



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

January 14, 2010

Dear Health Care Professional,

In November, I wrote to thank you for your efforts during the 2009 H1N1 influenza outbreak and to provide information about the development and the Food and Drug Administration (FDA) approval of the H1N1 vaccines. I mentioned our continuing robust efforts to monitor the safety of these vaccines and now would like to reassure you that, to date, the safety assessment is very encouraging.

Monitoring Vaccine Safety

As a key part of our missions, FDA, the Centers for Disease Control and Prevention (CDC), other agencies across the Department of Health and Human Services, and other parts of the federal government, including the Department of Defense and the Department of Veterans Affairs, have enhanced and expanded our vaccine safety monitoring systems to detect and quickly investigate any unexpected, rare, or serious adverse events. These additional systems enhance our ability to determine whether any adverse events can be attributed to H1N1 influenza vaccines. A detailed description of vaccine safety efforts is available online at www.flu.gov.

At the heart of our monitoring efforts are two surveillance systems used to help identify safety issues: the Vaccine Adverse Event Reporting System (VAERS) and the CDC's Vaccine Safety Datalink (VSD).

- VAERS is a "passive" surveillance system in which health care professionals, manufacturers, patients, parents, and others submit adverse event reports. VAERS data is used by FDA and CDC to identify whether safety signals exist (i.e., new, unexpected, or rare adverse events), although the system generally cannot be used to determine if a vaccine caused the reported adverse event.
- VSD is a collaboration among CDC's Immunization Safety Office and eight large managed care organizations that allows for planned vaccine safety studies as well as active surveillance for newly licensed vaccines, or changes to vaccine recommendations. The VSD project includes a large linked database with the ability to follow vaccinated and unvaccinated persons over time, as well as the capability to verify exposure and diagnoses through chart review. Because of this ability, VSD is able to detect associations between health events and vaccination and help determine whether adverse events after vaccination are causally related to the vaccines.

FDA and CDC are assessing H1N1 vaccine safety on a continuing basis and have published a detailed report describing the safety profile of H1N1 vaccines in the United States (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58e1204a1.htm>). This report analyzes the safety data after 11.3 million doses of live, attenuated monovalent vaccine (LAMV) for intranasal administration and 34.9 million doses of monovalent, inactivated, split-virus or subunit vaccines for injection (MIV) were distributed. As noted in the report, FDA and CDC evaluated 3,783 reports of adverse events submitted to VAERS through November 24, 2009. The analysis of VSD data was based on 438,376 people vaccinated with H1N1 vaccines (323,345 MIV and 115,031 LAMV) in

managed-care organizations in the VSD as of November 24. No substantial differences between H1N1 and seasonal influenza vaccines were noted in the proportion or types of serious adverse events reported. No increase in any of the pre-selected adverse events under surveillance, such as Guillain-Barré syndrome, has been seen in VSD data.

According to the January 8, 2010 update of FDA and CDC vaccine safety monitoring activities, as of December 30, 2009, the total number of doses of H1N1 vaccines distributed was 99.3 million and the vast majority (94%) of adverse events reported to VAERS were classified as "non-serious" (e.g., soreness at the vaccine injection site). Weekly updates on FDA and CDC vaccine safety monitoring activities are available through the VAERS web site (<http://vaers.hhs.gov/resources/h1n1update#top>).

The National Vaccine Advisory Committee (NVAC) created the H1N1 Vaccine Safety Risk Assessment Working Group to review 2009 H1N1 vaccine safety data. This working group of outside experts conducts regular, rapid reviews of available data from the federal safety monitoring systems and presents them to NVAC and federal leadership for appropriate policy action and follow-up available at (<http://www.hhs.gov/nvpo/nvac/index.html>).

To date, our experience with the H1N1 influenza vaccination program has met high safety expectations, based on the track record of the licensed seasonal vaccines, including live attenuated and inactivated vaccines. We are also collaborating with other agencies around the world to share our vaccine safety information and experiences. Should any safety concerns arise, we will evaluate them thoroughly and bring them to the public's attention quickly.

While H1N1 influenza disease transmission appears to be waning, there is a significant possibility it will return. Twelve states – California, Georgia, Hawaii, Indiana, Maine, Nevada, New Hampshire, New Jersey, New Mexico, New York, Tennessee, and Virginia – continue to report regional influenza activity.

Therefore, it is still important to vaccinate people in high-risk groups as soon as H1N1 vaccine is available in their communities, and people who are not in high-risk groups should get a vaccine when it becomes available to them. As more vaccine has become available, we encourage you to continue to talk with your patients about the benefits and risks of H1N1 vaccines especially for pregnant women and others at high risk of severe influenza infection and its complications.

While antiviral resistance remains at low levels, future potential development of resistance is still a concern, so immunization is the best protection.

Health care providers, as the front lines of medicine, are an important part of the system. I encourage you to report any adverse effects that you believe are linked to any vaccine, including the 2009 H1N1 influenza vaccines, to VAERS (<http://vaers.hhs.gov/index>).

Thank you again for your critical work during this challenging time.

Sincerely,



Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs