United immunising against COVID-19: when policy meets science

*Webinar 1: Starting shot for vaccines*

**Tuesday 20 April | 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
EU Vaccination Strategy

• Securing the production of vaccines sufficient supplies through Advance Purchase 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
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.
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.
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.
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

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

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
Thank you