



Health systems, medical products and innovation: Challenges and priorities

EU4Health programme 2021-2027: a vision for a healthier European Union

Plenary session #3

22 January 2021

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Health systems

Main challenges:

- **COVID-19 related disruption to health systems:**
 - Backlog of **non-COVID care** (outpatient visits, elective surgeries, diagnostic tests etc.)
 - Impact of COVID-19 on **mental health**
- **Population ageing** (associated increase in the prevalence of chronic diseases and disabilities)
- **Cost pressures** (demographic changes, advances in medical technology) hindering the **financial sustainability of health care systems**
- Burden of behavioral **risk factors for health**
- **Gaps in care accessibility** (affordability, availability)
- **Health workforce shortages** (doctors, nurses)
- **Health inequalities** (by disease, socio-economic)

Proposed solutions:

- Support of the implementation (piloting) of **new care models**; promoting **care integration**;
- Supporting actions to improve **mental health** (adolescents, adults)
- Strengthening **health promotion and disease prevention activities** - focus on persistent (modifiable) risk factors and the young
- **Tackling health inequalities** in access to care (vulnerable groups, rural areas)
- Promoting more advanced health workforce planning; support for **training, upskilling and innovation** (modalities of care delivery) **projects**
- **Supporting national systems' performance** through health indicator development, high-quality analysis, policy advice and knowledge brokering
- Development and support of health system **stress tests** (voluntary)
- Supporting the **exchange, transfer and upscaling of best practices**

Health data and digitalization of health care

Main challenges:

- Low availability of **health data across borders**
- **Low interoperability** of health data and systems (technical, semantic)
- **Data privacy** and **protection**
- **Digital divide** creating inequities in access to eHealth tools

Proposed solutions:

- **Supporting the digital transformation of health systems**
- Creation of the **European Health Data Space (EHDS)** and better access to data for:
 - Better **healthcare delivery** (primary use)
 - Better **research and policy-making** (secondary use)
- Advancing the **uptake of digital tools** and services
- Promoting **digital skills among health workers**
- Enhancing **European Reference Networks (ERNs)**

Pharmaceuticals

Main challenges:

- Inadequate patient access to new medicines; unsustainable pricing policies
- Lessons learnt from COVID-19 re. shortages
- Lack of need-driven innovation especially in areas of unmet need
- Quality of medicines and active ingredients, green pharmaceuticals and reap the benefits of digitalization
- (Vaccines) need for swift reaction / emerging pathogens / safety and efficacy

Proposed solutions:

- **Repurposing** existing medicines
- Support actions on **shortages**
- Boost the development of novel antimicrobials and address **AMR**.
- **Support innovative clinical trials** to speed up development (design and monitoring safety),
- Foster **international convergence** (inspections, *ICH, Eur.Pharm*)
eProduct information
- Foster the development of **environmentally-friendly production and disposal** of medicines;
- Support actions to enhance affordability, (e.g best practice exchanges on **pricing, reimbursement**)
- (Vaccines) Strengthening post-marketing surveillance, tackling vaccine misinformation

Blood, tissues and cells

Main challenges:

- Blood and transplants are essential to support public health
- Need for national stockpiling of essential crisis relevant products at Union level including plasma
- Supporting national systems and sustainable and safe supply of such substances

Proposed solutions:

- Strengthen the **oversight systems in blood and transplant services**
 - Upscaling and provide sustainable development of **real-world data registries in transplant and transfusion**
 - Develop organizational flexibility in **EU transplant programs**
 - Increase **supply of blood, plasma and plasma-derived products.**

Health technology assessment (HTA)

Main challenges:

- Facilitate patient access to innovative health technologies across the EU
- Promote innovation with added value
- Efficient and robust HTA at national and EU level (reduce duplication, pool resources and expertise)
- Address challenges caused by pandemics like COVID-19 (need for timely evaluation of effectiveness of COVID-19 treatments and diagnostics)

Proposed solutions:

- Support the **preparation and implementation** of the **new EU framework for HTA**:
 - High-quality, timely HTA reports
 - Transparent system
 - Project-type cooperation → permanent
 - Support to IT infrastructure

Medical Devices

Main challenges:

- Improving the **availability, accessibility** and **affordability** of medical devices and critical medical products, esp. in crisis situations;
- Effective implementation of the **new Medical Devices Regulation (MDR)** and **In Vitro Diagnostics Regulation (IVDR)**

Proposed solutions:

- Encouraging sustainable production, supply, procurement and management of **critical medical devices**
- **Monitor shortages** of critical medical devices, coordinate actions and response
- Setup and management of **support infrastructures** (EUDAMED, Expert Panels etc)
- **Promoting cooperation** across Member States

Conclusions – overview:

- **Health systems**

- **Health promotion and disease prevention** activities
- **Mental health**
- **Health workforce planning; training, upskilling and innovation**
- Support (piloting) of **new care models**; promoting **care integration**;
- Tackling **health inequalities** (vulnerable groups, rural areas)
- **Health indicator development**, analysis and knowledge-brokering
- Health system **stress tests** (voluntary)
- Exchange, transfer and upscaling of **best practices**

- **eHealth and digitalisation of health care**

- Creation of the *European Health Data Space*
- Advancing the **uptake of digital tools**,
- **promoting digital skills**(health workers)
- Enhancing *European Reference Networks*

- **Pharmaceuticals**

- Support actions to fix **medicine shortages**
- Tackling **AMR**
- Support **innovative clinical trials**
- Foster **international convergence** (inspections, *ICH, Eur.Pharm*)
- **Environmentally-friendly** production and disposal of medicines
- Best practice exchanges on **pricing, reimbursement**
- (**Vaccines**) strengthening **post-marketing surveillance**, tackling **misinformation**

- **Blood, tissues and cells**

- **Stronger oversight** systems, **real-world data registries** (transplant, transfusion)

- **Health technology assessment**

- Implementation of **HTA framework**

- **Medical Devices**

- **MDR** implementation
- **IDVR** implementation

Thank you

- Feedback/ideas? → Join one of the breakout sessions @ 11:10 AM (running in parallel)

A) Health systems

- Mod: **Maya MATTHEWS** (DG SANTE),
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B) Medicines, vaccines and medical devices

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