THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

AUG 1 0 2007

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Release of Department of Defense Antiviral Stockpile during an Influenza Pandemic

Reference: (a) "Policy for Release of Tamiflu® Antiviral Stockpile during an Influenza Pandemic", January 10, 2006 (HA 06-002, hereby rescinded)

This memorandum supersedes the above reference regarding the Department of Defense's (DoD) Tamiflu® Antiviral Stockpile during an Influenza Pandemic.

The DoD has established a stockpile of Tamiflu® and Relenza® antiviral medications. Both are anticipated to be effective against pandemic influenza (PI). In addition, DoD established an additional supply of Tamiflu® that is stored and maintained at medical treatment facilities. These antiviral medications are for use during World Health Organization (WHO) Pandemic Phases Three through Six (reference: "2005 WHO Global Influenza Preparedness Plan") in supporting execution of the COCOM, Service, or agency Pandemic Influenza Plans (which are tied to the DoD Global Synchronization Pandemic Influenza Plan).

The attachment provides guidelines for the release, prioritization, and release authority of these antiviral medications. My point of contact for this policy is LTC Wayne Hachey, at (703) 575-2669 or *Wayne.Hachey@ha.osd.mil.*

S. Ward Casscells, MD

Attachment:
As stated

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Director, Health and Safety, US Coast Guard

HA POLICY: 07-015

Health Affairs Policy for Release of Department of Defense Antiviral Stockpile during an Influenza Pandemic

The Department of Defense (DoD) established, and continues to add to, a stockpile of Tamiflu® and Relenza® antiviral medications. These antiviral medications are for use during World Health Organization (WHO) Pandemic Phases Three through Six (reference: "2005 WHO Global Influenza Preparedness Plan") in supporting execution of the Combatant Commands, Service, or agency Pandemic Influenza Plans (which are tied to the DoD Global Synchronization Pandemic Influenza Plan).

Stockpiles of treatment courses of Tamiflu® and Relenza® are pre-positioned in the Pacific Rim, Europe, and the continental United States (CONUS). Before use, appropriate screening and education programs related to antiviral administration should be developed by the secretaries of the military departments, consistent with the package insert, in accordance with Health Affairs Policy: 03-007 "Policy for Use of Force Health Protection Prescription Products." These pre-positioned stockpiles of Tamiflu® and Relenza® are not released to the Services or the geographic combatant commanders (GCCs), but remain within the control of the Assistant Secretary of Defense (Health Affairs) (ASD (HA)). In addition, the ASD (HA) may authorize transport of some of the stockpiles to different locations depending on the overall risk and mission. Authority to release the stockpile is vested in ASD (HA) who will release all, or a portion of, the stockpile to the Joint Chiefs of Staff (JCS) should the risk to DoD personnel become imminent. The ASD (HA) will be advised on this decision by the Service Surgeons General, JCS, commanders of combatant commands (CCDRs), the Joint Preventive Medicine Policy Group (JPMPG), and other advisory bodies. After ASD (HA) approval, the Defense Logistics Agency (DLA) will initiate antiviral shipments using standard medical logistics supply chain processes or, if required, alternate GCC-directed means (military ground or air transport). On a case-by-case basis, the ASD (HA) will consider requests from the JCS/CCDRs to create small stockpiles at other locations or in specific units, or authorize the release of portions of the stockpile. This is particularly applicable when large numbers of personnel are deployed in a high risk area, to include U.S. Northern Command (USNORTHCOM) operations in CONUS, for an extended time.

Following ASD (HA) release of antiviral medications from the stockpile, the JCS, in coordination with USNORTHCOM as the Global Synchronizer, and affected CCDRs will apportion these medications to the GCCs for use overseas, and to the Services for use within CONUS. Subsequent use will be based on the ASD (HA) guidance.

Military treatment facilities (MTF) will maintain an additional supply of Tamiflu®, equal to 10 percent of the population at risk (PAR), which represents the beneficiary population enrolled for care at the respective MTFs. This supply of Tamiflu® at MTFs is designated for use by that facility and its subordinate or supported units or facilities specifically to respond to a pandemic or other associated health emergency. Authority to release this supply of Tamiflu® is vested in the Services, for

CONUS MTFs and the GCCs for MTFs outside of the continental United States. The owning Service or GCC may delegate this authority in writing to the major command or component level. Following release from the appropriate authority, the commander of the MTF has operational control of the antiviral medicine. Operational decisions regarding use of this supply will be consistent with the priorities for antiviral use presented in this policy in addition to current clinical guidelines by cognizant public health and infectious disease specialists and organizations.

Antiviral chemoprophylaxis will not provide protection once discontinued. Unless the attack rate is significantly reduced or the supply of antiviral medications increases, treatment should represent the primary use of these medications. Antiviral chemoprophylaxis should not begin until the public health emergency officer (PHEO) confirms that pandemic influenza exists, or is likely to occur, in the unit of interest. Commanding officers, with the guidance of their PHEOs, should time medication use to maximize drug effectiveness. Depending on the efficacy of non-pharmacologic measures, the overall antiviral requirements may be reduced substantially. In this instance, increased antiviral utilization for outbreak and post-exposure prophylaxis strategies can be considered.

Options for post-exposure prophylaxis include administering a course of therapy consistent with low dose/long term administration or a high dose/short term strategy. Both represent prophylaxis and are provided following exposure to a known or strongly suspected case. Using Tamiflu®, the course of therapy for the low dose/long term approach is one 75mg capsule per day for 10 days whereas the alternate high dose/short term strategy provides two capsules per day for 5 days. The advantage of the low dose/long term strategy is a longer protective interval for exposed but not infected individuals. The risk associated with this approach is the probability of administering a sub-therapeutic dosage to those who, following exposure, are infected but have not yet manifested symptoms. A sub-therapeutic treatment course may also foster the development of drug resistance. The advantage to high dose/short term strategy decreases the possibility of administering a sub-therapeutic course, reduces the possibility of development of antiviral resistance and provides a potentially effective treatment course for those who are infected but are in a presymptomatic stage. The disadvantage to this approach is a decreased duration of protection for uninfected recipients. However, the degree of viral shedding by the treated index case after five days of therapy should be significantly reduced with a subsequent reduced risk of transmission to household members.

The CONUS MTFs will receive some antiviral medications through the Strategic National Stockpile (SNS) for use in the general beneficiary population per the interagency agreement between the Department of Health and Human Services and the DoD, "Support of Contingency Medical Material Requirements," dated May 5, 2005. Antiviral therapy for the general beneficiary population should compare to that of the local civilian population. PHEOs should coordinate with both state and local public health authorities to ensure that this process is anticipated. Authorized beneficiaries residing overseas will likely require access to DoD antiviral medications. Because the supply of both Tamiflu® and Relenza® are limited and replenishment may not be possible, prioritization guidelines are necessary. Prioritization and use guidelines will vary depending on both the disease severity and the supply of antiviral medications. The following prioritization matrix lists the priority for the use of antivirals in four differing conditions depicting high and low supply with high and low disease severity, and should be used as a general guide. The categories of personnel in each block are listed highest to lowest priority from top to bottom of each matrix block, respectively. Guidance regarding which matrix should be employed will be based on the current supply status and disease characteristics and will be posted on the DoD Watchboard (*www.dod.mil/pandemicflu*) as needed. As additional clinical data develops further modifications to this policy will also be posted on the DoD Watchboard. Local disease attack rates and antiviral characteristics should also be considered as the effectiveness of layered community containment measures are likely to be variable based on the demographics of the community and the timing and consistency of implementation.

Matrix for Varying Disease Severity and Antiviral Capacity			
	Antiviral Drug Supply		
		Low	High
Pandemic Severity	High	SCF (T,P or PEP) CF(T) HP (T) AF (T) OF (T) F (T) B (T)	HP (T) SCF (T,P or PEP) CF (T, P or PEP) AF (T, P or PEP) OF (T, P or PEP) F (T, or PEP) B (T or PEP)
	Low	HP (T) SCF (T, P or PEP) CF (T) AF (T) OF (T) F (T) B (T)	

Definitions:

High Pandemic Severity: Case fatality rate of greater than or equal to 1 percent consistent with National Pandemic Categories 4 and 5.
Low Pandemic Severity: Case fatality rate of less than 1 percent consistent with National Pandemic Categories 3 and 1.
High Supply: Attack rate is sufficiently low to permit outbreak prophylaxis as operationally required and post exposure treatment or prophylaxis.
Low Supply: Attack rate is sufficiently elevated above pre pandemic planning assumptions which limit outbreak prophylaxis as operationally required and post exposure treatment or prophylaxis.
(HP) Hospitalized Patients: Individuals who have contracted pandemic influenza and are hospitalized or who would be hospitalized if resources were available and who are likely to benefit from antiviral therapy.
(CF) Critical Forces: Personnel necessary to respond to global military contingencies and provide health care for force structure as defined by the JS.

Sub-groups:

Personnel required to maintain national strategic and critical operational capabilities as defined by the Joint Staff (JS).
Deployed forces engaged in or supporting critical operations in an area with high risk of PI
Personnel necessary to maintain a functioning health care system.

(SCF) Select Critical Forces: Represent those small numbers of individuals who, due to the unique and critical nature of their function, require maximum protection regardless of the available resources as defined by the JS.
(AF) Alert Forces: Non-deployed forces that are on alert or designated to conduct critical contingency operations as defined by JS.
(OF) Operational Forces: Personnel necessary to maintain critical mission-essential capabilities at each organizational level.
(F) Forces: All other active duty or activated Reserve and National Guard personnel.
(B) Beneficiaries: All other beneficiaries who develop PI and do not require hospitalization OCONUS beneficiaries may not have access to the SNS. In this instance, consideration to liberalize access to antiviral therapy for high risk individuals may be appropriate.
(T) Treatment: 75mg of Tamiflu® or 10mg of Relenza® twice a day for 5 days. The impact on viral shedding is dependent on early treatment. Some clinical benefit may be realized with initiation of therapy up to one week following onset of symptoms.
(P) Prophylaxis:
Outbreak or Operational Prophylaxis 75 mg of Tamiflu® or 10 mg of Relenza® one a day for the duration of likely exposure. Maximum duration of each course of prophylaxis is 6 weeks for Tamiflu® and 4 weeks for Relenza®. The use of prolonged or large-scale prophylaxis should be targeted and limited. Reliance on this mode of prophylaxis will quickly exhaust antiviral supplies.
(PEP) Post Exposure Prophylaxis can be accomplished by administering a low dose over a prolonged period or a higher dose over a shorter period. Each provides 10 doses of antiviral medication for individuals with close and prolonged contact with a known or strongly suspected case (assumed to average four individuals per positive case). To be effective this should be initiated at the same time the index case begins treatment.
(PAR) Population at Risk: Corresponds to the beneficiary population enrolled for care at respective MTF's.
NOTE: All priority groups may incorporate Active, Reserve, or National Guard personnel on Title 10 or 32 status, and DoD civilians depending on role or function.
National Pandemic Categories are as defined in the CDC document "Interim Pre-Pandemic Planning Guidance: Strategy for Pandemic Influenza Mitigation in the United States," dated February 2007 and posted on *http://pandemicflu.gov/*.

The DLA has developed a distribution plan using the Service-specific medical logistics supply chain processes and standard commercial contract carriers. Pandemic plans within DoD should be thoroughly coordinated between the medical and transportation communities at every level, and include plans for distribution and administration of antiviral medications. Upon ASD (HA) approval, DLA will implement antiviral medication shipment in support of mission-critical priorities in coordination with U.S. Transportation Command (USTRANSCOM), with a goal of global delivery within 48 hours after DLA has been notified. Should the usual modes of DLA logistic support

be inadequate, USTRANSCOM will be tasked with delivery from CONUS DLA storage depots to designated CONUS locations, while the GCCs may be similarly tasked for delivery within their respective areas of responsibility. Because it may become necessary for USTRANSCOM to assume the antiviral delivery mission, I request that the JCS and USTRANSCOM coordinate with DLA to provide a redundant delivery system using military assets. Following antiviral release, each MTF commander receiving the assets will have the responsibility of ensuring that this medication will be distributed and administered in accordance with this and subsequent policy guidance.

The intent is to maintain DoD capability to respond to a pandemic by identifying funds required to sustain stock levels for antiviral medications using the supplemental funding process for avian influenza directed by the DoD Comptroller. In addition to the supplemental funding process, implementation of the Food and Drug Administration's approved shelf-life extension program will be used to maintain stock levels over an extended period of time.

Immunization is the primary method to prevent influenza and its serious complications. Pending availability of the vaccine, antiviral medications will be used both to treat and prevent pandemic influenza. The use of antiviral medications will support ongoing global military operations and national security priorities until a vaccine becomes available.