Providers Asked to Report H1N1 Vaccine Events

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The Food and Drug Administration encourages health care providers to watch for and report any adverse events associated with vaccination against the pandemic influenza A(H1N1) virus, FDA commissioner Dr. Margaret A. Hamburg said in an open, online letter to American health care professionals.

"The benefits of preventing serious consequences from infection with the 2009 H1N1 influenza virus far outweigh the risks associated with vaccination," Dr. Hamburg said. She emphasized that no shortcuts were taken during production of the vaccine, and that the vaccines are released for distribution only when they are deemed sterile and potent by both the vaccine manufacturer and the FDA.

Dr. Hamburg reviewed the egg-based process for vaccine manufacture and the process of measuring the amount of vaccine antigen, both of which impact the number of vaccine doses available at a given time. As of Nov. 10, more than 41 million doses of the H1N1 vaccine had been allocated for distribution throughout the United States, she said.

Dr. Hamburg also emphasized the safety and effectiveness of the vaccine, shown in early clinical trials, and she encouraged physicians to share information about vaccine production, distribution, and safety with their patients.

The letter can be accessed online at www.fda.gov/NewsEvents/PublicHealthFocus/ucm189691.htm. Health care professionals can report adverse events via the Vaccine Adverse Event Reporting System at http://vaers.hhs.gov/index. ■