STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H. Commissioner



Dannel P. Malloy Governor Nancy Wyman Lt. Governor

Immunization Program

TO: **Health Care Providers**

That Colle Mick Bolduc FROM:

Vaccine Coordinator-Connecticut Vaccine Program (CVP)

July 24, 2017 **DATE:**

SUBJECT: Merck Hepatitis B vaccine

The primary purpose of this communication is to notify you on the supply of Merck's pediatric Hepatitis B vaccine.

Merck Hepatitis Vaccine

Merck has notified the CDC that their pediatric Hepatitis B vaccine (Recombivax HB[®]) will be unavailable between early August 2017 & mid-January 2018. Glaxo SmithKline has sufficient supplies of their Hepatitis B vaccine (Engerix-B®) to address the gap in Merck's supply during this time period. Enclosed is a copy of the communication Merck will be sending to its customers about the supply issue. All pediatric Hepatitis B vaccine orders placed through the CVP will be filled with Engerix-B[®] until further notice.

As always, if you have any questions, please feel free to contact me at (860) 509-7940.





Merck 770 West Point Pike PO Box 250 West Point, PA 19486-0250



July 21, 2017

Dear Health Care Professional:

The purpose of this letter is to provide you with an important update on the availability of select Merck vaccine products. We will be out of stock or in a limited supply situation for some of our vaccines listed below during the remainder of 2017 and into 2018. This letter is intended to provide you with the current information on the supply situation as of the date of this letter.

We understand that supply interruptions are disruptive to you and your patients and sincerely apologize for the inconvenience. Due to the long lead times and complex nature of vaccine manufacturing, unanticipated events can impact available supply. Worldwide demand for the vaccines listed below, combined with updates to our manufacturing process, have impacted Merck's ability to satisfy the global market demand for these vaccines.

RECOMBIVAX HB [Hepatitis B Vaccine (Recombinant)] – 0.5 mL (5mcg) in single-dose vials and prefilled Luer-Lok® syringes — NDC 006-4981-000 and 006-4093-02:

Based on our most recent assessment, we will not be able to meet the anticipated, normal demand for these vaccines in 2017. Subject to on-going demand, both prefilled syringes and vials will be available until the mid July 2017 timeframe, at which time we expect to be out of stock until early 2018.

RECOMBIVAX HB[®] [Hepatitis B Vaccine (Recombinant)] 1 mL (10mcg) in single-dose vials and prefilled Luer-Lok[®] syringes— NDC 006-4995-41 and 006-4094-02:

Due to the prioritization of other impacted formulations, Merck has temporarily ceased production of this formulation of RECOMBIVAX ${\rm HB}^{\circ}$. We are currently stocked out of all packages and will remain out of stock for the remainder of 2017 through 2018.

<u>VAQTA</u> (Hepatitis A Vaccine, Inactivated) – 25U/0.5 mL in single-dose vials and prefilled Luer-Lok® syringes – NDC 006-4831-41 and 006-4095-02:

Supply of these vials should remain constant for most of 2017 with the potential for

intermittent outages depending on demand. We anticipate that there will be a limited availability of the prefilled syringes (NCD 006-4095-02) beginning in 3Q2017.

<u>VAQTA</u> (Hepatitis A Vaccine, Inactivated) – 50U/1-mL in single-dose vials and prefilled Luer-Lok® syringes – NDC 006-4841-41 and 006-4096-02:

Supply has also been impacted this year due to an increase in demand. Vials (ten vials per pack) are currently in stock. Prefilled syringes are currently out of stock with a resupply anticipated in 3Q2017.

Customers participating in a Merck vaccine contract or pricing program that contains performance requirements for the affected vaccines will receive a separate notification detailing any temporary adjustments to the performance requirements under that contract or pricing program.

For ongoing updates to the supply status for all of our vaccine products, please refer to our Supply Status communication on www.MerckVaccines.com or call the Merck Vaccine Customer Center at 877.VAX.MERCK (877-829-6372), Monday through Friday, 8:00 AM to 7:00 PM, ET. To automatically receive updates on supply status via email, go to www.MerckVaccines.com/supplystatusemail.

We sincerely apologize for the inconvenience that this creates for our customers and are working to resolve this situation as quickly as possible.

Thank you for your patience as we work through these supply challenges.

Sincerely,

Beth Freer
US Marketing Leader, Pediatric Vaccines

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