United immunising against COVID-19: when policy meets science

Webinar 1: Starting shot for vaccines

Tuesday 20 April I 16:00 – 17:00 CET

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EU role in vaccination for COVID-19

- Public health policy is a Member State competence
- Exceptions for cross border health threats where legislation exists (surveillance, alert, risk assessment and risk management coordination)
- EU pharmaceutical legislation for evaluation and authorisation of medicines, including vaccines (and areas included in Article 168 of the Treaty)
- Supported by several agencies especially European Medicines Agency (EMA) and European Centre for Disease Prevention and Control (ECDC)

EU Vaccination Strategy:
Objectives

- 17 June 2020 – Endorsed by all Member States
- Accelerate **development**, **manufacturing** and **deployment** of vaccines against COVID-19
- Ensure **quality, safety** and **efficacy** of vaccines
- Secure **swift and equitable access** to them for Member States and their populations while leading the global solidarity effort

European Commission

EU Vaccination Strategy

- **Securing the production of vaccines sufficient supplies** through Advance Purchase Agreements (APA) with vaccine producers via the Emergency Support Instrument

- **Adapting the EU's regulatory framework and making use of existing regulatory flexibility** to accelerate the development, authorisation and availability of vaccines *at scale needed*

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EU Vaccination Strategy:

What has been achieved so far

- To date, 4 safe and effective vaccines against COVID-19 have been authorised for use in the EU following positive scientific recommendations by the European Medicines Agency:
  - BioNTech-Pfizer
  - Moderna
  - AstraZeneca
  - Johnson & Johnson

- Contracts have been concluded with 6 promising vaccine developers, securing a portfolio of more than 2.6 billion doses.

- At the same time, the Commission has started work to anticipate and tackle new variants of the virus and to rapidly develop and produce on a large-scale vaccines effective against those variants.

EU Vaccination Strategy:

The Commission has also concluded exploratory talks with

- Novavax with a view to purchasing up to 200 million doses, and
- Valneva with a view to purchase up to 60 million doses.

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Vaccine Delivery

- In line with the EU vaccine strategy, once authorised and produced, each vaccine will be available to Member States at the same time and at the same conditions

- The distribution will start progressively, and the first doses will go to the priority groups identified by Member States (e.g. healthcare professionals, persons over 60 years of age)

- For most contracts concluded, the majority of delivery is foreseen to be completed in 2021.

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Vaccine Delivery

14 April – President von der Leyen announced negotiations with BioNTech-Pfizer for a third contract which will foresee the delivery of 1.8 billion doses of vaccine over the period of 2021 to 2023.

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Communication from 17 Feb 2021 – “HERA incubator”

- Proposes immediate action to prepare Europe for the increased threat of coronavirus variants
- It is the new **European bio-defence preparedness plan against COVID-19 variants called “HERA Incubator”**
- It will work with researchers, biotech companies, manufacturers and public authorities in the EU and globally to
  - detect new variants,
  - provide incentives to develop new and adapted vaccines,
  - speed up the approval process for these vaccines,
  - ensure scaling up of manufacturing capacities.

HERA Incubator - Focus on 5 key action areas

Rapid detection of new variants

- Sequencing capacities
- Exploring use of detection assays
- Data sharing and exchange
- Wastewater monitoring
- Support to low income countries

Swift adaptation of vaccines

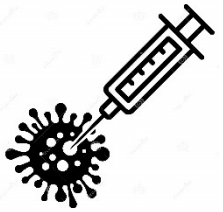
- Bringing together research and evidence on VOC
- Aligning research with existing/new vaccines and their technologies
- Vaccine development for children and adolescents

Setting up a EU Clinical Trials network

- Launch of VACCELERATE
- Ensure MS involvement
- Streamline the process between clinical trials and the regulatory approval process

Fast tracking of regulatory vaccine approval process

- Amending the regulatory procedure to accelerate vaccine approval
- Amending EU pharmaceuticals legislation
- Ensuring support to manufacturers



Upscaling of vaccine production and swift delivery

- Creating the “EU-FAB” project
- Mapping of potential bottlenecks of vaccine production
- Exploring use of flexible production models
- Providing capacity support
- Facilitate technology transfer
- APAs

SOTEU 2020 – President von der Leyen

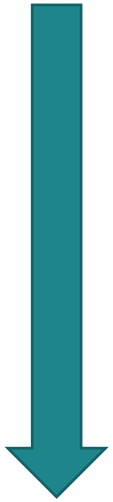
- We need to build **a stronger European Health Union**
- Opportunities for **strengthening EU preparedness and response** to serious cross-border health threats
- Set up a "**European BARDA**" – an agency for biomedical advanced R&D to support capacities and readiness to respond to cross-border threats and emergencies – whether of natural or deliberate origin

https://www.eppgroup.eu/newsroom/publications/a-european-solidarity-pact-against-the-coronavirus-pandemic

Mission of HERA

- Enable the EU and its Member States to rapidly deploy the most advanced medical countermeasures in the event of a health emergency
- Assembly of **ecosystems of public and private capabilities**
- This will be done by covering the **whole value chain** and by providing **end-to-end solutions**

Flexible and resourced financing & procurement capacities



Knowledge anticipation, generation and dissemination: horizon scanning, market intelligence, foresight

Development: late stage research, innovation and development

Production: flexible and scalable manufacturing capacities

Distribution: EU level stockpiling and distribution

Training

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