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To: Pediatric Vaccine Providers

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Subject: Rotarix[®] Vaccine Added to MDPH Formulary

The Massachusetts Department of Public Health (MDPH) is pleased to announce the addition of Rotarix[®] vaccine, manufactured by GlaxoSmithKline (GSK), to its current formulary effective December 2, 2013. MDPH had previously been distributing only Rotateq[®] vaccine, manufactured by Merck, for all rotavirus vaccine orders. This expansion is a result of a formal recommendation to the Department by the Massachusetts Vaccine Purchasing Advisory Council (MVPAC) after deliberations during their October 2013 meeting. The addition of Rotarix[®] offers providers a choice for rotavirus vaccine formulation.

Vaccine Ordering

Please be sure to use the latest version of the MDPH *Vaccine Order Form* and *Vaccine Aggregate Report Form*, attached to this memorandum and also available on the MDPH website at www.mass.gov/dph/imm. Please select the brand of rotavirus 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 yet registered with the MIIS please go to: <https://contactmiis.info/enrollmentSite.asp> and click "Begin Site Enrollment". If you have questions, please 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 would like to 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 the other vaccines you are ordering. Then, select the rotavirus formulation that you wish 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 subsequent order.

MDPH asks that if you wish to switch formulations you only do so once per year. If you decide to switch the rotavirus vaccine formulation used in your practice, please deplete 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.

If your site is changing from Rotateq[®] vaccine to Rotarix[®] vaccine, please reduce your order quantity by one-third the doses used on your initial order. You will only need 2 doses of Rotarix[®] vaccine to complete the series versus the 3 doses needed for Rotateq[®] vaccine.

Vaccine Descriptions and Recommendations

The table below outlines the characteristics and recommended schedules of the Advisory Committee on Immunization Practices (ACIP) for the 3-dose RotaTeq[®] (RV5) and 2-dose Rotarix[®] (RV1) vaccine series.

Please note: if you decide to **change formulations** in your practice, those infants who start the series with Rotateq[®] and finish with Rotarix[®] will **need a total of 3 doses of rotavirus vaccine** to complete the series.

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.

Characteristics and Schedules of Currently-Licensed Rotavirus Vaccines

Characteristic/Schedule	RotaTeq [®] (RV5) (Merck)	Rotarix [®] (RV1) (GlaxoSmithKline)
Vaccine composition	Reassortant strains G1 x WC3; G2 x WC3; G3 x WC3; G4 x WC3; P1A[8] x WC3	Human strain 89-12 (type G1P1A[8])
Indications	Prevention of rotavirus gastroenteritis caused by G1,G2,G3,G4 serotypes	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4 and G9)
Applicator	Latex-free dosing tube	Tip cap of the oral applicator of diluent may contain natural rubber latex. The vial stopper and transfer adapter are latex-free.
Requires reconstitution	No	Yes
Volume per dose	2 mL	1 mL
Number of doses in series	3	2
Recommended ages for doses	2, 4 and 6 mos	2 and 4 mos
Minimum age for first dose	6 weeks	
Maximum age for first dose	14 weeks and 6 days	
Minimum interval between doses	4 weeks	
Maximum age for last dose	8 months 0 days	

- The **maximum age at 1st dose** for both vaccines is **14 weeks 6 days**. Vaccination RV1 or RV5 should **not** be initiated for infants aged **15 weeks and 0 days or older**.*
- The **maximum age for the last dose** of both vaccines is **8 months 0 days***
- For infants to whom dose 1 of rotavirus vaccine is administered inadvertently at age 15 weeks and 0 days or older, the rest of the rotavirus vaccination series should be completed according to the schedule and by age 8 months and 0 days.*
- **If any dose in the series was RotaTeq[®] (RV5), or the vaccine product is unknown** for any dose in the series, administer a total of **3 doses** of rotavirus vaccine.*
- Completion of the series with the same product is preferable. If the originally used product is not available or not known, vaccination with either product is acceptable.*

* These are off-label recommendations made by the ACIP.

Sources:

[CDC. ACIP Prevention of Rotavirus Gastroenteritis Among Infants and Children 2009;58\(RR-2\).](#)

CDC. Epidemiology and Prevention of Vaccine Preventable Diseases. [Rotavirus Chapter](#).

Rotarix Package Insert http://us.gsk.com/products/assets/us_rotarix.pdf

RotaTeq Package Insert

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142288.pdf>