

Nicholas A. Toumpas
Commissioner

José Thier Montero
Director

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH SERVICES

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DATE: August 11, 2008

TO: Medical Personnel
Office Manager
Vaccine Manager

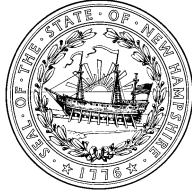
FROM: Marcella Bobinsky, Program Manager
Immunization Program

SUBJECT: Transition to Pentacel due to Hib shortage

**A COPY OF THE FOLLOWING
INFORMATION MUST BE
PASSED ON TO ALL
PHYSICIANS AND VACCINE
PRESCRIBING PERSONNEL IN
YOUR PRACTICE
AS SOON AS POSSIBLE**

NOTICE:

You have received this message based upon the information contained within the Swift Information System (SIS) notification database. If you have a different or additional o fax number that you would like us to use please notify us as soon as possible by e-mail at LJOHNSON@DHHS.STATE.NH.US



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To: All NHIP Providers

From: Marcella Bobinsky, NH Immunization Program Manager

Re: Transition to Pentacel due to Hib shortage

Most of you are aware that Hib vaccine has been in short supply since the beginning of 2008. The Centers for Disease Control and Prevention (CDC) published an interim recommendation that asked providers to postpone the fourth dose until the supply of Hib vaccine improves. The CDC also began allocating Hib vaccine that it distributes to state immunization programs through the Vaccine for Children (VFC) program.

On July 24, 2008, the CDC informed state immunization programs nationwide that beginning in August 2008, each state would receive 35% to 50% of their Hib vaccine allocation in the form of Pentacel, the new combination vaccine produced by Sanofi. (Pentacel is a combination of DTaP, IPV, and Hib.)

The introduction of Pentacel will not eliminate the Hib shortage. In fact, the CDC has said that the availability of ActHIB will decrease. Therefore, to insure that every infant has the opportunity to receive the first **three** doses of Hib vaccine, the New Hampshire Immunization Program (NHIP) is asking every practice to:

1. Administer Pentacel vaccine to every infant that starts its primary series. Depending on the infant's immunization history, hepatitis B, pneumococcal-conjugate (Pevnar), and rotavirus vaccines should also be administered at the first visit.

Continue to administer Pentacel as the **second** and **third** doses of the DTaP-IPV-Hib series. Depending on the infant's immunization history, hepatitis B, pneumococcal-conjugate (Pevnar), and rotavirus vaccines should also be administered.

(MORE)

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2. Infants and children that have already started their DTaP-IPV-Hep B series (with single-antigen or combination vaccines such as Pediarix) should continue receiving these vaccines.

CDC expects the Hib shortage to ease with the reintroduction of Merck Hib vaccine in the fall of 2008. Until that time, the fourth dose of Hib continues to be suspended including the fourth dose of Pentacel. We will provide you with additional information about the Hib shortage as it becomes available.

Attached you will find a fact sheet, VIS recommendation, and dates/times/instructions for conference calls with NHIP nurses and the vaccine distribution team. The Vaccine Manager in your practice will receive up-to-date paperwork within the week.



Pentacel[®]: Fact Sheet for Clinical Staff

- **Pentacel[®]** is a 5 in 1 pediatric combination vaccine for diphtheria, tetanus, pertussis, poliomyelitis, and *Haemophilus influenzae* type b (DTaP, IPV, Hib).
- **Pentacel[®] is approved** for 6 weeks of age up through 4 years of age (Prior to 5th birthday).
- **Pentacel[®] recommended schedule** is 2 months, 4 months, 6 months, and 15-18 months.
- **The minimum intervals: minimum age is** 6 weeks for dose 1, minimum age for dose 2 is 10 weeks with 4 weeks between doses 1 and 2; the minimum age for dose 3 is 14 weeks with 4 weeks between doses 2 and 3. The fourth dose must be administered a minimum of 6 months after dose 3 and the child must be at least 12 months of age or older.
- **The fourth dose of Pentacel[®] is presently being withheld due to the current Hib vaccine shortage.** A dose of DTaP should be administered in place of the fourth Pentacel[®] dose at 15-18 months until further notice.
- **Pentacel[®] may be given** with routinely recommended vaccines. Different injection sites should be used.
- **Pentacel[®] may be used to complete a primary series begun** with Pediarix[®] or individual DTaP, Polio (IPV) and *Haemophilus influenzae* type b (Hib) vaccines.
- **A child who begins the series with Pentacel[®]** may change to Pediarix[®] or individual DTaP, IPV and Hib vaccines.
- **Clinical studies of Pentacel[®] have shown comparable** antibody response to Daptacel[®] (DTaP), ActHIB[®] and IPV vaccines.
- **Safety: Most common local and systemic adverse reactions** included redness, swelling, or tenderness at the injection site; fever, fussiness and crying.
- **Contraindications:** any known systemic hypersensitivity or a life-threatening reaction to any component of Pentacel[®] vaccine after previous vaccines with the same components of DTaP, IPV or Hib. History of encephalopathy within 7 days of a previous dose of any pertussis-containing vaccine. Progressive neurological disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy. If Guillain-Barré syndrome occurred within 6 weeks of a previous vaccine containing tetanus toxoid, withholding the Pentacel[®] vaccine should be considered.

How Supplied: Packaging and Mixing:

- **Pentacel[®]** is packaged in a box of 5 doses with 2 vials for each dose.
- The box will contain 5 single vials of DTaP/IPV liquid and 5 single vials of ActHIB[®] powder.
- DO NOT use individually.

Vaccine Information Statement:

- Explain: Pentacel[®] is a new vaccine containing 5 vaccines against 5 vaccine preventable diseases. This means their child will receive less shots to complete their immunizations by the age of 24 months.
- Use the multi-vaccine Vaccine Information Statement (VIS) "Your Baby's First Vaccines," January 30, 2008.
- OR use individual VISs for DTaP, Polio and *Haemophilus influenzae* type b.

To Reconstitute:

- Gently shake the DTaP/IPV liquid.
- Withdraw the DTaP/IPV liquid with a syringe.
- Inject liquid into the vial with ActHIB[®] powder.
- Gently shake vial thoroughly.
- Immediately withdraw 0.5 mL of Pentacel[®] vaccine.

Administration:

- Pentacel[®] should be administered immediately after reconstitution.
- For infants <12 months administer Pentacel[®] intramuscularly (IM) into the anterolateral aspect of the thigh.
- For older children the deltoid muscle may be used.

Prevent Administration Errors: Label your Vaccine:

Pentacel



ActHIB



Storage:

- Store at 2-8° C (35-46°F).
- Do Not Freeze.
- Do not use after expiration.
- Label vaccine well.
- To prevent errors do not remove Pentacel vials from box. Physically separate Pentacel[®] from Pediarix[®] in the refrigerator.

Documentation of Pentacel[®] administration:

- The lot number is on the side of the Pentacel[®] box and on the ActHIB[®] powder vial.
- Document Pentacel[®] under each individual vaccine i.e. DTaP, IPV and Hib.

??Questions??

On **August 13, 15, and 22**, at 8:30 AM the NH Immunization Program will offer a conference call to answer questions regarding the ordering and administration of Pentacel[®].

Dial In Number: **1-866-304-8625**

Conference Code Number: **604 308 5421**

Contact the NH Immunization Program at 800-852-3345 EXT. 4482 or 271-4482

Above information revised from literature by **sanofi Pasteur**, the vaccines division of sanofi-aventis group.