FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
1 October 2004

HSA Issues Advisory to Patients on Vioxx as its Manufacturer Voluntarily Withdraws the Product

The Health Sciences Authority (HSA) refers to Merck Sharp & Dohme's (MSD) announcement on its independent decision to voluntarily withdraw Vioxx from the worldwide market. HSA issues an advisory to inform patients of this action and to advise them to consult with a physician about alternative medications.

Background Information

2 The withdrawal has been prompted by MSD's concern about the possible increase in risk of cardiovascular events (heart attack and stroke) in patients taking Vioxx for long term treatment.

3 HSA has been monitoring Vioxx since its approval for marketing in Singapore in 1999 and we have not detected any signals on this cardiovascular risk locally to date. The risk to an individual patient having a heart attack or stroke in relation to consumption of Vioxx is very small.

4 A prospective randomised placebo-controlled APPROVe (Adenomatous Polyp Prevention on Vioxx) trial was designed to evaluate the efficacy of Vioxx 25 mg in preventing recurrence of colorectal polyps in patients with a history of colorectal adenomas. This study was recently interrupted when it was found that there was a small increase in relative risk for cardiovascular events beginning after 18 months of continuous treatment in the patients taking Vioxx compared to those taking placebo. Following MSD's decision to voluntarily withdraw this drug, HSA is working with MSD (Singapore) to coordinate the local withdrawal of Vioxx.

Advisory for Patients

5 Vioxx was approved for acute and chronic treatment of arthritis, relief of pain and treatment of primary dysmenorrhea. There are many other medications available locally for these conditions. Patients who are on Vioxx are advised to consult their physicians about the discontinuation of Vioxx and alternative COX-2 selective or non-selective, non-steroidal anti-inflammatory drugs (NSAIDs).

6 MSD has set up a telephone hotline to handle any enquiries at Tel: 6393 7636 related to this withdrawal. Enquiries to HSA can be directed to its

Pharmacovigilance Unit at its Centre for Drug Administration at Tel: 6866 3530 and 6866 3531.

7 A list of frequently asked questions is attached in Annex A for easy reference.

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ANNEX A

FREQUENTLY ASKED QUESTIONS
ON MSD'S VOLUNTARY WITHDRAWAL OF VIOXX (ROFECOXIB)

1 The pharmaceutical company, Merck Sharp & Dohme (MSD), has announced that its product marketed under the name "Vioxx" is being voluntarily withdrawn worldwide with immediate effect. This decision was taken independently by MSD without input from regulatory authorities.

2 The Health Sciences Authority (HSA) is working with the local agent to coordinate the local withdrawal of the product. Our healthcare professionals have also been informed of the withdrawal.

3 The following frequently asked questions have been prepared for the information of patients and members of the public. The public may also call the following Hotlines for further clarification.

Merck Sharpe & Dohme (Singapore) Hotline : **6393 7636**

Health Sciences Authority Hotlines: **6866 3530**
6866 3531

Q1. What is Vioxx?

Vioxx is a medicinal product manufactured by Merck Sharp & Dohme (MSD). It contains the active ingredient "Rofecoxib" which belongs to the class of medicines known as COX-2 selective nonsteroidal anti-inflammatory drugs (NSAIDs).

Vioxx was registered in Singapore in 1999 and approved for the treatment of arthritis, acute pain in adults, and painful menstrual cycles. It is classified as a Prescription-Only-Medicine (POM) and must be prescribed by doctors.

Q2. Why has MSD decided to withdraw Vioxx?

MSD's decision to withdraw Vioxx from the market was prompted by a recent clinical trial finding that there was an increased risk of cardiovascular events (such

as heart attacks and strokes) in patients who had been taking Vioxx continuously for more than 18 months.

Q3. Are patients currently taking Vioxx at risk and what should they do?

The risk of an individual patient suffering a heart attack or stroke related to Vioxx is very small.

Patients who are currently taking Vioxx should contact their doctors to discuss discontinuing the use of Vioxx and what alternative treatments are available and appropriate.

Q4. Are there any long-term health risks to patients who have taken Vioxx?

The new finding showed the increased risk of heart attack and strokes in patients taking Vioxx continuously at 25 mg daily for a prolonged period of time (more than 18 months). Patients who had taken Vioxx for short-term treatment are not likely to be at risk. Patients with concerns are advised to consult their doctors.

Q5. What are the other drugs similar to Vioxx available locally?

Other COX-2 selective NSAIDs registered in Singapore include Arcoxia (etoricoxib), Celebrex (celecoxib) and Bextra (valdecoxib). There are also older, non-selective NSAID products available such as ibuprofen, diclofenac, ketoprofen and naproxen.

Patients should consult their doctors to determine which alternative treatment is appropriate for them.

For more information, please access the following:
http://www.hsa.gov.sg/html/business/00000000000000001560.html#49

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A. About the Health Sciences Authority

At the Health Sciences Authority [HSA], we apply medical, pharmaceutical and specialised scientific expertise to safeguard public health and safety in Singapore. As one multidisciplinary agency, we serve as the national regulator of all therapeutic products by providing a seamless yet rigorous regulatory process to the healthcare and biomedical sciences industries. We also operate the national blood bank, Bloodbank@HSA, protecting the integrity of the nation's blood supply. As the national reference agency, we exploit specialised scientific, forensic, investigative and analytical capabilities in order to serve the administration of justice and enhance safety in our community. For more details, visit **www.hsa.gov.sg**.