

CDC Update on Antiviral Drug Availability during the 2013 Influenza Season January 17, 2013

- **Update on Antiviral Availability:**

On January 10, 2013, the U.S. Food and Drug Administration (FDA) released [information indicating there may currently be intermittent shortages of oseltamivir phosphate \(Tamiflu\) oral suspension \(6mg/mL 60 mL\)](#),² due to increased demand for the drug.

- **Compounding of Tamiflu 75 mg Adult Capsules to make an Oral Suspension:**

The manufacturer's website has [instructions for pharmacists](#)² available online on how [to compound an oral suspension from Tamiflu 75 mg \(adult\) capsules](#)². These instructions are based on the current FDA-approved labeling to provide for an alternative oral suspension when commercially manufactured oral suspension formulation is not readily available.

In some cases, clinicians can consider substituting a 30 or 45 mg capsule for children (if dose is appropriate) rather than suspension, particularly if there are spot shortages of suspension. These capsules may be opened and mixed with sweetened liquids, such as regular or sugar-free chocolate syrup, if oral suspension is not available.

- **Should State Stockpiles of Antiviral Drugs be Released?**

Some states have stockpiled antiviral drugs to prepare for a pandemic influenza outbreak. Antiviral drugs purchased through HHS subsidy program contracts may only be used during a declared pandemic and a public health emergency declared by the HHS Secretary. As such, at this time, the emergency antiviral drugs in state stockpiles should not be used to treat seasonal influenza cases.

- **Stockpile Expiry Extension for a Maximum of 7 years:**

FDA approved supplemental new drug applications for Relenza inhalation powder (May 2009) and Tamiflu capsules (Dec. 2007), that provided an expiration dating period of seven years. Approvals of new drug applications are generally prospective. However, FDA concluded that, provided the products have been stored under the labeled storage conditions, it would be scientifically supportable for the expiry extension for a maximum of seven years to apply to lots that had been previously manufactured. ***Lots that exist within state stockpiles that are currently packaged with an expiration date of less than seven years may be extendable provided the products have been stored under the labeled storage conditions.*** Therefore, in June 2010, FDA stated that it would not take enforcement action with regard to the storage of certain lots of Relenza inhalation powder and Tamiflu capsules that were retained for use in future emergencies, provided that the products have been stored under labeled storage conditions.

As antiviral drug products in state inventories approach their labeled expiration dates, please verify if these products have a shelf life that has been extended as communicated by the FDA (see link below) or the manufacturer. We encourage states to retain these assets up to their extended expiration date**.

- **Use of Stockpiled Tamiflu Capsules Beyond 7-Year Shelf Life:**

HHS is aware that some lots of antiviral drug products in state stockpiles are approaching expiration or have already passed the extended 7-year shelf life expiry. Based on FDA's review of scientific data, FDA has concluded that, *provided the products have been stored under labeled storage conditions, it is scientifically supportable for certain lots of Tamiflu capsules held in strategic stockpiles to be used for a maximum of ten years beyond their date of manufacture*. FDA will not take enforcement action with regard to the storage or emergency use of these lots of Tamiflu capsules, provided that the products have been stored under labeled storage conditions. Note that this applies to Tamiflu capsules only and is not applicable to Relenza inhalation powder.

Also, at this time, as indicated above, Tamiflu capsules purchased through HHS subsidy program contracts held in state stockpiles should not be used to treat seasonal influenza cases. CDC will provide updates as needed about the use of such product

- **Retaining State Stockpiles:**

HHS would like to reiterate the importance of retaining state antiviral stockpiles if applicable. Please review carefully the expiration date in accordance with the above guidance before discarding inventory.

**Please see the FDA EUA termination information at

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm216249.htm>