October 2014 to 23 November 2014 on the proposed subsidiary legislation to transfer the regulatory controls of pharmaceutical products under existing laws to the Health Products Act (Cap. 122D). This is part of HSA's ongoing initiative to update and streamline the existing regulatory controls for health products and bring them under a single legislation, namely the Health Products Act (HPA), to ensure that the controls remain relevant and adequate to different operational and business models.

2 Health products span a wide range from low to high risk products. The HPA provides the legislative and regulatory framework for different categories of health products. Medical Devices were the first category of health products regulated under the Act, with phased implementation from 2007 to full implementation in 2012. Cosmetic Product regulations under the Act were also implemented in phases from 2008 to 2011.

3 Currently, the legislative controls for pharmaceutical products are spread out under different Acts, namely the Medicines Act (Cap. 176) and Poisons Act (Cap. 234). Consolidating the relevant controls under the HPA will provide greater clarity to stakeholders as they would only need to refer to a single legislation.

Pharmaceutical products will be introduced as "therapeutic products"

4 With this, the next category of health products – pharmaceutical products – to be regulated under the Act will be introduced as *"therapeutic products"* in the First Schedule of the HPA. A therapeutic product (TP) is defined as a health product that is intended for a therapeutic, preventive, palliative or diagnostic purpose, and its scope includes chemical and biologic drugs. This category of products is a subset of medicinal products already regulated under the Medicines Act. Other categories of health products, such as Cellular and Tissue Therapeutic Products and Complementary Health Products, amongst others, will continue to be regulated under the Medicines Act. They will be considered for consolidation under the HPA at a later date.

Public health continues to be safeguarded

5 In streamlining its regulatory framework for therapeutic products, HSA has adopted a measured and consultative approach, and worked closely with the industry and healthcare professionals. HSA has also studied the regulatory systems in reference countries, including the UK Medicines and Healthcare Products Regulatory Agency, US Food and Drug Administration, Health Canada and Australia Therapeutic Goods Administration, to ensure that the regulatory controls remain robust while allowing for adjustments and enhancements.

6 The relevant fundamental controls for TP under the existing laws will be retained and transferred to the HPA. In transferring the controls, 4 sets of subsidiary legislation will be implemented under the HPA to cover all aspects of TP regulation, including clinical trials, manufacture, registration, import, supply, presentation, advertisement, adverse event reporting and enforcement.

7 The first in a series of public consultations are the 2 sets of subsidiary legislation, which cover the controls on advertisements and retail pharmacies licensing of TP. The key proposed changes include:

- Removal of the existing permit system for advertisements of TP. Instead, advertisers will self-regulate based on broad principles and requirements prescribed in the Regulations while HSA will strengthen its post-market controls.
- All direct-to-consumers advertisements of Pharmacy Only Medicines will carry advisories/ warnings as required by HSA.
- Inclusion of provisions on telepharmacy by licensed retail pharmacies into the HPA for better clarity.

8 The public consultation for the other 2 sets of subsidiary legislation on the licensing regime of therapeutic products and its dealers, as well as that of clinical trial controls, will be conducted in the month of November.

Views Sought

9 Through this public consultation, HSA seeks the inputs and views of all stakeholders to ensure a smooth transition of the licensing controls and minimise any potential impact to stakeholders as much as possible. Stakeholder feedback will help in refining the proposed regulatory framework for therapeutic products before it is finalised for implementation in the third quarter of 2015.

10 HSA welcomes feedback on the proposed regulations for advertisement controls and pharmacies licensing of TP. The Public Consultation document 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) or fax (6478 9076) from 27 October 2014 to 23 November 2014.

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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.