



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




KAREN L. SMITH, MD, MPH  
Director and State Health Officer

EDMUND G. BROWN JR.  
Governor

December 23, 2015

IZB-FY-15-16-8

TO: Vaccines for Children (VFC) Providers

FROM: Sarah Royce, M.D., 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 recently notified the Centers for Disease Control and Prevention (CDC) about expected manufacturing delays for Pentacel<sup>®</sup> (DTaP-IPV/Hib combination vaccine), which are expected from now through the summer of 2016. The number of doses available nationwide is expected to be 70% of the normal supply. In order to manage this supply limitation, CDC has instituted a limit on the number of Pentacel<sup>®</sup> doses states can order on a monthly basis. Until this situation is resolved, California's VFC Program will be instituting a similar limitation on all Pentacel<sup>®</sup> orders.

## 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 first half of 2016. 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 (up to 70% of average monthly 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<sup>®</sup> are available:

- Effective January 1, 2016, all Pentacel<sup>®</sup> requests must be submitted monthly to the California VFC Program. For providers on a bi-monthly or quarterly order frequency, these Pentacel<sup>®</sup> orders will be considered as supplemental orders. Orders for all other VFC vaccines should be submitted at their normal frequency.
- All Pentacel<sup>®</sup> orders will be limited to up to 70% of historical average monthly usage. Therefore we suggest looking at your practice's monthly usage and applying this reduction to determine Pentacel<sup>®</sup> doses to order. Orders for individual DTaP, IPV, and Hib vaccines should be increased to compensate for the reduction in Pentacel<sup>®</sup>.
- During this period the California VFC Program recommends reserving Pentacel<sup>®</sup> for the first three doses, and substituting individual vaccines for the fourth doses of DTaP and Hib:
  - DTaP: DAPTACEL<sup>®</sup> (Sanofi Pasteur), Infanrix<sup>®</sup> (GlaxoSmithKline)
  - Hib: ActHIB<sup>®</sup> (Sanofi Pasteur), PedvaxHIB<sup>®</sup> (Merck)

### Sample Schedule Using Individual Vaccines for the Fourth Doses of DTaP and Hib:

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

- IPV: IPOL<sup>®</sup> (Sanofi Pasteur) is also available as needed, although it is not needed at 12-18 months if three doses of Pentacel<sup>®</sup> were given as the primary series. A fourth dose of IPV is recommended on or after the fourth birthday.
- Providers should review the specific age indications and recommended dosing schedule for all vaccines. For example, the two-dose PedvaxHIB<sup>®</sup> primary series schedule differs from the three-dose schedule for ActHIB<sup>®</sup>. Once the clinic determines which schedule and vaccines will be used to accommodate the Pentacel<sup>®</sup> 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 Field Representative or the VFC Customer Service Center at 877-243-8832.