EUROPEAN CLUSTER COLLABORATION PLATFORM

Health in Europe:

Where does out ecosystem stand?

Summary

EU Clusters Talks
8 February 2023, 8:30 – 9:45 CET

An initiative of the European Union

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Health in Europe: Where does our ecosystem stand?

The European Cluster Collaboration Platform organised this EU Clusters Talk on 8 February 2023, 8:30 – 9:45 CET, to explore the activities of the Health Emergency Response Authority (HERA), discuss the development of the health ecosystem, and learn about current problems that clusters and their members are struggling with.

Agenda of the meeting
Moderation: Jennifer Baker
1. News from the European Cluster Collaboration Platform
   Nina Hoppmann, team member of the European Cluster Collaboration Platform
2. Video: About HERA
3. Perspectives from the European Commission
   Elodie Durand, Policy Officer - Medical Counter Measures, HERA, European Commission
   Chiara Orlandi, Policy Officer – Medical Devices, DG SANTE, European Commission
4. Panel debate
   Max Pöhlmann, Project & Cluster Manager, BioM Biotech Cluster Development
   Michael Kerschbaumer, Project Manager "Innovation", SFG Steirische Wirtschaftsförderungsgesellschaft
   Montse Daban, Director of Science Policy and Internationalisation, Biocat
5. Funding opportunities
   Nina Hoppmann, team member of the European Cluster Collaboration Platform

Key messages
- European SMEs in the health ecosystem are very innovative. There are many ideas for our current challenges in the development pipeline.
- However, a critical challenge is the market access for these innovative solutions. The long timeframe and limitations in public and private funding support lead to many ideas not reaching market readiness.
- To limit risks for SMEs, a European initiative for innovative procurement in healthtech is suggested.
- Many SMEs would benefit greatly from a better access to health data. Sharing data across the EU should be improved. Due to the sensitivity of the topic, a communication campaign for the public would need to be launched.
- The European Union needs a stronger say in health issues. We should increase sharing knowledge, data, and products in the EU.

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1. News from the European Cluster Collaboration Platform

Nina Hoppmann, team member of the European Cluster Collaboration Platform

After the introduction by moderator Jennifer Baker, the following news items were presented:

1. Donations in the area of health for Ukraine can be made via DG ECHO. Priority needs are medical equipment, critical emergency care equipment, antibiotics, antidotes, antivirals, and medicines for cancer treatment.
2. 30th anniversary of the EU Single Market. Register your local event.
3. Invitation to join the C2Lab in Lund, Sweden, on 21-22 March 2023
4. Invitation to register for the Matchmaking event and high-level pharmaceutical forum between the EU and Latin America and the Caribbean
5. New examples in the Policy Toolkit

2. Perspectives from the European Commission

Elodie Durand, Policy Officer – Medical Counter Measures, HERA, European Commission

Chiara Orlandi, Policy Officer – Medical Devices, DG SANTE, European Commission

Elodie Durand presents the tasks and achievements of HERA, which was set up in 2021. HERA has a "**preparedness and response role**" and covers a **broad range of medical countermeasures** for whole value chain - from data and intelligence all the way to stockpiling. She explains that HERA operates in a big network and has a dedicated forum for the dialogue with the industry, which is called **Join Industrial Cooperation Forum**. The European Clusters Alliance is member of this forum.

In the case that a public health emergency is declared, HERA's crisis mode will be activated to make countermeasures available. The core governance body is the **Health Crisis Board**. HERA has a budget of 6 billion EUR between 2022-27, which is split between the EU4Health, Horizon Europe, and UCPM/rescEU programmes.

Elodie Durand also speaks about the **work plan** that HERA develops yearly. The priorities outlined in the work plan 2023 are:

- Development of a state-of-art IT system
- Further development of medical countermeasures for epidemic and pandemic preparedness
- Reservation of manufacturing capabilities for vaccines (EU FAB)
- Financing mechanism referred to as "HERA INVEST"
- Strategy on EU-level stockpiling
- DURABLE laboratory network

Speaking about the regulatory framework for medical devices, Chiara Orlandi explains that the bar to reach the level of requirements is increasing. Two recent legislations for medical devices and in vitro diagnostics medical devices are fully applicable. To facilitate the transition, both Regulations set specific provisions to continue placing on the market and use of devices during the transition phase.

In addition, early January 2023 the European Commission has adopted a proposal for amendment for the transitional provisions.

In the short term, the Commission has several non-legislative measures to coordinate the implementation of the regulation. The Medical Device Coordination Group published a position paper with 19 actions, among others, activities to **increase the capacity of notifying bodies and preparedness of manufacturers**. For this, there are also grants under the EU4Health programme. Furthermore, other actions are on-going, including **bridging measures**, gaining momentum to increase the number of notified bodies, and continuously **monitor** the availability of medical devices.

Looking at long-term measures, she highlights the work on a pilot project on scientific advice for clinical development strategies for high-risk devices, the collaboration with the Enterprise Europe Network for targeted support to SMEs, and tailored solutions for orphan devices.

3. Panel debate

The discussion among the panellists focuses on innovation in the health ecosystem, access to market, crisis preparedness, and coordination.

HERA

Max Pöhlmann shares that the national frameworks need to be set now to make HERA a successful endeavour. In Germany, there is an **ongoing dialogue** to have efficient responses to future health threads. The preparation is ongoing to bridge the gap between industry and policymakers. The legal framework needs to empower the companies to develop innovative medicines in the future.

Montse Daban adds that HERA's objectives should also take into account the **green and digital transition** of the health ecosystem. The authority is about **alerts and coordination**, which is a big change that arose because of the covid-19 pandemic. More coordination, research and preparedness are the main aims.

Innovation support and access to market

Michael Kerschbaumer, representative of the Enterprise Europe Network, shares his feeling that the political developments have not reached the ground and the SMEs yet. They see a density of highly innovative SMEs and start-ups in the healthtech sector that try to get to the market, however, there are **limited instruments for them to scale up and bridge the "innovation valley of death"**. He sees a problem in the **backlog of ideas** that can help solve many of the current issues. He points out that there is hardly any venture capital available. Due to the extended timelines in healthtech sector, where solutions can take up to 20 years to reach market readiness, **investments are too short-term**. While checks and balances are necessary, we also need a long-time support system.

In addition, Michael Kerschbaumer suggests a **European initiative for innovative procurement in healthtech** to take out the risk for the single procurers.

Max Pöhlmann agrees that we are at the point where translation to market solutions needs to be made quicker. He says that SMEs struggle with bureaucracy and the framework to get to clinical trials.

Montse Daban reminds that the ideas need to fill the market need and focus on the needs of the patients, users, and society. While we are facing the problem of a slow path of innovation reaching the market, gatekeepers are working on fast tracks to accelerate the process. She stresses the **importance of evidence** for the new technologies. Regarding **flexible financing schemes** for health systems, she remarks that we need a strong reflection on potential ways of implementation.

Chiara Orlandi confirms that innovation is one of the key areas for DG SANTE. Among long term initiatives, they are about to launch a **study on governance and innovation** in the medical devices sector. She highlights that access to market is what we want to guarantee and this should be done in a reasonable timeframe, preserving the level of evidence required. To assist manufacturers, they plan an initiative to make use of the expert panels for the clinical strategy.

Data

Max Pöhlmann highlights that many companies would benefit if we increased the **sharing of health data**. He opens the question of how the data resources could be made available to small companies. Montse Daban suggests that clusters can work with the policymakers and other clusters to bring movement into the ecosystem regarding this idea. Dialogue is important to change the mindset in the ecosystem.

Michael Kerschbaumer shares that there are many **AI applications in development at the stage of diagnostics**. For these companies, it is difficult to get access to data. A push could be achieved by an anonymised open data approach, e.g., for the training of AI networks. Montse Daban adds that the **European Health Data Space** is expected to be incentivising the different Member States to bring this matter to the top of their priority list. Opening data must be systematic and inclusive.

In addition, Max Pöhlmann advises that a lot of work lies in the **communication to the public**. Clusters can support in communication activities to explain the advantages of making data available. Due to the sensitivity of the topic, it needs an inclusive approach to avoid fragmentation in national solutions.

Role of clusters

Montse Daban sees a transformation in the ecosystem and its different areas. The best tools to support companies are **funding, support to reach EU and international markets, and talent**. The clusters are helping with the "business as usual" and in extraordinary situations. Michael Kerschbaumer add that the Enterprise Europe Network organises events and collaboration opportunities to support SMEs. However, systemic changes need to come from the policy side.

EU – Member States competencies

Max Pöhlmann shares that there is a debate on how the new legal framework makes it cheaper for health insurance providers to buy drugs. There is a risk that companies that produce medicines and drugs won´t launch a product if they cannot make profit with it in their countries. Michael Kerschbaumer says that they experience a drug shortage in Austria because companies buy drugs and sell them in Germany for a higher profit. They agree that the **EU needs to have more say in critical issues** and that we need to **share knowledge, data, and products in the EU** to stay competitive on the global market.

4. Funding opportunities

Nina Hoppmann, team member of the European Cluster Collaboration Platform

Closing the EU Clusters Talk, Nina Hoppmann shares the following examples of funding opportunities:

1. Environmentally sustainable and climate neutral health and care systems; Deadline: 13 April 2023
2. Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks; Deadline: 13 April 2023
3. Maintaining access to regular health and care services in case of cross-border emergencies; Deadline: 13 April 2023
4. Development and harmonisation of methodologies for assessing digital health technologies in Europe; Deadline: 13 April 2023
5. Call from Ventures Thrive: Investment in deep-tech start-ups; Deadline: 16 March 2023.

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