Counterterrorism and Emerging Threat

Mission in counterterrorism and emerging threats

- Safeguard regulated medical products
- Foster Medical countermeasure (MCM) development

MCM and H1N1 Activities

- Emergency Use Authorizations (EUA)
  Unapproved uses (Peramivir),
  Extended use and availability
    - Antivirals extended expiry, medkits USPS
- Shelf Life Extension Program
- Strategic National Stockpile
- Respiratory Protection Devices

ISSUE: FDA's mission in Counterterrorism and Emerging Threats

CURRENT STATUS:

FDA plays a vital and multifaceted role in securing the homeland through its broad regulatory oversight, monitoring infrastructure and responding to terrorist attacks and naturally occurring emerging threats (e.g., pandemic influenza) with timely and appropriate countermeasures. FDA fosters the development of safe and effective medical countermeasures to mitigate the effects of such threats by actively engaging Federal, State and local partners.

Medical Countermeasures and H1N1 Activities

- Facilitating issuance of EUAs – FDA Commissioner authorizes the use of an unapproved medical product or an unapproved use of an approved medical product during a declared military or domestic emergency involving a heightened risk of attack with specified CBRN agent(s), or a declared emergency under section 319 of the Public Health Service Act which has significant potential to affect national security.
    - During the 2009 H1N1 influenza public health emergency the Commissioner authorized EUAs for:
        - Antiviral medications Oseltamivir and Zanamivir , and Peramivir, making critical treatments widely available to the public and hospitalized patients.

        - In-vitro medical diagnostic devices increasing US laboratory capability to identify the 2009 H1N1 influenza virus.
        - N95 respirators for the general public and health care workers.
    - In January 2005, FDA authorized the first EUA for emergency use of Anthrax Vaccine Adsorbed to protect DOD personnel deemed to be most at risk of exposure to anthrax.
    - In October 2008, FDA authorized the emergency use of doxycicline hyclate tablet emergency medkits as part of a pilot program for US Postal Service workers in Minneapolis.
- Working with DHHS regarding issues surrounding home stockpiling of FDA regulated products as medical countermeasures.
    - FDA authority does not allow for a pre-incident EUA.
- Working with CDC and DHHS to explore the possibility of broadening the DoD/FDA Shelf Life Extension Program (SLEP). .
    - Ongoing requests by states, and others, for inclusion in SLEP.
    - Addressing various legal, programmatic and resource challenges through interagency workgroups and policy decisions.
- Working with CDC to address the on-going use of non-FDA approved in vitro diagnostic devices by the Laboratory Response Network (LRN)
- Providing assistance to DHHS regarding mask and respirator use during emergency responses such as a pandemic influenza outbreak.
    - CDC, OSHA, and FDA have developed various non-integrated documents & guidance regarding the use respiratory protective devices for emergency situations (i.e., H1N1 response) .
    - Only a few N95 models are FDA cleared for use by the general public in public health medical emergencies.
- Serving as FDA MCM technical experts, reviewers, coordinators, and points-of-contact to state and federal officials, committees, and working groups (including DHHS Agencies, DoD, DHS, and other government partners). The FDA Commissioner is a member of the Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Board.

NEXT STEPS AND FUTURE CONSIDERATIONS:

FDA continues to work with agency stakeholders to facilitate development and availability of medical countermeasures to be used in the event of a terrorist attack or emerging threat.

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