

## Centers for Disease Control and Prevention *Pandemic Flu Q&A*

**Q: What antivirals will be distributed in the event of a pandemic?**

A: Antivirals that may lessen the impact of influenza include the adamantanes (amantadine and rimantadine) and the neuraminidase inhibitors (oseltamivir and zanamivir). Tamiflu (oseltamivir), and Relenza (zanamivir) have shown effectiveness against the H5N1 virus and are being stockpiled in the SNS. Appropriate use of these agents during pandemic influenza may reduce morbidity and mortality and diminish the overwhelming demands that will be placed on the healthcare system

**Q: What is the status of the H5N1 vaccine?**

A: Currently, there is no FDA approved vaccine against the H5N1 virus. HHS is in the process of procuring “prepandemic vaccine,” which is vaccine developed based on current strains of H5N1 (prior to a pandemic). This vaccine is being held by the manufacturer in bulk form until the clinical trials for dosing, efficacy and safety are completed.

**Q: What is the target ratio for SNS antivirals (Tamiflu/Relenza)?**

A: SNS is currently purchasing antivirals in a ratio of 80% Tamiflu to 20% Relenza. The SNS also includes smaller quantities of rimantadine. Each State should purchase antivirals in a ratio that best fulfills their needs. HHS will be providing additional guidance to States to assist them in making this decision.

**Q: Are there special handling/transportation requirements for these antivirals?**

A: Antivirals should be stored as follows as stated in their FDA approved package inserts:

**Tamiflu capsules:** Store the capsules at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]\*

**Tamiflu suspension:** Store dry powder at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]\*. Store constituted suspension under refrigeration at 2° to 8°C (36° to 46°F). Do not freeze.

**Relenza:** Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature)\*

\* Refers to U.S. Pharmacopeia Temperature guidelines

**Q: Who will store antivirals purchased through the HHS federal subsidized antiviral procurement plan (Critical Task 5)?**

A: No decisions have been made on whether States will be allowed to contract with SNS for storage of their antivirals (purchased through the federal subsidized antiviral procurement plan).

While awaiting this decision, States should be planning for storage of antivirals in a central location within the State. Additional guidance on this decision will be forthcoming.

**Q: How many regimens of antivirals will be procured at the state and federal levels?**

A: The HHS goal is to have 81 million antiviral regimens available for the U.S. population. Of this 81 million, 50 million regimens will be procured and stored in the SNS. Of this 50 million, approximately 44 million regimens will be held for pandemic usage by states and 6 million reserved for domestic containment efforts. HHS will subsidize state purchases of up to 31 million treatment courses of Tamiflu and Relenza, apportioned to States based on population.

**Q: How will states be subsidized?**

A: HHS is working to negotiate contracts with the antiviral manufacturers to attain best pricing for state procurements and will subsidize 25 percent of the procurement costs states incur, up to 31 million doses as apportioned by State population. Additional guidance regarding state purchases will be released by HHS.

**Q: Will DSNS deliver our allotment directly to the pre-identified loci (Critical Task 7)?**

A: As currently planned, DSNS will deliver to one predetermined location in each project area.

**Q: In addition to vaccine and antivirals, what other medical supplies that can be used in the event of a flu pandemic are currently stockpiled in the SNS?**

A: The DSNS is procuring ventilators, personal protective equipment (masks, gowns, gloves, etc.), and IV antibiotics (for infections secondary to influenza) that may be needed during a pandemic. Federal Medical Stations (FMS) are also stockpiled. Each FMS has beds, medical supplies, and some administrative and housekeeping supplies. An FMS has a variety of medicines, and can treat 250 patients with non-acute medical needs (not specific to influenza) for up to three (3) days.

**Q: How will states request SNS antivirals?**

A: States will be able to request SNS antivirals through their governor similarly to how they would request other SNS assets. Additional information on this process will be forthcoming. All requests for critical assets will be further assessed by HHS and CDC at the time of an event.

**Q: How will states request pre-pandemic and pandemic vaccine?**

A: No decisions on vaccine distribution and request processes have been made at this time. Additional information on this process will be forthcoming. All requests for critical assets will be further assessed by HHS and CDC at the time of an event.

**Q: How will states request SNS Federal Medical Stations?**

A: States will be able to request FMS supplies through their governor similarly to how they would request other SNS assets. Additional information on this process will be forthcoming. All requests for critical assets will be further assessed by HHS and CDC at the time of an event.

**Q: What is the federal funding breakdown?**

A: Congress appropriated \$3.8 billion to help prepare the nation for a pandemic influenza event. Of this money, \$3.3 billion was allocated to HHS for:

- \$ 1.8 B – Vaccine production and development
- \$731 M –Antiviral procurement (includes procurements and research)
- \$162 M –Procurement of other medical supplies
- \$350 M –State and local readiness
- \$161 M –Domestic preparedness
- \$ 94 M - International Activities
- \$ 38 M – Communications

**Q: Can state-owned antivirals be submitted to the Shelf Life Extension Program (SLEP)?**

A: The Shelf Life Extension Program, managed by the FDA, allows for product in the Strategic National Stockpile (SNS) to receive an extended expiration date if it meets specific conditions. At this time, the SLEP is only available for federally-owned pharmaceuticals. State assets are not currently eligible for the SLEP. FDA is working with HHS and States to assess the feasibility of making State assets eligible for the extension program.

**Q: How is the response to a pandemic outbreak different from a typical SNS response?**

A: Pandemic influenza is a unique emergency health event because local communities will be simultaneously affected. Traditionally, the SNS has planned and prepared to respond to one to three concurrent short-term events that require federal assistance. In a pandemic event, SNS will need to respond to the needs of every State and territory. Federal assets will be delivered to States and States will then be responsible for delivering SNS assets to the local facility (hospitals, nursing homes, long term care facilities, etc) level. States may not be able to utilize traditional “Points of Dispensing” (POD) plans for these SNS assets because of contagion issues, and should be planning alternative receipt and dispensing methods. Additionally, Critical Task #6 of the supplemental pandemic influenza funding guidance requires recipients to identify loci throughout the jurisdiction in which the recipient plans to pre-position antiviral drugs if pandemic influenza were judged imminent.

**Q: Is Tamiflu in the 12-hour Push Package?**

A: Antivirals and items procured specifically for pandemic influenza response are not part of a 12-hour Push Package. These items are in SNS inventory and will be delivered independently.

**Q: Will a 12-hour Push Package be sent in the event of a Pandemic?**

A: A 12- hour Push Package does not contain the items that would be critical during pandemic influenza. States may request a 12-hour Push Package through the standard request process if a bioterrorist event or other emergency occurred at the same time, or if this additional resource is deemed necessary.

**Q: When are additional planning documents scheduled to be released by HHS and CDC?**

A: The HHS operational plan is being finalized and is expected to be released shortly. CDC's response plan should be completed shortly thereafter.

**Q: Where can I find additional information about pandemic planning?**

A: More information can be found at HHS's website at <http://www.pandemicflu.gov/>, or CDC's pandemic planning website at <http://www.cdc.gov/flu/pandemic/>.

**Q: What are the size/weight specifications for packaged Tamiflu, Relenza and Rimantadine?**

\*Please note that the product you may receive from the manufacturer may vary in dimension

- **Tamiflu (oseltamivir)**
  - Case dimensions 12.5" x 7.6" x 7.8"
  - Case weight 3lbs.
  - 88 blister cards per case, 10 capsules per blister card
  - 44 cases per pallet (11 cases per pallet layer- 4 layers per pallet)
  - Pallet weight with product - 437 lbs
  - Pallet height is 36"
  - Pallet size is standard 40"X 48"
  - 3,872 courses per pallet (one blister card equals one course)
  
- **Relenza (zanamivir)**
  - Case dimensions 17"x 6" x 9 1/4"
  - Case weight 4 lbs
  - 16 kits per case
  - 60 cases per pallet (10 cases per pallet layer- six layers per pallet)
  - Pallet weight with product – 271 lbs.
  - Pallet height 45"
  - Pallet size is standard 40"X 48"
  - 960 courses per pallet (1 kit equals one course)
  
- **Rimantidine**
  - Case Dimensions: 6.75" x 4.75" x 3.5"
  - Case Weight: 1.05lbs.
  - Number of cases per Pallet - varies, 659 on sample pulled
  - Number of cases per layer - 54 per sample pulled
  - Number of layers per pallet varies - 12 on sample pulled
  - Pallet Weight w/Product varies - 724 lbs. on sample pulled