Summary notes:

European Commission's Webinar

EU4Health Programme 2021-2027

22 January 2021 10h-12h CET

1. Plenary session

Speakers:

- o Sandra Gallina, Director General, DG SANTE, European Commission
- o Matthew Hudson, Director Resource management and better regulation DG SANTE, European Commission
- o John F Ryan, Director Public Health, DG SANTE, European Commission
- o Andrzej Rys, Director Health systems, medical products and innovation DG SANTE, European Commission
- o Matthew Hudson, Director Resources and Better Regulation DG SANTE, European Commission

The full agenda of the event can be found here:
https://ec.europa.eu/health/sites/health/files/funding/docs/ev_20210122_ag_en.pdf

Due to technical difficulties of the European Commission streaming, the conference was not publicly broadcasted until 10h40 – the notes start then

Complete overview on the programme:

EU4Health programme official website: https://ec.europa.eu/health/funding/eu4health_en

Public health - challenges and priorities

John F Ryan, Director Public Health, DG SANTE, European Commission

Vaccination has been a priority for the European Commission (EC) for some time.

- Vaccination challenges:
  - 2018 Council Recommendation for cooperation on vaccine-preventable diseases
  - Promote vaccine uptake – better monitoring
  - Support neighbouring countries – diseases do not respect borders
  - Fight vaccine hesitancy, promote trust
  - Ensure a better production of vaccines – better forecasting and planning
  - Share research findings
  - Ensure a better production. The promotion of trust in the vaccine is also an important point
- Preparedness and response:
  - Regulation on serious cross-border threats. Strengthen preparedness, surveillance, reporting; declaration of an EU emergency situation
  - Stronger and more operational agencies
  - The EC has proposed an agency: the Health Emergency Response Authority (HERA). Reinforced in EU Pharmaceutical strategy
    Proposal and preparatory actions in 2021; operational in 2023.
- Health information and data:
  - Robust, timely and comparable data for policy-making and research
  - Sustainable health information infrastructure

  The shortages of data have been witnessed during the COVID-19 pandemic, although they were observed before, as well as the unavailability and inequality of health systems data. Strong comparable data bases are needed, the more accurate the information is, the more accurate the response can be.

  A part of the programme will make sure that the data is available, in order to have an evidence-based approach.
- International cooperation:
  - Support to global commitments
  - EU4Health will be open to third countries; specific provisions apply

  It is important that the approaches serve as an example, and that they are developed in other regions of the world. The programme also needs to benefit global health.

Health systems, medical products and innovation - challenges and priorities

Andrzej Rys, Director Health systems, medical products and innovation DG SANTE, European Commission

Health systems

<u>Main challenges</u>:

- COVID-19 related disruption to health systems:
    - Backlog of non-COVID care (outpatient visits, elective surgeries, diagnostics 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 behavioural risk factors for health
- Gaps in care accessibility (affordability, availability)
- Health workforce shortages (doctors, nurses)
- Health inequalities (by diseases, socio-economic)

<u>Proposed solutions</u>:

- 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
- Tacking 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

<u>Main challenges</u>:

- 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

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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 (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 digitalisation
- (Vaccines) need for swift reaction/emerging pathogens/safety and efficacity

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 organisational flexibility in EU transplant programs
    - Increase supply of blood, plasma and plasma-delivered 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 causes 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, especially in crisis situations
- Effective implementation if 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

EU4Health Programme implementation

Adrian Pereş, Head of EU4Health Task Force (EU4H TF), DG SANTE, European Commission

Key messages:

- This is the first EU4health webinar. It is the main EU financial instrument for health for the next 7 years.
- Following consultations, the EC will adopt a work programme with deadlines and details. It will include consultation with relevant stakeholders. In the future the EC will be interacting more and more with stakeholders. Their contribution will be used to formulate the priorities.
- Once adopted, the regulation will establish a steering group which will be consulted by the EC. It will also ensure consistency between the programme and health policies in MS. It will inform the EP on the proceedings.
- The annual programme will then be adopted.
- The first work programme is expected to be adopted the second quarter of the year, with a budget of 300 million euros.
- Many of the actions to be launched in 2021 will focus on the response on the COVID-19 pandemic, but the programme will also support the upcoming EU plan for cancer.
- A minimum 20% of the budget will be used for health promotion and prevention, a maximum of 12.5% for global commitments, and a maximum of 8% for administrative expenses to implement the programme.
- HADRA will soon be established and will be responsible for the work programme implementation, with a strong control.
- The EC will regularly evaluate the programme, and may develop additional indicators if necessary.
- **The programme is not adopted yet, still a long way to go.**