



# Prioritisation of threats and medical countermeasures

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*Broad spectrum antiviral workshop  
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# Intelligence gathering

## PREPAREDNESS

## Threat assessments and intelligence gathering

### Threat prioritisation exercise

Agents with  
pandemic  
potential

CBRN

AMR

Preliminary list of critical  
medical countermeasures

Preparatory actions for the IT  
platform for intelligence  
gathering combining  
epidemic and MCM intelligence

Support to ensure **interoperability** between Member  
States' IT platforms and HERA IT tool

### Establishment of the HERA laboratory network

Support to Member States' **capacity  
building for WGS and PCR**

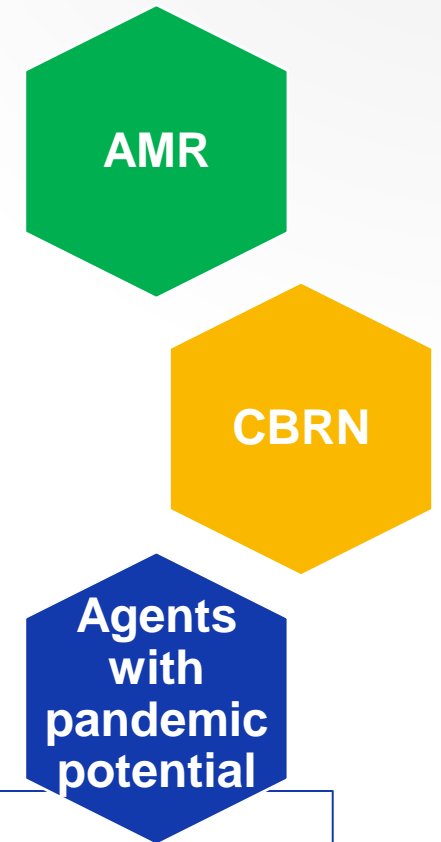
Assessment of gaps and needs  
for the institutionalisation of  
**wastewater surveillance  
beyond COVID-19**

Study on market research on  
**innovative diagnostic solutions**



# Threat prioritisation

- ❖ **Aim:** identify **3 serious cross-border health threats** to guide HERA's action on monitoring, research and development, production, procurement and stockpiling of MCMs
  - ❖ 'All hazards approach' - identification of **threat categories**, using publicly available data/lists
  - ❖ Selection of priority threat category considering burden on health, mode of transmission, risk of spreading, but also the availability of prophylaxis/treatment
  - ❖ Extensive consultation and alignment with Member States' priorities, EU and international stakeholders



this category includes largely, but not exclusively, **respiratory RNA viral families:** Arena-, Bunya-, Corona-, Flavi-, Filo-, Orthomyxo-, Paramyxo-, Picorna-, Pox- and Togaviridae viral families

# Development of MCM list

- ❖ The list of critical MCMs will include **high-priority MCMs for development**, including next generation vaccines, broad spectrum antivirals, antibiotics against AMR, other MCMs in cooperation with MS, EMA and ECDC



## PREPAREDNESS MODE

- ❖ HERA will draw a **broad list of critical MCMs**
- ❖ HERA will gather intelligence on **selected critical MCMs**
- ❖ HERA will identify gaps (where authorised treatments are not available) and needs in terms of market interest on MCMs for a **short list for R&D**

## CRISIS MODE – Council Regulation on the emergency framework

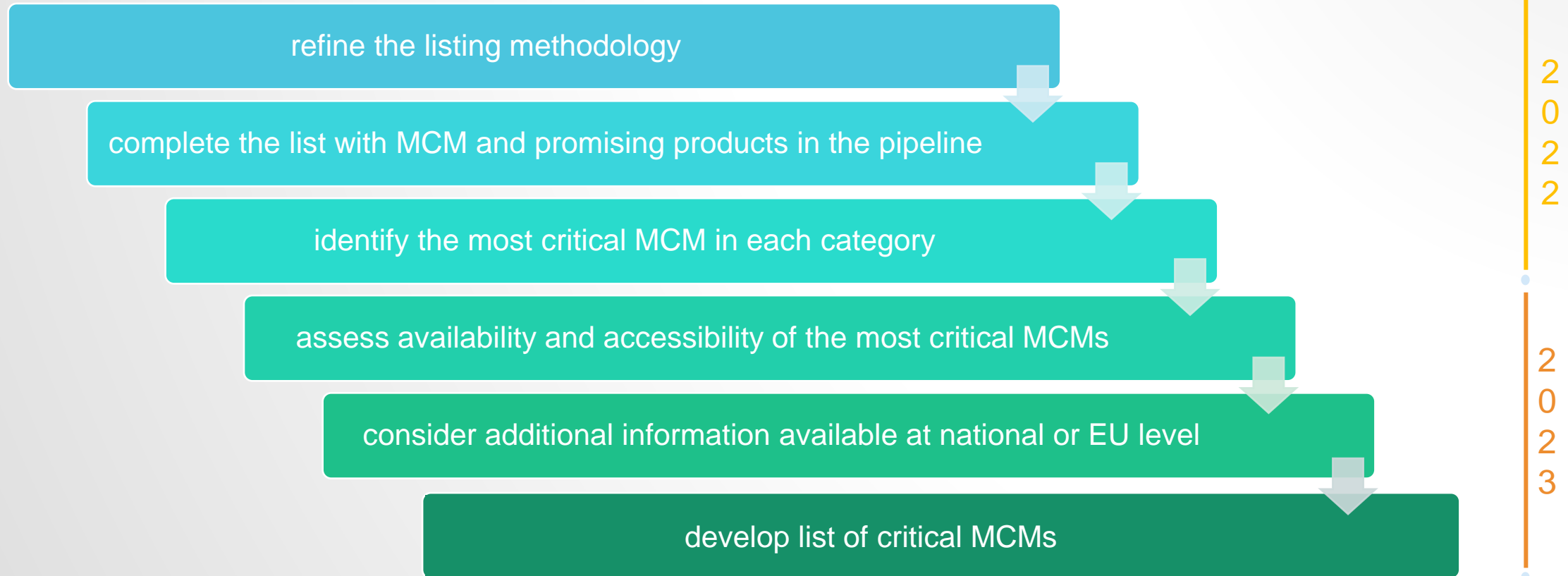
- ❖ HERA will activate **emergency research plans** for R&D (incl. clinical trials) of novel/repurposed MCMs
- ❖ HERA will support **production and deployment** of (un)authorised MCMs

# Scope of the MCM list

- HERA is working with Member States on a **catalogue of MCMs and MCM categories** that will be used as a basis for the MCM prioritisation

<b>ANTIINFECTIVES FOR SYSTEMIC USE<sup>1</sup></b> <b>Antivirals</b> <u>Baloxavir marboxil (Xofluza)</u> <u>Brincidofovir</u> <u>Imzab</u> <u>Remdesivir (Veklury)</u> <u>Ribavirin</u> <u>Tecovirimat</u> <u>Zanamivir (Dectova)</u> <u>Variola minor antiviral</u> <u>Neuraminidase inhibitors</u> <b>Vaccines</b> <u>ACAM2000</u> <u>AstraZeneca</u> <u>Comirnaty</u> <u>Dengvaxia</u> <u>Imvanex/Imvamune</u> <u>Ixiaro</u> <u>Jcovden</u> <u>LC16M8</u> <u>Spikevax</u> <u>Vaxzevria</u> <u>Ervebo (rVSVΔG-ZEBOV-GP, live)</u> <u>combination Ad26.ZEBOV-GP [recombinant] and MVA-BN-Filo [recombinant]</u>	<u>whole virus</u> <u>Yellow fever live attenuated vaccine</u> <u>Influenza vaccines</u> <u>Variola minor vaccine</u> <u>Venezuelan equine encephalitis virus vaccine</u> <u>Junin mammarenavirus vaccine</u> <b>Immune sera and immunoglobulins</b> <u>mAb</u> <u>Ronapreve (casirivimab and imdevimab )</u> <u>Vaccinia Immune Globulin Intravenous</u> <u>immunoglobulins Ebola</u> <u>Tick-borne encephalitis immunoglobulins</u> <u>Regkirona</u> <b>IN-VITRO DIAGNOSTICS</b> <b>Antibody tests</b> <u>antibodies CCHF</u> <u>antibodies MERS-CoV</u> <u>antibodies SARS-CoV-2</u> <b>Antigen tests</b> <u>antigen CCHF</u> <u>antigen SARS-CoV-2</u> <b>ELISA tests</b> <u>ELISA Margburg virus</u> <b>PCR tests</b>	<b>Threat specific MCMs</b>	<b>Horizontal MCMs</b>	<b>PPE</b> <b>Respiratory protection</b> <u>Particulate respirators</u> <b>Eyewear protection</b> <u>Goggles</u> <u>Protective glasses</u> <b>Coveralls</b> <b>Head and face protection</b> <u>Face shields</u> <u>Caps</u> <u>Hoods</u> <u>Head covers hairnets</u> <b>Other protection</b> <u>Gloves</u> <u>Aprons</u> <u>Protecting clothing/scrubs</u> <u>Shoe protective (covers, overboots, overshoes)</u> <b>OTHER IN VITRO DIAGNOSTICS</b> <b>Reagent and test kits</b> <u>CRP tests and and other markers of inflammation tests</u> <u>Blood grouping</u> <u>Other Clinical chemistry</u> <u>Immunochemistry</u> <u>Reagents, including lysis buffers</u> <u>Other plastic consumables, pipette tips</u> <b>MEDICAL DEVICES</b> <b>Devices for imaging</b> <u>Computed tomography (CT) scanners</u> <u>Ultrasound machines, and accessories</u> <u>Electrocardiograph, and accessories</u> <u>Fiberscopes</u> <b>Devices for suture</b> <b>Surgical sutures</b> <b>Mechanical sutures</b> <b>Clips</b> <b>Devices for dermatological and ophthalmological use</b> <b>Wound dressings</b> <b>Other devices for sores and ulcers</b> <b>Surgical instruments</b> <b>Various</b> <b>ANTISEPTICS</b> <u>chlorhexidine</u> <u>ethanol</u> <u>Povidone iodine</u> <b>DISINFECTANTS</b> <u>alcohol based hand rub</u> <u>chlorine base compound</u>
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# Establishing the list of critical MCMs



# End-to-end support



# Thank you



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