CDC Update on Antiviral Drugs
2017-2018 Influenza Season

Updated: March 20, 2018

- **Update on antiviral availability:**

CDC is in regular contact with influenza antiviral drug manufacturers regarding supply. Please visit the CDC antiviral drug supply page for more information:
https://www.cdc.gov/flu/professionals/antivirals/supply.htm

In addition, the U.S. Food and Drug Administration (FDA) releases information on the availability of influenza antiviral drugs. For current availability of antivirals, please refer to:
https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm.

- **Compounding Tamiflu 75 mg adult capsules to make oral suspension:** When commercially manufactured liquid suspension formulation is not readily available, pharmacists may compound an oral suspension from oseltamivir 75mg capsules as described in the FDA-approved manufacturer package inserts as an alternative. Instructions for pharmacists available online on how to compound an oral suspension from Tamiflu 75 mg (adult) capsules (see full prescribing information; please note generic products are also now 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 or received from the Strategic National Stockpile during the 2009 H1N1 response are recommended to be reserved for use in a declared pandemic or public health emergency.

- **Initial 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 7 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 7 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 7 years may be extendable provided the products have been stored under the labeled storage conditions***. 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 or pass 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 antiviral drug products in state stockpiles 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 10 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.

- **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. **As of 03/20/18:** CDC is working with FDA to determine if state stockpiles of oseltamivir capsules and zanamivir may receive further extensions.

**The FDA EUA termination information has been archived on the FDA website and is available at https://wayback.archive-it.org/7993/20170722095242/https:/www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm216249.htm.