INFANRIX Vaccines
Questions and Answers for Immunization Providers – April 2014

1. What are the INFANRIX® products?

"INFANRIX" refers to a combination vaccine for diphtheria, tetanus, and acellular pertussis. INFANRIX® products include INFANRIX hexa®, INFANRIX®-IPV/Hib and INFANRIX®-IPV. INFANRIX hexa® is currently used for the routine infant series at 2, 4 and 6 months of age. INFANRIX®-IPV/Hib will replace PEDIACEL® for routine use. INFANRIX®-IPV will replace QUADRACEL®.

GSK Product Name	Corresponds To	Replaces Sanofi Product
INFANRIX hexa®	DTaP-Polio-Hib-Hepatitis B	-
INFANRIX®-IPV/Hib	DTaP-Polio-Hib	PEDIACEL®
INFANRIX®-IPV	DTaP-Polio	QUADRACEL®

2. Why are we changing over to these new products?

Over the past two years, there have been periodic shortages of DTaP containing vaccines. The introduction of an additional supplier will improve the security of DTaP vaccine supply and will reduce the potential for vaccine shortages in Canada.

3. When will we be changing over to the new products?

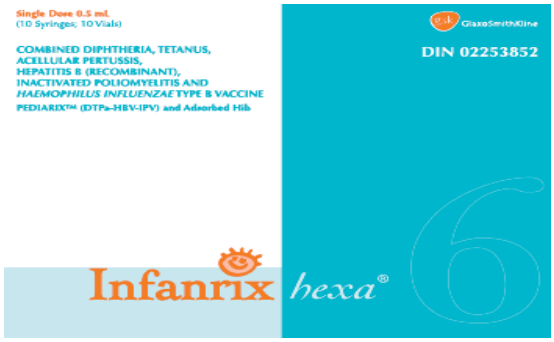
Health units' supplies of PEDIACEL® and QUADRACEL® are expected to last until the end of April 2014. As the supply of these products decrease, please order the corresponding GSK products (INFANRIX® -IPV/Hib and INFANRIX®-IPV). INFANRIX hexa® is currently in use and can be re-ordered as needed.

4. What do the INFANRIX® products look like?

Due to the similarity of the name "INFANRIX" on these three products, it is recommended that immunization providers familiarize themselves with each product's carton as well as the respective syringe and vial. This can help to avoid potential administration errors.

For more detailed information about vaccine administration, please refer to the BC Immunization Manual Section IV – Administration of Biological Products which refers to the 7 'rights' of medication administration.

INFANRIX hexa® (DTaP-HB-IPV-Hib)



Carton dimensions: 142mm 178mm x 29mm

INFANRIX®-IPV/Hib (DTaP-IPV-Hib)

Carton dimensions: 142mm x 178mm x 29mm

INFANRIX®-IPV (DTap-IPV)

Carton dimensions: 103mm x 178mm x 29mm

5. How are the INFANRIX® products supplied?

INFANRIX hexa®

This product is supplied in 10 dose packages with 10 syringes containing INFANRIX hexa® suspension (combined diphtheria and tetanus toxoids, acellular pertussis, hepatitis B (recombinant) and inactivated poliomyelitis vaccine) and 10 corresponding vials of the Hib component. The Hib component is supplied as a lyophilized white powder in a glass vial. [1] The vaccine is reconstituted by adding the contents of the syringe to the vial.

INFANRIX®-IPV/Hib

This product is supplied in 10 dose packages with 10 syringes containing INFANRIX®-IPV suspension (combined diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) and 10 corresponding vials of the Hib component. The Hib component is supplied as a lyophilized white powder in a glass vial. Upon storage, a white deposit may sometimes be observed in the liquid component of the syringe; this does not constitute a sign of deterioration.[2] The vaccine is reconstituted by adding the contents of the syringe to the vial.

INFANRIX®-IPV
This product is available in 10 dose packages and is supplied as single prefilled syringes. During storage a white deposit may sometimes be observed in the liquid component of the syringe; this does not constitute a sign of deterioration.[3]

6. What if I forget to reconstitute the INFANRIX hexa® and INFANRIX®-IPV/Hib therefore not giving a dose of Hib to my client?

If this error is made, remove the unused Hib component from the box and return to BCCDC; report this as an error through your internal health authority systems. You can administer Act-Hib® separately to those who qualify for a Hib dose.

7. When were the INFANRIX® products approved for use in Canada?

INFANRIX hexa®
This product was first approved for use in Canada in 2004. Since February 2009, INFANRIX hexa® has been used as part of the routine infant schedule in BC.

INFANRIX®-IPV/Hib
This product was approved for use in Canada in 2004.

INFANRIX®-IPV
This product was approved for use in Canada in 1999.[4]

8. Where else in Canada and in the world are these products used?

Currently INFANRIX® products are used widely within Canada. INFANRIX® hexa is used in the Yukon, Prince Edward Island, Quebec and British Columbia. INFANRIX®-IPV and INFANRIX®-IPV/Hib are used in Quebec, Alberta, Saskatchewan and British Columbia. Globally, INFANRIX® products are being used in the U.K., Germany, France, Italy, Spain, Netherlands, Belgium and the U.S.A. In some countries the brand names are different but the product is the same. However products and schedules are subject to change. Queries about the specific product received by a client should be directed to the appropriate jurisdiction.

9. Do the INFANRIX® products provide the same level of protection as the current comparable products?

The different products have not been directly compared to one another in head-to-head trials. However the INFANRIX® products' efficacy has been demonstrated against pertussis and these products also provide the needed immunogenicity against the respective diseases.

10. Are the INFANRIX® products and PEDIACEL® and QUADRACEL® products considered interchangeable?

For the primary infant series (the first three doses), the same product should be used. The exception to this is if the original product is unavailable or is unknown.[6] This is because the pertussis components of these products are different. PEDIACEL® vaccines contain five pertussis antigens, whereas INFANRIX® vaccines contain three antigens. The concentration of each of the three types of pertussis antigens in INFANRIX® are 5 µg greater than in the five component pertussis vaccines (PEDIACEL®).[5]

11. Can INFANRIX hexa® be given as a booster dose regardless of product used for the primary series?

Yes, if a child less than 7 years of age requires a dose of Hepatitis B vaccine then INFANRIX hexa® can be used as a booster dose regardless of the product used for the primary series. Using these products interchangeably for the 18 month and 4-6 year booster doses is not known to adversely affect the immunogenicity and effectiveness.[7] Depending on the age of presentation, a child may receive an additional Hib dose. This is not expected to result in any additional adverse events.

12. What product would I give a 2 month old infant who was at high risk for Hep B and had received monovalent Hep B vaccine separately at 0 and 1 month of age?

Infants at high risk of Hep B acquisition who were started on the 0, 1 and 6 schedule would likely have received these immunizations in another province or country. INFANRIX®-IPV/Hib is the preferred product for these infants. The immunization schedule would be as follows:
2 months: INFANRIX®-IPV/Hib
4 months: INFANRIX®-IPV/Hib
6 months: INFANRIX hexa®
In B.C., the Hep B protocol for high risk infants recommends monovalent Hep B vaccine at 0 months and INFANRIX hexa® vaccine at 2, 4 and 6 months of age.

13. Will PEDIACEL® and QUADRACEL® still be available for me to use?

Yes, PEDIACEL® will continue to be available and can be used to immunize clients who require this product. Indications for the use of PEDIACEL® are provided on corresponding biological product page within the BC Immunization Manual. A small quantity QUADRACEL® will be available for use with clients who have a latex allergy. Other Canadian provinces have also switched over from PEDIACEL® to INFANRIX®-IPV/Hib: Alberta and Saskatchewan have been using INFANRIX®-IPV/Hib since April 1 2013.

14. Can HSCT stem cell clients receive either PEDIACEL® or INFANRIX®-IPV/Hib?

Yes, either PEDIACEL® or INFANRIX®-IPV/Hib can be used for HSCT stem cell clients. However INFANRIX hexa® should not be given to these clients as they require a double dose of Hepatitis B.

15. How do the rates of adverse events compare between the current comparable products?

The adverse event profiles for the GSK and Sanofi DTaP products are similar. However rates of fever may increase when INFANRIX®-IPV/Hib is used for the booster dose. INFANRIX® products, like all other vaccines, go through rigorous safety testing before they are deemed safe to use.

16. I've noticed that Panorama invalidates the Hepatitis B antigen when I input the third dose of INFANRIX hexa®. Why is this happening?

Hepatitis B is one component of the INFANRIX hexa® vaccine. The minimum intervals/ages for hepatitis B component are used when forecasting INFANRIX hexa® as it is the most stringent validation criteria compared to the other antigens. If Panorama has invalidated the Hepatitis B component, it means that this antigen is considered invalid as the requirements for minimum spacing/age were not met. As per the BC Immunization Manual, Section IV Administration of Biological Products, if some of the components of a combination vaccine are valid, repeat only the component(s) that are invalid if a product is available, such as the monovalent Hepatitis B vaccine. As per the BC Immunization Manual, the third dose of INFANRIX hexa® must be given:

a) At least 16 weeks after dose 1 AND
b) At least 8 weeks after dose 2 AND
c) At least 24 weeks of age

REFERENCES:

[1] GlaxoSmithKline. Product Monograph INFANRIX hexa® [Internet]. Mississauga (ON): 2013. Available from http://www.gsk.ca/english/docs-pdf/product-monographs/Infanrix-hexa.pdf

[2] GlaxoSmithKline. Product Monograph INFANRIX®-IPV/Hib [Internet]. Mississauga (ON): 2013. Available from http://www.gsk.ca/english/docs-pdf/product-monographs/Infanrix-IPV-HIB.pdf

[3] GlaxoSmithKline. Product Monograph INFANRIX®-IPV [Internet]. Mississauga (ON): 2013. Available from http://www.gsk.ca/english/docs-pdf/product-monographs/Infanrix-IPV.pdf

[4] Notice of Compliance Search: INFANRIX/IPV. Public Health Agency of Canada. Available from http://webprod5.hc-sc.gc.ca/noc-ac/index-eng.jsp

[5] Literature review on DTaP based Penta- and Hexavalent vaccines approved for clinical use in Canada. 2006. Public Health Agency of Canada. Available from http://www.phac-aspc.gc.ca/naci-ccni/l_review-eng.php

[6] Canadian Immunization Guide. Part 1: Principles of Vaccine Interchangeability. Public Health Agency of Canada. Available from http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-06-eng.php

[7]National Advisory Committee on Immunization. *Interchangeability of diphtheria, tetanus, acellular pertussis, polio, Haemophilus influenzae type b combination vaccines presently approved for use in Canada for children <7 years of age*. Canada Communicable Disease Report 2005;31(ACAS-1):1-10. Available from http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/05pdf/acs-dcc3101.pdf