Emergency Use Authorization Toolkit

Current Issues and Updates

Fall 2011

Current Issues and Updates provides periodic updates on new and evolving issues related to the topics covered in the ASTHO *Emergency Use Authorization Toolkit*.

Emergency Use Authorization

Doxycycline Mass Dispensing EUA

The FDA issued an EUA for oral formulations of doxycycline for post-exposure prophylaxis (PEP) of inhalational anthrax in July 2011.[1] The FDA reported that the doxycycline EUA was **not** issued in "response to a current immediate threat or increased risk of exposure to *Bacillus anthracis* (*B. anthracis*), the agent that causes anthrax."[2] The EUA permits stakeholders such as state and local health agencies to "dispense oral formulations of doxycycline in circumstances when they reasonably believe that there is a need for mass dispensing because their constituents have been, are suspected to have been, or are imminently likely to be exposed to *B. anthracis* spores."[2]

The FDA issued the doxycycline EUA in response to a request by the CDC to facilitate the nation's preparedness and response efforts.[1] This EUA supports pre-event planning and preparedness activities (e.g., stockpiling of oral formulations of doxycycline) by state and local health agencies.[2] Should an actual anthrax emergency arise, this EUA also enables public health officials and other responders to rapidly initiate treatment without delay through various distribution and dispensing mechanisms, such as open and closed points of distribution.[2]

In issuing the EUA, the FDA stated that an EUA was needed because "such preparedness and response activities may include elements that could otherwise violate provisions of the FD&C Act [Federal Food, Drug, and Cosmetic Act] under FDA's legal interpretations."[2] While doxycycline is "FDA-approved for PEP for inhalational anthrax, certain aspects of emergency distribution, dispensing, and use of oral formulations of doxycycline products are not approved by FDA (i.e., not covered by their FDA-approved applications)."[2] Thus, this EUA allows the covered doxycycline products "to be legally distributed, stockpiled, and dispensed for the unapproved uses for which they are being authorized."[2] For example, during an anthrax emergency, "doxycycline may be dispensed without individual patient prescriptions, which would not be consistent with FDA's legal interpretations of the FD&C Act."[2]

The FDA noted that "this EUA differs from previously issued EUAs because it is intended to facilitate pre-event planning and preparedness activities for an anthrax emergency, as well as response efforts should an actual anthrax emergency occur."[2] This EUA also allows for "flexibility in developing some of the information materials for health care professionals and for recipients by providing a minimum set of elements that must be provided to them; previous EUAs required that specific fact sheets be used."[2]

The text of the EUA for doxycycline mass dispensing, fact sheets for healthcare practitioners and consumers, and other supporting materials are available at www.fda.gov/emergencypreparedness/counterterrorism/ucm182568.htm.

EUA Sources

[1] Hamburg M. FDA. Letter to Thomas Frieden, CDC, authorizing doxycycline mass dispensing EUA. July 21, 2011.

[2] FDA. "Interim Questions and Answers: Emergency Use Authorization for Oral Formulations of Doxycycline for Post-Exposure Prophylaxis of Inhalational Anthrax." Available at www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm269226.htm. Accessed March 9, 2012.

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