



WHAT ARE MEDICAL COUNTERMEASURES?

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.

MCMs

PREVENT
PROTECT AGAINST
TREAT OR
DIAGNOSE



DISEASES OR HEALTH EFFECTS CAUSED BY

CBRN

THREAT AGENTS

CHEMICAL
BIOLOGICAL
RADIOLOGICAL
NUCLEAR



EMERGING
INFECTIOUS
DISEASES

EXAMPLES of MCMs

BIOLOGIC PRODUCTS

- Vaccines
- Blood products
- Antibodies



DEVICES

- Diagnostic tests
- Personal protective equipment (PPE)



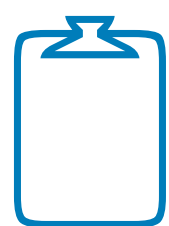
DRUGS

- Antimicrobials
- Chemical threat antidotes
- Treatments for radiation injury



- Gloves
- Respirators/masks
- Gowns

FDA's MCM ROLES [some examples]



FDA IS RESPONSIBLE FOR ASSESSING **SAFETY & EFFECTIVENESS** OF MCMs FOR FDA APPROVAL



ACTIVITIES INCLUDE:
→ Review evidence for approval
→ Regulatory science
→ Policy & legal support
→ Professional development



FDA WORKS WITH PARTNERS TO ADVANCE **DEVELOPMENT & AVAILABILITY** OF MCMs

- Governments (state, local, territorial, tribal, national, international)
- Domestic & international organizations
- Medical & scientific community
- Industry

+ PHEMCE

Public Health Emergency
Medical Countermeasures
Enterprise (Federal agencies)

TO PREPARE FOR & RESPOND TO EMERGING THREATS

121

MCMs APPROVED
SINCE 2012*

60+

EUAs
SINCE 2005

FDA CAN ISSUE **EMERGENCY USE AUTHORIZATIONS** TO ENABLE **ACCESS** TO MCMs PRIOR TO APPROVAL (OR FOR UNAPPROVED USES)



FDA ALSO HAS OTHER LEGAL AUTHORITIES TO FACILITATE EMERGENCY ACCESS TO 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.

? **LEARN MORE**
OR **ASK US**



www.fda.gov/medicalcountermeasures

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U.S. FOOD & DRUG
ADMINISTRATION

*Number includes approved MCMs listed in the MCMi annual program update in fiscal years 2012-2017