



HERA HEALTH EMERGENCY
PREPAREDNESS AND
RESPONSE AUTHORITY

#HealthUnion

DG HERA activities on zoonotic influenza

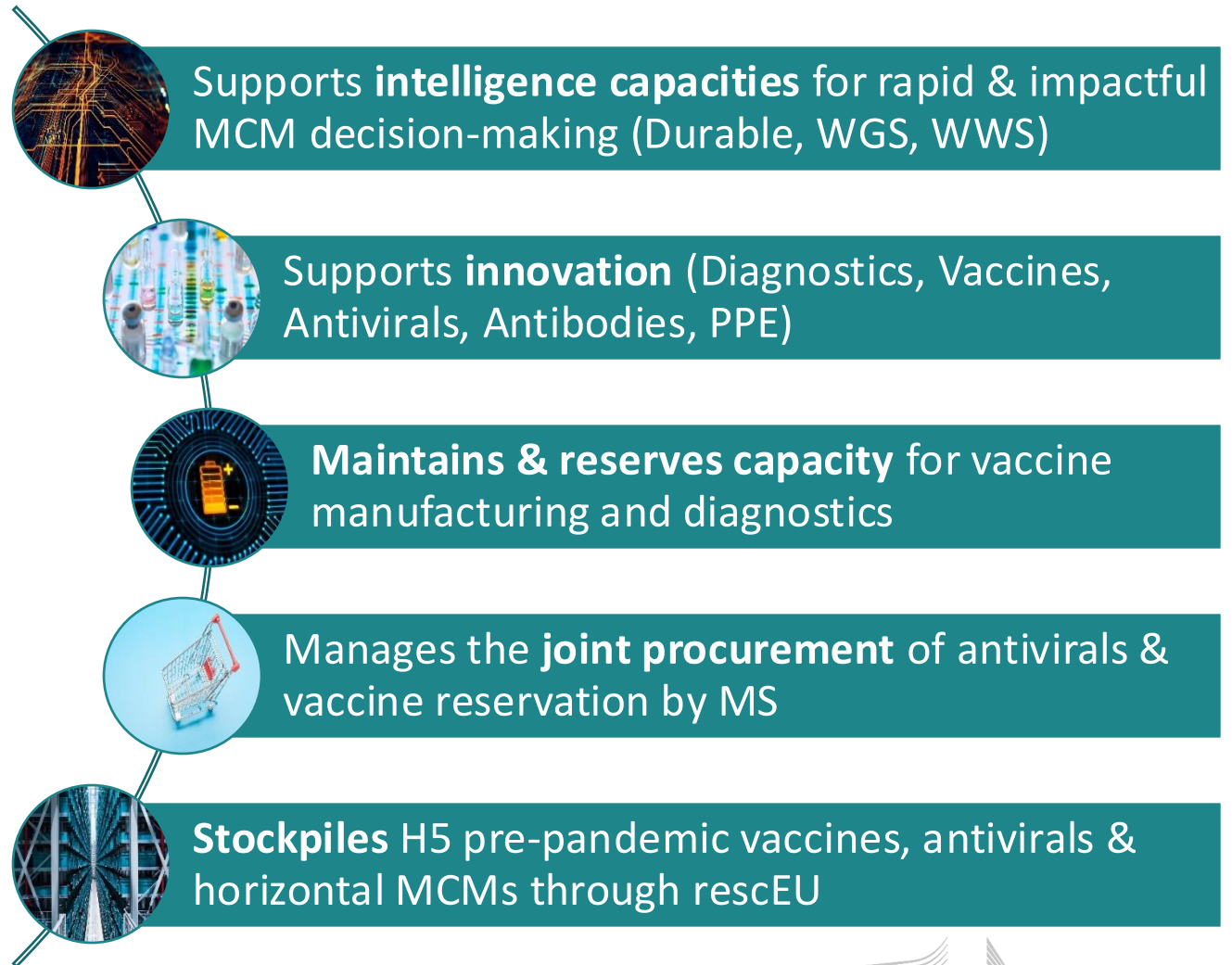


Union Support Capacities

The right **intervention...**



...for the right **MCM**

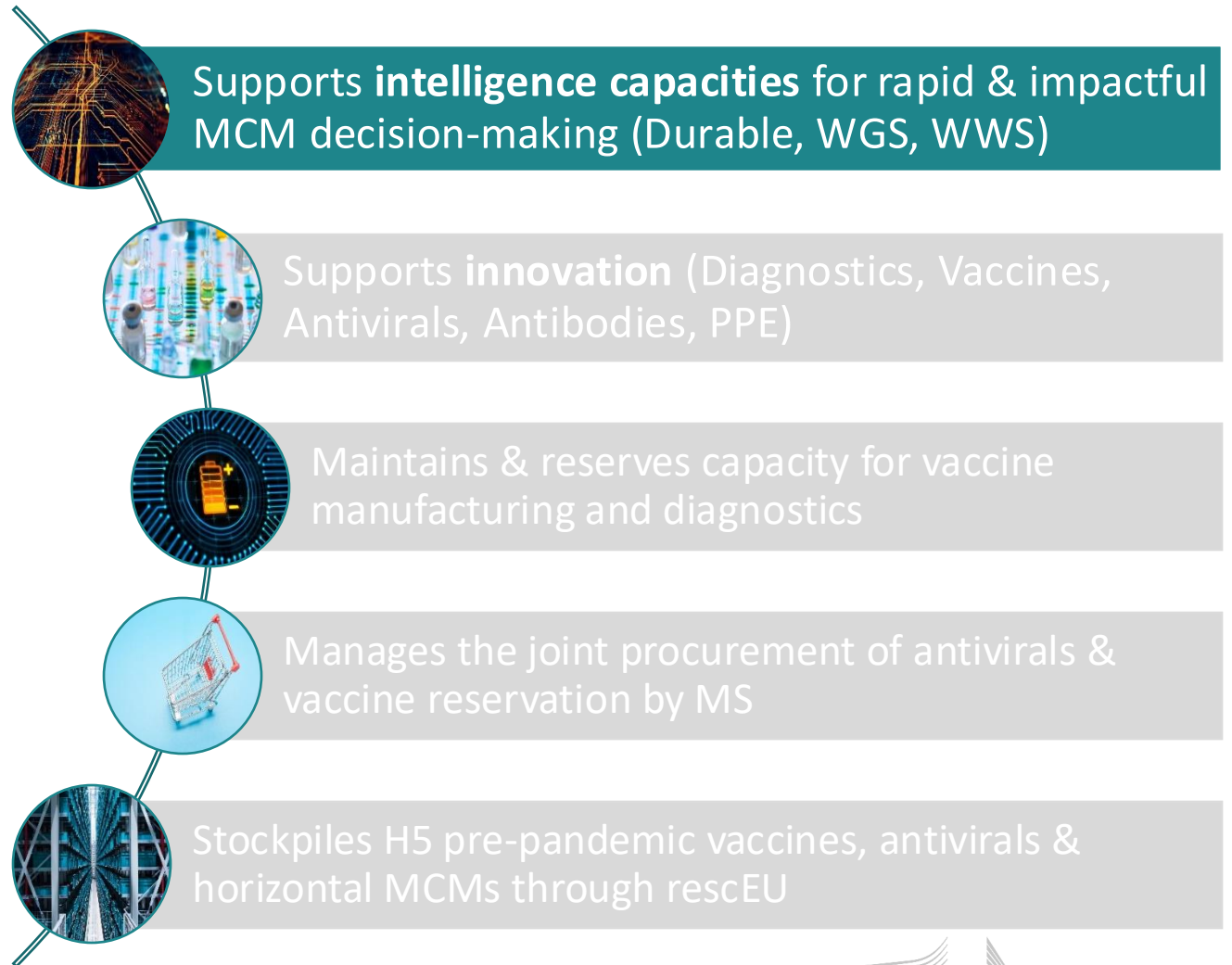


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More details in [HERA's annual work plan 2025](#)

- **Genomics** : ECDC/HERA grants to EU-MS strengthen PCR/sequencing capacities + contribution agreement with Africa CDC for the PGI 2.0
- **DURABLE** : consortium providing in depth characterization and studies for the development of MCM (e.g. immunogenicity study for Seqirus zoonotic influenza vaccine)
- **WES** : Wastewater and environmental surveillance
- **Digital capacities**
 - global level: **EIOS**, WHO Collaboratory
 - EU level: **ATHINA**, EU-HIP, Ontology (with JRC)



- **21 Direct grants to EU Member States** EUR 39 M in 3 years and 25 MS involved so far. Increase MS capacity to respond to the COVID-19 and strengthen whole genome sequencing and RT-PCR testing capacity in non-crisis time that could be used also for other pathogens.
- **Pathogen Genomic Initiative** with Africa CDC
 - **Integrated Genomic Surveillance project** - EUR 3 M in 3 years. 5 African Union countries
Scale up genome sequencing-based surveillance on AMR and strengthen data sharing.
 - **DETECT project** - EUR 3 M in 3 years. 11 African Union countries
Strengthen laboratory network capacities for health outbreak detection and response.
- + genomics in Wastewater monitoring projects



“Delivering a Unified Research Alliance of Biomedical and public health Laboratories against Epidemics” ; EU4Health – € 25 Mio | 48 months

Multi-disciplinary consortium

20 biomedical, research & public health institutes led by “Institut Pasteur”

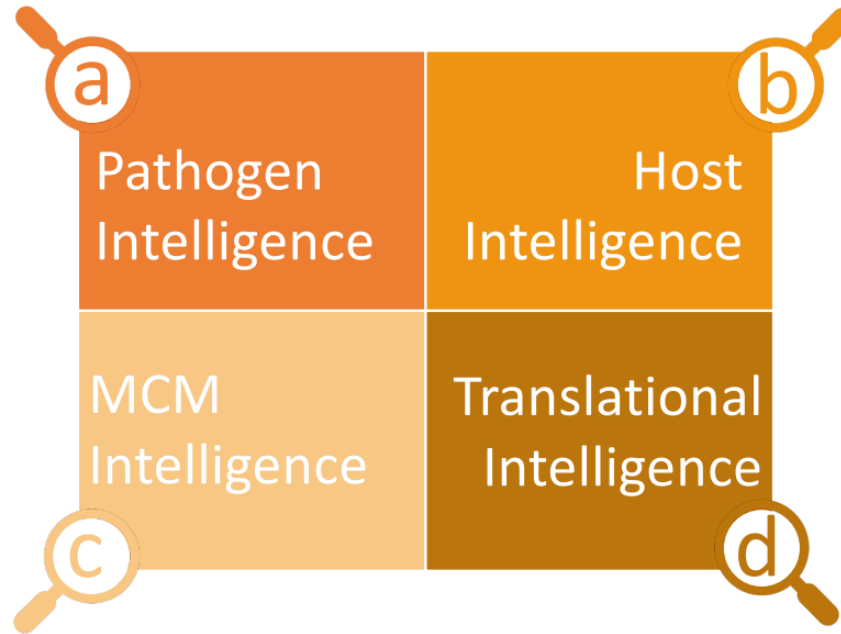
In-depth characterisation of pathogens to inform MCM preparedness

Flexible approach, global reach



e.g. virus discovery, trait mapping (sequence → structure → function → antigenicity)...

e.g. antiviral screening, shared compound libraries, and reference virus panels, predictive modelling of antiviral synergies...



e.g. analysis of humoral, cellular, and innate responses, including immune imprinting, mucosal immunity, and age-dependency...

Rapid evidence support for HERA (Preparedness and crisis modes)
Translating virology, immunology, and modelling results into actionable guidance during outbreaks

Decision on medical countermeasures

DURABLE: Not a surveillance or reference network

ECDC in DURABLE steering board. Articulation with newly established **EURL for public health**

What
DURABLE
can provide
on
Influenza

- Expert knowledge & in-depth studies on emerging variants at human animal interface
- Assessment of **immunogenicity** of vaccines post marketing
- Assays & strains for **evaluation of vaccination response** *beyond* licensing requirements
- Baseline **immunity studies** in non-exposed & exposed individuals *beyond* diagnostic routine

Example: Protocols for pre-pandemic zoonotic vaccine studies

Sampling protocol Netherlands / Netherlands and Finland

Surveillance and immunological study among healthcare and animal workers

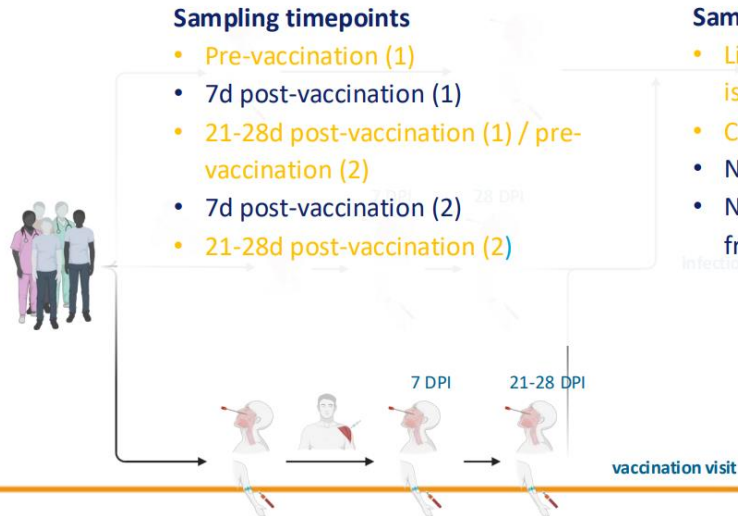


Sampling timepoints

- Pre-vaccination (1)
- 7d post-vaccination (1)
- 21-28d post-vaccination (1) / pre-vaccination (2)
- 7d post-vaccination (2)
- 21-28d post-vaccination (2)

Sampling types

- Lihep blood (40ml) – T-cell assays and PBMC isolation (stored in Finland)
- Clotted blood (10ml) – Serum
- Nasosorption – Nasal lining fluid
- Nose brush – Epithelial and immune cells from the nose



Proposed immunology Netherlands / Netherlands and Finland

Antibody assays

- **Antibodies**
 - Protein micro-array to measure **breadth** of binding antibody responses (selection of HAs)
 - HI and microneutralisation assays to detect functional **HA-specific antibodies** (relevant HA-viruses)
 - NAI assays to detect presence of functional **NA-specific antibodies** (relevant NA-viruses)
- **Reagents**
 - Purified proteins (PMA), 7+1 recombinant viruses (HAI), 6+2 recombinant virus with mismatched HA (NAI)

Proteinmicroarray

Seasonal H1s
Seasonal H3s
Seasonal Bs
Prototype H5 (A/Anhui/1/05)

Mammal H5
(A/Astrakh/3212/20)
Tbc: Bovine H5 (A/Texas/37/24)

HAI

Seasonal H1 (A/Vic/48972/22)
Seasonal H3 (A/Thai/8/22)
B/Vic (B/Aus/1359417/21)
B/Yam (B/Phuket/3073/13)

Prototype H5 (A/Anhui/1/05)
Mammal H5 (A/Eur Pol/1/22)
Human H5 (A/Hun/09285/21)
Vaccine H5
(A/Astrakh/3212/20)
Bovine H5 (A/Texas/37/24)

NAI

Seasonal N1 (A/Vic/48972/22)
Seasonal N2 (A/Thai/8/22)

Avian N1 (A/Anhui/1/05)
Avian N1 (A/Eur Pol/1/22)
Avian N6 (A/Hun/09285/21)
Avian N8 (A/Astrakh/3212/20)
Bovine N1 (A/Texas/37/24)

Microneutralisation

Avian N8 (A/Astrakh/3212/20)
Tbc: Bovine H5 (A/Texas/37/24)



Global consortium for wastewater and environmental surveillance for public health

- global community of practice, network of networks
- institutionalise wastewater surveillance for public health
- establish a global wastewater sentinel system

- **FWC on wastewater surveillance (EUR 32 M):** collection & testing of wastewater samples at the request of the Commission, with focus on strategic locations, towards global sentinel system
 - **EU sentinel system**
 - **Aviation Programme & Mass Gatherings Programme**
- **EU-WISH Joint Action (EUR 15 M):** to support activities to enhance, extend and consolidate wastewater surveillance for public health in Europe, and beyond
- **Administrative agreement with JRC (EUR 2 + 5 M):** to receive scientific support as regards WES, to implement the EU and global sentinel system, to develop the EU Wastewater Academy
- Collaboration with **WHO (EUR 3 M) & UNEP (EUR 3.8 M) + Africa CDC, PAHO...**

Wastewater & environmental Surveillance

THE EU SUPER SITES – EU SENTINEL SYSTEM

28

Wastewater
treatment plant



14

Airport



12

Hospital



Super-Sites

Status

- Active
- In preparation
- Under discussion



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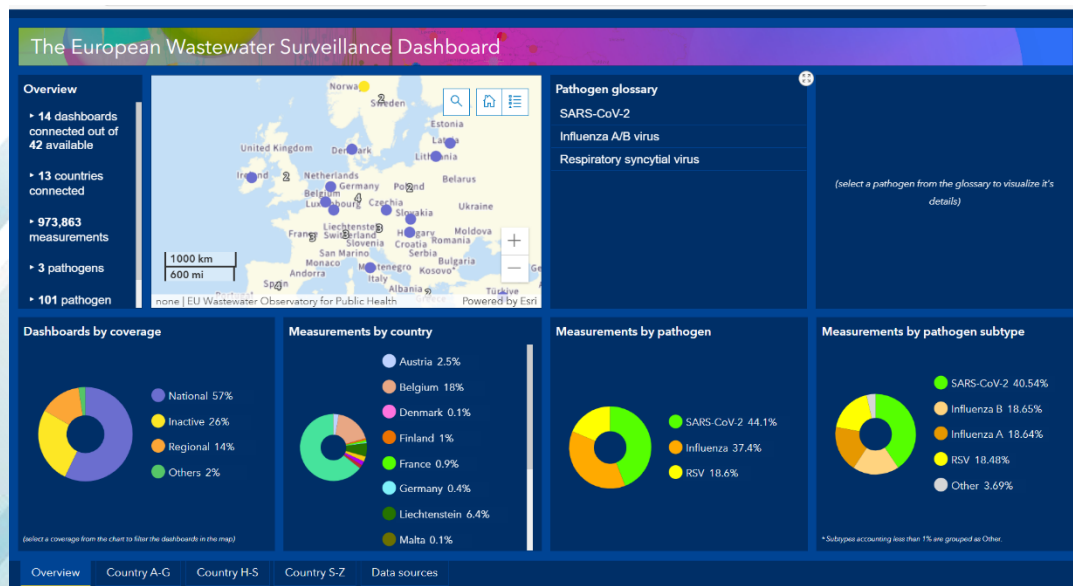
Other



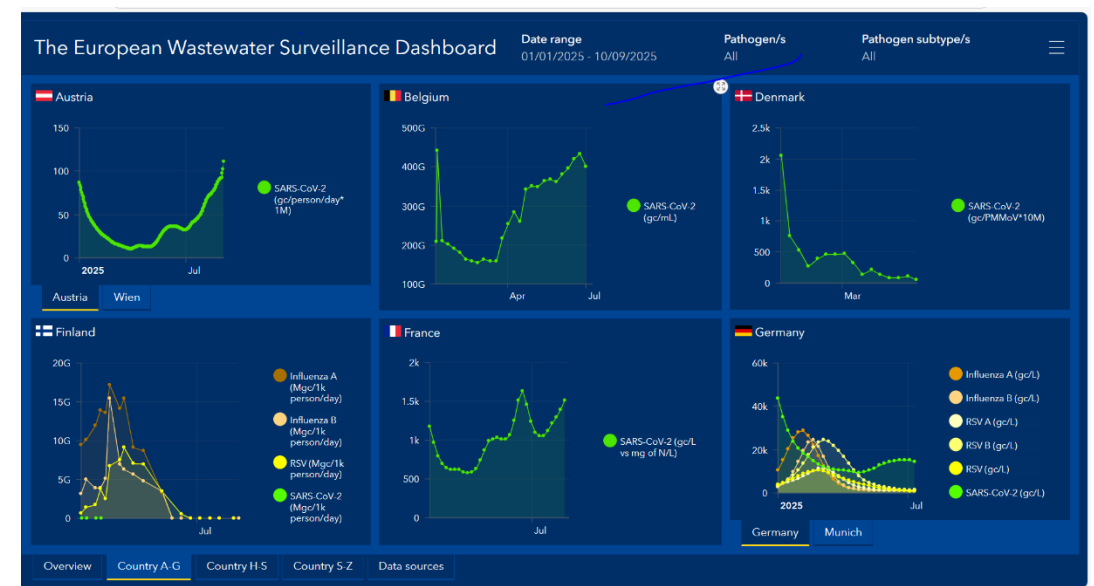
WES Dashboard

- Integrates data from various sources throughout Europe
- Combining near real-time wastewater monitoring with existing national and research-based dashboards

Overview

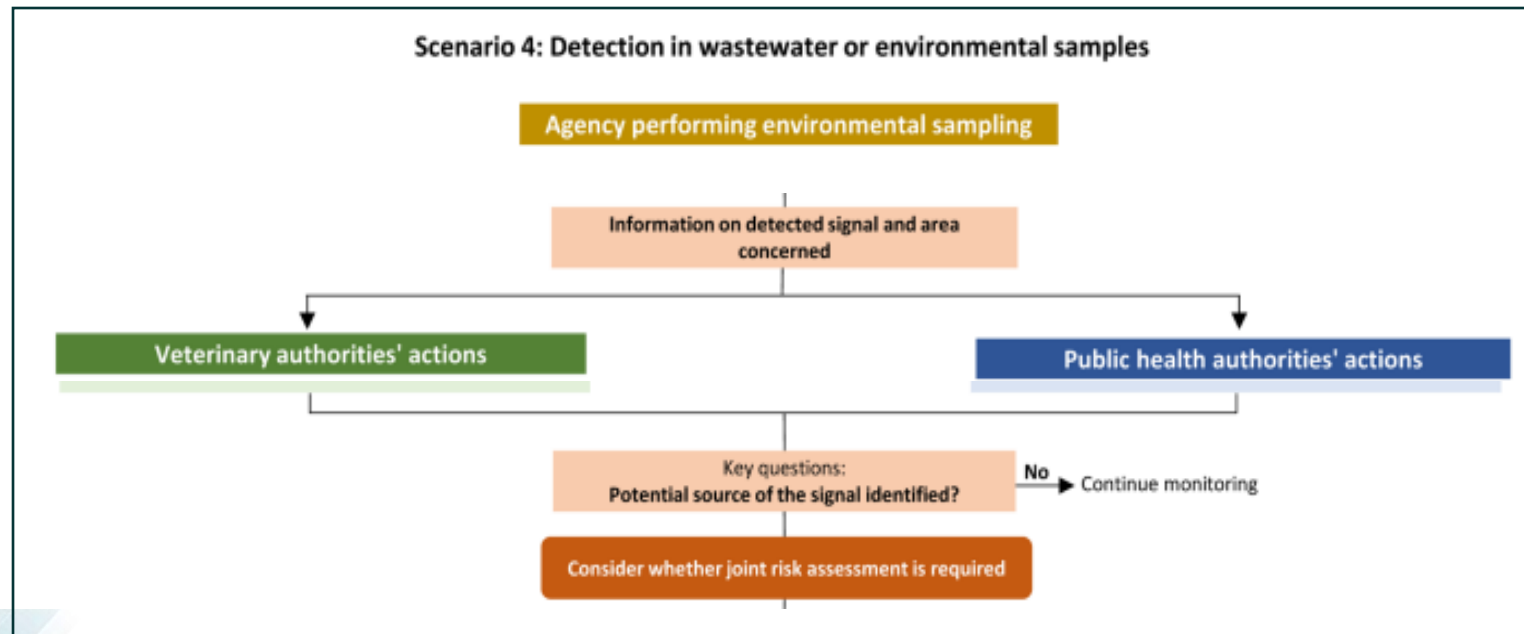


View by country



Influenza A/B (incl. H5N1) among monitored pathogens in 1st year pilot

- ECDC guidance: [Coordinated One Health investigation and management of outbreaks in humans and animals caused by zoonotic avian influenza viruses](#)



- Air sampling : environmental surveillance beyond wastewater monitoring

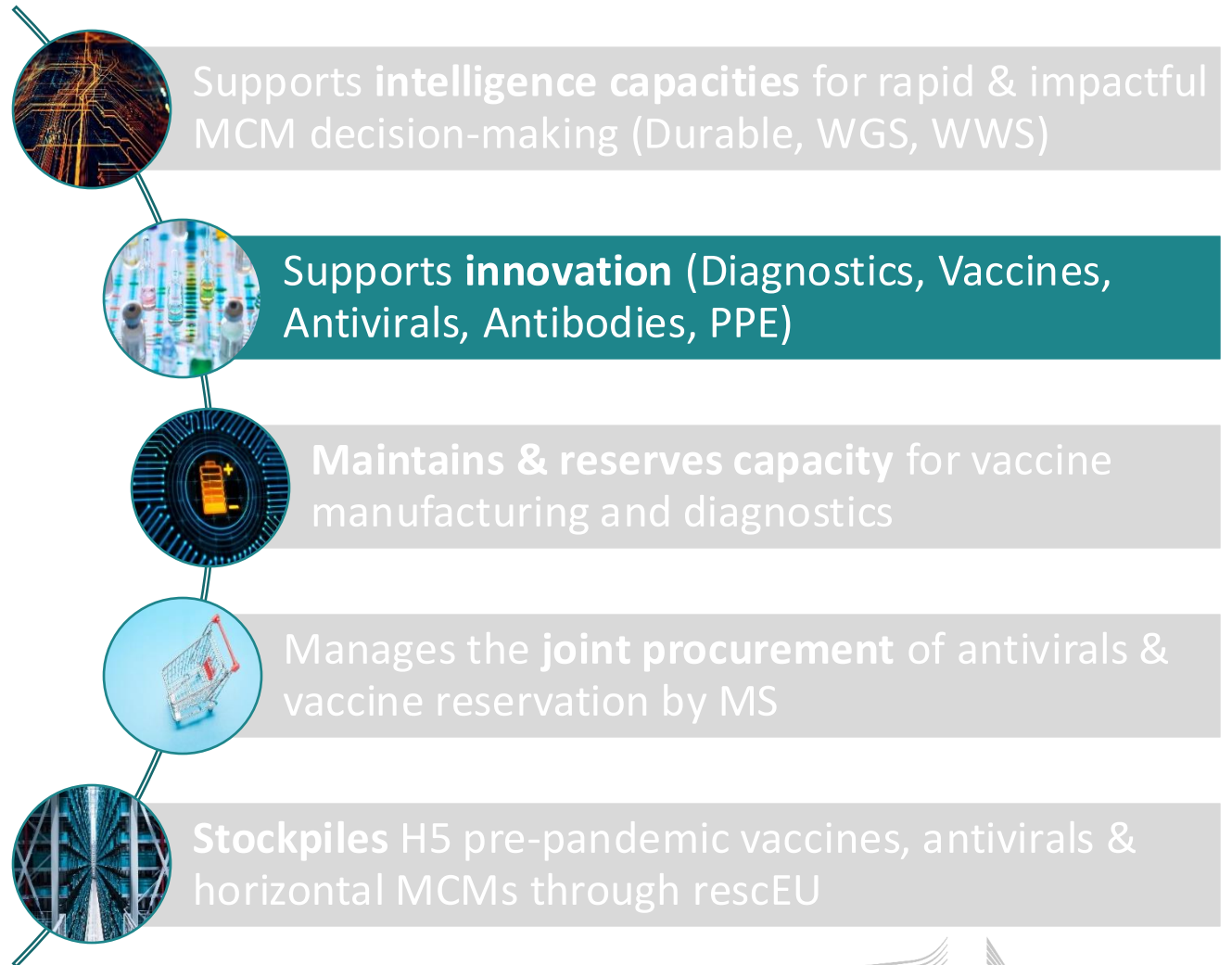
JRC/HERA report: [Suppressing indoor pathogen transmission: A Technology Foresight study](#)

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The right **intervention...**



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Innovation priorities informed notably by the CT-CM, Be READY, DURABLE and other EU initiatives

Clinical Trial Coordination Mechanism, [opinion on zoonotic H5N1 influenza](#) (May 2025)

- **Pre-pandemic vaccine** : sufficient immunogenicity data, but need to ensure the biobanking from individuals vaccinated for cross-immunity testing when new clades circulate
- **Pandemic vaccines** : need for advanced platform technologies for seasonal influenza vaccines, in particular advance mRNA platform technology considering its adaptability characteristics
- **Antivirals** : sufficient data on available antivirals (Oseltamivir, Baloxavir) in primary care but more data needed for use in severe cases. Need to map and advance the antiviral development pipeline

Goal: translate great gains in vaccine development into highly innovative products made in Europe for priority threat: Influenza

- HERA to fund the clinical development of next generation vaccines from phase I to phase III across approx. 8 yrs.
- Derisking cutting-edge innovation with an earmarked budget of approx. **225 Mio EUR**
- Looking for:
 - Higher scalability of manufacturing,
 - new administration routes,
 - improved immunogenicity,
 - broader protection

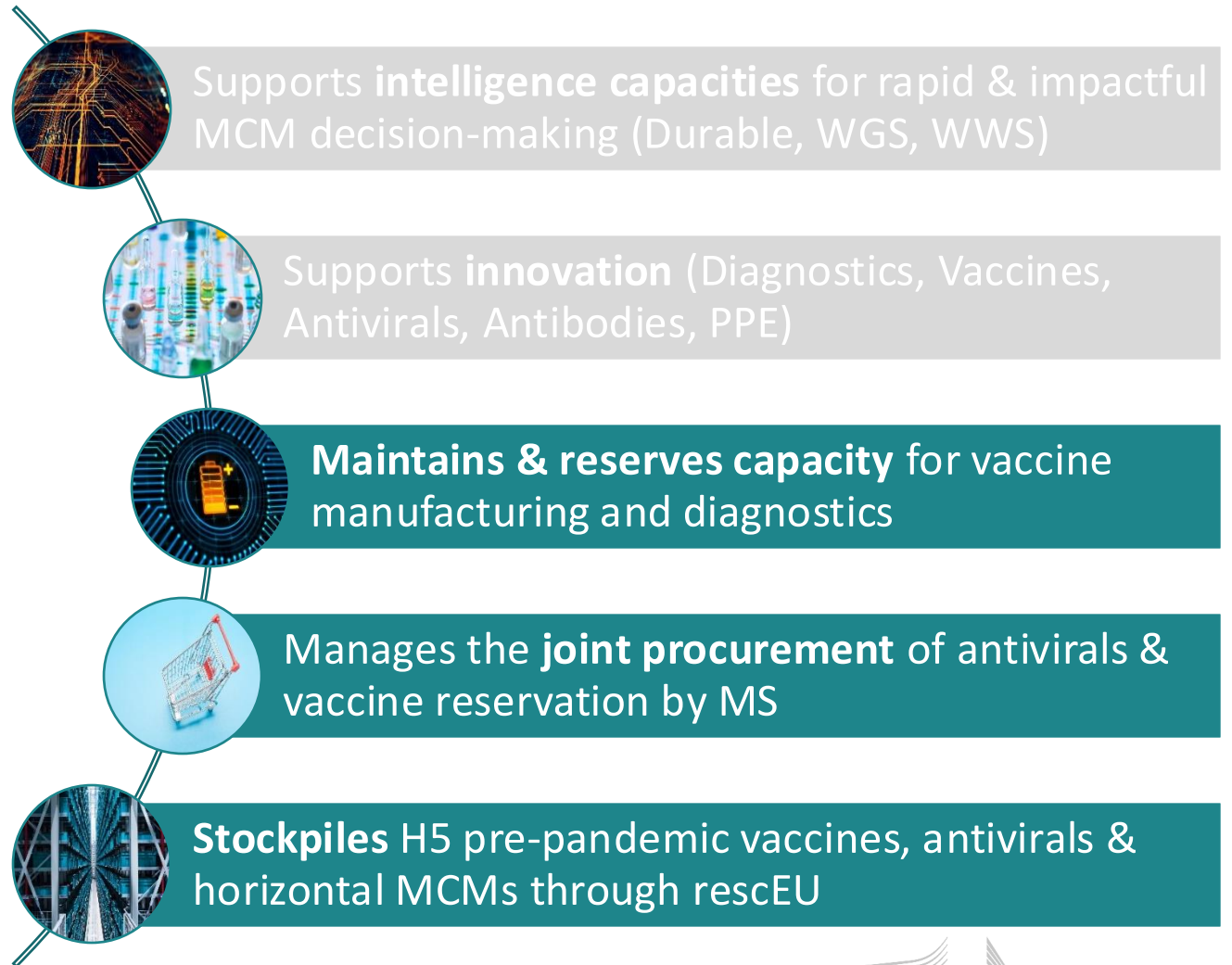


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- Manufacturing
 - **EU FAB**: Network of Ever-Warm Production Capacities For Vaccines and Therapeutics Manufacturing – EUR 325M / year (extension to PPE, reagents, medical devices and potentially therapeutics)
 - **RAMP-UP**: network of EU-based pharmaceutical and MCM manufacturers, innovators, and supplier
- Supply chain vulnerability analyses
multi-track analyses (EMA for critical medicines) = seasonal influenza vaccines, PCR tests, PPE...
- Stockpiling : **ResCEU stockpiles** (last resort EU stocks)
 - Antivirals (oseltamivir, zanamivir, baloxavir)
 - pre-pandemic vaccines
 - PPE (single-use and reusable FFP2/3 respirators, surgical masks, etc.)
 - Medical devices (ventilators, oxygen concentrators, ICU equipment, etc.)
- Procurement: **joint procurement**, central procurements

Manufacturing, Procurement, Stockpiling

Joint procurement: Voluntary mechanism to purchase MCMs with MS budget; EC coordinates the procurement and negotiates contracts on behalf of MS

	<i>Name, Manufacturer</i>	<i>Joint procurement status</i>
Pre-pandemic vaccines	Aflunov , Seqirus	No JP
	Zoonotic Influenza Vaccine Seqirus , Seqirus	Ongoing
	Celldemic , Seqirus	No JP
Pandemic vaccines	Adjupanrix , GlaxoSmithKline Biologicals	Ongoing
	Foclivia , Seqirus	Ongoing
	Incellipan , Seqirus	In preparation
	Pandemic influenza vaccine H5N1 AstraZeneca , AstraZeneca	In preparation
Antivirals	Xofluza (Baloxavir-Marboxil), Roche	In preparation
	Zanamivir – IV, Dectova	No JP
	Zanamivir – inhalation – Relenza	No JP
	Osetamivir – oral - Tamiflu	No JP

+ **dynamic procurement system (DPS)** for PPE

+ other type of procurement: central procurement, direct procurement...