SINGAPORE, 9 November 2009

HSA UPDATES

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HSA UPDATES NO 12 /2009

HSA REQUESTS SINGAPORE PHARMACEUTICAL PTE LTD TO SUSPEND DEXTROPROPOXYPHENE SALES (DOLPOXENE®, DOLPOCETMOL®)

The Health Sciences Authority (HSA) has requested Singapore Pharmaceutical Pte Ltd to suspend the sales of dextropropoxyphene-containing products with effective from 9 November 2009 due to the findings that the risk benefit profile of dextropropoxyphene is no longer favourable.

2 Dextropropoxyphene is a weak synthetic opioid analgesic and is licensed for the treatment of mild to moderate pain. It is marketed in Singapore as Dolpoxene®, which contains only dextropropoxyphene and Dolpocetmol®, which contains a combination of dextropropoxyphene and paracetamol.

HSA's risk-benefit assessment of dextropropoxyphene

3 HSA has been closely monitoring the safety profile of dextropropoxyphene following withdrawal of dextropropoxyphene-containing products by UK in 2005 and the European Union in June 2009. Based on the assessment of the data available to-date, HSA and its Pharmacovigilance Advisory Committee (PVAC) have concluded that the risk of dextropropoxyphene outweighs its benefits in the treatment of mild to moderate pain.

4 The review took into consideration the following factors:

i) the limited therapeutic efficacy of dextropropoxyphene as compared to commonly used analgesics;

ii) the availability of other therapeutic alternatives such as paracetamol, NSAIDs and opioids; and

iii) the potential risk of fatal overdose associated with dextropropoxyphene as well as the risk-benefit assessments of other regulatory agencies.

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In addition, it has also been highlighted in several literature articles that norpropoxyphene, the metabolite of dextropropoxyphene, has been associated with cardiac toxicities.

5 The potential risk of fatal overdose with dextropropoxyphene and cardiac toxicities associated with its metabolite, norpropoxyphene are considered unacceptable in view of dextropropoxyphene's modest efficacy. As such, the importation, sales and marketing of Dolpoxene® and Dolpocetmol® at the wholesale level was suspended with effect from 9 November 2009.

HSA's Advisory

6 Patients who are taking this medicine should consult their doctors for an assessment of treatment alternatives based on their individual medical situation and needs.

7 Healthcare professionals are advised not to initiate new patients on dextropropoxyphene therapy and to consider alternative treatment options for their patients who may be currently on dextropropoxyphene products for pain relief.

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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, 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. 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 http://www.hsa.gov.sg/.

- **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.

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