SINGAPORE, 29 NOVEMBER 2011

HSA UPDATES

"HSA UPDATES" addresses topics of current public interest, and is subject to change as more information becomes available.
HSA UPDATES NO 7/2011

HSA UPDATES ON THE PHASING-OUT OF SERRATIOPEPTIDASE-CONTAINING PREPARATIONS AS MEDICINAL PRODUCTS

The Health Sciences Authority (HSA) has conducted a re-evaluation of the risk-benefit of serratiopeptidase for its current approved clinical uses. Serratiopeptidase products were first registered in 1991 shortly after the implementation of Singapore's drug registration system. While the clinical evidence then was sufficient to support the registration of these products based on the regulatory standards at that point in time, new data from recent clinical trials has shown that it does not provide significant clinical benefit over the use of placebo for the approved indications.

2 The re-evaluation exercise by HSA was undertaken following the voluntary withdrawal of Danzen (serratiopeptidase) Tablets in Japan in February 2011 by the proprietor, Takeda. Based on the data submitted by various product licence holders, including clinical studies conducted by the proprietor as well as data from published clinical studies, HSA's present evaluation concluded that there is no substantive scientific evidence to support the classification of serratiopeptidase as a medicinal product.

3 On this basis, the HSA has taken the regulatory decision to phase out serratiopeptidase-containing preparations as medicinal products. Considering the long history of use in the Singapore with minimal safety concerns, the phase-out process will follow a gradual approach to ensure that immediate impact on patients and industry stakeholders is minimized. With this, currently registered products will be allowed to continue their marketing authorization until the respective product licence expires.

4 There are currently 10 serratiopeptidase preparations registered as medicinal product in Singapore. Details of the specific product and the validity period of the respective product licence can be found on the HSA website at the Online Medicinal Product Search, the last product licence will expire in November 2012. Consequently, serratiopeptidase will be phased out as a medicinal product in Singapore.

5 Notwithstanding the regulatory decision taken on serratiopeptidase-containing medicinal products, serratiopeptidase is not precluded as an ingredient in other health products such as health supplements. For further enquiries, please email: hsa_medprod_enquiry@hsa.gov.sg.

HEALTH SCIENCES AUTHORITY
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- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

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