REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ص/٢٧١
رقم الصادر : ١٢/١/٨٧١٤
بيروت، في : ٢ - ايار ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Sterile Disposable Syringe 3ml – Luer Slip

الجهاز المعني بالمتابعة:

- Sterile Disposable Syringe 3ml – Luer Slip
- Trade Mark: Livingstone International Pty Ltd
- Local Representative:

بناء على التقرير الصادر عن الوكالة الأوسترالية TGA والذي يشير الى وجود خلل في عملية تعقيم الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأوسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
وليد عمار

Museum Street - Hussein Mansour Blg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2013-RN-00739-1
Product Name/Description[iii]	Sterile Disposable Syringe 3mL - Luer Slip Batch Numbers: T09AK Product Code: DSL003MLSC Product Code for loose pack: DSL003MLSC(L) Supplied between11 May 2011 to 1 July 2013 ARTG Number: 140670
Recall Action Level[iv]	Retail
Recall Action Classification[v]	Class II
Recall Commencement Date[vi]	24/07/2013
Responsible Entity[vii]	Livingstone International Pty Ltd
Reason / Issue[viii]	Livingstone International would like to advise that batch number T09AK of Sterile Disposable Syringe 3mL - Luer Slip may not be sterile.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Livingstone International is requesting users to quarantine and return any affected stock.
Contact Information[xi]	1300 727 204 - Livingstone International

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.

- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are three distinct recall actions - recall, recall for product correction and hazard alert.

- Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
- Recall for product correction - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- Hazard alert - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

[x] Recall Action Instructions: What the customer should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.