

## Vaccine Update



November 2005

Dear Health-Care Provider:

Previously we sent you a communication explaining that several cases of Guillain-Barré Syndrome (GBS) were observed following administration of Menactra vaccine. The purpose of this letter is to provide you with the most recent information available and to highlight package insert changes that have been made in response to this situation.

To date, no causal link has been established between Menactra vaccine administration and the 6 observed cases of GBS, and no new cases of GBS have been confirmed following Menactra vaccine administration since October 6<sup>th</sup>. Because meningococcal disease continues to be a significant public health problem, the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) continue to recommend immunization for all 11 and 12 year olds at the pre-adolescent visit, adolescents entering high school, and college freshmen living in dormitories.

The Menactra vaccine package insert (enclosed) has been updated to alert physicians that GBS has been reported in temporal relationship following administration of Menactra vaccine, to warn against administration of Menactra vaccine to persons who have previously experienced GBS, and to reinforce the importance of adverse event reporting through the Vaccine Adverse Event Reporting System (VAERS). Please take note of the updated "Contraindications," "Warnings," and "Post-Marketing Report" sections.

In addition, patient surveillance networks that report adverse events have been significantly increased in size to better capture serious but rare adverse events such as GBS. One of the most important components of the vaccine safety monitoring system is the prompt completion by health-care providers and others of VAERS reports. Reporting forms and information about reporting requirements or completion of the form can be obtained from VAERS through a toll-free number 1-800-822-7967.

Sanofi pasteur places public health and patient safety as our highest priorities. Our company takes the reports of adverse events very seriously, and we continually monitor all of our vaccines to ensure we deliver the safest and most effective products possible. We appreciate your continued support and will keep you informed as more information becomes available.

Thank you,

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Vice President, Scientific & Medical Affairs US

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