



SINGAPORE, 18 JANUARY 2013

## HSA UPDATES

***“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.***  
**HSA UPDATES NO 1/2013**

### **HSA UPDATES ON THE VOLUNTARY WORLDWIDE SUSPENSION OF THE SALES OF TREDAPTIVE™ (EXTENDED RELEASE NIACIN/LAROPIPRANT) BY MERCK SHARP & DOHME**

Merck Sharp & Dohme (MSD), in consultation with the Health Sciences Authority (HSA), is suspending the sales of Tredaptive™ (extended release niacin/laropiprant) following a preliminary assessment of the findings of the HPS2-THRIVE (Heart Protection Study 2- Treatment of HDL to Reduce the Incidence of Vascular Events) study. HSA has reviewed the data from the study and taken steps to suspend the licence of Tredaptive™.

2 Tredaptive™ has been licensed in Singapore since 30 Mar 2009 for patients with high cholesterol and triglycerides who cannot control their cholesterol levels by diet alone. It can be used by itself or with other medicines to control cholesterol levels.

#### **More about the HPS2-THRIVE study**

3 HPS2-THRIVE was designed to compare extended-release niacin and laropiprant plus statin therapy versus statin\* therapy alone. The study enrolled 25,673 patients considered to be at high risk for cardiovascular events and followed for an average of 3.9 years.

4 In the study, the preliminary findings showed that adding the combination of extended-release niacin and laropiprant to statin therapy did not significantly further reduce the risk of major vascular events such as heart attack and stroke compared to statin therapy alone. In addition, there was a statistically significant increase in the incidence of some types of non-fatal serious adverse events (such as muscle weakness, infections and adverse reactions involving the skin and gut) in the group that received extended-release niacin/laropiprant.

5 The investigators of the study are conducting additional analyses to further understand the results of the study.

\* Statins are a class of drugs used for the management of high cholesterol. Examples of statins include simvastatin, lovastatin and pravastatin.

## Local situation

6 HSA has been closely monitoring the safety profile of Tredaptive™ since the product was marketed in Singapore. To date, the local adverse reactions received for Tredaptive™ are in line with the known safety profile for Tredaptive™. MSD had on 7 January 2013, issued a Dear Healthcare Professional Letter to highlight to healthcare professionals the preliminary results from the HPS2-THRIVE study and advising them not to start new patients on Tredaptive™.

7 With this latest update from MSD, HSA is working with MSD to effect the recall of Tredaptive™. HSA is also working with MSD to communicate this information to healthcare professionals with advice to review the treatment plans for patients taking Tredaptive™ as soon as possible, to discontinue the medication and consider other changes in therapy to achieve their treatment goals for high cholesterol.

## HSA's Advisory

8 Patients currently taking Tredaptive™ are advised to consult their doctors as soon as it is possible and not to stop their medication unless otherwise advised by their doctors.

**HEALTH SCIENCES AUTHORITY  
SINGAPORE  
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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/>.

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