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Susan Mosier, MD, Secretary | Department of Health & Environment | Sam Brownback, Governor

MEMORANDUM

TO: All Vaccine Providers

FROM: Phil Griffin, Deputy Director
Bureau of Disease Control and Prevention

DATE: November 30, 2015

RE: Pentacel Manufacturing Delay

As announced in the December 2, 2015 *What's Happening Wednesday*, Sanofi Pasteur is having difficulty delivering the full supply of Pentacel that the market is requesting at this time. This is projected to be resolved within the next six months.

Key Points

- This event is **not** the same circumstances as experienced in 2012. This event is limited to two lots of vaccine compared to an entire facility shut down in 2012.

- The Kansas Immunization Program (KIP) will continue to monitor updates from CDC as well as updates directly from the manufacturers of the vaccine, and will adjust plans as needed and keep our providers informed.

- KIP encourages providers to continue to assure full vaccination schedules are followed. Providers should order vaccine as they normally would at this time. KIP will distribute the Kansas allocated vaccine based on the orders of the providers in conjunction with review of inventory on hand and history of vaccination administration.

- We are providing tools attached to this memorandum, supplied by CDC, to assist in the event a provider finds they do not have an adequate supply of Pentacel to follow the routine practice of the office. There are viable alternatives with minimal impact on vaccine delivery.

- If you have questions or concerns, please contact your KIP Regional Nurse Consultant.

Centers for Disease Control and Prevention (CDC)
National Center for Immunization and Respiratory Diseases (NCIRD)
Atlanta, GA

December 2015

Guidance for Vaccinating Children during the 2015-16 Pentacel® Manufacturing Delay

Sanofi Pasteur is experiencing a manufacturing delay with Pentacel (DTaP-IPV/Hib) vaccine. As a result, Sanofi Pasteur is not able to meet all of the Pentacel vaccine demand throughout the first half of 2016. However, Sanofi Pasteur has sufficient supplies of the relevant single antigen vaccines (DAPTACEL, ActHIB, and IPOL) to address the anticipated gap in Pentacel supply. Sanofi Pasteur is communicating directly to healthcare providers with information about the Pentacel delay via a health care provider letter.

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

Options include:

- Using DTaP, IPV, and Hib vaccines to complete a series begun with Pentacel. There is a sufficient supply of DTaP, IPV and Hib vaccines 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.

- 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 below.

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 2015-16 Pentacel® Manufacturing Delay

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. This is an ACIP off-label recommendation.

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
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

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

ActHIB, Kinrix, PedvaxHIB, and Pentacel are the trademarks of their respective owners. Use of brand names is for identification purposes only and does not imply an endorsement by the Centers for Disease Control and Prevention.

Sample Schedule for Using Pediarix (DTaP-IPV-HepB) and Hib Vaccines When Vaccinating Children during the 2015-16 Pentacel® Manufacturing Delay

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*	DTaP
							IPV
			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*	DTaP
							IPV
				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*	DTaP
							IPV
					Hib		

* 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. This is an ACIP off-label recommendation.

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

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
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

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

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References

Recommended Immunization Schedule for Persons 0 through 18 Years of Age
http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Advisory Committee on Immunization Practices General Recommendations on Immunization
http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases “Pink Book” 13th Edition
http://www.cdc.gov/vaccines/pubs/pinkbook/index.html