衞生署藥物辦公室
藥物註冊及進出口管制部
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
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本署檔號 OUR REF.: DH PS PRIE/7-30/15
(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

4 October 2012

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

Dear Dr. LIANG,

Recall of Inflexal V 2012/2013 seasonal influenza vaccine

Your attention is drawn to that the Department of Health (DH) endorsed a licensed drug wholesaler, Amedis Company Limited (Amedis), to conduct voluntary recall of all batches of Inflexal V 2012/2013 seasonal influenza vaccine (registration number: HK-50625) (Inflexal influenza vaccine) from the market as a result of the precautionary measure by the Swiss manufacturer, Crucell.

According to Amedis two batches of the product in the manufacturing site in Switzerland were found contaminated with bacteria. Crucell is investigating the root cause of the problem. As a precautionary measure, Crucell initiated a recall of Inflexal influenza vaccine.

Based on information available so far, only two batches of Inflexal influenza vaccine (lot no. 3000287.03 and 3000291.02) had been imported into Hong Kong and they are unlikely to be affected. The two batches of Inflexal influenza vaccine were manufactured in August and were imported into Hong Kong in mid-September. The date of manufacture of the products in Hong Kong is different from the date of the manufacture of the two affected batches in Switzerland. The Certificate of Analysis showed that the products imported into Hong Kong had passed all quality tests, including sterility testings. DH has contacted the Swissmedic subsequently and confirmed that the imported two batches had been certified to be released into the market on 18 September 2012 and on 24 September 2012 respectively.

A total of 21071 boxes containing single injection of Inflexal influenza vaccine and 2211 boxes containing 10 injections of Inflexal influenza vaccine were imported to Hong Kong. Upon investigation, DH found that 3179 boxes of single injection and 1737 boxes of 10 injections had been sold to about 300 private doctors.

Based on the information available so far, DH considers that the potential risk of contamination of the two imported batches is remote. Nonetheless, DH considers the recall should

be completed as scheduled according to international practice. DH urges that all doctors should cooperate with the recall and stop using the products and immediately return them to the wholesalers.

Please remind your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms Christine CHEUNG)
for AD(D)

新聞公報

全面回收「欣福苗」針劑（附圖）
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衞生署同意持牌藥物批發商保亞醫衞有限公司（保亞醫衞），自願從市面回收所有批次的欣福苗針劑－2012／2013季節性流感疫苗產品（「欣福苗」）（註冊編號：HK-50625），是次回收是因應瑞士生產商Crucell對「欣福苗」採取的一項全球預防措施。

衞生署發言人表示，保亞醫衞通知署方，因爲在瑞士的生產廠房發現有兩個批次的產品被細菌污染。瑞士生產商Crucell現正調查問題的起因。作爲預防措施，Crucell已進行全球回收該款未獲Swissmedic正式批准銷售的「欣福苗」。

根據現時所得的資料，共有兩個批次的「欣福苗」針劑（批號：3000287.03及3000291.02）曾進口本港，而這兩個批次受污染的風險極低。這兩個批次的「欣福苗」於八月製造，並於九月中進口本港。本港這兩個批次的製造日期與在瑞士發現受污染的兩個批次的製造日期不同。根據產品品質分析證書顯示，進口本港的兩個批次已通過所有的品質測試，包括無菌測試。衞生署亦已聯絡Swissmedic，並證實進口本港的兩個批次在今年九月十八日及九月二十四日已獲Swissmedic的批准銷售。

爲迎合即將來臨的流感季節對流感疫苗的大量需求，Swissmedic特別允許流感疫苗在通過根據品質分析證明書下所有品質測試後，可付運予批發商，不過，產品需於Swissmedic正式簽署放行證明書後，才可在市場出售。保亞醫衞共進口21,071盒一支裝的「欣福苗」針劑及2,211盒十支裝的「欣福苗」針劑，照規定需等待Crucell通知，當Swissmedic已簽發放行證明書才可發售。不過，衞生署在調查中發現，有3,179盒一支裝的「欣福苗」針劑及1,737盒十支裝的「欣福苗」針劑，在未取得Crucell通知前，已供應給本港大約300名私家醫生。衞生署已警告保亞醫衞須獲得正式放行證明書通知才可分銷有關產品。

根據現時所得的資料，涉及該兩個已進口批次產品的潛在風險極低。不過，署方認爲一旦回收開始，應根據國際慣例完成。衞生署建議所有醫生應配合回收行動，並停用有關針劑產品及立即把產品退回批發商。任何人士如在接受注射有關疫苗後出現不適，應諮詢醫生的意見，以就其情況作出評估。

保亞醫衞已設立電話熱線（8100 8606）解答相關查詢。衞生署會密切監察回收情況。署方至今未有接獲與產品有關的不良反應報告。

完

２０１２年１０月４日（星期四）
香港時間２３時２４分

Press Releases

Total recall of Inflexal V Injection (with photo)
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The Department of Health (DH) endorsed a licensed drug wholesaler, Amedis Company Limited (Amedis), to conduct voluntary recall of all batches of Inflexal V 2012/2013 seasonal influenza vaccine (registration number: HK-50625) (Inflexal influenza vaccine) from the market as a result of the global precautionary measure by the Swiss manufacturer, Crucell.

A DH spokesman said that Amedis informed DH that two batches of the product in the manufacturing site in Switzerland were found contaminated with bacteria. Crucell is investigating the root cause of the problem. As a precautionary measure, Crucell initiated a global recall of Inflexal influenza vaccines not yet officially released by the Swissmedic.

According to information available so far, only two batches of Inflexal influenza vaccines (lot no. 3000287.03 and 3000291.02) had been imported into Hong Kong and the risk of contamination of the two imported batches are remote. The two batches of Inflexal influenza vaccines were manufactured in August and were imported into Hong Kong in mid-September. The date of manufacture of the products in Hong Kong is different from the date of the manufacture of the two affected batches in Switzerland. The Certificate of Analysis showed that the products imported into Hong Kong had passed all quality tests, including sterility testings. DH has contacted the Swissmedic subsequently and confirmed that the imported two batches had been certified to be released into the market on September 18, 2012 and on September 24, 2012 respectively.

To meet the high demand of influenza vaccines in the coming influenza season, it is a special practice of the Swissmedic that influenza vaccines are allowed to be shipped to wholesalers when the vaccines have passed all quality tests under the Certificate of Analysis. However, they can only be sold to the market after the Swissmedic has officially signed the release certificates. A total of 21,071 boxes containing single injection of Inflexal influenza vaccines and 2,211 boxes containing 10 injections of Inflexal influenza vaccines were imported to Hong Kong pending notification from Crucell that the official release certificates have been issued. However, upon investigation, DH found that 3,179 boxes of single injection and 1,737 boxes of 10 injections had been sold to about 300 private doctors before receiving the notification. DH has already warned Amedis that notification of the official release certificate must be received before distribution of the product.

Based on the information available so far, it is considered that the potential risk of contamination of the two imported batches is remote. Nonetheless, DH considers the recall should be completed as scheduled according to international practice. DH urges that all doctors should co-operate with the recall and stop using the products and immediately return them to the wholesalers. However, people who had received the vaccines feel unwell, they should consult their doctors for assessment.

Amedis has set up a hotline at 8100 8606 to answer related

enquiries. DH will closely monitor the recall. So far DH has not received any adverse reports in connection with the product.

Ends/Thursday, October 4, 2012
Issued at HKT 23:25

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