

**Public Communication -  
Health Canada Endorsed Important Safety Information on  
Infanrix Hexa®**



November 2, 2012

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

GlaxoSmithKline, in consultation with Health Canada, would like to inform you of its decision to voluntarily recall one Lot (A21CB242A) of Infanrix Hexa® vaccine as a result of detection of contamination in the environment where material used to make the recalled vaccine had been placed. No contamination was found in the vaccine.

- The recall is a precautionary measure.
- **No contamination** has been found in the vaccine.
- No reported adverse events appear to be linked to the reasons for the recall.

Infanrix Hexa® is a vaccine used in children for protection against diphtheria, tetanus (lockjaw), pertussis (whooping cough), hepatitis B, poliomyelitis (polio) and *Haemophilus influenzae* type b diseases. Vaccination is the best way to protect against these diseases.

Infanrix Hexa® is only currently offered through vaccination programs in British Columbia and the Yukon Territory.

Recent investigations detected contamination in the environment where one of the components of this Lot was placed.

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

GlaxoSmithKline has sent a letter to healthcare professionals informing them about this recall. This information may be obtained on the Canadian website of GlaxoSmithKline ([www.gsk.ca](http://www.gsk.ca)) or on the Health Canada Web site.

Should you have any questions or require additional information regarding the use of Infanrix Hexa® please contact your healthcare professional.

For media inquiries, please contact GlaxoSmithKline Communications at (905) 819-3363.

GSK sincerely apologizes for this situation and is working closely with health authorities to prevent any impact on children's immunization schedule.

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® should be reported to GSK or your local health department at the following addresses:

GlaxoSmithKline Inc.  
7333 Mississauga Road  
Mississauga, Ontario  
L5N 6L4  
Phone: 1-800-387-7374

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

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events Following Immunization (AEFI) Form.

The [Adverse Events Following Immunization Reporting Form](http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php) (<http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php>) and [Guidelines](http://www.phac-aspc.gc.ca/im/ae-fi_guide/index-eng.php) ([http://www.phac-aspc.gc.ca/im/ae-fi\\_guide/index-eng.php](http://www.phac-aspc.gc.ca/im/ae-fi_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, please 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

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  
P.O. 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  
P.O. 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  
P.O. 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  
P.O. 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  
P.O. 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>