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To: Pediatric Vaccine Providers

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Date: September 24, 2013 (REVISED)

Subject: Two New Vaccines Added to MDPH Formulary:
1) Choice of pediatric hepatitis A vaccine: Havrix (in addition to VAQTA)
2) Choice of pediatric hepatitis B vaccine: Engerix-B (in addition to Recombivax HB)

The Massachusetts Department of Public Health (MDPH) is pleased to announce the addition of two vaccines to its current formulary effective October 1, 2013. This expansion is as a result of a formal recommendation to the Department by the Massachusetts Vaccine Purchasing Advisory Council (MVPAC) after deliberations during their July 2013 meeting.

Vaccines Available

1) Havrix, manufactured by GlaxoSmithKline (GSK), is the second pediatric hepatitis A vaccine added to the current MDPH vaccine formulary. MDPH had been supplying Merck's VAQTA formulation for all pediatric hepatitis A vaccine orders. The addition of Havrix offers providers another option for pediatric hepatitis A vaccine.

Havrix and VAQTA are both recommended for:

- **Children**: Children 12-23 months should initiate a 2-dose HepA series with an interval between doses of 6-18 months;
- **Catch-up:** Unvaccinated children or adolescents should complete a 2-dose series, with an interval between doses of 6-18 months. Please Note: currently MDPH only supplies hepatitis A vaccine for catch-up vaccination of VFC eligible children.

The ACIP recommends off-label use for the 2nd dose of Havrix, stating it can be given up to 18 months after the first (package insert says 6-12 months.)

Limited data indicate that vaccines from different manufacturers are interchangeable. Completion of the series with the same product is preferable. However, ACIP has an off-label recommendation: If the originally used product is not available or not known, vaccination with either product is acceptable in order to avoid missed opportunities. Please see the table below for recommended doses in those 18 years of age and younger.

Recommended Doses of Currently-Licensed Single-Antigen Formulations of Hepatitis A Vaccine for Use in Those 18 Years of Age and Younger

Age Group	Havrix Hepatitis A Vaccine (GlaxoSmithKline)			VAQTA (Merck)		
	Dose (EL.U.)	Volume	No. Doses	Dose (U)	Volume	No. Doses
Children and Adolescents (1-18 years)	720	0.5 mL	2	25	0.5 mL	2

Sources:
CDC. Epidemiology and Prevention of Vaccine Preventable Diseases. Hepatitis A Chapter.
CDC. ACIP. Prevention of Hepatitis A Through Active Prevention. MMWR 2006;55[No. RR-7].
CDC. Recommended Immunization Schedule for Persons Ages 0 Through 18 Years – United States, 2013. MMWR 2013;Supplement/62
Package insert for Havrix and VAQTA.

2) Engerix-B, manufactured by GlaxoSmithKline (GSK), is the second pediatric hepatitis B vaccine added to the current MDPH vaccine formulary. MDPH had been supplying Merck's Recombivax HB formulation for all pediatric hepatitis B vaccine orders. The addition of Engerix-B offers providers another option for pediatric hepatitis B vaccine.

Recombivax HB and Engerix-B are both recommended for:

- **Infants**: Routinely at birth, 1-2 months and 6-18 months of age. Infants born to hepatitis B surface antigen (HBsAg) positive mothers should receive HBIG and a schedule of Hep B at birth, 1 month and 6 months. The final (third or fourth) dose should be administered no earlier than 24 weeks of age. Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.
- **Catch-up:** Unvaccinated children and adolescents should complete a 3 dose series on a 0, 1-2 months, 6 month schedule.

Recombivax HB (adult formulation, 10µG/1.0mL) is licensed for use in children 11-15 years of age as a 2-dose alternative schedule (given≥ 16 weeks apart) and completed by age 16 (please see package insert). Engerix-B formulation is approved for alternative dosages and 4-dose schedules which may be used for specific populations, e.g., infants born to HBsAg positive mothers, recent exposure to virus and travelers to high-risk areas (please see the package insert).

No differences in immunogenicity have been observed when 1 or 2 doses of hep B vaccine produced by one manufacturer are followed with doses from another. The ACIP recommends providers complete the series with whatever product is available to avoid missed opportunities.

Please see the table below for recommended doses in those 19 years of age and younger.

Recommended Doses of Currently-Licensed Single Antigen Hepatitis B Vaccines for Use in Those 19 years of Age and Younger

Age Group	Single-Antigen Vaccine			
	Recombivax HB (Merck)		**Engerix-B** (GlaxoSmithKline)	
	Dose (µG)	**Volume** (mL)	**Dose** (µG)	**Volume** (mL)
Infants, Children and Adolescents - Birth through 19 yrs	5	0.5	10	0.5

Sources:
CDC. Epidemiology and Prevention of Vaccine Preventable Diseases., 12th edition. Hepatitis B Chapter and *Haemophilus influenzae* Chapter.
CDC. ACIP. MMWR 2005; 54 [No. RR-16].
CDC. Recommended Immunization Schedule for Persons Ages 0 Through 18 Years – United States, 2013. MMWR 2013; Supplement/62.

Vaccine Ordering

Please be sure to use the latest version of the MDPH *Vaccine Order Form* and *Vaccine Aggregate Report Form* attached and also available on the MDPH website at www.mass.gov/dph/imm. Select the brand of hepatitis A and/or hepatitis B vaccine you prefer by checking the box under the Vaccine column.

Vaccine ordering and usage reporting is also available by using the Vaccine Management Module in the Massachusetts Immunization Information System (MIIS). If you have not already registered with the MIIS please go to: https://contactmiis.info/enrollmentSite.asp and click "Begin Site Enrollment". If you have questions, you can call the MIIS Help Desk at 617-983-4335 or e-mail them at MIIShelpdesk@state.ma.us

If you currently order vaccines using the Vaccine Management Module in the MIIS and you want to change the formulation you currently receive, you will need to perform an additional step the first time you order the new formulation. Because the new formulation is not currently in your inventory, you will need to select "Add Vaccine From Formulary" at the bottom of the screen after you request doses of all other vaccines. Then, select the formulation that you want to receive. Because this vaccine will appear in your inventory after you receive the vaccine shipment, you will not have to perform this additional step when you place your next order.

If you decide to choose a new formulation, please use up existing inventories prior to making the change. Please be sure that you never let vaccine doses expire before use or restitution (in the form of privately purchasing replacement doses) may be required. The Immunization Program will monitor vaccine orders to ensure that practices are routinely ordering the same vaccine brand and only infrequently making brand changes.

Questions

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

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