

# NFP4Health

Funding and Opportunities in the framework of  
AWP 2024

17 April 2024



This presentation is part of the action "NFP4Health" which has received funding from the European Union's Health Programme (2014-2020) under grant agreement No 101035965.

## ABSTRACT

The presentation discusses the evolution of healthcare policies in response to Covid-19 at the European level, emphasizing the establishment of a European Health Union. Key reforms include empowering agencies like the EMA and ECDC, leading to the creation of Hera to ensure the availability of medical countermeasures. Funding primarily comes from EU4Health and Horizon Europe, with an emphasis on threat prioritization and intelligence gathering. Efforts are also directed towards addressing data sharing challenges and promoting innovation through partnerships and grants. Initiatives focus on production, procurement, and stockpiling of medical countermeasures, including addressing medicine shortages. Differentiation between procurement and grants is clarified, with forthcoming action grants outlined under the EU for Health Work Program. The importance of engaging stakeholders and advocating for procurement opportunities is highlighted, along with various procurement methods and activities structured around key categories. Ongoing and upcoming opportunities, including those for 2024, are presented, with a commitment to fulfilling the mandate despite budget constraints. Collaboration and support in maximizing the impact of these opportunities are encouraged.

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## STATEMENT OF ORIGINALITY

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In the context of Covid-19, significant shifts occurred within the healthcare landscape, accompanied by notable institutional advancements at the European level. The forthcoming presentation will outline the current state of the security framework within the European sphere. The President of the European Commission initiated a novel approach toward establishing a European Health Union several years ago, resulting in consequential policy and institutional reforms. These include the enhanced mandates of entities such as the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC), as well as revisions to regulations concerning serious cross-border health threats. These changes underpin the European Union's strategy for pandemic preparedness and response, with the formation of Hera in September 2021 signifying a pivotal moment in this trajectory.

During the Covid-19 crisis, the inadequacy of swiftly accessible medical countermeasures became apparent. Hera's primary objective is to ensure the availability and accessibility of such countermeasures, encompassing pharmaceuticals, medical devices, and personal protective equipment (PPE), among other essential goods and services aimed at mitigating serious cross-border health threats. Operationalizing this objective involves comprehensive engagement across the entire value chain, spanning intelligence gathering, research and development, clinical trials, production, procurement, distribution, and stockpiling. Collaboration with international stakeholders across various sectors further augments these efforts.

With regards to funding, the operational budget of €6 billion over six years relies primarily on three main programs: EU4Health, Horizon Europe, and Rescue EU for Health, albeit subject to recent budgetary reductions. Despite this, EU4Health remains Hera's primary funding source, supporting the majority of projects.

Identifying and prioritizing threats is crucial for guiding our actions effectively. In 2022, agents with pandemic potential, antimicrobial resistance (AMR), and chemical, biological, radiological, and nuclear (CBRN) threats were identified as primary concerns. Subsequently, in response to evolving geopolitical and environmental challenges, biosecurity and environmental threats were integrated into Hera's threat prioritization framework. To address these threats, a catalogue of over 500 medical countermeasures has been compiled, further categorized based on specific needs such as stockpiling, supply chain monitoring, and research and development support.

The intelligence gathering activities encompass laboratory and digital capacities, both crucial for proactive threat detection and response. This includes strengthening sequencing and surveillance capabilities, fostering international collaborations, and enhancing digital platforms for real-time data analysis and information sharing.

In conclusion, ongoing efforts aim to bolster Europe's preparedness and response capabilities against a spectrum of health threats, ensuring resilience and sustainability in the face of evolving challenges.

The primary challenge in data sharing during outbreaks is a focal point of concern and an overview of innovative efforts is provided. As previously mentioned, reliance centres on two principal programs: Horizon Europe, primarily supporting early-stage research, and EU4Health, concentrating on late-stage development, aiming to expedite product market entry. Through EU4Health, endeavours are made to advance partnerships with numerous international entities, including the World Health Organization (WHO), Coalition for Epidemic Preparedness Innovations (CEPI), and Global Alliance for Vaccines and Immunization (GAVI). Additionally, the European Investment Bank (EIB) is acknowledged within this framework, with €100 million to



EIB funding programme "**InvestEU**", consisting in venture loans at preferential interest rates, usually ranging between EUR 20-40 million (those need to be repaid). When investing, EIB covers a **maximum of 50% of investment costs**, i.e. public or private investors will need to finance the other half of the investment. In simplified terms, the HERA Invest initiative serves as a risk mitigation tool for private investment by covering potential losses before other investors.

Subsequently, an outline of endeavours concerning the production, procurement, and stockpiling of medical countermeasures is presented. The EU Fab network comprises adaptable production capacities able of activation during health emergencies. With an investment of €160 million, procurement aims to procure up to 325 million vaccines annually through joint procurement mechanisms. Currently, active contracts not only encompass Covid-19 therapeutics and vaccines but also extend to pandemic influenza and monkeypox. Stockpiling remains a cornerstone of activities, with €1.2 billion invested under the Rescue program in collaboration with DG ECHO. This initiative primarily targets the accumulation of medical countermeasures to address chemical, biological, radiological, and nuclear (CBRN) threats.

Lastly, an expanded focus on addressing medicine shortages within the European Union is introduced. The Commission's communication released at the close of 2023 outlines two primary objectives: preventing and mitigating critical shortages at the EU level and ensuring the security of supply for essential medicines. Hera's role entails establishing the Critical Medicines Alliance, tasked with formulating recommendations for coordinated EU-level actions against medicine shortages. The alliance's focus centres on critical medicines with the highest risk of shortages and impacts on healthcare systems. Its efforts may potentially lead to institutional changes and legislative actions, such as the proposed Critical Medicines Act. In conclusion, this overview provides clarity regarding objectives and priorities.

Firstly, a differentiation between procurement and grants has been clarified. Procurement involves the process of call for tenders, where the Commission purchases products or services, while grants are issued through calls for proposals, providing financial support to beneficiaries. Unlike procurement, grants do not typically cover the entire cost of the action, and the resulting outcomes remain under the ownership of the beneficiary. Under procurement, the Commission retains ownership of products or services acquired through signed contracts, whereas grants operate under the principles of profit and non-profit, respectively. Broadly defined, a grant constitutes a direct financial contribution from the Commission to facilitate actions aligned with Union policy objectives. These may include action grants, aimed at executing specific tasks to achieve policy objectives, or operating grants, intended to sustain the operations of entities aligned with Union policy.

Five forthcoming action grants have been presented, with an anticipated application window from May 23rd to September 5th, and signing expected to occur in June 2025. Please note that additional information sessions will be arranged for these grants, allowing subject matter experts to provide detailed insights. While specific questions cannot be addressed until the call publication due to regulatory constraints, general inquiries will be entertained at the conclusion of this presentation. Additionally, participants are encouraged to refer to the 2024 EU for Health Annual Work Program for further details on these actions.

The upcoming grant opportunities under the EU for Health Work Program include:

- CP-g-24-10 Call for proposals on the European Hub for vaccine development (102M€)
- CP-g-24-11 Call for proposals for next-generation respiratory protection (20M€)



- CP-g-24-12 Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (17M€)
- CP-g-24-105 Call for proposals to support the development of novel antivirals (10M€)
- CP-g-24-13 Direct grants to Member States' authorities: Support to the development of sustainable, forward-looking national and Union stockpiling strategies

Recent outbreaks have underscored the critical importance of timely vaccine production and development capabilities within the EU. This action seeks to establish a comprehensive hub for vaccine development, fostering collaboration between vaccine developers and research entities.

Next, we have the Next Generation Respiratory Protection initiative, aimed at enhancing respiratory PPE capabilities to effectively respond to health emergencies. The focus is on designing innovative, scalable respirators with rapid production capabilities.

The Support for Innovative Manufacturing Technologies and Processes initiative aims to advance pharmaceutical manufacturing technologies for more efficient, sustainable, and scalable production of medicines, particularly in response to health emergencies. Furthermore, the Support for the Development of Novel Antivirals initiative seeks to diversify and advance the pipeline of broad-spectrum antiviral candidates, crucial for mitigating viral infections.

Lastly, the initiative to support the development of sustainable stockpiling strategies entails a direct grant to Member State authorities, aligning national strategies with Union stockpiling objectives. The speaker recognized the challenge of engaging certain stakeholders and raising awareness about procurement opportunities, particularly among public and academic research institutions more accustomed to the grant model. Despite the familiarity with grant-based calls, they sometimes overlook procurement possibilities. Therefore, the significance of national contact points for EU for Health has been evidenced to advocate for procurement and highlight market opportunities within respective countries.

Procurement can be implemented through various methods, including open procedures, competitive procedures, negotiated procedures, and direct contracts. While open procedures are the most common, HERA also utilizes competitive and negotiated procedures based on specific cases. Additionally, HERA often establishes framework contracts and issue requests for services under these contracts, as evident from the opportunities presented for 2023 and 2024. HERA procurement activities are structured around four main categories aligned with the mandate. These include intelligence gathering, innovation support for medical countermeasures, procurement of medical countermeasures, especially for emergency situations, and initiatives promoting the availability and accessibility of medical countermeasures, particularly antibiotics.

Before delving into the 2024 opportunities, the three ongoing opportunities from 2023 and three crucial actions for 2024 are highlighted. These actions are closely linked to the framework contracts being launched this year.

- CP-p-23-14 Support to the Commission on identifying priority threats and medical countermeasures.
- CP-p-23-16 - Support innovation and access to antimicrobials.
- CP-p-23-20 Continuous support to existing wastewater activities including the establishment of an EU sentinel system.



The first ongoing opportunity pertains to supporting the Commission in identifying priority threats and medical countermeasures. Next, there's an open call for tenders supporting innovation and access to antimicrobials, focusing on paediatric tuberculosis formulations. Finally, there's an upcoming opportunity for continuous support to existing wastewater activities, including the establishment of a new sentinel system.

Moving on to the 2024 opportunities, the EU for Health Action involves a request for service under an established framework contract. This action aims to maintain our ongoing efforts in medical countermeasure support. Additionally, there's an action for the purchase, innovation, and deployment of medical countermeasures in emergency situations, which serves as a contingency measure activated when needed.

Furthermore, two actions focusing on innovation are in the pipeline for 2024, aiming to expedite the development of medical countermeasures. These actions will leverage insights from the Critical Medicines Alliance to address critical medicines and antimicrobial needs. Lastly, ongoing intelligence gathering, and global wastewater sentinel system initiatives will continue through requests for services under the established framework contracts.

- CP-p-24-14 Ever-warm facilities (EU FAB) for vaccines production – the Commission's Health Emergency Preparedness and Response Authority (HERA).
- CP-p-24-19 Purchase, innovation and deployment of medical countermeasures in emergency situations (HERA).
- CP-p-24-15 Support to speed up the development of access to and/or uptake of medical countermeasures including critical medicines (HERA).
- CP-p-24-16 Support innovation, supply capacity and access to critical medicines and antimicrobials (HERA).
- CP-p-24-17 Support to the Commission on gathering intelligence on priority threats and medical countermeasures.
- CP-p-24-18 Establishment of a global wastewater sentinel system (HERA).
- CP-p-24-90 HERA's training and exercise programme for management of medical countermeasures.

In conclusion, while budget constraints may have impacted certain areas of work, HERA commitment to fulfilling the mandate remains unwavering. HERA continues to pursue opportunities across all relevant areas, albeit within adjusted parameters. Support in promoting procurement opportunities is deemed invaluable, especially amid challenges in reaching the right stakeholders.

