

Note: This 12-7-15 Advisory is not the most recent Pentacel Advisory. Please visit Advisories and Alerts section of the Immunization Program website for more information: www.mass.gov/dph/imm

Massachusetts Department of Public Health (MDPH)
Immunization Program

Pentacel[®] Vaccine Shortage December 2015

-- Only Available for Three Doses in Schedule --

1. Guidance about Immunization Schedules
2. Advice about Vaccine Ordering

12-7-15 **REVISED**

The MDPH Immunization Program was recently informed that effective **immediately**, there will be reduced availability of Sanofi Pasteur's Pentacel (DTaP-IPV/Hib) vaccine through the first half of 2016. As a result, the Centers for Disease Control and Prevention (CDC) will again be managing the public supply of this vaccine by allocating doses of Pentacel vaccine to each state.

Providers who currently use Pentacel for the first four doses in the series can now use it for only three doses.

Currently, CDC has adequate supplies of DTaP, polio, Hib, Pediarix (DTaP-IPV-HepB) and Kinrix (DTaP-IPV) vaccines at the central vaccine distributor, McKesson, so there will be **no** restrictions or limitations for MDPH orders for these vaccines at this time. Providers that use GlaxoSmithKline's Pediarix combination vaccine will not be impacted by the shortage of Pentacel.

- **At the current time, Massachusetts expects to receive about 70% of the amount of Pentacel normally received, but will have sufficient single antigen and combination vaccines to make up for the decrease in Pentacel.**
- **Because of the availability of other vaccines, NO child should get behind schedule with their immunizations.**

1. Immunization Schedule Guidance

For providers who use Pentacel, MDPH suggests the following schedule for children up to two years of age.

- Use Pentacel for the first three doses in the series.
- Use the individual antigens DAPTACEL and ActHIB for the 4th dose in the series.

Sample Shortage Immunization Schedule for Children Up to Two Years of Age, Using Three Doses of Pentacel and Single Antigens¹

Age	Vaccines
Birth	HepB
2 months	Pentacel, PCV13, RV, HepB
4 months	Pentacel, PCV13, RV
6 months	Pentacel, PCV13, RV, HepB
6 months and older	Influenza
12 months	MMR, Varicella, Hep A ²
15 months	Hib, PCV13
18 months	DTaP, HepA ²

¹ For additional guidance, see <http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>

² An acceptable alternative schedule for Hep A is at 18 and 24 months of age.

Providers should keep in mind the following guidance:

- Take advantage of the places in the schedule where there is a range of ages for administration of that antigen. Do **not** delay vaccines beyond the ages in the ACIP schedule.
- Complete a vaccine series with the formulation available. While the ACIP recommends the vaccination series be completed with the same brand when feasible, they state it is acceptable to complete it with any available formulation to **avoid missed opportunities**.
- A child who began the series with Pentacel (DTaP-IPV/Hib) may receive single antigen products to complete the series.
- Providers can switch to using Pediarix (DTaP-IPV-HepB) for doses 1, 2 and 3 of the DTaP. For a *Sample Schedule for Transition from Pentacel to Pediarix*, see page 4 of this document.
- Please remember, Kinrix (DTaP-IPV) is a combination vaccine that is **only** approved for the 5th dose of DTaP and 4th dose of IPV vaccines in children 4 through 6 years of age. Providers wishing to decrease the number of injections may choose to administer Kinrix in children who received other vaccines for their earlier doses in the series.

Providers should review the specific age indications, recommended dosing schedule and minimum ages and intervals for all vaccines. See the Resources section on page 3 of this document.

Reconstitution Issues

Sanofi's DAPTACEL **cannot** be used to reconstitute their ActHIB formulation of Hib vaccine to administer as a combination vaccine in the same syringe. If this happens, CDC says that the ActHIB component would be considered invalid and must be repeated. See pages 130-131 of [CDC's Pink Book, 13th Ed. *Haemophilus influenzae* type B Chapter](#).

2. Vaccine Ordering

For providers who have been using Pentacel for all 4 doses in the series, please adjust your monthly vaccine orders accordingly. If you normally order 100 doses of Pentacel per month, you should now order:

- 70 doses of Pentacel
- 30 doses of DTaP (DAPTACEL) in addition to your usual monthly amount
- 30 doses of Hib (ActHIB)

For providers who were previously using Pentacel for only the first 3 doses in the series, you do not need to adjust your vaccine ordering at this time but be sure to notify the Vaccine Unit prior to your next vaccine order.

If you choose to switch from Pentacel to Pediarix for routine use in your office, please be sure to update your monthly order quantities of single antigen vaccines (Hep B, DTaP, Hib, IPV) accordingly. Please call the Vaccine Unit (617-983-6828) for additional guidance. Keep in mind that MDPH does not encourage frequent switching of vaccine formulations so be sure to have a plan to use all remaining supplies of Pentacel to avoid vaccine wastage.

MDPH Vaccine Management Unit staff will be closely reviewing provider orders in order to meet their needs and work within the allocations allowed by the CDC.

Providers must track their inventory closely during this shortage to maximize the number of available doses for all practices and clinics. Please use all doses ordered so that vaccine does not go unused or be allowed to expire which will result in vaccine restitution.

MDPH will be monitoring the national Pentacel vaccine supply and will communicate with providers as soon as more information becomes available by email and on the MDPH website at www.mass.gov/dph/imm.

Questions

For questions about **immunization schedules**, please call the Immunization Program at 617-983-6800 and ask to speak to an immunization epidemiologist.

For questions about **vaccine availability and ordering**, please contact the Vaccine Management Unit at 617-983-6828.

Thank you again for your understanding and flexibility during this challenging period. We appreciate your efforts to protect our children against vaccine preventable diseases.

Resources:

CDC Current Vaccine Shortages and Delays webpage

http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm?s_cid=cs_000

Sanofi Pasteur Supply Letter Notification to Providers

<https://www.vaccineshoppe.com/mailing/VSH/2015/12allo30341/index.html>

Advisory Committee on Immunization Practices (ACIP) Routine and Catch-Up Schedules

www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

CDC's Recommended Minimum Ages and Interval Table

www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.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>

(See next page for a *Sample Schedule for Transition from Pentacel to Pediarix*)

Sample Schedule for Transitioning from Pentacel (DTaP-IPV/Hib) to Pediarix (DTaP-IPV-HepB) and Hib Vaccines

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
HepB	HepB					
		Pentacel	Pediarix	Pediarix ¹		DTaP ²
			Hib	Hib	Hib	

2 prior doses of Pentacel

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

3 prior doses of Pentacel

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

¹ Administration of a 4th dose of HepB vaccine is permissible when a combination vaccine containing HepB is given after the birth dose. This is an ACIP off-label recommendation.

² 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 ¹	Recommended Use
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, PedvaxHIB²)	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)	Only for 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

¹ For more information about combination vaccines, see IAC's [Combination Vaccines](#).

² Not provided by MDPH