FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
25 JULY 2013

VOLUNTARY RECALL OF LOT L930 OF ACET 325 SUPPOSITORIES (ACETAMINOPHEN) DUE TO POTENTIAL DOSAGE LABELLING ERROR

The Health Sciences Authority (HSA) informs members of the public of the voluntary recall of lot **L930** of ACET 325 suppositories by Medicell Pharmaceutical (S) Pte Ltd. These products from Canada may have potential dosage labelling error during manufacturing. In the affected lot, a small number of the suppositories containing 650mg of acetaminophen were incorrectly labelled as ACET 325 (i.e. containing 325mg of acetaminophen) on the blister wrap.

2 ACET suppositories contain acetaminophen, also commonly known as paracetamol. These suppositories are inserted via the rectum and used for the relief of fever and mild to moderate pain. The distribution of the affected lot L930 of suppositories has been limited to 8 healthcare institutions in Singapore (please refer to the list in **Annex** to facilitate checks by consumers who obtained ACET suppositories from these institutions).

3 Of the 1,000 boxes of lot L930 of suppositories brought into Singapore, 934 boxes were collected back by Medicell Pharmaceutical (S) Pte Ltd and none were found to be mislabelled. The remaining 66 boxes of the affected lot may have been dispensed to patients and HSA has assessed that the likelihood of labelling error in these stocks is very low. Nevertheless, as a precautionary measure, HSA urges patients to check that they are not in possession of the affected lot of suppositories by checking for the name ACET 325 and lot number L930 on the blister wrap (please refer to **Annex** on how to locate the lot number).

HSA's Actions

4 HSA has assessed, in consultation with local medical experts, that the health risk to the individual consumer is low as acetaminophen is generally a well-tolerated medicine and used only when required to relieve fever and pain, generally not over a long duration. However, there is a potential of overdosing in susceptible patients if the suppositories are given over a prolonged duration. Susceptible patients would include children with low body weight, the elderly and those with existing liver problems. To date, HSA has not received any reports of adverse events related to this labelling error.

5 Although the likelihood of the dosage labelling error is very low, HSA is working with the company as a precautionary measure to recall the mislabelled ACET 325 suppositories of lot L930 which may have been distributed to consumers.

Consumer Advisory

6 Consumers are advised to:

a. check whether the individually blister wrapped suppositories from the boxes or plastic packaging containing them state that they are **ACET 325** and from the **lot L930** (Please refer to **Annex** for more details), and

b. stop using and return the **ACET 325** suppositories from lot **L930** to the pharmacies or healthcare institutions from which they were purchased, where they may be exchanged for unaffected lots of the suppositories.

7 Those who have already used the affected product should not be unduly alarmed as the labelling error has been assessed to pose minimal risk to health. Nevertheless, should a consumer experience any adverse effects from using the affected lot of suppositories (such as nausea, vomiting or stomach pain), they are advised to seek medical advice from their doctor.

8 Consumers may wish to contact Medicell Pharmaceutical (S) Pte Ltd at Tel: +65 6289 4696 or Email: dennisfortich@medicellpharma.com should they have enquiries about the recall.

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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/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

- **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. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

ANNEX

VOLUNTARY RECALL OF LOT L930 OF ACET 325 SUPPOSITORIES (ACETAMINOPHEN) DUE TO POTENTIAL DOSAGE LABELLING ERROR

List of healthcare institutions that received the affected batch of lot L930 of ACET 325 suppositories

- Mount Elizabeth Hospital Novena
- Mount Elizabeth Hospital Orchard
- Changi General Hospital
- Raffles Hospital
- KK Women's and Children's Hospital
- Tan Tock Seng Hospital
- Alexandra Hospital
- Khoo Teck Puat Hospital

Consumers who obtained ACET 325 suppositories from these institutions should check whether the individually blister wrapped suppositories from the boxes or plastic packaging containing them state that they are **ACET 325** and from the **lot L930**, as indicated in the pictures below:

Pictures: Affected batch of lot L930 of ACET 325 suppositories