SINGAPORE, 09 JANUARY 2012

PUBLIC CONSULTATION ON PROPOSED

HEALTH PRODUCTS ACT (AMENDMENT OF FIRST SCHEDULE) ORDER

INTRODUCTION

The Health Sciences Authority (HSA), a statutory board of the Ministry of Health, plans to bring the existing controls for regulating western medicines under the Medicines Act (Cap 176) and Poisons Act (Cap 234) to the Health Products Act (Cap 122D). The scope and legislative controls for this group of products have been mapped over to the Health Products Act and will be introduced as *"therapeutic products"* in the First Schedule of the Health Products Act.

RATIONALE FOR TRANSFER OF CONTROLS TO THE HEALTH PRODUCTS ACT

2 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 with respect to the licensing for import and supply of these products sometimes makes compliance with the legal requirements unnecessarily complicated.

3 With the objectives to streamline and consolidate the regulations governing the controls for western medicines, the legal provisions from the two Acts, *viz.* Medicines Act (Cap 176) and Poisons Act (Cap 234), will be amalgamated under a single piece of legislation, i.e. the Health Products Act.

4 HSA is aiming for a lateral port-over of the licensing regime from the two Acts to the Health Products Act. The regulatory policies will remain fundamentally unchanged with fine-tuning of the regulatory controls and the scope of products will be preserved as per under the Medicines Act.

PROPOSED CHANGES

5 In transferring the legislative controls for this group of products to the Health Products Act, the product category "*therapeutic products*" will be described in the First Schedule of the Health Products Act. The draft Health Products Act (Amendment of First Schedule) Order can be viewed here:
http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/corporate/public_consultation.Par.60708.File.tmp/Annex%20A-HP%20(Amd1Sch)%20for%20Public%20Consult.pdf

PERIOD OF CONSULTATION

6 HSA invites members of public and stakeholders from the health products industry as well as healthcare professionals to participate in this consultation. This consultation exercise will commence on 09 January 2012 and end on 05 February 2012.

MODE OF CONSULTATION

7 All feedback should be submitted by 05 February 2012 via the electronic submission form.

8 Where feasible, the feedback party shall identify the specifics in the proposed draft which they are commenting on. In cases where a party chooses to suggest revisions to the text of the draft, the party should state clearly the specific changes to the text they are proposing.

9 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.

10 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.