



Medicines and medical devices breakout group EU4Health programme

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Shortages of crisis relevant products

Challenges

Increase of needs, supply issues, dependency

Solutions

Encouraging sustainable production, monitoring, procurement and management of crisis relevant products within the Union, support stockpiling

Medicinal Products

Challenges

Uptake innovative medicinal products, foster patients centred innovation, competitiveness and equal access in all MS, medicines in the environment

Solutions

Pharma strategy; coordination of clinical trials; support blood establishments; international cooperation; synergies with other EU funds

Safe and effective vaccines

Challenges

Need for swift reaction,
emerging pathogens

Solutions

Coordinate monitoring of post-
marketing and safety and efficacy data
as well as vaccine misinformation

Medical Devices

Challenges

Reinforce the safety of devices
and foster innovation,
implementation of legislation

Solutions

Expert panels; Strengthen cooperation
across MS, communication to
authorities and stakeholders e.g.
EUDAMED,

Speakers

- **Challenges and solutions from the EMA perspective**

Prof Dr Hans-Georg Eichler, EMA's Senior Medical Officer

- **View from medical technology**

Jesús Rueda Rodríguez, Director International Affairs, Medtech Europe
(European trade association for the medical technology industry)

- **Possibilities in the Pharma side**

Edith Frenoy, European Federation of Pharmaceutical industries and
associations (EFPIA), Director Market Access, HTA Policy lead



EUROPEAN MEDICINES AGENCY
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EU4Health Webinar

Challenges and solutions: an EMA perspective

Hans-Georg Eichler
Senior Medical Officer, European Medicines Agency

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Challenges and solutions: An EMA perspective

Clinical trials: Compared to other regions, EU was not strong in implementing large (platform) trials for COVID-19 medicines → lack of robust, decision-relevant information for regulators and other healthcare decision-makers → need for infrastructure, governance, and funding of large, pan-EU trials

Health care data (“real world data”): COVID-19 highlighted how healthcare data will be a much-needed source of information on long term (good or bad) effects of vaccines and treatments, to inform regulatory and other decisions. This is even more true for personalised, complex treatments for a range of other diseases expected in the near future → need for a coordinated “learning healthcare system” across the EU.

Collaboration of healthcare decision-makers: regulators, HTA bodies, payers, guideline-writing groups have different roles but share the need for robust clinical information about treatments. Given the cost and complexity of knowledge generation → need for collaboration on research questions, data sources and methodologies across decision-makers.

EU4Health – View from Medical Technology

Jesús Rueda Rodríguez
MedTech Europe

EU4Health - View from Medical Technology

Key lesson from the global pandemic:
EU wide coordination in healthcare

Preparation

Ensuring access to Technology

Agility

Facing new challenges in Healthcare

EU Stockpiling &
Procurement

Research &
Innovation for key
areas

Digital Health
Space &
Transformation

Surveillance &
Solutions to
emerging threats

Collaboration between all relevant actors – Institutions,
Member States & Civil Society Essential to Success.



EU4Health Programme

Edith Frénoy, EFPIA



Presentation





What could EU4Health address?

Mitigate shortages

- common reporting framework for shortages
- collection of better and more detailed epidemiological data

Support prevention, early diagnosis and treatment

- strategic investments in integrated care models, supported by Electronic Health Records and telehealth solutions

Support timely access to advances in treatments

- strong EU clinical HTA framework
- developing and maintaining state of the art clinical trial networks
- investments in infrastructure, tools and methodologies to collect and analyse Real World Data



European Federation of Pharmaceutical
Industries and Associations



Thank you



Questions for reflection

- *What is the biggest challenge/problem in your specific area?*
- *What could be alternative possible solutions to that?*
- *What are the successful solutions from past projects?*