



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Addressing misinformation on COVID-19 vaccines

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An agency of the European Union



# Outline

- 1 Misinformation during the COVID-19 pandemic
- 2 How EMA tackles misinformation
- 3 What are we communicating?
- 4 Transparency
- 5 Social media regular updates
- 6 Engagement and collaboration

# Misinformation during the COVID-19 pandemic

- Spreading of misinformation during the COVID-19 pandemic has **a large public health impact**
- It undermines trust in medicines – e.g. **limits uptake of life saving vaccines**
- **Social media** used to amplify an “infodemic” where massive amounts of information are shared and **disinformation and misinformation can easily spread**
- The spreading of false messages is also supporting the **polarisation of the public debate on topics related to COVID-19**
- It is critical to **address confusion or misleading information**



# How EMA tackles misinformation

- **Identification**
  - (Social) Media monitoring
  - Queries from members of the public
  - Collaboration with EU & international public health bodies
- **Two-way dialogue** to listen to the public's concerns & engagement
- **Address concerns proactively** - 'pre-bunking' or trying to address concerns before these can take hold and proliferate
- Make EMA's voice **heard** – **e.g. social media**
- **Communicate the fact-based science** supporting EMA regulatory decisions
- **Ensure full transparency** on EMA actions and decisions, and on data supporting such regulatory outcomes



## HOW EMA TACKLES MISINFORMATION

# Addressing misinformation on vaccine safety

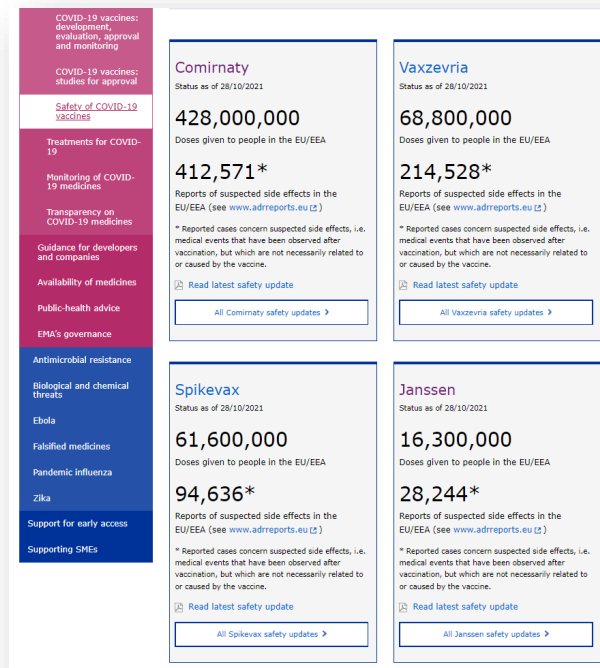


**False reports** relating to the number of side effects in Eudravigilance with COVID-19 vaccines

FALSE



- EMA is now producing an **overview of safety updates with statistics on reported side effects**:
  - contextualising number of suspected side effects with **doses given in the EU/EEA**
  - **response to stakeholders'** request for further transparency and enhancing visibility of safety updates, EMA



## HOW EMA TACKLES MISINFORMATION

# Addressing misconceptions about the pace of vaccine development and authorisation

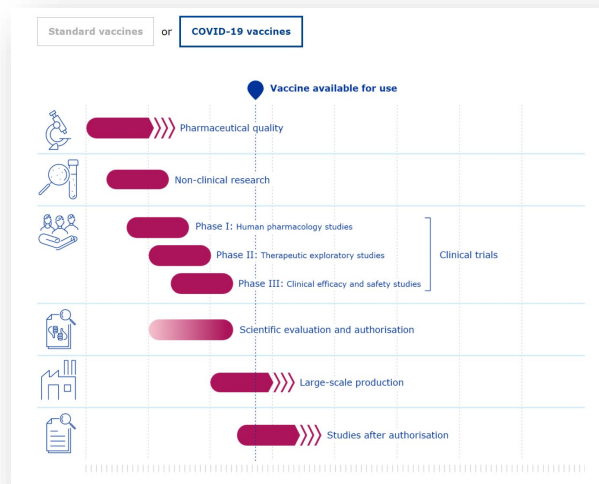


**Misinformation circulating** that there is insufficient data on the quality, safety and effectiveness on COVID-19 vaccines due to their rapid development and authorisation.

INCORRECT



- EMA has published information explaining how **development and authorisation can be condensed without compromising standards**
- There are **extensive study results** underpinning the authorisation of vaccines
- **Full transparency** on basis for authorisation (European Public Assessment Report & publication of clinical data)



# How are we communicating?

- **New information** on development & approval of COVID-19 vaccines – specifically targeting the general public
- **Responding to queries** from members of the public and media
- **Press, public meetings & social media** on key developments
- **Media interviews** with experts
- Providing content for [European Vaccination Information Portal](#) and supporting the European Commission
- EMA/Member States' **safety communications**



HOW ARE WE COMMUNICATING?

# Status of COVID-19 medicines

## COVID-19 vaccines in the EU

Status as of 17.11.2021



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### Currently under rolling review

- Gam-COVID-Vac (Sputnik V)
- COVID-19 Vaccine (Vero Cell) Inactivated (Sinovac)
- Vidprevtyn (Sanofi Pasteur)



### Marketing authorisation application submitted

- Nuvaxovid/NVX-CoV2373 (Novavax CZ AS)



### Authorised for use in the European Union

- **Comirnaty**
- **Spikevax** (previously COVID-19 Vaccine Moderna)
- **Vaxzevria** (previously COVID-19 Vaccine AstraZeneca)
- **COVID-19 Vaccine Janssen**

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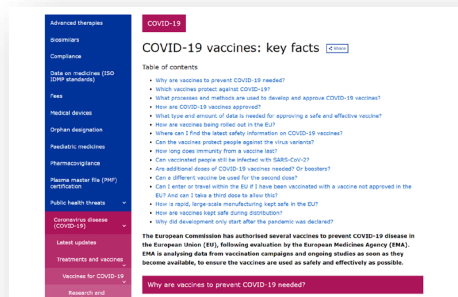
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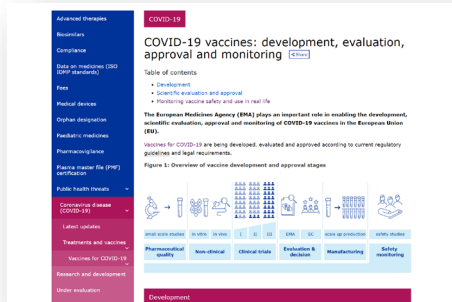


# HOW ARE WE COMMUNICATING?

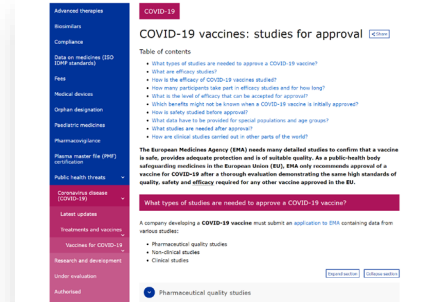
## Proactive materials on COVID-19 vaccines



- Key facts
- For general public
- Addresses commonly received questions



- Detailed information on how COVID-19 vaccines are developed, evaluated, approved and monitored post-marketing
- Professional audiences and general public
- Graphics to illustrate key concepts

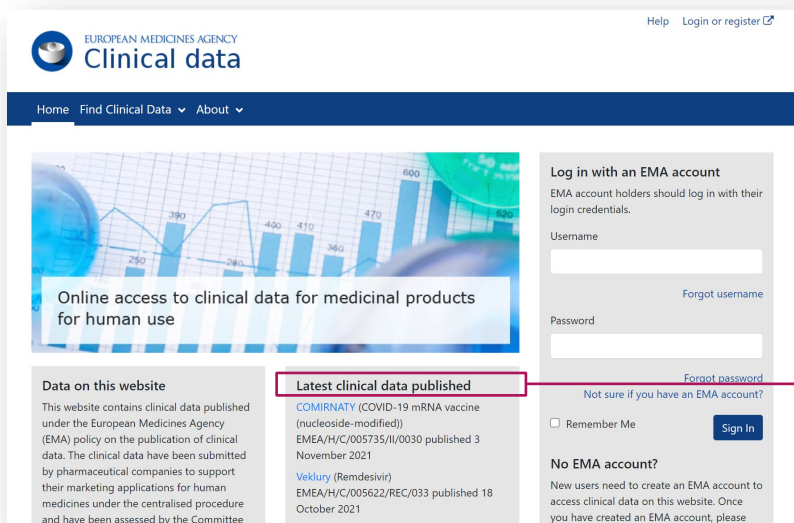


- Information on studies needed to approve a COVID-19 vaccine
  - Quality, Safety & Efficacy
- Professional audiences and general public

# TRANSPARENCY

## Publication of clinical data for all COVID-19 medicines

<https://clinicaldata.ema.europa.eu/web/cdp/home>



The screenshot shows the EMA Clinical Data website. At the top, there is a navigation bar with 'Home', 'Find Clinical Data', and 'About'. Below this, a large banner features a bar chart and the text 'Online access to clinical data for medicinal products for human use'. To the right of the banner is a login section titled 'Log in with an EMA account' with fields for 'Username' and 'Password', and links for 'Forgot username' and 'Forgot password'. Below the login section is a 'Sign In' button. On the left side, under 'Data on this website', it states that the site contains clinical data published under the EMA policy. On the right side, under 'Latest clinical data published', it lists three entries: COMIRNATY (COVID-19 mRNA vaccine), Veklury (Remdesivir), and COVID-19 Vaccine Janssen (Adenovirus type 26).

**Online access to clinical data for medicinal products for human use**

**Data on this website**  
This website contains clinical data published under the European Medicines Agency (EMA) policy on the publication of clinical data. The clinical data have been submitted by pharmaceutical companies to support their marketing applications for human medicines under the centralised procedure and have been assessed by the Committee

**Latest clinical data published**

- COMIRNATY** (COVID-19 mRNA vaccine (nucleoside-modified))  
EMA/H/C/005735/II/0030 published 3 November 2021
- Veklury** (Remdesivir)  
EMA/H/C/005622/REC/033 published 18 October 2021
- COVID-19 Vaccine Janssen** (Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein)  
EMA/H/C/005737/0000 published 26 July 2021

### Latest clinical data published

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**Veklury** (Remdesivir)  
EMA/H/C/005622/REC/033 published 18 October 2021

**COMIRNATY** (COVID-19 mRNA vaccine (nucleoside-modified))  
EMA/H/C/005735/0000 published 10 September 2021

**Veklury** (Remdesivir)  
EMA/H/C/005622/R/0015 published 18 August 2021

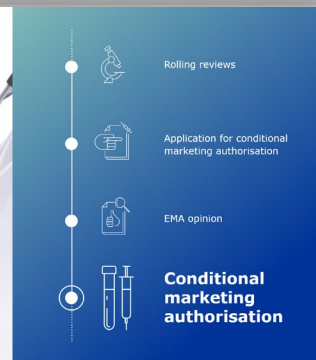
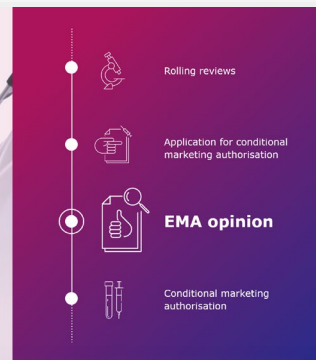
**Vaxzevria** (COVID 19 Vaccine (ChAdOx1 S [recombinant])) EMA/H/C/005675/0000 published 30 July 2021

**COVID-19 Vaccine Janssen** (Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein)  
EMA/H/C/005737/0000 published 26 July 2021

**In progress ✓**

- Booster and extra doses
- Vaccines for younger children

# EMA social media channels:



# Engagement and collaboration

## Who are we working with?

- Engaging with **patients and healthcare professionals** in EMA's pandemic task force, regular meetings, user testing information materials
- Working together** with [European Commission](#), ECDC, national medicines regulators
- Listening to **public concerns** on vaccines, to explain the science

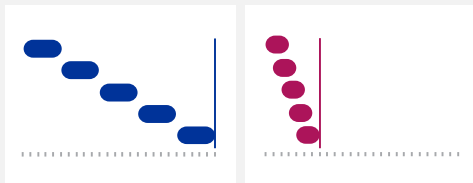
The screenshot shows the European Commission website with the title "Safe COVID-19 vaccines for Europeans". It features a video player showing a person in a lab coat and gloves handling a vial. To the right of the video, there is text stating: "The European Commission has secured up to 2.6 billion doses of COVID-19 vaccines so far and negotiations are underway for additional doses. Vaccine deliveries to EU countries have increased steadily and vaccination is gathering pace. The Commission is also working with industry to step up vaccine manufacturing capacity." Below this, it says: "At the same time it has started work to tackle new variants, aiming to rapidly develop and produce effective vaccines against these variants on a large scale. The HERA Incubator will help respond to this threat." Further down, it mentions: "The EU is committed to ensuring that safe vaccines reach all corners of the world. The Commission and EU countries have pledged over €2.2 billion to COVAX, the global initiative aimed at ensuring equitable access to COVID-19 vaccines, and are supporting vaccination campaigns in partner countries."

**Figures on vaccination**

Figure	Value
doses delivered in the EU	60.7 million
doses administered in the EU	43.1 million

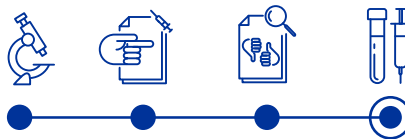
# EMA public meetings

**Listen to the public and stakeholder groups** on their needs, questions and any concerns, so that these can be considered in the relevant regulatory processes.



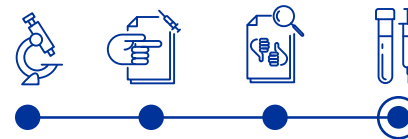
### #EMAPublicMeeting1 11 December 2020

EU regulatory process for approval of COVID-19 vaccines and EMA's role



### #EMAPublicMeeting2 8 January 2021

Basis for the approval and use of first COVID-19 vaccines & safety monitoring

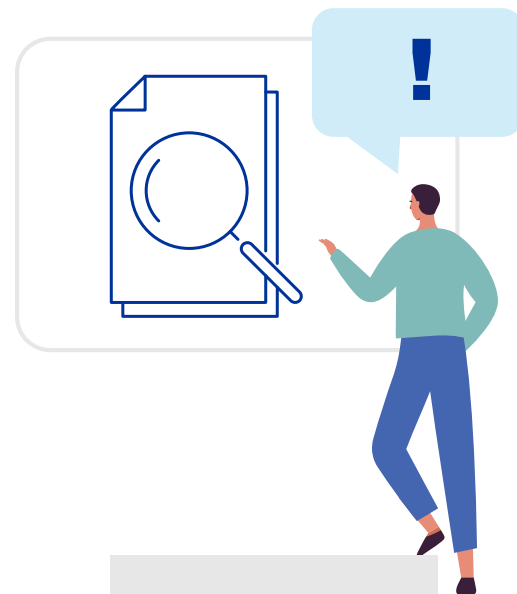


### #EMAPublicMeeting3 26 March 2021

Update on COVID-19 vaccines, and their expected impact at community level.

# Conclusions

- **Misinformation has serious consequences** which we all need to combat
  - get the facts from public health authorities
- **Reliable information, good and timely communication and transparency** are key
- **EMA provides transparency & access to clinical data** to understand the rationale behind important decisions
- **Engagement** is crucial:
  - actively listening to the public and our stakeholders
  - involving them in our activities



# Latest updates on EMA's corporate website:

## [COVID-19 pandemic](#)

Follow **#EMAPublicMeeting4**



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Code: **#EMAPublicMeeting4**

