

For Influenza Vaccine Summit Partners: Influenza Vaccine Delay Update

Background

On August 26th, 2004, Chiron Corporation announced that while completing its final internal release procedures for Fluvirin® influenza vaccine, 8 out of 60 lots of vaccine (approximately 4 million doses) were identified as not meeting product sterility specifications and discarded. Chiron believes that they have identified the root cause for the problem but will delay the release of further Fluvirin® vaccine doses until additional tests have been done to ensure their safety. Chiron also confirmed that the one million doses that they had shipped to distributors on July 23rd, 2004, remain in their full control. These doses will not be recalled as they have passed FDA testing and are safe.

As a result, Chiron expects to deliver about 46 – 48 million total Fluvirin® doses this year plus 2 million doses into the Centers for Disease Control and Prevention (CDC) stockpile. This is a slight decrease from the original 50 million doses expected prior to this problem but remains higher than the 38 million doses provided by Chiron last year.

Altogether, there will be over 100 million doses of influenza vaccine available this year in the United States. Limited doses have already been shipped from Aventis Pasteur, the other manufacturer of injectable influenza vaccine, but they expect to deliver about 20 million doses in September with the rest (32 million doses) arriving in October. MedImmune expects on time delivery of its approximately 1.5 million doses of intranasal influenza vaccine in October.

Chiron vaccine is expected to be delivered in early October

Chiron believes strongly that they have identified the root cause of the sterility problem and have taken steps to rectify it. As such, the company expects to begin shipping Fluvirin® in early October, assuming satisfactory results from the ongoing release testing of the remaining vaccine lots. Since October and November are the primary months when influenza vaccine is given, the impact of the delay on the upcoming 2004-2005 influenza vaccination season should be minimal. Furthermore, as in past years, CDC urges continuation of Influenza vaccination into December and beyond if vaccine is available.

The CDC has stated that they expect no negative impact on influenza vaccination efforts and does not envision any need for tiered vaccine recommendations at this time.

Chiron has stated that once vaccine is released for shipment, there will be NO prioritization of shipments to distributors.

Prioritizing of vaccine to high risk patients

As the United States influenza vaccine supply is expected to be adequate by October, at present the CDC does not envision any need for tiered vaccination recommendations for this upcoming season. Thus, no prioritization of vaccine for those at higher risk of

complications from influenza is recommended; however, strong recommendations to immunize those at high risk of complications from influenza continue.

Note that Chiron's Fluvirin® is only approved for those older than 4 years of age and as such the younger pediatric populations should not be impacted by this delay.

What is important for Summit Constituents to know

The CDC has stated clearly that this not a crisis. The Summit Executive Committee concurs but believes that a reassuring and unified message needs to be delivered by all Summit partners to their constituents. This is NOT the same production situation that occurred in 2000-2001 that resulted in the severe delay in shipment of influenza vaccine from three manufacturers. However, there are certain expectations that accompany this delay in shipment of the Chiron vaccine that Summit partners should communicate to their constituents.

First, health care professionals (HCPs) who have ordered Chiron vaccine will not be receiving their shipments until early October. As such, any clinics scheduled or patients seen prior to vaccine delivery will have to be rescheduled. It is highly encouraged that HCPs consider implementing some form of reminder/recall system to ensure that those seeking vaccine return for it in October, especially if they are at high risk of complications from influenza. Clinics should be rescheduled for mid-October but the CDC has stated that they will work to keep communities informed as to when they might expect vaccine to arrive.

Second, it is likely that local discrepancies in vaccine supply will occur. Those HCPs who ordered their vaccine from another manufacturer will already have begun to receive their full supply of vaccine. It is important to reassure those HCPs who have ordered Chiron vaccine that their vaccine will be delivered in October, in plenty of time for them to vaccinate their patients. It remains imperative that the Summit works to defuse any sense that vaccine is being preferentially distributed to one HCP population over another.

Finally, the Summit has been, and will continue to be, included on all urgent communication regarding the influenza vaccine supply. As the CDC has stated, there is a fine line between enabling people to understand and expect some delay in their ability to receive influenza vaccination and causing too much concern such that the public races out to get to the head of the line for vaccine in September. More doses of vaccine than last year will be available. Remember, even with the public's rush to get vaccinated last year, there were still some doses of vaccine left over.

The CDC is working very closely with all the manufacturers and maintains its close ties with the Summit. If any further changes occur to the expected production of influenza vaccine, the CDC will update the Summit as soon as possible.