

MEDICAL COUNTERMEASURES (MCMS)

FDA-REGULATED MEDICAL PRODUCTS

Medical countermeasures, or MCMS, are FDA-regulated products that may be used in a **PUBLIC HEALTH EMERGENCY** stemming from a terrorist attack with or accidental release of a biological, chemical, or radiological/nuclear agent, or a naturally occurring emerging infectious disease.

WHAT ARE MCMS?

PREVENT, PROTECT AGAINST, TREAT OR DIAGNOSE DISEASES OR HEALTH EFFECTS CAUSED BY **CBRN** THREAT AGENTS



C | **CHEMICAL**
B | **BIOLOGICAL**
R | **RADIOLOGICAL**
N | **NUCLEAR**
& EMERGING INFECTIOUS DISEASES

EXAMPLES OF MCMS



BIOLOGIC PRODUCTS
• Vaccines
• Blood products
• Antibodies



DRUGS
• Antimicrobials
• Chemical threat antidotes
• Treatments for radiation injury



DEVICES
• Diagnostic tests
• Personal protective equipment (PPE)
- Gloves
- Respirators/certain masks
- Gowns



EXAMPLES OF FDA'S MCM ROLES

1

FDA assesses the safety & effectiveness of MCMS for FDA approval

ACTIVITIES INCLUDE:

- Review evidence for approval
- Professional development
- Regulatory science
- Policy & legal support



- **GOVERNMENTS**
(state, local, territorial, tribal, national, international)
- **DOMESTIC & INTERNATIONAL ORGANIZATIONS**

- **MEDICAL & SCIENTIFIC COMMUNITY**
- **INDUSTRY**

+ **PHEMCE:** Public Health Emergency Medical Countermeasures Enterprise (Federal agencies)



2

FDA works with partners to advance development & availability of MCMS to prepare for & respond to emerging threats



3

FDA can issue Emergency Use Authorizations to enable to access MCMS prior to approval (or for unapproved uses)

FDA also has other legal authorities to facilitate emergency access to MCMS

290 MCMS

APPROVED
SINCE 2012*

450+

EUAs

SINCE 2005

enabling access to **850+** MCMS

FDA MEDICAL COUNTERMEASURES INITIATIVE (MCMi)

MCMi is an FDA-wide initiative across FDA product centers (including CBER, CDER, and CDRH) and offices to coordinate MCM development, preparedness, and response, led by the Office of Counterterrorism and Emerging Threats, in the Office of the Chief Scientist.



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