



**SINGAPORE, 15 JUNE 2005  
HEALTH SCIENCES AUTHORITY**

## **PUBLIC CONSULTATION ON THE PROPOSED HEALTH PRODUCTS BILL**

### **INTRODUCTION**

The Health Sciences Authority (HSA), a statutory board of the Ministry of Health, plans to table a Bill in Parliament to enact the proposed Health Products Act. The proposed Act will serve to amalgamate the existing controls for regulating medicines, which currently reside in various pieces of legislation, into one omnibus Act. The proposed Act will also provide more flexibility for the application of different aspects of control for different types of health products through the use of type-specific subsidiary legislation. It is envisaged that the proposed Act will eventually become the principal legislative vehicle for regulating all types of health products for human use, including medical devices, pharmaceuticals, traditional medicines and health supplements.

2 HSA is seeking the views and feedback from the public and stakeholders from the health products industry as well as healthcare professionals on the proposed Health Products Bill. The draft Bill is available on the HSA website at [www.hsa.gov.sg](http://www.hsa.gov.sg). All feedback should be emailed to [hsa\\_feedback@hsa.gov.sg](mailto:hsa_feedback@hsa.gov.sg) by 31 July 2005.

### **EXISTING LEGISLATION FOR REGULATING HEALTH PRODUCTS**

3 Currently, the controls for regulating medicines reside in four separate pieces of legislation – namely, the Medicines Act (Cap 176), the Medicines (Advertisement and Sale) Act (Cap 177), the Poisons Act (Cap 234) and the Sale of Drugs Act (Cap 282). All four Acts have been in place for many years, with the Medicines Act being the newest, having been enacted in 1975, while the older ones date back to pre-independent Singapore. They have remained essentially unchanged over the years aside from some minor and technical amendments.

4 Together, these four Acts (along with their subsidiary legislation) form the legal basis of the regulatory controls on medicines and health-related products in Singapore. While they each focus on controlling the different aspects and activities involved in dealing with these products, e.g. manufacture, import, distribution, promotion and sale, there are also areas in which their respective controls overlap.

## **RATIONALE FOR HAVING A CONSOLIDATED LEGISLATION**

5 Over the years, HSA has received feedback that having the regulatory controls fragmented and spread out in different Acts makes them confusing and difficult to understand. In addition, the overlapping of controls in some areas sometimes makes compliance with the legal requirements unnecessarily complicated.

6 Therefore, one of the key objectives in having the proposed Health Products Act is to amalgamate the existing legal provisions of the controls on medicines and health-related products under one omnibus legislation. This move will reorder the legal provisions and make the regulatory controls easier to understand, and will be of particular benefit to those in the health products industry.

7 HSA is also taking this opportunity to update the penalty provisions for contravening the controls, which, in many cases, are outdated and do not reflect the current economic realities. For example, the maximum Court fine for the offence of providing false information in the process of applying for a licence under the Medicines Act is only \$5,000. The maximum fine for a corresponding offence in the proposed Health Products Act has been adjusted to \$20,000.

## **EXPECTED IMPACT ON REGULATION OF HEALTH PRODUCTS**

8 The proposed Health Products Act *per se* will not result in any immediate change in HSA's regulatory policies for any particular type of health product – regardless of whether that particular type of product is or is not currently subject to control, as the proposed new Act will essentially just consolidate the controls already in existence. In the process of this consolidation, HSA has sought to preserve the fundamental controls in the regulatory framework, most notable of which are the controls on manufacture, import, distribution, promotion and sale. In this respect, the legal provisions in the proposed new Act will also be generalised so that they can potentially be applied to different types of health products.

9 One key new feature of the proposed Health Products Act is that it will incorporate a legislative mechanism that allows for the modular application of the different controls to different types of health products. As such, while the proposed new Act may contain the full range of controls, it will be easier to customise the regulatory regime with appropriate levels of controls for each particular type of health product. This will provide HSA with more flexibility in adjusting the controls for the different product types, and help to minimise over-regulation as well as under-regulation, which is not uncommon in a 'one-size-fits-all' regulatory regime.

10 In terms of its longer-term impact, this proposed new Act will provide a uniform platform upon which the regulatory framework for all the different types of health products can be developed and reviewed. HSA has plans to conduct further consultation with the various segments of the health product industry as well as the general public, to refine the regulatory controls for the different types of health products – be it to relax some of the existing controls on a certain type of products, or to implement new controls for certain types of products.

11 Looking forward, once the desired regulatory regime for each of these types of health products has been elucidated, the necessary controls can be effected under the proposed new Act, using the modular application mechanism and type-specific subsidiary legislation. It is envisaged that the proposed Act will eventually become the principal legislative vehicle for regulating all types of health products for human use, including medical devices, pharmaceuticals, traditional medicines, health supplements, and any other types of health products that are of interest.

## **MODE OF CONSULTATION**

12 All feedback should be sent by **31 July 2005** to the following email address:

**hsa\_feedback@hsa.gov.sg**

13 Where feasible, parties should identify the specific clause of the draft Bill on which they are commenting. In any case in which a party chooses to suggest revisions to the text of the draft Bill, the party should state clearly the specific changes to the text they are proposing.

14 Parties submitting comments should include their personal/company particulars as well as their correspondence address, contact numbers and email addresses. Submissions from anonymous or unidentified sources will not be considered.

15 HSA would like to highlight that the contents of any written feedback submitted, and the identity of the source, may be disclosed at the conclusion of this consultation. Commenting parties may request confidential treatment for any part of the feedback submitted that the commenting party believes to be proprietary, confidential or commercially-sensitive, and such requests will be taken into consideration.

**Health Sciences Authority  
15 June 2005**

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