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State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

March 21, 2008

Dear Colleague,

Antiviral medications are one of several approaches to protect people during a pandemic. They support U.S. national pandemic response goals of slowing the spread of pandemic influenza disease, reducing the impacts on health, and minimizing societal and economic disruption. The Federal Government encourages businesses to consider stockpiling antiviral medications as part of a comprehensive pandemic preparedness plan

In response to questions concerning private institutional, business and personal stockpiles, the California Department of Public Health developed this *Antiviral Medication Stockpile Guidance for Local Agencies and Businesses*. This guidance supersedes the original guidance released in 2005 that addressed the prescribing of antiviral medications for individuals and will be updated as federal guidance and issues emerge. The new guidance offers information and planning considerations for private and public agencies.

Please address any questions or comments about the *Antiviral Medication Stockpile Guidance for Local Agencies and Businesses* to Dr. Howard Backer, CDPH Immunization Branch at howard.backer@cdph.ca.gov.

Thank you for your ongoing pandemic influenza planning and preparedness efforts.

Sincerely,

Gilberto F. Chavez, M.D., M.P.H.
State Epidemiologist
Deputy Director
Center for Infectious Diseases

Enclosure: Antiviral Medication Stockpile Guidance for Local Agencies and Businesses.



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Antiviral Medication Stockpile Guidance for Local Agencies and Businesses March 21, 2008

Introduction

Antiviral medications are one of several approaches to protect people during an influenza pandemic, and are one of the pharmaceutical interventions to achieve the U.S. national pandemic response goal to potentially slow the spread of pandemic influenza disease, reduce the impacts on health, and minimize societal and economic disruption. Antiviral medications should not be the primary defense strategy against pandemic influenza, since their ultimate effectiveness in treating pandemic illness cannot be predicted in advance.

Vaccination against the pandemic virus is likely to provide the most reliable and durable protection against pandemic illness, but the optimal vaccine can only be developed once the pandemic begins; therefore no vaccine or only limited quantities of vaccine may be available during the first pandemic wave in the U.S. However, antiviral medications can be stockpiled by healthcare providers, local agencies and businesses to be readily available at the onset of the pandemic.

Other key response measures include non-pharmaceutical interventions to reduce the transmission of disease by decreasing social interaction and limiting contact between sick and well individuals. Optimal planning and preparation for an influenza pandemic requires coordinated efforts and shared responsibilities with all sectors in society including individuals and families, communities, employers in public and private sectors, and all levels of government.

Antiviral Medication Stockpiles

Antiviral medication stockpiles have been established by Federal and State governments. The current national target for these antiviral medication stockpiles is 81 million courses, including 6 million courses to contain or suppress initial pandemic outbreaks overseas and in the U.S. and 75 million courses targeted primarily for treatment of ill persons. CDPH received approximately \$54 million from State general funds in Budget year 2005-2006 to acquire 3.7 million courses of antiviral medications and complete the full purchase of California's federally subsidized allocation of antiviral medications. The total number of courses currently available to California through state

and federal stockpiles is approximately 9.3 million courses, sufficient to provide one treatment course to approximately 25% of the State population.

Consistent with current federal recommendations, state and federal pharmaceutical stocks would be reserved for:

- Treatment and post exposure prophylaxis of cases and their contacts in an early, limited introduction of novel virus in California;
- Treatment for an ill international traveler who arrives in the U.S. with a high risk of recent exposure to a novel virus;
- Treatment of ill patients during an established World Health Organization (WHO) Phase 6 pandemic; and
- Post-exposure prophylaxis of exposed persons in closed institutional settings such as skilled nursing facilities and prisons.

Using antiviral medication stockpiles for treatment is the current designated strategy because:

- Studies show that treatment with neuraminidase inhibitors (oseltamivir [Tamiflu] and zanamivir [Relenza]) within 48 hours of illness onset may be effective in shortening the duration of seasonal influenza illness and in reducing complications and disease severity defined by a need for hospitalization;
- Treatment meets the expectations of health care providers and patients who present for medical care; and
- In a setting of limited antiviral medication supply, treatment is the most dose-sparing strategy for available resources, when compared to prophylaxis.

Use of Antiviral Medications during a Pandemic

Antiviral medications may be effective during a pandemic when used for prophylaxis (taken prior to symptoms to prevent illness), in one of two strategies:

- 1) **Post-exposure prophylaxis (PEP)** is taken after likely exposure due to close contact with a sick person. One dose per day is taken for 10 days. The total of 10-doses is the same as required for a single treatment (given twice daily for 5 days) and defines a "course." PEP may be used for:
 - a. Household contacts of persons with influenza illness as a component of community mitigation;
 - b. Persons in the health care sector with patient contact;
 - c. Persons with compromised immune systems who are unable to be protected by vaccination; and
 - d. Persons living in closed settings such as nursing homes and prisons.
- 2) **Outbreak prophylaxis** is given to persons who have high, ongoing risk of exposure to ill persons, or those performing jobs to maintain critical infrastructure during a pandemic. Outbreak prophylaxis provides protection against infection

only while the medication is being taken, thus ideally would continue for the duration of a community outbreak when there is an increased risk of infection. This is estimated to require 40 to 80 days or longer of prophylaxis (corresponding with 4 or 8 antiviral medication courses).

Evolving federal strategies include use of antiviral medications for prophylaxis, as supplies allow, in occupational and household settings.¹ Initial discussion of a federal workgroup suggests that, after the top priorities of initial containment and treatment of all persons with influenza illness outlined for current supplies, additional antiviral medication supplies could be prioritized for:

- 1) Prophylaxis of health care workers. This is consistent with the need to maintain effective health care and to protect persons who are at greatest risk due to their occupational exposure.
- 2) Prophylaxis of critical emergency service personnel and workers with unique roles maintaining critical infrastructures.
- 3) Protection of groups at high risk who cannot be protected by vaccination (outbreak or PEP) and persons living in closed settings such as nursing homes and prisons (PEP).
- 4) Post-exposure prophylaxis for household contacts of persons with pandemic illness.

Roche Pharmaceuticals now states that production – including U.S. based production of 80 million courses per year of oseltamivir – now exceeds demand. Since there are no longer limitations on purchase of antiviral medications, consideration for treatment and prophylaxis may be considered and additional medications purchased. This makes it feasible for healthcare institutions and businesses to consider stockpiling antiviral medications. The Federal Government encourages businesses to consider stockpiling antiviral medications as part of a comprehensive pandemic preparedness plan that may contribute to employee health and safety, business continuity, and community preparedness and discourages the appropriation of privately held stockpiles by governmental authorities.²

Many California local health departments, hospitals, and private businesses have purchased or are considering purchase of antiviral stockpiles. Barriers to local jurisdiction, institutional, or business stockpiles include:

- Cost
- Concerns that state or local policy will be inconsistent with their intended use

¹ Proposed Guidance on Antiviral Drug Use Strategies during an Influenza Pandemic. U.S. Department of Health and Human Services. Draft November 6, 2007. Document available at www.pandemicflu.gov.

² Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic. U.S. Department of Health and Human Services. Draft, October 29, 2007. Document available at www.pandemicflu.gov.

- Concerns that supplies will be commandeered during an emergency
- The uncertainty of the ultimate efficacy of antiviral medications against influenza illness. Seasonal influenza viruses have developed widespread resistance to one type (adamantine group) of antiviral medications and a small proportion of seasonal influenza viruses have shown resistance to oseltamivir³
- Short shelf life of medications requiring rotation of stock supplies and/or replacement upon expiration
- Currently, antiviral medications purchased from the federal contract, using federal funding, can only be used during declared WHO Phase 6 influenza pandemic and cannot be rotated with inventory during seasonal influenza

Antiviral medications are subject to similar potential controls as other critical supplies during an emergency.

- 1) Under a proclaimed state of emergency, the Governor is authorized to commandeer property and personnel pursuant to Government Code 8472. This allows the Food and Drug Branch in the California Department of Public Health to assume control of wholesale inventories of medications and supplies.
- 2) Health & Safety Code 101040 authorizes Local Health Officers to take "any preventive measure that may be necessary to protect and preserve the public health from any public health hazard". Although the term "preventive measure" is defined in a limiting manner, it could be used to justify controlling stocks of antiviral medication supplies.
- 3) Institutions and private corporations may be required to provide an inventory of antiviral medications to the State during an emergency. (Health and Safety Code, section 120176)

CDPH Recommendations

CDPH recognizes that healthcare provider, local agency, and business stockpiles may be beneficial to the overall response capacity to an influenza pandemic and suggests the following guidelines:

- 1) There is no CDPH expectation or requirement that healthcare providers, businesses or employers stockpile antiviral medications.
- 2) CDPH encourages local agencies and businesses considering an antiviral stockpile to evaluate their need for and use of antiviral medications during a pandemic as part of a comprehensive employee health and safety and business continuity plan. However, pandemic planning should recognize that antiviral medications alone do not assure continuity of normal operations.

³ Centers for Disease Control and Prevention, "Questions on Influenza Antiviral Drug Resistance", 2007, www.cdc.gov/flu/about/qa/antiviralresistance.htm

- 3) Except for antiviral medications purchased from the U.S. Department of Health and Human Services (HHS) contract, the healthcare provider, local agency, and business purchased stocks may be used to:
 - Assure early treatment to employees who are ill;
 - Provide outbreak prophylaxis to critical personnel or post-exposure prophylaxis to workers (and possibly their families) to maintain effective emergency response and continuity of business operations, consistent with evolving federal guidance; and
 - Protect overseas employees and operations.
- 4) Strategies, doses, and duration of treatment or prophylaxis should be consistent with current recommendations.
- 5) CDPH strongly encourages businesses or employers planning for antiviral medication stockpiles to:
 - a. Plan for coordination with the local health department;
 - b. Comply with Federal and State laws and regulations regarding the receipt, storage, prescribing and dispensing of pharmaceuticals. The laws and regulations may change during a declared emergency of an influenza pandemic;
 - c. Consider ethical and equity concerns about which employee groups or workers will receive antiviral medication;
 - d. Determine the most appropriate stockpiling and dispensing model (e.g., using existing health care facility providers versus onsite occupational providers; maintaining medications at wholesale drug distributors versus on-site stockpiling); and
 - e. Obtain medical consultation from an occupational medical provider or local health department to develop a policy and procedure for appropriate use of antiviral medications. Prior to use, it is important to confirm the latest information on efficacy of antiviral medications to a specific pandemic influenza strain.

CDPH Guidance

This *Antiviral Medication Stockpile Guidance for Local Agencies and Businesses* supersedes the November 2005 guidance that discouraged prescribing antiviral medications to individuals to store use during a pandemic. The California Department of Public Health (CDPH) recognizes that pre-pandemic prescribing of antiviral medications for individual use should be an informed decision between a physician and patient. Physicians who choose to prescribe antiviral medications should provide medical consultation to confirm the effectiveness of the medication against the pandemic strain and instruct their patients on how and when to use the medications.

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This Guidance will be updated as federal guidance and other planning and response issues emerge.