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Guidance for Vaccinating Children during the

2013 Pentacel®, Daptacel® and Pediarix Shortage

May 16, 2013

Centers for Disease Control and Prevention (CDC)
National Center for Immunization and Respiratory Diseases

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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May 13, 2013

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Sanofi Pasteur's Pentacel (DTaP-IPV/Hib) and Daptacel (DTaP) are expected to remain in short supply throughout the summer of 2013. As a result of the ongoing Pentacel vaccine shortage that began in April 2012, GlaxoSmithKline (GSK) has experienced increased demand for Pediarix (DTaP-IPV-HepB) vaccine. GSK has taken steps to meet this increased demand, but will not be able to supply this vaccine at the same rate over the next 4-6 months before Pentacel is available without restrictions, which is currently anticipated to occur in September 2013.

Practices using these vaccines may need to find alternatives during the shortage. **Single-component DTaP, IPV, HepB, and Hib vaccines and other age-appropriate licensed combination vaccines are available to complete series begun with Pentacel or Pediarix.** Currently, there is a sufficient supply of these products to meet the anticipated demand.

During this period of 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.

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.
- A child who began the series with Pentacel, then received single-component products at one or more visits, may receive Pediarix in lieu of DTaP, IPV, and HepB at subsequent visits when all three vaccines are indicated.
- 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. PRP-OMP products (PedvaxHib and Comvax) are preferred for American Indian/Alaska Native children

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, Pediarix, or both are available at http://www. cdc.gov/vaccines/vac-gen/shortages/default.htm#1.

Please note that the following sample schedules reflect typical scenarios; they do not cover every possible situation.

01 Sample schedules for completing a series using single-component DTaP, Hib, HepB, and IPV vaccines for children previously vaccinated with DTaP-IPV/Hib (Pentacel) only

- A vaccine series begun with a combination vaccine can be completed using single-component vaccines.
- The same manufacturer's vaccine should be used for all doses in a series when feasible. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available.
- When scheduling the doses needed to complete a series, follow the ACIP Routine and Catch-Up Schedules (http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html) and the recommended minimum ages and intervals (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval- table.pdf).
- For more information, contact your state or local health department's immunization program.

1 prior dose of DTaP-IPV/Hib (Pentacel)

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

2 prior doses of DTaP-IPV/Hib (Pentacel)

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

3 prior doses of DTaP-IPV/Hib (Pentacel)

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

*The 4th dose can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose. This is an ACIP off label recommendation.

**Any schedule in which two or more Hib products (including combinations) are given should use the 4-dose schedule rather than 3-dose schedule

Vaccine	Use for
DTaP	Any dose in the 5-dose series for children 6 weeks through 6 years
DTaP-IPV/Hib (Pentacel)	Doses 1, 2, and 3 of DTaP and IPV; any dose of Hib for children 6 weeks through 4 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
HepB-Hib (Comvax)	Any dose in the HepB or Hib series
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

*This is an off label ACIP recommendation.

2013 Recommended immunization schedule for persons aged 0 through 18 years of age www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

Licensure of a *Haemophilus influenzae* Type B (Hib) Vaccine (Hiberix) and Updated Recommendations for Use of Hib Vaccine *MMWR*: 58(36);1008-1009 www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm?s_cid=mm5836a5_e.

02 Sample schedules for completing a series using single-component DTaP, IPV, and HepB vaccines for children previously vaccinated with DTaP-IPV-HepB (Pediarix) only

- A vaccine series begun with a combination vaccine can be completed using single-component vaccines.
- The same manufacturer's vaccine should be used for all doses in a series when feasible. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available.
- When scheduling the doses needed to complete a series, follow the ACIP Routine and Catch-Up Schedules (http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html) and the recommended minimum ages and intervals (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval- table.pdf).
- For more information, contact your state or local health department's immunization program.

1 prior dose of DTaP-IPV-HepB (Pediarix)

Birth	2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
HepB	Pediarix		HepB			
		DTaP	DTaP		DTaP*	DTaP
		IPV	IPV			IPV
	Hib	Hib	Hib***	Hib		

2 prior doses of DTaP-IPV-HepB (Pediarix)

Birth	2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
HepB	Pediarix	Pediarix	HepB**			
			DTaP		DTaP*	DTaP
			IPV			IPV
	Hib	Hib	Hib***	Hib		

3 prior doses of DTaP-IPV-HepB (Pediarix)

Birth	2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
HepB	Pediarix	Pediarix	Pediarix*			
					DTaP*	DTaP
						IPV
	Hib	Hib	Hib***	Hib		

* The 4th dose can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose. This is an off label ACIP recommendation.

**Administration of 4 doses of HepB vaccine is permissible when a combination vaccine containing HepB is given after the birth dose. This is an off label ACIP recommendation.

*** Any schedule in which two or more Hib products (including combinations) are given should use the 4-dose (rather than 3-dose) Hib series.

Vaccine	Use for
DTaP	Any dose in the 5-dose series for children 6 weeks through 6 years
DTaP-IPV/Hib (Pentacel)	Doses 1, 2, and 3 of DTaP and IPV; any dose of Hib for children 6 weeks through 4 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
HepB-Hib (Comvax)	Any dose in the HepB or Hib series
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

*This is an off label ACIP recommendation.

2013 Recommended immunization schedule for persons aged 0 through 18 years of age www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

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03 Sample schedules for completing a series using single-component DTaP, IPV, Hep B, Hib vaccines for children previously vaccinated with DTaP/IPV-Hib (Pentacel) and DTaP-IPV-HepB (Pediarix)

- A vaccine series begun with a combination vaccine can be completed using single-component vaccines.
- The same manufacturer's vaccine should be used for all doses in a series when feasible. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available.
- When scheduling the doses needed to complete a series, follow the ACIP Routine and Catch-Up Schedules (http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html) and the recommended minimum ages and intervals (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval- table.pdf).
- For more information, contact your state or local health department's immunization program.

1 prior dose of Pentacel, 1 prior dose of Pediarix

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

1 prior dose of Pentacel, 2 prior doses of Pediarix

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

2 prior doses of Pentacel, 1 prior dose of Pediarix

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

*Administration of 4 doses of HepB vaccine is permissible when a combination vaccine containing HepB is given after the birth dose. This is an off label ACIP recommendation.

** The 4th dose can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose. This is an off label ACIP recommendation.

*** Any schedule in which two or more Hib products (including combinations) are given should use the 4-dose (rather than 3-dose) Hib series.

Vaccine	Use for
DTaP	Any dose in the 5-dose series for children 6 weeks through 6 years
DTaP-IPV/Hib (Pentacel)	Doses 1, 2, and 3 of DTaP and IPV; any dose of Hib for children 6 weeks through 4 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
HepB-Hib (Comvax)	Any dose in the HepB or Hib series
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

*This is an off label ACIP recommendation.

2013 Recommended immunization schedule for persons aged 0 through 18 years of age www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

Licensure of a *Haemophilus influenzae* Type B (Hib) Vaccine (Hiberix) and Updated Recommendations for Use of Hib Vaccine *MMWR*: 58(36);1008-1009 www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm?s_cid=mm5836a5_e.

04 Sample schedules for completing a series using DTaP-IPV-HepB (Pediarix) and Hib vaccines for children previously vaccinated with DTaP-IPV/Hib (Pentacel) only

- A vaccine series begun with a combination vaccine can be completed using single-component and combination vaccines.
- The same manufacturer's vaccine should be used for all doses in a series, when feasible. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available.
- When scheduling the doses needed to complete a series, follow the ACIP Routine and Catch-Up Schedules (http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html) and the recommended minimum ages and intervals (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval- table.pdf).
- For more information, contact your state or local health department's immunization program.

1 prior dose of DTaP-IPV/Hib (Pentacel)

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

2 prior doses of DTaP-IPV/Hib (Pentacel)

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

*Administration of 4 doses of HepB vaccine is permissible when a combination vaccine containing HepB is given after the birth dose. This is an off label ACIP recommendation.
** The 4th dose can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose. This is an off label ACIP recommendation.
***Any schedule in which two or more Hib products (including combinations) are given should use the 4-dose (rather than 3-dose) Hib series.

Vaccine	Use for
DTaP	Any dose in the 5-dose series for children 6 weeks through 6 years
DTaP-IPV/Hib (Pentacel)	Doses 1, 2, and 3 of DTaP and IPV; any dose of Hib for children 6 weeks through 4 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
HepB-Hib (Comvax)	Any dose in the HepB or Hib series
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

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2013 Recommended immunization schedule for persons aged 0 through 18 years of age www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
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05 Sample schedules for completing a series using Comvax (HepB-Hib) vaccine for children previously vaccinated with Pentacel (DTaP-IPV/Hib) only

- A vaccine series begun with a combination vaccine can be completed using single-component and combination vaccines.
- The same manufacturer's vaccine should be used for all doses in a series when feasible. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available.
- When scheduling the doses needed to complete a series, follow the ACIP Routine and Catch-Up Schedules (http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html) and the recommended minimum ages and intervals (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval- table.pdf).
- For more information, contact your state or local health department's immunization program.

1 prior dose of Pentacel (DTaP-IPV/Hib)

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

2 prior doses of Pentacel (DTaP-IPV/Hib)

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

3 prior doses of Pentacel (DTaP-IPV/Hib)

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

* The 4th dose can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose. This is an off label ACIP recommendation.
**Any schedule in which two or more Hib products (including combinations) are given should use the 4-dose (rather than 3-dose) Hib series.

Vaccine	Use for
DTaP	Any dose in the 5-dose series for children 6 weeks through 6 years
DTaP-IPV/Hib (Pentacel)	Doses 1, 2, and 3 of DTaP and IPV; any dose of Hib for children 6 weeks through 4 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
HepB-Hib (Comvax)	Any dose in the HepB or Hib series
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

*This is an off label ACIP recommendation.
2013 Recommended immunization schedule for persons aged 0 through 18 years of age www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
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Sample schedules for completing a series using Comvax (HepB-Hib) vaccine for children previously vaccinated with Pediarix (DTaP-IPV-HepB) only

- A vaccine series begun with a combination vaccine can be completed using single-component and combination vaccines. (Check format of bullet points here – G.)
- The same manufacturer's vaccine should be used for all doses in a series when feasible. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available.
- When scheduling the doses needed to complete a series, follow the ACIP Routine and Catch-Up Schedules (http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html) and the recommended minimum ages and intervals (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval- table.pdf).
- For more information, contact your state or local health department's immunization program.

1 prior dose of Pediarix (DTaP-IPV-HepB)

Birth	1 month	2 months	4 months	6 months	12-15 months	15-18 months	4-6 years
			DTaP	DTaP		DTaP*	DTaP
		Pediarix	IPV	IPV			IPV
Hep B				Comvax**			
		Hib	Hib		Hib***		

2 prior doses of Pediarix (DTaP-IPV-HepB)

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

* The 4th dose can be given as early as 12 months of age, provided at least 6 months have elapsed since the 3rd dose. This is an off label ACIP recommendation..
**Administration of 4 doses of HepB vaccine is permissible when a combination vaccine containing HepB is given after the birth dose. This is an off label ACIP recommendation.
***Any schedule in which two or more Hib products (including combinations) are given should use the 4-dose (rather than 3-dose) Hib series.

Vaccine	Use for
DTaP	Any dose in the 5-dose series for children 6 weeks through 6 years
DTaP-IPV/Hib (Pentacel)	Doses 1, 2, and 3 of DTaP and IPV; any dose of Hib for children 6 weeks through 4 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
HepB-Hib (Comvax)	Any dose in the HepB or Hib series
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

*This is an off label ACIP recommendation.
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