

**Health Canada Endorsed Important Safety Information on  
Infanrix Hexa®**



October 30, 2012

Dear Health Care Professional:

**Subject: Voluntary recall of GlaxoSmithKline (GSK) Infanrix Hexa®  
Vaccine Lot A21CB242A due to potential microbiological  
contamination**

GlaxoSmithKline, in consultation with Health Canada, would like to inform you of the decision to voluntarily recall one Lot (A21CB242A) of Infanrix Hexa® vaccine as a result of potential microbial contamination.

- The recall is a precautionary measure due to potential microbial contamination
- Do not administer doses from the affected lot
- No contamination has been found in the final product released for distribution.
- No reported spontaneous adverse events appear to be linked to the reasons for the recall.

Infanrix Hexa® is indicated for active primary immunization against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and disease caused by *Haemophilus influenzae* type b in infants and children 6 weeks to 2 years, and is presented as a sterile suspension for injection, DIN 2253852.

Infanrix Hexa® is only currently offered in a Universal Mass Vaccination (UMV) program in British Columbia and Yukon.

Recent investigations identified the potential for microbiological contamination in the environment where vaccine bulk antigens for Infanrix Hexa®, Infanrix™-IPV and Infanrix™-IPV/Hib vaccines were placed. The release tests (including sterility tests) on intermediates and on the final containers met pre-established acceptance criteria. No contamination was found in the final product released for distribution.

A search of the GSK worldwide safety database did not identify any reported spontaneous adverse events that appear to be linked to microbial contamination. GSK has decided to initiate a voluntary recall of the abovementioned Lot as a precautionary measure.

## ACTIONS REQUESTED OF HEALTHCARE PROFESSIONALS

1. DO NOT ADMINISTER DOSES FROM THE AFFECTED LOT
  - Please quarantine and **do not administer** any unused doses of the affected Lot of Infanrix-Hexa<sup>®</sup>.
  - Please follow the local procedures for the return receipt of these doses.
2. POST-IMMUNISATION PATIENT FOLLOW-UP
  - Patients to whom doses from the affected Lot have been already been administered should be monitored as per routine post-immunisation practice.
  - Please report any Adverse Events following Immunisation as detailed below.

GSK sincerely apologizes for this unforeseen situation and will work closely with providers and authorities to minimize any disruption to delivery of the childhood immunization program in Canada.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving Infanrix Hexa<sup>®</sup> should be reported to GSK or the Public Health Agency of Canada at the following addresses:

GlaxoSmithKline Inc.  
7333 Mississauga Road  
Mississauga, Ontario  
L5N 6L4

Phone: 1-800-387-7374 (option 3 for GSK Medical Information)

**To correct your mailing address or fax number, contact GlaxoSmithKline Inc.**

### **How to report a suspected adverse event following immunization:**

If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Form and send it to the local health department in your [province or territory](#). The list of contacts is also provided below.

The [Adverse Events Following Immunization Reporting Form](http://www.phac-aspc.gc.ca/im/aefi-form-eng.php) (<http://www.phac-aspc.gc.ca/im/aefi-form-eng.php>) and [Guidelines](http://www.phac-aspc.gc.ca/im/aefi_guide/index-eng.php) ([http://www.phac-aspc.gc.ca/im/aefi\\_guide/index-eng.php](http://www.phac-aspc.gc.ca/im/aefi_guide/index-eng.php)) can be found on the Public Health Agency of Canada Web site or in the *Canadian Compendium of Pharmaceuticals and Specialties*

**If you have any questions or have difficulties contacting your local health department, contact the Vaccine Safety Section at the Public Health Agency of Canada at:**

Telephone: 613-954-5590, 1-866-844-0018

Fax: 613-954-9874, 1-866-844-5931

Should you have any questions or require additional information regarding the use of Infanrix Hexa<sup>®</sup> please contact GlaxoSmithKline Inc., Medical Information Department at 1-800-387-7374 (option 3).

Sincerely,

***Original signed by***

Dr. Glenn Crater  
Vice President, Medical and Chief Medical Officer  
GlaxoSmithKline Inc.

**Provincial/Territorial Contacts for Adverse Events Following Immunization Form**

**Alberta**

Alberta Health and Wellness  
Community Health Branch  
Immunization Program  
10025 Jasper Ave NW  
PO Box 1360  
Edmonton, AB T5J 2N3  
Phone: 780-415-2824  
Web site: [www.albertahealthservices.ca/](http://www.albertahealthservices.ca/)

**British Columbia**

British Columbia Centre for Disease Control  
Epidemiology Services  
655 West 12th Avenue  
Vancouver, BC V5Z 4R4  
Phone: 604-707-2517  
Fax: 604-707-2515  
Web site: [www.bccdc.ca](http://www.bccdc.ca)

**Manitoba**

Manitoba Department of Health  
Communicable Disease Control Branch  
4th Floor-300 Carlton Street  
Winnipeg, MB R3B 3M9  
Phone: 204-788-6737  
Fax: 204-948-3044  
Web site: [http://www.gov.mb.ca/health/publichealth/cdc/docs/aefi\\_form.pdf](http://www.gov.mb.ca/health/publichealth/cdc/docs/aefi_form.pdf)

**New Brunswick**

Communicable Disease Control (CDC) Branch  
Office of the Chief Medical Officer of Health  
Department of Health  
2nd Floor HSBC Place, 520 King Street  
P.O. Box 5100  
Fredericton, NB E3B 5G8  
Main CDC Office Number: 506-444-3044  
Web site: <http://www2.gnb.ca/content/gnb/en/departments/ocmoh.html>

**Newfoundland and Labrador**

Public Health  
Department of Health and Community Services  
PO Box 8700  
St. John's NL A1B 4J6  
Phone: 709-729-5019, 709-729-0115  
Fax: 709-729-0730  
Web site: <http://www.health.gov.nl.ca/health/publichealth/cdc/immunizations.html>

**Nova Scotia**

Department of Health and Wellness  
Summit Place, 6th Floor  
1601 Lower Water Street, P.O. Box 487  
Halifax, NS B3J 2R7  
Phone: 902-424-8160  
Fax: 902-424-0550  
Web site: <http://www.gov.ns.ca/hpp/cdpc/>

**Northwest Territories**

Office of the Chief Medical Health Officer  
Department of Health and Social Services  
Box 1320  
Yellowknife, NT X1A 2L9  
Phone: 867-920-8646  
Fax: 867-873-0442  
Web site: <http://www.hlthss.gov.nt.ca/default.htm>

**Nunavut**

Office of the Chief Medical Health Officer  
Department of Health and Social Services  
Box 1000, Station 1000  
Iqaluit, NU X0A 0H0  
Phone: 867-975-5700  
Fax: 867-979-3190

**Ontario**

Direct all forms to your local public health unit. Contact information for each health unit can be found on the following Web page:

[http://www.health.gov.on.ca/english/public/contact/phu/phuloc\\_mn.html](http://www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html)

Phone: PHD Info line 1-866-532-3161

TTY: 1-800-387-5559

**Prince Edward Island**

Office of Chief Health Officer

Department of Health and Wellness

Box 2000

Charlottetown, PEI C1A 7N8

Tel: 902-368-4996

Fax: 902-620-3354

Web site: <http://www.gov.pe.ca/health/index.php3>

**Quebec**

Phone: Call Info Santé in your region

Web site: [http://www.msss.gouv.qc.ca/sujets/santepub/vaccination/index.php?accueil\\_en](http://www.msss.gouv.qc.ca/sujets/santepub/vaccination/index.php?accueil_en)

**Saskatchewan**

Saskatchewan Ministry of Health

Population Health Branch

3475 Albert Street

Regina, SK S4S 6X6

Phone: 1-800-667-7766

Web site: <http://www.health.gov.sk.ca/>

**Yukon**

Vaccine Program Manager

Yukon Territorial Government

Department of Health and Social Services

#2 Hospital Road

Whitehorse, YT Y1A 3H8

Phone: (867) 667-8330

Web site: <http://www.hss.gov.yk.ca>