



North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section

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May 23, 2012

MEMORANDUM

TO: North Carolina Immunization Program (NCIP) Participants

FROM: Beth Rowe-West, RN, BSN
Head, Immunization Branch

SUBJECT: *UPDATE:* Pentacel® and Daptacel® Vaccine Ordering and CDC Guidance

The purpose of this memo is to update providers regarding a change in NCIP ordering practices, and to share guidance developed by the Centers for Disease Control and Prevention (CDC), because of manufacturing delays for Pentacel® and Daptacel® vaccines. The attached CDC guidance is designed to help minimize the impact of reduced supplies of these vaccines on your immunization practices.

Sanofi Pasteur is temporarily implementing order limitations for Pentacel® (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and Haemophilus b conjugate [tetanus toxoid conjugate] vaccine) and Daptacel® (diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed). These limitations have resulted from a manufacturing delay that will temporarily reduce supply below the level needed to fully satisfy market demand.

Ordering limitations for Pentacel® and Daptacel® vaccines went into effect April 20, 2012 for all NCIP customers and are likely to remain in effect until the end of September 2012. **Effective immediately, NCIP will cease the substitution of single-antigen products for reduced Pentacel® orders, as opposed to the process outlined in the April 23, 2012 memo. Providers should expect their Pentacel® orders to be reduced to approximately 2/3rds of their last, pre-April 2012 order. In addition, providers MUST order appropriate DTaP, Hib, and polio replacement vaccines. Failure to do so will result in delayed orders which will impact your ability to fully vaccinate your patients.**

Because there are other manufacturers of comparable single-antigen and combination vaccines, little to no impact to the routine childhood immunization schedule is anticipated. One of these combination products, Pediarix®, contains DTaP and IPV, as well as hepatitis B vaccine, but does not contain Hib vaccine. Differences in vaccine components, as listed in the Pentacel® guidance, will need to be considered when ordering these replacement vaccines to ensure that infants receive all of their necessary vaccine antigens. Sanofi Pasteur's order limitations were put in place to help maximize the availability of the existing DTaP supply and minimize the impact to your practice. Providers should continue to follow CDC's recommended immunization schedule and order vaccines which are appropriate for the patient population you serve.

NCIP understands the challenges that health care providers, patients, and parents face when there are limited supplies of vaccine, and apologizes for any inconvenience caused by these temporary order restrictions. Please contact the NCIP Help Desk, 1-877-873-6247, for guidance about ordering vaccines.

Cc: SMT Field Staff Central Office Staff Vaccine Manufacturers
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**Centers for Disease Control and Prevention (CDC)
National Center for Immunization and Respiratory Diseases (NCIRD)
Atlanta, GA**

May 11, 2012

Guidance for Vaccinating Children during the 2012 Pentacel[®] and Daptacel[®] Shortage

Sanofi Pasteur's Pentacel (DTaP-IPV/Hib) and Daptacel (DTaP) are expected to be in short supply throughout the summer of 2012. Practices using these vaccines may need to find alternatives during the shortage.

Providers should continue to follow the recommended immunization schedule and ensure that patients receive all recommended doses of DTaP, Hib, and polio vaccines.

Vaccines for Children (VFC) providers should contact their state or local immunization program for guidance about ordering vaccines.

Options include:

- Using DTaP, IPV, and Hib vaccines to complete a series begun with Pentacel. There is a sufficient supply of these products to meet the anticipated demand.
- Other combination vaccines containing DTaP and Hib vaccines may also be used to complete the series.

Considerations when changing vaccine products:

- The Advisory Committee on Immunization Practices (ACIP) recommends using the same brand of vaccine for all doses of a vaccination series, when feasible. If providers do not know or do not have available the brand of vaccine previously administered, another brand may be used.
- With the exception of Hiberix, which is licensed only for use as the last dose (booster) in the Hib series, Hib vaccines are interchangeable. If different brands of a vaccine require different numbers of doses, use the higher number when mixing brands. The Hib vaccine component in Pentacel is licensed as a four-dose series.

Additional vaccine information and sample schedules using single component and combination vaccines for children who have already received one, two, or three doses of Pentacel are available on the <http://www.cdc.gov/vaccines/recs/schedules/default.htm>.

Use of brand names is for identification purposes only and does not imply an endorsement by the Centers for Disease Control and Prevention.

Sample Schedules for Using DTaP, Hib, and IPV Vaccines When Vaccinating Children during the 2012 Pentacel Shortage

The following are sample schedules for completing a series using DTaP, Hib, and IPV vaccines for children previously vaccinated with Pentacel (DTaP/IPV-Hib).

- When assessing for needed vaccines, ensure that minimum intervals between doses and the minimum age have been met for each.

1 prior dose of Pentacel

2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
Pentacel	DTaP	DTaP		DTaP*	DTaP
	Hib	Hib	Hib		
	IPV	IPV			IPV

2 prior doses of Pentacel

2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
Pentacel	Pentacel	DTaP		DTaP*	DTaP
		Hib	Hib		
		IPV			IPV

3 prior doses of Pentacel

2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
Pentacel	Pentacel	Pentacel		DTaP*	DTaP
			Hib		
			IPV		

*The 4th dose of DTaP can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose.

Vaccine	Use for
DTaP	Any dose in the series for children 6 weeks through 6 years of age
Hib (ActHIB, PedvaxHIB)	Any dose in the series for children 6 weeks through 4 years of age
Hib (Hiberix)	The last (booster) dose in the Hib series for children 12 months* through 4 years of age
IPV	Any dose in the polio series for persons 6 weeks of age and older
DTaP/IPV (Kinrix)	Dose 5 of DTaP and dose 4 of IPV for children 4 through 6 years of age. Do not use for doses 1 through 3 of DTaP and IPV or dose 4 of DTaP

*Off label Advisory Committee on Immunization Practices recommendation

ActHIB, Hiberix, Kinrix, PedvaxHIB, and Pentacel are the trademarks of their respective owners. Use of brand names is for identification



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Sample Schedule for Using Pediarix (DTaP-IPV-HepB) and Hib Vaccines When Vaccinating Children During the 2012 Pentacel® Shortage

The following are sample schedules for completing a series using Pediarix (DTaP-IPV-HepB) and Hib vaccines for children previously vaccinated with Pentacel (DTaP/IPV-Hib).

- When using combination vaccines, ensure that minimum intervals between doses and the minimum age have been met for each of the component vaccines.

1 prior dose of Pentacel

Birth	1 month	2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
HepB	HepB		Pediarix	Pediarix*			
		Pentacel					DTaP**
				Hib	Hib	Hib	

2 prior doses of Pentacel

Birth	1 month	2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
HepB	HepB			Pediarix			
		Pentacel	Pentacel				DTaP**
					Hib	Hib	

3 prior doses of Pentacel

Birth	1 month	2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
HepB	HepB			HepB			
		Pentacel	Pentacel	Pentacel			DTaP**
							Hib
							IPV

*Administration of a 4th dose of HepB vaccine is permissible when a combination vaccine containing HepB is given after the birth dose.

** The 4th dose of DTaP can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose. Off label Advisory Committee on Immunization Practices recommendation.

Vaccine	Use for
DTaP	Any dose in the 5-dose series for children 6 weeks through 6 years of age
DTaP/IPV/HepB (Pediarix)	Doses 1, 2, and 3 of DTaP and IPV; any dose of HepB for children 6 weeks through 6 years of age
HepB	Any dose in the HepB series for children at birth and older
Hib (ActHIB, PedvaxHIB)	Any dose in the Hib series for children 6 weeks through 4 years of age
Hib (Hiberix)	The last (booster) dose in the Hib series for children 12 months* through 4 years of age
IPV	Any dose in the polio series for persons 6 weeks of age and older
DTaP/IPV (Kinrix)	Dose 5 of DTaP and dose 4 of IPV for children 4 through 6 years of age Do not use for doses 1 through 3 of DTaP and IPV or dose 4 of DTaP

*Off label Advisory Committee on Immunization Practices recommendation

For further information, contact your state or local health department immunization program.

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References

2012 Recommended Immunization Schedule for Persons 0 through 6 Years of Age

<http://www.cdc.gov/vaccines/recs/schedules/downloads/child/0-6yrs-schedule-pr.pdf>

MMWR. Licensure of a Haemophilus influenzae Type b (Hib) Vaccine (Hiberix) and Updated Recommendations for Use of Hib Vaccine 58(36); 1008-1009

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm?s_cid=mm5836a5_e

Advisory Committee on Immunization Practices General Recommendations on Immunization

<http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>

CDC Current Vaccine Shortages and Delays web page

<http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm>

Directory of State Health Department immunization program websites

<http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/grantee-imz-websites.htm>

Epidemiology and Prevention of Vaccine-Preventable Diseases “Pink Book” 12th Edition

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Sanofi Pasteur Supply Notification Letter to Providers

https://www.vaccineshoppe.com/assets/pdf/Important%20Supply%20Information_MKT24949.pdf

