



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Commission's role in the authorisation process and facilitation of roll-out vaccination

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An agency of the European Union



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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



Authorisation process – role of the Commission

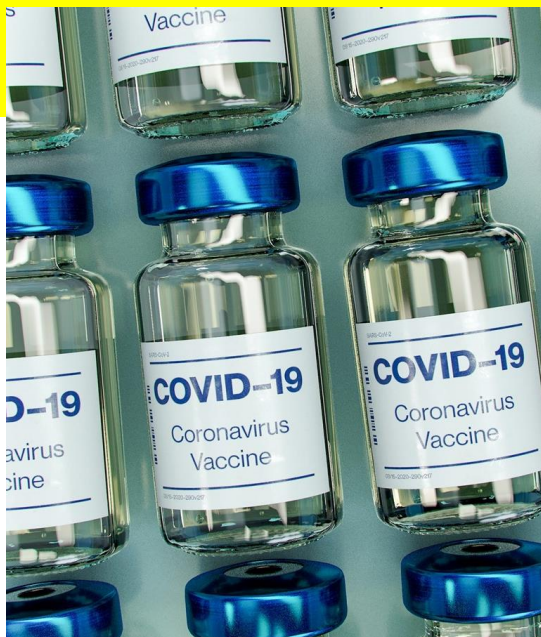


- First EMA (Committee for Medicinal Products for Human Use) carries out an **independent scientific assessment** of the application and submits its scientific opinion to the European Commission which is responsible for issuing a marketing authorisation that is valid for the entire EU



- Following EMA's positive recommendation: **EC verifies soundness of all supporting elements** e.g scientific justifications, product information, educational material to health care professionals, labelling, obligations for the vaccine developer, conditions for use, and possible obligations for MS
- EC also **ensures that necessary information is available to patients and health care professionals** across the EU in their national language.
- Before final decision: EC consults with the MS

Authorisation process – public information



- If qualified majority of MS in favour, the EC adopts a decision authorising the marketing of the vaccine
- EC notifies the developer
- Published in the Union register of medicinal products:
https://ec.europa.eu/health/documents/community-register/html/index_en.htm
- The vaccine can now be marketed everywhere in the EU.

Preparedness for COVID-19 vaccination strategies and vaccine deployment

15 OCTOBER 2020 COMMISSION COMMUNICATION

Key elements to be taken into consideration by Member States for their COVID-19 vaccination strategies:

- **capacity** of services to deliver COVID-19 vaccines
- **easy and affordable access** for target populations;
- **deployment of vaccines** with different characteristics and storage and transport needs
- **clear communication** on benefits, risks and importance of COVID-19 vaccines



COVID-19 vaccination strategies and vaccine deployment plans – survey among MS



- Many MS plan to use **existing vaccination services** and **current reserves of PPE**
- Many plan to stockpile equipment via **national or EU joint procurement procedures**
- The majority will offer COVID-19 vaccination **free of charge** for citizens
- The majority have an Immunization Information System or other type of registry, and are updating it to process COVID-19 vaccination data

Main concerns and issues affecting public confidence



TOPICS REPORTED BY NATIONAL FOCAL POINTS FOR VACCINATION TO EC:

- **Safety** and **efficacy**
- (Unknown and long-term) **side effects**
- **Speed** at which vaccines were developed
- **Thoroughness** of vaccine testing, and lack of **risk assessment**
- Lack of information and **disinformation** (fake news)
- Distinction between **mandatory** and **voluntary** vaccination
- **Country of origin** of the vaccine manufacturer



Ongoing communication activities aimed at building public confidence

- Sharing available **scientific data** and of the current situation
- **Monitoring** questions/doubts, and **fighting misinformation**
- Dialogue with **target groups** and continuous update of the general population
- Use of **social media**, **mass media**, television programmes and radios to circulate information
- Direct communication between **public health authorities** and **general practitioners (GPs)**



Additional resources

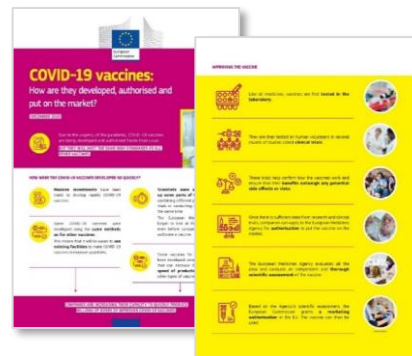
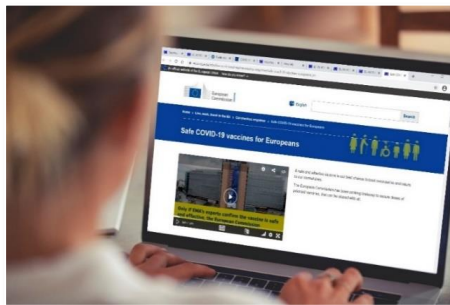
The [Commission has just published a new website](#) on safe and effective vaccination in the EU. The webpages are already translated in all EU languages

Factsheets: <https://we.tl/t-MWKdIkt7d8>

The [ECDC published a report](#) on key aspects related to the initial phases following the introduction of one or more COVID-19 vaccines

Videos and testimonials available for use:

[The authorisation video](#)
[Testimonial Peter Piot](#)
[Testimonial Nurse Delalić](#)
[Testimonial Patient Borislava](#)



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Thank you