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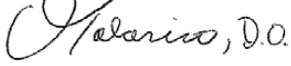
State of California—Health and Human Services Agency  
California Department of Public Health



EDMUND G. BROWN JR.  
Governor

April 26, 2012

TO: Vaccines for Children (VFC) Providers

FROM: John Talarico, D.O., M.P.H., Chief   
Center for Infectious Diseases  
Division of Communicable Disease Control, Immunization Branch

SUBJECT: Temporary Decrease in Pentacel<sup>®</sup> Vaccine Supply

## Background

Sanofi Pasteur has notified the Centers for Disease Control and Prevention (CDC) about a manufacturing delay for its Pentacel<sup>®</sup> (DTaP-IPV/Hib combination) and DAPTACEL<sup>®</sup> (DTaP) vaccines. This has led to an immediate decrease in the doses available to customers nationwide. Until this delay is resolved, estimated to be in early fall 2012, Sanofi Pasteur is limiting orders for Pentacel<sup>®</sup>. Effective April 23, 2012, CDC has reduced Pentacel<sup>®</sup> vaccine allocations for each state's Vaccine for Children (VFC) Program to approximately 2/3 of the prior monthly distribution.

As CDC has adequate supplies of DAPTACEL<sup>®</sup> at the VFC program's vaccine distribution center, no allocations or limitations for VFC orders of DAPTACEL<sup>®</sup> are in place at this time. (However, see the linked [letter from Sanofi Pasteur regarding additional limits on DAPTACEL<sup>®</sup> on orders for children ineligible for the VFC Program.](#))

## Impact of Pentacel<sup>®</sup> Supply Limits on Routine Immunization and VFC Orders

The impact of this shortage is likely to be minimal on the routine childhood immunization schedule. VFC Program supplies for individual DTaP, IPV and Hib vaccines, available from all manufacturers, are sufficient to meet provider demand through the summer months. Doses for your patients should NOT be deferred or delayed.

In order to keep within the state's monthly allocation, the California VFC Program is reducing all requests for Pentacel<sup>®</sup> to a limited monthly supply (approximately 60-70% of average usage). These reductions are based on a practice's order frequency, historical vaccine usage and the State's allocation. To compensate for this reduction, ordering limits for individual DTaP, IPV, and Hib vaccines have been increased.

## VFC Orders

The following ordering guidelines will be in place for all VFC providers until adequate supplies of Pentacel® are available:

- Effective April 26, 2012, all Pentacel® requests must be submitted monthly to the California VFC Program. For providers on a bi-monthly or quarterly order frequency, these Pentacel® orders will be considered as supplemental orders. Orders for all other VFC vaccines should be submitted at their normal frequency.
- All Pentacel® orders will be limited to approximately 60-70% of historical average usage. Therefore we suggest looking at your practice's monthly usage, and applying this reduction to determine Pentacel® doses to order. Orders for individual DTaP, IPV, and Hib vaccines should be increased to compensate for the reduction in Pentacel®.
- During this period the California VFC Programs recommends reserving Pentacel® for the first three doses, and substituting individual vaccines for the fourth doses of DTaP and Hib:
  - DTaP: DAPTACEL® (Sanofi Pasteur), Infanrix® (GlaxoSmithKline)
  - Hib: ActHIB® (Sanofi Pasteur), PedvaxHIB® (Merck), Hiberix® (GlaxoSmithKline). Note: Hiberix® is temporarily unavailable. However, when it does become available, keep in mind that this product is only licensed for the Hib booster dose at age 12-15 months.
  - IPV: (IPOL® (Sanofi Pasteur)) is also available as needed.

Sample Schedule Using Individual Vaccines for the 4<sup>th</sup> Doses of DTaP, Hib:

<b>Age</b>	<b>Vaccines</b>
Birth	Hep B
2 months	Pentacel®, RV, PCV13, Hep B
4 months	Pentacel®, RV, PCV13
6 months	Pentacel®, RV, PCV13, Hep B
6 months and older	Influenza
12-15 months	MMR, Varicella, Hib, PCV13
15-18 months	DTaP, Hep A

- Providers should review the specific age indications and recommended dosing schedule for all vaccines. For example, the two-dose PedvaxHIB® primary series schedule differs from the three-dose schedule for ActHIB®. Once the clinic determines which schedule and vaccines will be used to accommodate the Pentacel® shortage, ALL staff should be informed and educated on the new vaccines and schedule.

If you have any questions about this communication, please contact your VFC Representative or VFC Customer Service at 1-877-243-8832.