



STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Thomas M. Miller, M.D.
Acting State Health Officer

December 28, 2015

Dear Vaccines for Children (VFC) Provider:

SUBJECT: Pentacel Vaccine Delay
Influenza Orders 2016-2017
Monthly Vaccine Ordering
Contact Information

Pentacel Vaccine Delay

Ordering limitations for Pentacel vaccine went into effect December 2, 2015 for all providers and are likely to remain in effect throughout the summer. This is a necessary step due to a manufacturing delay that will temporarily reduce supply below the level needed to fully satisfy market demand. The Alabama VFC Program will be limited in the amount of Pentacel[®] that is available during this time as we deal with monthly allocations from the Centers for Disease Control and Prevention (CDC). During this delay, the Alabama VFC Program recommends that providers who are currently following the 4-dose Pentacel[®] schedule temporarily suspend this schedule and follow a 3-dose Pentacel[®] schedule. A suggested 3-dose schedule to maximize the combination use and limit the number of injections for the child would be to use Pentacel[®] at 2 months, 4 months and 12 months and single DTaP and Hib at 6 months. The CDC has created guidance for vaccinating children during this manufacturing delay that can be found at <http://www.cdc.gov/vaccines/vac-gen/shortages/downloads/pentacel-delay.pdf>.

The Alabama VFC Program apologizes for any inconvenience that this may cause for your practice. We will advise you on any further updates with this vaccine delay as the information becomes available.

Influenza Orders 2016-2017

Please Note - Influenza vaccine orders will be filled in the order they are received. A waiting list will be created once vaccine allotment amounts have been met.

Orders for influenza vaccine for the 2016-2017 influenza season are now being accepted from VFC providers. You may find the order form on-line at www.adph.org/immunization.

Please keep in mind when placing your influenza order that the ACIP recommends that children 6 months through 8 years receiving seasonal influenza for the first time receive 2 doses. Other children just need one dose of seasonal influenza vaccine.

Monthly Vaccine Ordering

In order to minimize the loss of vaccine through expiration/spoilage/over-ordering, the Alabama VFC program is changing the ordering schedule of all VFC providers. On January 1, 2016, all VFC providers will now be placed on a monthly ordering schedule instead of remaining on the current 3-month ordering schedule. Please ensure that your practice is only ordering the amount of vaccine that it will need for a one month period of time. This should decrease the need of providers to keep large amounts of vaccine on hand and decrease the overall vaccine loss throughout the state.

Contact Information

To enhance communication between the VFC Program and providers, please provide your email address and PIN number on all forms submitted to the VFC Program.

Please review all of the enclosed information carefully. Please call 1-866-674-4807 if you have questions or concerns regarding your vaccine orders.

Thank you for your participation in the Alabama VFC Program.

Sincerely,



Denise Strickland
Director, Vaccines for Children Program

Enclosures

cc: Karen Landers, M.D., F.A.A.P.
Harrison Wallace
Mary G. McIntyre, M.D., M.P.H.
Cindy Lesinger

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 health care 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.

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 DTaP, IPV and Hib vaccines to meet the anticipated demand.
- > Other combination vaccines containing DTaP 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.



U.S. Department of
Health and Human Services
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 | | 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 | | 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* |
| | | | Hib | Hib | Hib | | IPV |

| 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 | | IPV |

| 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 |
| | | | | | 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.

**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>
- > 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" 13th Edition
<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

2016-2017 INFLUENZA VACCINE ORDER FORM ALABAMA VACCINES FOR CHILDREN PROGRAM

Date: _____

VFC Provider Name _____

Shipping Address _____

VFC PIN _____

Contact Person _____

Phone # (____) _____

Fax # (____) _____

E-mail Address: _____

Special Delivery Instructions (e.g. days/hours closed): _____

Influenza orders will be submitted to the National Centralized Distribution Center in the order they are received.

Please fax your order to Chevonne Tyner or Beverly Jones at 1-800-706-8507.

Please call 1-866-674-4807 with any questions.

Please indicate the vaccine presentation you prefer. If preferred presentation is not available, you will receive what is available. All presentations come in packages of 10.

| Influenza Vaccines | | | Doses |
|---|--|-----------------|-------|
| Influenza • Quadrivalent (Age 6 months and older) | Fluzone® 10 dose vials | sanofi pasteur | |
| Influenza • Quadrivalent (Age 6 months to 35 months) | Fluzone® No-Preservative 10 pack – 1 dose syringes | sanofi pasteur | |
| Influenza • Quadrivalent (36 months and older) | Fluzone® No-Preservative <input type="checkbox"/> Single dose vials <input type="checkbox"/> Single dose syringes | sanofi pasteur | |
| Influenza • Quadrivalent (36 months and older) | Fluarix® <input type="checkbox"/> Single dose syringes | GlaxoSmithKline | |
| Influenza • Trivalent (4 yrs and older) | Fluvirin® <input type="checkbox"/> 10 dose vials | Novartis | |
| Influenza • Quadrivalent Live, Intranasal (Age 2-18 years) | FluMist® 10 pack – 1 dose sprayers | MedImmune | |