

## No end in sight for adult hepatitis B vaccine shortage

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**T**he lengthy and ongoing shortage of adult hepatitis B vaccine has baffled some public health doctors.

“Why is there a shortage for a stable vaccine that has been around for years?” asks Dr. Vinita Dubey, associate medical officer of health for Toronto Public Health’s division of communicable diseases. “This is a real public health concern.”

The shortage recently prompted Ontario’s Ministry of Long-Term Care to announce that it was suspending the Grade 7 hepatitis B program for the upcoming school year. According to the Public Health Agency of Canada (PHAC), other provinces and territories have also been forced to amend immunization programs.

“There are logistical challenges of trying to catch people up on immunizations that may have been delayed due to the shortage,” Charlene Wiles, a PHAC media relations advisor, writes in an email. “Canadian jurisdictions have been offering hepatitis B immunization routinely for children and high-risk groups now for many years. However it is possible that those not previously immunized and at risk as an adult could be vulnerable.”

The shortage began in January 2009, when Merck & Co., Inc. announced that equipment upgrades at its vaccine plant in West Point, Pennsylvania, would disrupt production of the adult version of its hepatitis B vaccine (Recombivax HB®). The vaccine will likely remain unavailable for the near future.

“We do not anticipate availability of the adult formulation of our Hepatitis B vaccine for the rest of 2010 and will provide an update on availability of the adult formulation when more information is available,” Jennifer Allen Woodruff, a spokeswoman for Merck, writes in an email. “Over the last couple of years, supply disruptions have occurred due to unexpected manufac-



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Merck & Co., Inc. does not anticipate that the adult formulation of its hepatitis B vaccine will be available for the rest of 2010.

turing issues that prompted modification to some of our processes and equipment. As a result, some of our vaccines have been in back order and other vaccines have been unavailable for order for some time.”

Woodruff says that Merck is addressing its production issues in several ways: by investing in manufacturing capabilities to increase capacity and create redundancy; by building new vaccine-production facilities in Durham, North Carolina, and Carlow, Ireland; by expanding vaccine manufacturing in Elkton, Virginia, and Mirabel, France; and by modernizing equipment and processes at its West Point facility.

“Of course, these changes take time because of the complexity of the vaccine manufacturing process and because some require regulatory approvals moving forward,” writes Woodruff.

In the mean time, GlaxoSmithKline (GSK) has been attempting to address the shortage by ramping up production

of its adult hepatitis B vaccine (Adult Engerix-B®).

“The shortage of hepatitis B vaccines is not limited to Canada, this is a global supply shortage,” Liana N. Del Medico, a GSK product communications manager, writes in an email. “GSK has made significant efforts to increase our supply and has been actively filling the market void created by our competitor’s supply shortage on hepatitis vaccines.”

Del Medico says that GSK is working with various Canadian jurisdictions to help meet the needs of school-based hepatitis B programs. “GSK hopes to have supply for the coming school year.”

Canada has purchased more than 350 000 doses of GSK’s vaccine, according to PHAC. Though the adult version of the hepatitis B vaccine is in short supply in Canada, there is sufficient supply of the pediatric version. — Roger Collier, *CMAJ*

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