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Call for proposals to support access to medical devices for cross border health threats (HERA) **(CP-g-23-13)**

European Commission

Support access to medical devices for cross border health threats (HERA) (CP-g-23-13)

- Certain medical devices, including in vitro diagnostics, face issues entering and/or continuing on the market due to **limited demand** (e.g., small group of patients), due to **lack of revenue visibility** or other **business-related reasons**. This challenge is exacerbated for cross-border health threats preparedness given the need for solutions that are mostly used in the context of a crisis.

- This action aims to ensure the **availability of and access to solutions** for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, in the context of cross-border health threats.

- Additionally, this action intends to gather knowledge and information on **market gaps** and recommendations on potential investments in the field of medical devices.

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A consortium that provides a platform:

- Offering services featuring **regulatory support**, **business planning**, and **device development**, to help foster the advancement of devices relevant for serious cross-border health threats. This action **does not cover orphan medical devices**.

- To facilitate the **development**, **production**, and **distribution** of medical devices by supporting developers on matters related to **intellectual property**, **prototyping**, **engineering**, **laboratory** and **animal testing**, **grant-writing**, and **clinical investigation design**.

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The project funded under this action is expected to foster an **innovation ecosystem** by:

- Promoting **capacity building** and **knowledge sharing**.
- **Establishing connections** between individuals and/or entities;
- **Mentoring** projects through the **development process**;
- Assessing the scientific, engineering, pre-clinical and clinical innovation potential of the medical devices and adequately **guide projects through the best regulatory pathway**;
- Supporting in finding **funding/investment sources**, and assessing **market opportunities**;
- Providing **business**, **legal** and **regulatory** support at the stage of **submission for conformity assessment**.

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Target applicants

Scientific societies, academia, health authorities/institutions and NGOs, possibly also including SMEs active, with expertise in the area of the action.

Eligibility

Consortium of at least 3 applicants (beneficiaries; not affiliated entities with minimum 3 entities from 3 different eligible countries.

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In order to develop and deliver on the objective of the call, the consortium should demonstrate that it has the following competences (directly or indirectly through readily available expertise, i.e. a pool of experts):

- Expertise **on cross-border health treats**, with special focus on HERA's priority threats.
- **Legal and regulatory** proficiency in the field of **medical devices at EU/national levels.**
- **Intellectual property protection**, **business plan design** and **market readiness strategies** expertise.
- **Pre-clinical and clinical capabilities**, including proficiency in **laboratory and animal testing**, proficiency in **clinical evaluation** and practical steps for **medical devices validation**.
- **Scientific/technical capabilities**, including applied engineering and mathematics, prototyping and overall product development.
- Experience in **funding and investment mechanisms** at EU and international level (and, if possible, experience in national research and innovation programmes).