EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update of approved and candidate COVID-19 vaccines and therapeutics

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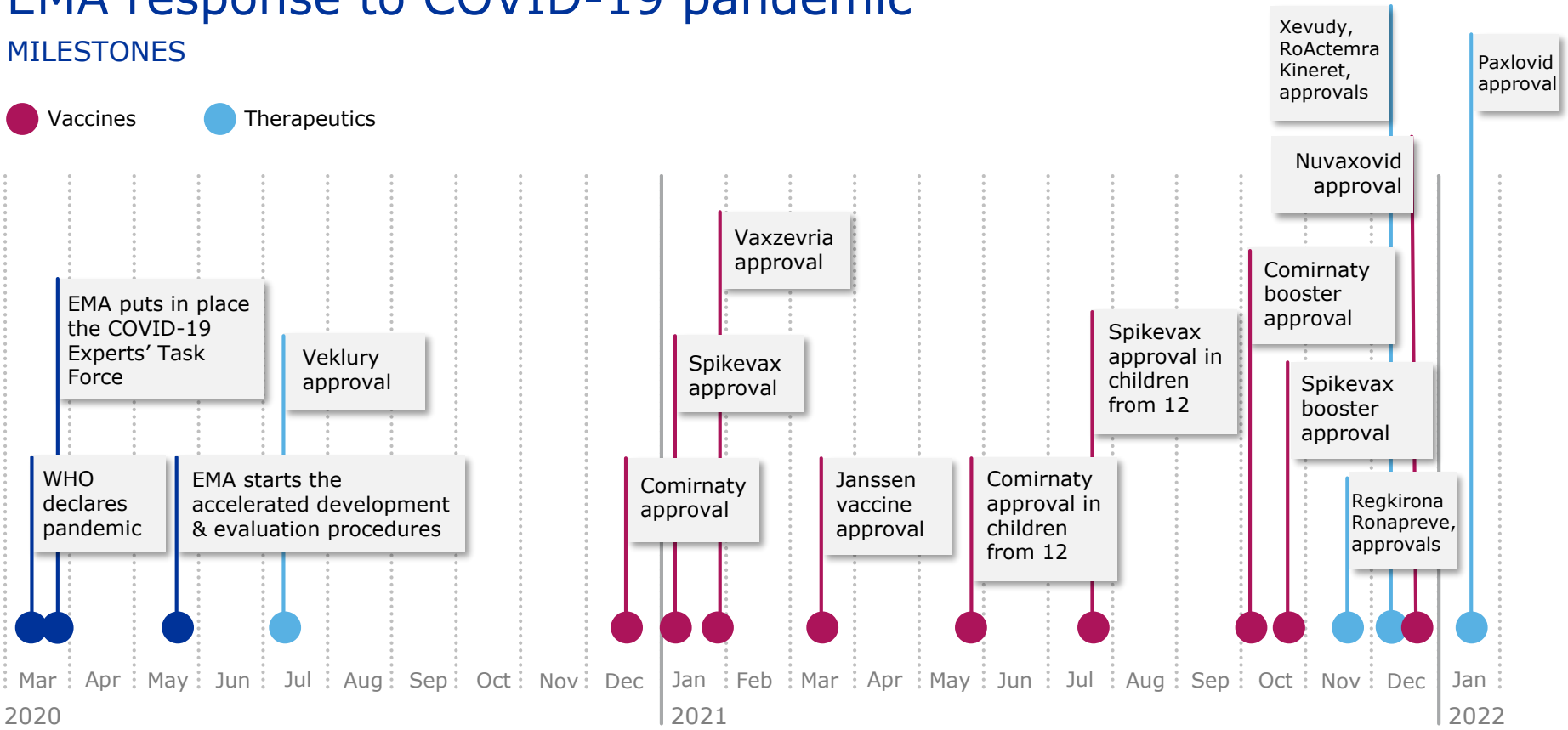
An agency of the European Union

Outline

- EMA response to the COVID-19 pandemic
- Effectiveness of COVID-19 vaccines – Omicron impact
- Need for booster doses
- Heterologous or mix-and-match vaccination
- COVID-19 vaccines in children
- COVID-19 vaccines in pregnancy
- Safety of booster doses
- Status of COVID-19 therapeutics in the EU
- Paxlovid – key aspects in clinical practice
- Conclusions

EMA response to COVID-19 pandemic

MILESTONES



Effectiveness of COVID-19 vaccines – Omicron impact

Vaccination remains a key component of the multi-layered approach needed to reduce the impact of Omicron

- In comparison with earlier variants, **Omicron infections appear to cause hospitalisation or ICU admission less frequently**.
- However, **the number of cases among older people has been increasing recently** in several EU/EEA countries, and this could result in severe cases and deaths.
- Available **vaccine effectiveness data are reassuring regarding the high protection conferred by current booster vaccines against severe disease and hospitalisation with Omicron**.
- Furthermore, **vaccines and boosters provide additional longer-term benefits** for individuals and society (e.g. preventing absence from work or education and post-acute COVID-19 syndrome).

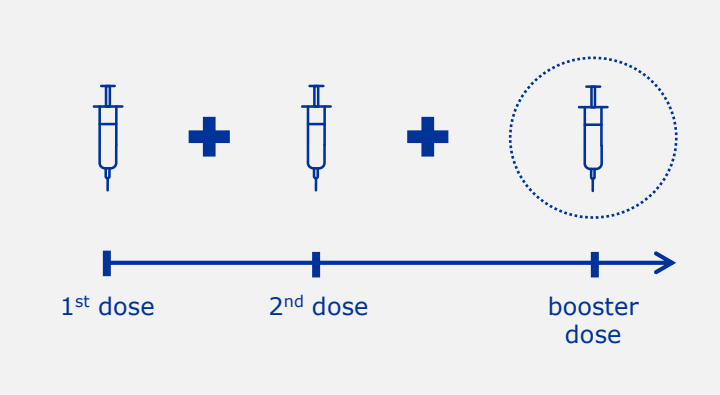
Assessment of the further spread and potential impact of the SARS-CoV-2 Omicron variant of concern in the EU/EEA, 19th update (europa.eu)

- **Unvaccinated people remain at much higher risk of severe outcomes compared to vaccinated people.**
- **Countries with lower vaccine uptake are expected to experience the highest disease burden.**

Need for booster doses

Booster doses restore protection against infection and disease and confer high levels of antibodies

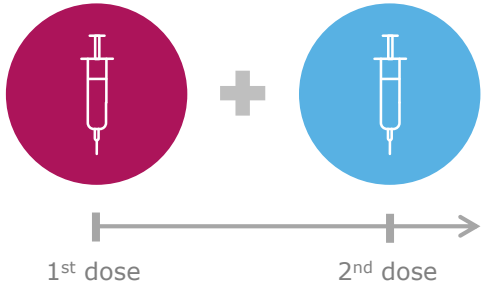
- **Timely administration of booster** doses according to national recommendations is expected to have **a significant effect in reducing the impact of COVID-19 caused by Omicron**
- Important to **increase uptake of the primary vaccination course in people who are currently unvaccinated or partially vaccinated**
- **Comirnaty and Spikevax**: booster approved after second dose in adults
- **Janssen**: booster approved from 2 months after first dose in adults
- **Extra dose of Comirnaty and Spikevax** approved for people with severely weakened immune systems aged 12 and older



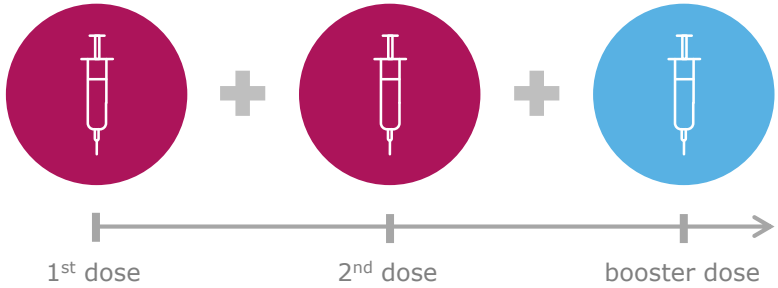
At present it is not possible to say how long the protection conferred by a third dose or booster dose will last

Heterologous or mix-and-match vaccination

Heterologous primary vaccination



Heterologous booster



- Heterologous primary vaccination used by several Member States
- The combination of vector viral vaccines and mRNA vaccines produces **good levels of antibodies against SARS-CoV-2** and a higher T-cell response than using the same vaccine (homologous vaccination) whether in the initial vaccination course or booster regimen
- The mix-and-match (heterologous) regimens are **generally well tolerated**

COVID-19 vaccines in children

Although severe COVID-19 and death remain rare among children, disease of all severities still occurs in this group

- Although children with underlying conditions are more vulnerable, healthy children represent **a large part of pediatric hospitalisations** in the EU (Delta)
- **Complications of COVID-19** in children can include **multisystem inflammatory syndrome (MIS-C)**. Children can also have **long-term consequences** of COVID-19, currently poorly understood.
- **COVID-19 vaccines approved in the EU for children** (including for younger children in the 5-11 group) because of a **positive benefit-risk balance.**
- **Data on the effectiveness of vaccines against the Omicron variant in children are still limited**. However, preliminary data from adults indicate COVID-19 vaccines remain effective against severe disease and hospitalisation caused by the Omicron variant.
- EMA is evaluating Comirnaty boosters for adolescents.

Currently limited data on impact of Omicron on MIS-C or 'long COVID' & how long vaccine protection in children lasts

COVID-19 vaccines in pregnancy

COVID-19 can be particularly dangerous for pregnant women and vaccination offers them protection

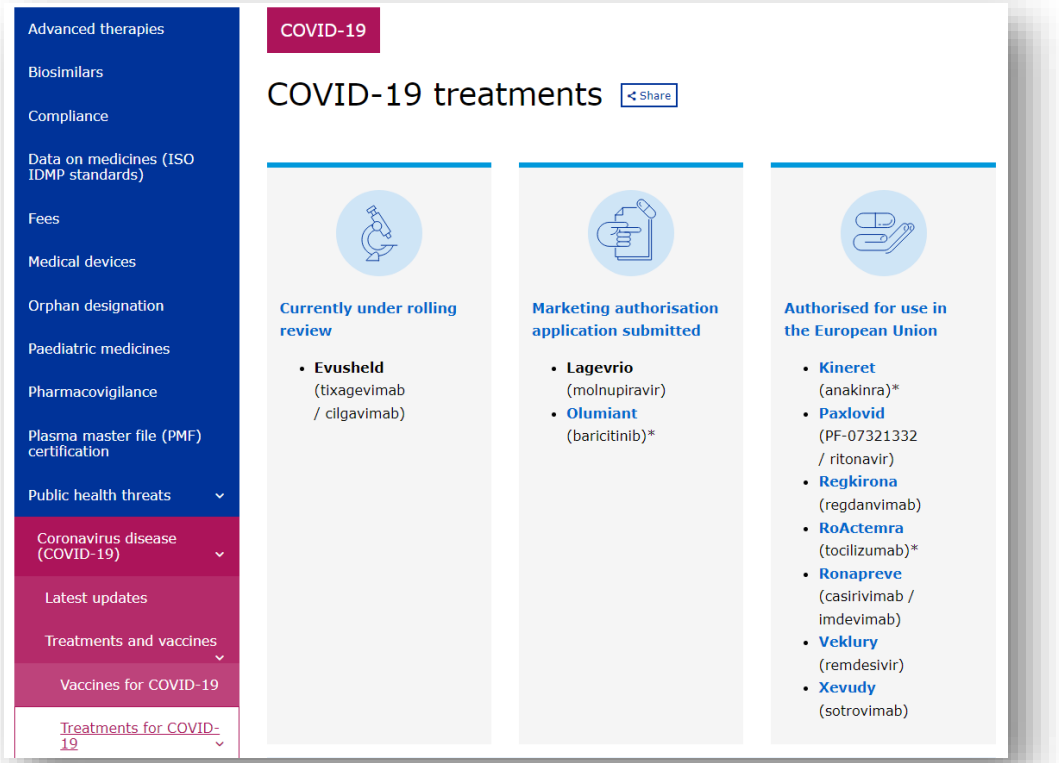
- mRNA vaccines shown to be **effective in preventing COVID-19** in this group
- Studies **on safety of mRNA** vaccines in pregnancy do not suggest any safety concern
- EMA's COVID-19 task force (ETF) undertook a detailed review of several studies involving around 65,000 pregnancies at different stages. The review did not find any sign of an increased risk of pregnancy complications, miscarriages, preterm births or adverse effects in the unborn babies following mRNA COVID-19 vaccination. Despite some limitations in the data, the results appear consistent across studies looking at these outcomes.

Safety of COVID-19 vaccines

This is the largest vaccination campaign ever and the safety profile of the vaccines is very reassuring

- Current data show that common side effects after booster are **similar to those after the second dose** for Comirnaty and Spikevax
- **Growing numbers** of people receiving booster, so far **no specific safety concerns** have been identified
- The risk of myocarditis/pericarditis or other very rare side effects after primary or booster vaccination are **carefully monitored**
- **Emerging data** (including data from the United States where **millions of children are vaccinated**) indicate that **COVID-19 vaccines are well tolerated in children**. Clinical trials previously carried out in children also showed that side effects of these vaccines are usually mild or moderate and go away in a few days.

Status of COVID-19 therapeutics in the EU



Therapeutics are being approved which will complement, but not replace, vaccines in the fight against COVID-19

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-treatments

Paxlovid – key aspects in clinical practice

First oral antiviral medicine for the treatment of COVID-19 in adults who do not require supplemental oxygen and at increased risk for progressing to severe disease

- Paxlovid contains **two active substances**, PF-07321332 and ritonavir, in **two different tablets**.
- Pivotal study showing rate of hospitalisation or death was 0.8% (8 out of 1,039) for patients who received Paxlovid, compared with 6.3% (66 out of 1,046) for those who received placebo. No deaths in the Paxlovid group versus 12 deaths[2] in the placebo group.
- Majority of patients in the **trial were infected with the Delta** variant. Based on laboratory studies, **Paxlovid is also expected to be active against Omicron** and other variants.

Paxlovid – key aspects in clinical practice

First oral antiviral medicine for the treatment of COVID-19 in adults who do not require supplemental oxygen and at increased risk for progressing to severe disease

- **Contraindicated in patients taking medicines highly dependent on CYP3A for clearance or potent CYP3A inducers** (for full details, see 4.3 SmPC).
- **Special warnings on risk of serious adverse reactions due to interactions with many medicinal products**, severe renal and hepatic impairment, hepatotoxicity and risk of HIV-1 resistance development (for full details, see 4.4. SmPC).
- No data on the use of Paxlovid in pregnant women to inform the drug-associated risk of adverse developmental outcomes; **women of childbearing potential should avoid becoming pregnant during treatment with Paxlovid** (for full details, see 4.6 SmPC).

https://www.ema.europa.eu/en/documents/product-information/paxlovid-epar-product-information_en.pdf

How EMA tackles misinformation

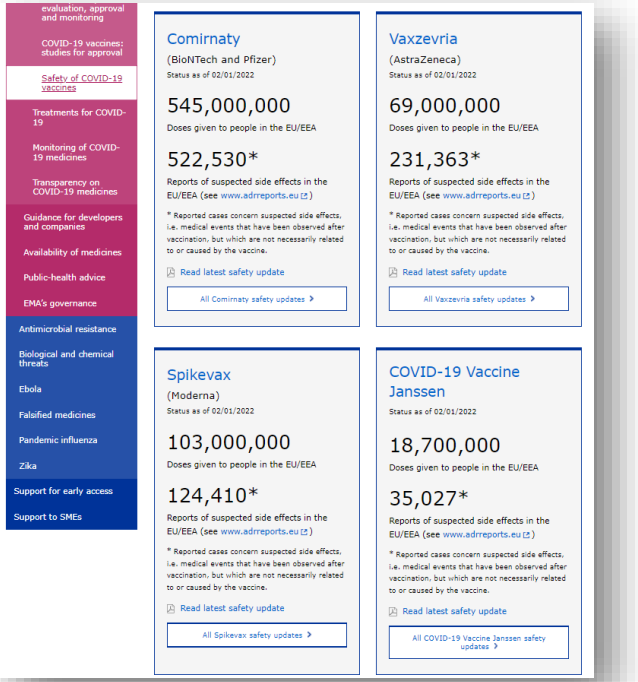
- **Identification**
  - (Social) Media monitoring
  - Queries from members of the public
  - Collaboration with EU & international public health bodies
- **Two-way dialogue** to listen to the public's concerns & engagement
- **Address concerns proactively** - 'pre-bunking' or trying to address concerns 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

Addressing misinformation on vaccine safety

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

FALSE

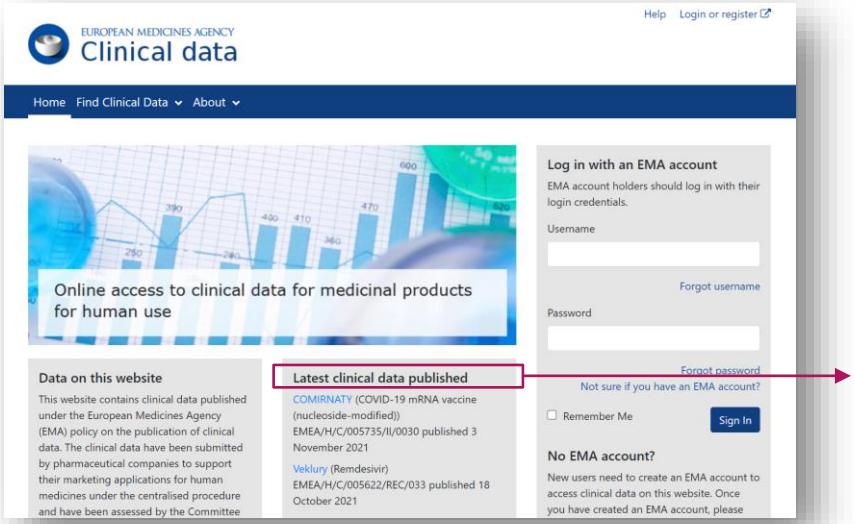
- EMA is now producing an **overview of safety updates with statistics on reported side effects**:
  - contextualising number of suspected side effects with **doses given in the EU/EEA**
  - **response to stakeholders'** request for further transparency and enhancing visibility of safety updates, EMA



TRANSPARENCY

Publication of clinical data for all COVID-19 medicines

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



Latest clinical data published

Spikevax (COVID-19 mRNA vaccine (nucleoside-modified)) EMEA/H/C/005791/II/0021 published 25 January 2022

COMIRNATY (COVID-19 mRNA vaccine (nucleoside-modified)) EMEA/H/C/005735/II/0030 published 3 November 2021

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

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

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

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

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

In progress √

- Booster and extra doses
- Vaccines for younger children
- Paxlovid

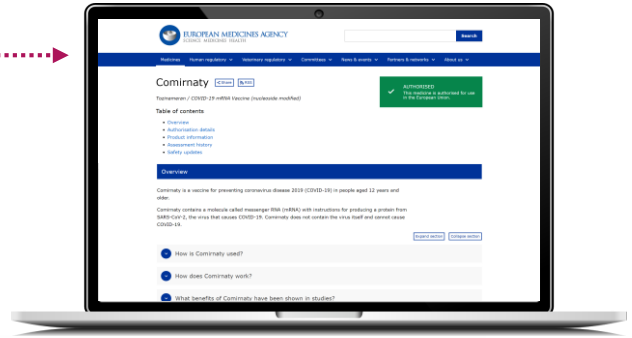
Conclusions (I)

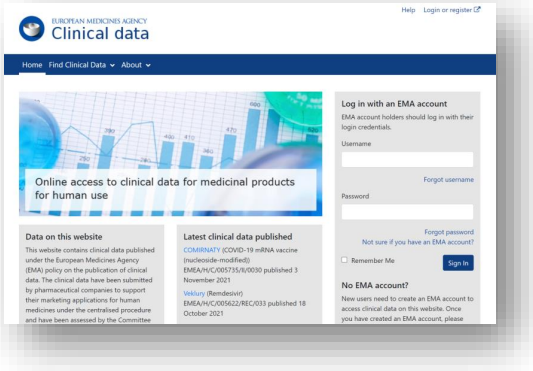
- Vaccines protect against the heavy burden of disease and death. **They remain a crucial tool in the fight against COVID-19**
- **Infections are very high in Europe** as a result of factors such as spread of Omicron variant, waning immunity and relaxation of social measures
- Vaccination coverage in some places is still low, leaving **many unvaccinated people vulnerable to severe disease**
- **Booster doses help restore the protection** of people who already had their primary cycle **including with Omicron**
- **Safe and effective therapeutics** will help in the fight against COVID-19**, but do not replace vaccination**
- EU citizens are encouraged to **get vaccinated and follow public health measures** recommended by authorities to keep themselves safe and infection levels low

Conclusions (II)

- **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

  https://clinicaldata.ema.europa.eu/web/cdp/home
- **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

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