REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٧١/٢٥
رقم الصادر: ١٢/٧/٢٨٤٤
بيروت، في: ٢٩ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة مستحضر طبي
Viscoelastic injection, Durolane 3ml

الجهاز المعني بالمتابعة:

- Viscoelastic injection, Durolane 3ml
- Trade Mark: Smith & Nephew Orthopaedic
- Local Representative:

بناء على التقرير الصادر عن الوكالة الأوسترالية TGA والذي يشير الى وجود مضاعفات خلال استعمال 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
د. 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-00779-1
Product Name/Description[iii]	Durolane 3ml (synovial fluid supplementation substance) Product Number: 1081110 Batch Number: 12068-1 ARTG Number: 200304
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Commencement Date[vi]	31/07/2013
Responsible Entity[vii]	Smith & Nephew Surgical Pty Ltd
Reason / Issue[viii]	The manufacturer has advised that there has been a higher than anticipated number of reports of post-injection knee pain and swelling. In some cases an increase in the intensity of the symptoms have been reported. Pain, swelling and stiffness may limit mobility or use of the limb. Recovery time might be increased and moderate to severe patient discomfort may result. Some patients may have swelling due to varying degrees of effusion and which may require aspiration. Most patients involved with the reported complaints recovered within the listed timeframe in the IFU and known from the clinical studies of the product. Few patients had a protracted recovery time beyond 3 weeks after injection.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Please report any issues or adverse reactions to the TGA (refer to "Report a problem with a medical device" http://www.tga.gov.au/safety/problem.htm#device) and to Smith & Nephew Surgical. Customers with affected units are requested to advise Smith & Nephew so that replacement stock can be arranged.
Contact Information[xi]	02 9857 3999 - Smith & Nephew Surgical

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