



FOR IMMEDIATE RELEASE

**HEALTH SCIENCES AUTHORITY
PRESS RELEASE**

24 DECEMBER 2010

HSA ALERTS PUBLIC ON ABBOTT'S VOLUNTARY RECALL OF MEDISENSE OPTIUM™ BLOOD GLUCOSE TEST STRIPS

The Health Sciences Authority (HSA) is overseeing the voluntary market recall of 43 affected lots of Abbott MediSense Optium™ Blood Glucose Test Strips by Abbott Laboratories (S) Pte Ltd. The blood monitoring device is not affected by this recall.

2 The affected test strips may give inaccurate results to diabetic patients, showing readings that are lower than their actual blood sugar level. This could lead to patients failing to control and manage their actual blood glucose adequately due to the inaccurate reading.

3 Based on information provided by the company, the probable reason behind the inaccurate readings is related to the test strips taking a longer than expected time to absorb the blood from the patients' finger, which could lead to inaccurate low readings of their blood sugar levels. This may be dependent on the prolonged storage of the strips and their exposure to higher temperatures (exceeding 30°C) for an extended period of time.

4 Abbott Laboratories (S) Pte Ltd has imported into Singapore 43 affected lots. There are three pack sizes of 25, 50 or 100 test strips per box in the affected lots. The 43 affected lot numbers are on the Annex 1 attached. Globally, there may be additional lots that are affected.

5 Abbott Laboratories (S) Pte Ltd has initiated a voluntary recall of the affected lots. This recall is expected to be completed within a week.

Public Advisory

6 HSA advises that:

- Patients who have purchased Abbott MediSense Optium™ Blood Glucose Test Strips in Singapore, to stop using the affected lots (as listed in the attached Annex 1) and seek replacement of unaffected batches
- Patients who have purchased their strips overseas, to check with Abbott Laboratories S Pte Ltd if the test strips are from the affected lots

- Patients who have used these affected test strips should consult a doctor if they have experienced symptoms of high or low blood sugar due to treatment after readings obtained from the affected strips
- Patients may contact their health care provider to determine other testing options especially if they need to adjust their insulin therapy.

7 For return of the affected test strips and other additional information, patients are advised to contact Abbott Laboratories (S) Pte Ltd at 1800 272 2881, or email to ADC-CS.SG@abbott.com.

8 HSA will continue to monitor the situation closely and will take all appropriate actions to protect public health and safety.

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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.

▪ About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework. It 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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OPTIUM™ BLOOD GLUCOSE TEST STRIPS**

**LIST OF THE AFFECTED LOTS OF ABBOTT MEDISENSE OPTIUM™
BLOOD GLUCOSE TEST STRIPS DISTRIBUTED
BY ABBOTT LABORATORIES (S) PTE LTD**

Country: Singapore	
Lot Numbers Affected	
45001A137	45001A157
45001A169	45001A173
45001A214	45001A225
45001A226	45001A252
45001A297	45001A298
45001A428	45001A449
45001A451	45001A579
45001A602	45001A636
45001A657	45001A762
45001A773	45001A850
45001G002	45001G050
45503	45507
45517	45546
45563	45621
45662	45786
45805	45835
45898	45968
45998	46146
46188	46190
46269	48030
48040	48086
48096	