HERA

**HEALTH EMERGENCY
PREPAREDNESS AND
RESPONSE AUTHORITY**

#HealthUnion

European Commission

HERA STAKEHOLDERS HUB:
A SECURE ECOSYSTEM FOR
COLLABORATIVE ENGAGEMENT

Launch & Registration guide

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The **HERA Stakeholders Hub** is initiated in response to the **"Communication on addressing medicine shortages in the EU" (Ref. COM(2023) 672 final)** whereby, DG HERA has been mandated to develop a matchmaking platform as a measure to mitigate critical shortages in the immediate and short term:

> "the Commission will also establish [...] a matchmaking platform, where economic operators and developers will be able to flag their capabilities and collaboration needs."

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SCOPE AND OBJECTIVES

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The **HERA Stakeholders Hub** will serve as a secure ecosystem for stakeholders to engage with HERA and other partners; it envisages the following capabilities:

- For the **external stakeholders**, to directly contact DG HERA **via a single channel**
- For all stakeholders, **to access and share information in secure workspaces**
- For economic operators, to **identify and build new industrial partnership** in the area of MCMs and critical medicines
- For **Critical Medicines Alliance and Joint Industrial Cooperation Forum (JICF) members, to interact in a secure environment**
- For **DG HERA, to triage stakeholders' request, manage stakeholders cooperations and meetings**, gather insights, knowledge and information on manufacturers capacities, operations and cooperations

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COMPONENTS

WORKSPACES

An exclusive area for members of selected HERA's groups to access and contribute to a repository of strategic documents and communications
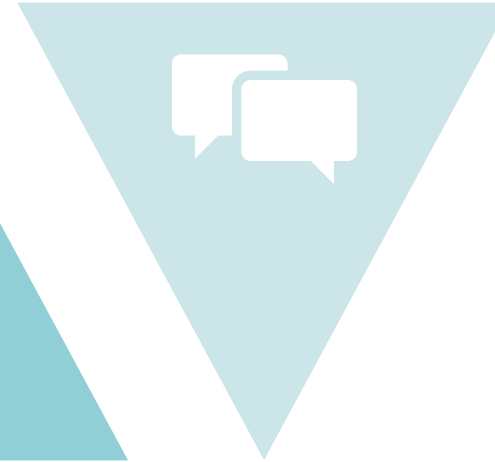
INFORM HERA

A streamlined contact form to prioritize and optimize stakeholder interactions, including encrypted spaces for stakeholders to share sensitive information

MATCHMAKING

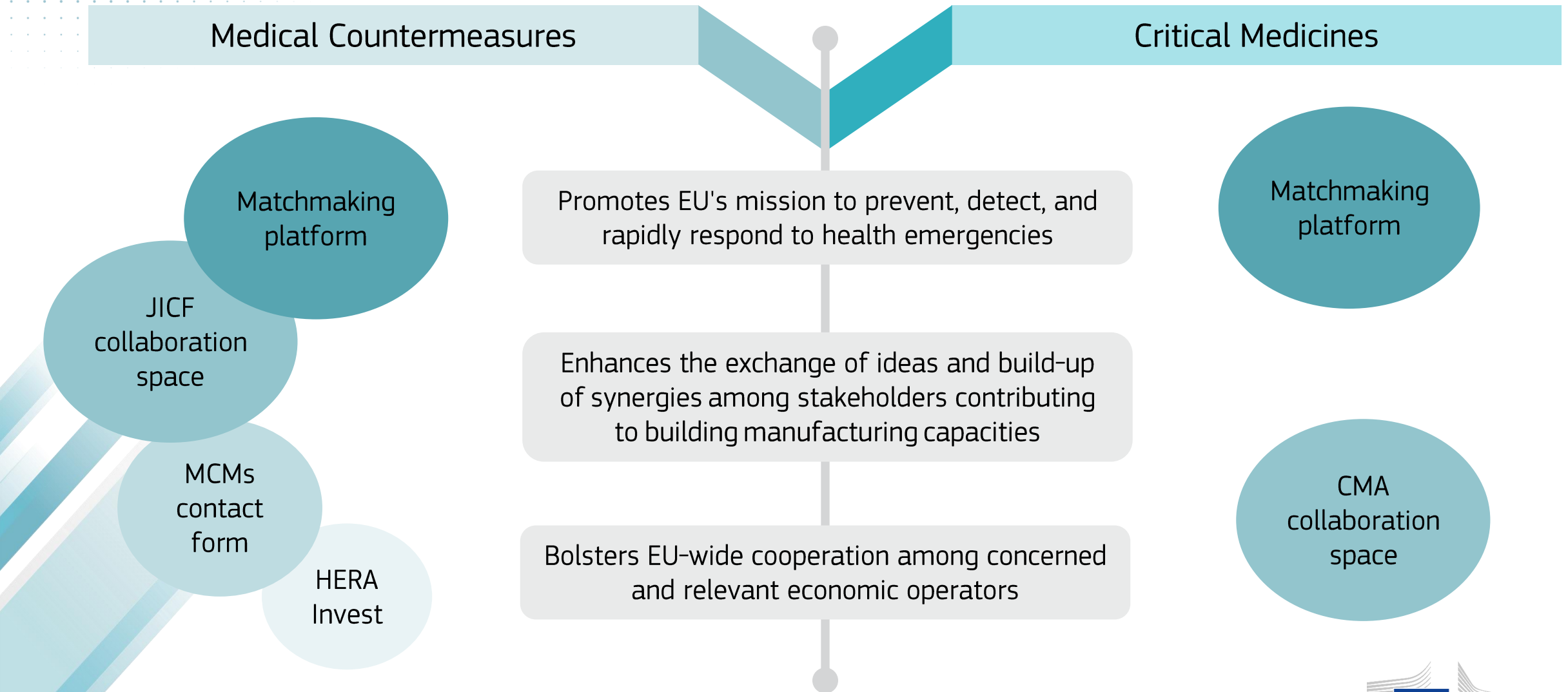Dual-component system to connect companies with partners for supply chain collaboration and research project partnerships

NEWS&EVENTS

Space to share with stakeholders relevant information about HERA's initiatives and events

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SCOPE AND COMPONENTS

Medical Countermeasures

Critical Medicines

Matchmaking platform

JICF collaboration space

MCMs contact form

HERA Invest

Matchmaking platform

CMA collaboration space

Promotes EU's mission to prevent, detect, and rapidly respond to health emergencies

Enhances the exchange of ideas and build-up of synergies among stakeholders contributing to building manufacturing capacities

Bolsters EU-wide cooperation among concerned and relevant economic operators

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REGISTRATION IN THE HERA STAKEHOLDERS HUB:
A QUICK GUIDE

○ **User types and permissions**

1. Organisation **Administrator** User: Can approve or revoke any subsequent Organisation Administrator Users or Organisation Member Users affiliated with the same organisation.

2. Organisation **Member** User: same visibility rights of the administrator but no right to revoke/approve organization users

○ **User responsibilities:**

❖ Users are responsible for all activities under their account or password
❖ User IDs and passwords are confidential
❖ Users must keep their profile details up to date
❖ Users can self-manage their account through the User profile at any time

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REGISTRATION TO THE HUB: HIGH LEVEL PROCESS

To accessing the Hub's functionalities:

✓ Each organization must be registered

✓ Every member of the organization must be registered and access functionalities

with own individual credentials

STEP 1	STEP 2	STEP 3
My Organisation	My Account	Review

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Only the **first user** for the organisation needs to fulfil the organisation registration by:

1. Access via EU Login system by clicking on "Log in"

   o please use corporate email (not general like gmail, outlook etc..)

2. Accept *Privacy Statements*, *Personal Data Processing* and *Terms & Conditions of use of the Hub*

3. Register your company details via 3 different ways:

   A. Via the Organisation Management Service (OMS) of the European Medicines Agency (EMA), if your organisation is registered in the OMS

   o Enter your company name and country. If multiple organisations are found, you can click on the "Details" and "Select" the appropriate organization

   B. Via EU VAT, if your organisation has a VAT issued in the EU using the VAT Information Exchange System (VIES)

   o Enter your EU VAT and country of issuance

   C. Manually, if none of the above options are applicable

Either in the context of the new organisation registration or when organisation is available:

1. Accessing via EU Login system by clicking on "Log in"

2. Create an Account – Create an account under a registered organisation or register a new organization

3. Validation Process for First User

   1. The first user to register for an organisation undergoes a validation process
   2. Once validated, they are approved as an Organisation Administrator User
   3. Any other subsequent user is not validated nor approved and can be made administrator by the organization Administrator user

> ➤ HERA recommends that each organisation has **at least two registered Organisation Administrator Users**
>
> ➤ Organisation Administrators must use an **email address that matches their organisation's website domain** when registering a new organisation

➢ You are encouraged to register your organization details via OMS if applicable and available, this will enable the retrieval of your organisation details automatically from OMS

➢ Please note by using registration via OMS and EU VAT number validation the approval process will be faster and smoother

➢ When registering your organization, additional minimum information are also requested. This is to boost search and matching capabilities in the matchmaking component and for the access to the relevant workspace (e.g. business areas, affiliation with associations etc)

➢ If you are member of the CMA (and related governance) and/or JICF, following successful registration as user, please notify to hera-stakeholders-hub@ec.europa.eu and HERA administrator will grant you access to the pertinent workspace(s) and shared area(s)

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○ The **HERA Stakeholders Hub is now live** and accessible at:

https://health-preparedness-industry-hub.ec.europa.eu/

Next steps:

○ A user manual is under preparation and will be released in due course

○ Additional enhancements are expected based on already identified features and your user experience

○ For any technical inputs or to report any technical issue, please do not hesitate to contact the HERA Hub Team at hera-stakeholders-hub@ec.europa.eu

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