Health systems – resilience, healthcare workforce, ERN, pharma, SoHO, medical devices & HTA

Workshop EU4Health Programme 2021

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Health

Health Systems - policy framework

Commission Communication of 2014 on
"effective, accessible and resilient health systems"

Commission Communication of 2018 on "enabling the digital transformation of health and care in the Digital Single Market"

Commission Communication of 2020 on
"Building a European Health Union"

Overall European Commission processes

- European Semester
- Recovery and Resilience Facility
- Technical Support Instrument

SANTE knowledge brokering

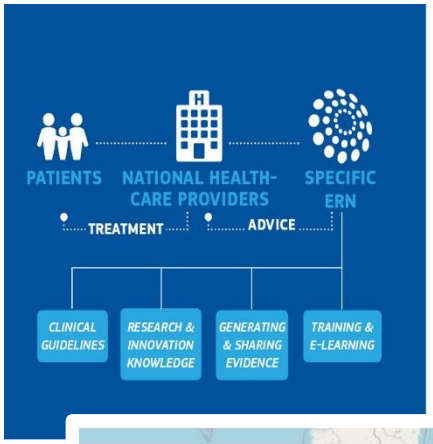
- State of Health in the EU
- Health systems performance assessment (HSPA)
- Expert Panel on Effective Ways of Investing in Health
- Best practice transfer

Health system challenges

Before & after COVID-19

1. ***Population ageing*** *(associated increase in prevalence of chronic conditions and disabilities)*
2. ***Cost pressures*** *(demographic change, advances in medical technology, additional strain on health system revenues due to economic downturn) hinder the* ***financial sustainability of health systems***
3. *Burden of behavioral* ***risk factors for health*** *(associated to non-communicable diseases)*
4. ***Insufficient capacity*** *(facilities, supplies, staff)*
5. ***Shortages*** *and* ***skills mismatch*** *in* ***health workforce***
6. ***Gaps*** *in healthcare* ***accessibility*** *(availability, affordability)*
7. ***Limited coordination/integration*** *of care,* ***weak primary*** *care*
8. ***Under-deployed eHealth*** *and* ***telemedicine***
9. ***COVID-19*** *related* ***disruption*** *to health systems:*
   - Obstacles in access to healthcare due to the emergency & backlog of non-COVID care
   - Impact of COVID-19 on mental health

European Reference Networks



EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW-PREVALENCE AND COMPLEX DISEASES
Share. Care. Cure.

European Reference Networks

European Commission | Health

What are ERNs and what do they do?

24 European Reference Networks for rare, low-prevalence and complex diseases:

- ✓ *Virtual remote consultations and clinical data on patient cases*
- ✓ *Advise and exchange of expertise (diagnosis & treatment)*
- ✓ *Knowledge Generation*
- ✓ *Research on rare diseases*
- ✓ *Education & professional training*

Share. Care. Cure.

European Reference Networks

Key assets and achievements so far

24 ERNs

European Reference Networks

2017

› 900 HEALTHCARE UNITS

› 300 HOSPITALS

25 Countries

2019
2021

Affiliated Partners

Call for new members

Established structure and foundation

- ✓ *Clear Legal Basis and "Institutional network"*
- ✓ ***24 Networks** started their clinical work*
- ✓ *Strong political support (EU) and perceived as a good example of **European cooperation***
- ✓ ***Joint ownership** (Member States authorities, patients, health professionals, hospitals, EU institutions)*
- ✓ *EU funding sources available*
- ✓ *Effective and consolidated governance structure and networking capacity*

ERNs: future actions

- ✓ *Direct grants for ERNs – simplification and improved efficiency*
- ✓ *Support work on ERN integration into national healthcare systems (Joint Action?)*
- ✓ *Enhancement of IT tool for virtual consultations (CPMS)*
- ✓ *Knowledge generation: ERN Virtual Academy, Professional mobility programme, Clinical Practice Guidelines,*
- ✓ *Support ERN research: ERN patient registries as part of the European Health Data Space*
- ✓ *Evaluation and monitoring:*
  - ➢ *Evaluation of Cross-border Healthcare Directive (2011/24/EU), including provisions on ERNs (2021-2022)*
  - ➢ *First periodic 5-year assessment of performance of ERNs and their members (2022-2023)*

Share. Care. Cure.

Pharmaceutical Strategy for Europe COM(2020) 761 final

Challenges in this area: Increase of needs; Supply issues and dependency; Quality and safety; Encouraging patient-centered innovation; Competitiveness and equal access in all MS

Areas to focus on are:

1) Monitor shortages and encourage sustainable production within the Union
2) Improve clinical trials
3) Strengthen inspections and harmonized standards
4) Mitigate the risk of medicines in the environment

Substances of Human Origin (SoHO)

Three Directives lay down quality and safety standards at EU-level for substances of human origin:

- For blood and blood components (Directive 2002/98/EC)
- For tissues and cells intended for human applications (Directive 2004/23/EC)
- For organs intended for transplantation (Directive 201053/EU)

They are complemented by Directives implementing technical requirements.

The **evaluation** (2019) of the EU legislation on blood, tissues and cells (BTC) confirmed that the legislation had improved safety and quality of BTC used for transfusion, transplantation or medically assisted reproduction. But the evaluation also highlighted a number of gaps and short-comings, which will be addressed in the **revision of the legislation on blood, tissues and cells** (ongoing).

The Commission is carrying out an impact assessment that will support a legislative proposal for a revised BTC legislation (planned to be adopted end of 2021).

Substances of Human Origin (SoHO)

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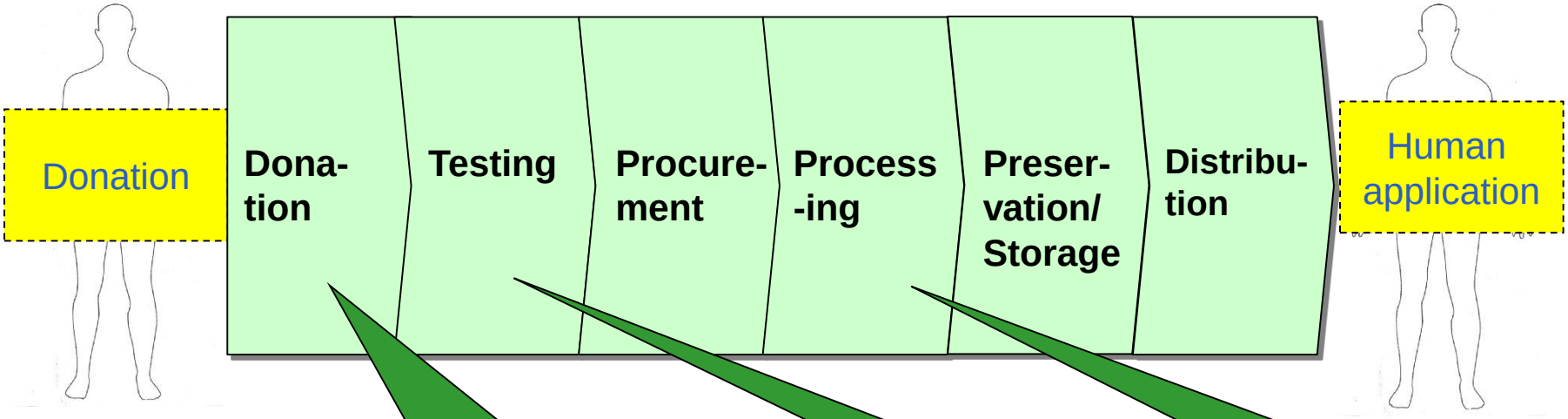
EU legal framework to ensure access to safe therapies: requirements set at 3 levels



ⓐ **Professionals**

- Selection/deferral, consent…
- HIV, Hepatitis B, Hepatitis C..
- Quality requirements (incl inactivation)

ⓑ **National Competent Authorities**

- Oversight: authorisation, inspection, vigilance, traceability,…

ⓒ **European Commission**

- EU-level support: networking, IT systems (e.g., rapid alert), …

Medical devices and *in vitro* diagnostics

Three Directives are being replaced by two new Regulations:

- Regulation (EU) 2017/745 on medical devices (date of application 26 May 2021)
- Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (date of application 26 May 2022)

Manufacturer has the obligation to demonstrate the device is safe and performs as intended. Conformity assessment for all but lowest risk devices is via certification by notified bodies

Many areas of implementation:

- Notified bodies oversight
- Clinical/performance evaluation and investigation
- Vigilance
- New Eudamed database and unique device identifier system
- Market surveillance
- Borderline and classification
- Standards
- Nomenclature
- Expert panels
- For IVDs, EU reference labs
- International
- New technologies

European Commission's medical devices website

HTA

Directive 2011/24 Cross-border healthcare, Article 15

- HTA Network (Strategic) + EUnetHTA Joint Action (Scientific and technical/2017-2021)

Commission Proposal for a Regulation strengthening EU cooperation on HTA (2018/0018(COD))

- provides for a sustainable legal framework for EU cooperation on HTA;
- focuses on clinical aspects of HTA activities, supports joint work (joint assessments, joint scientific consultations, horizon scanning) on innovative medicines and some high risk medical devices;
- facilitates additional voluntary joint work;
- under co-decision procedure, significant progress during DE and PT presidencies;
- EU4H funding earmarked for step-wise preparation and implementation of the new HTA legal framework.

European Commission

Thank you for your attention

Health and Food Safety