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藥物註冊及進出口管制部
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(IN REPLY PLEASE QUOTE THIS FILE REF.)

7 October 2011

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)
Dear Dr. LIANG,

Product Complaints for Sandostatin LAR for Inj 20mg and 30mg (octreotide)

The Department of Health has been informed by Novartis Pharm. (HK) Ltd. that it has received complaints for certain batches of its registered products Sandostatin LAR for Inj 20mg (batch number S0120 and S0126) and 30mg (batch number S0150). These batches were manufactured between December 2010 and April 2011 and released between March 2011 and July 2011.

The complaints are described as (i) difficulties in the handling of the product in terms of reconstitution of the suspension or "flocculation"; and/or (ii) difficulties in injection due to the higher than usual backpressure.

According to Novartis Pharm. (HK) Ltd., the potential impacts of the differing reconstitution and appearance characteristics of the products on the patient's health and safety were assessed. Their medical review did not identify any direct relation between the quality complaints and reports of medication error, lack of efficacy or injection site related cases. According to their assessment, the slightly different visual appearance and suspendability properties do not affect patient safety.

Novartis Pharm. (HK) Ltd. stated that it has reported the incident to the US FDA and the European Medicines Agency, and no action has been required by both overseas authorities so far.

In Hong Kong, Sandostatin LAR for Inj 20mg (HK-44140) and 30mg (HK-44141) are prescription-only medicines. So far, the Department of Health has not received any quality complaints related to the products. The Department will follow-up with the overseas authorities and will closely monitor the development of the issue.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax: 2147-0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.psdh.gov.hk at Drug Office under "Reporting an Adverse Drug Reaction".

Yours sincerely,

(Mr K W LAU)
for AD(D)