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

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2. Effectiveness of COVID-19 vaccines
3. Need for booster doses
4. Safety of booster doses
5. Heterologous or mix-and-match vaccination
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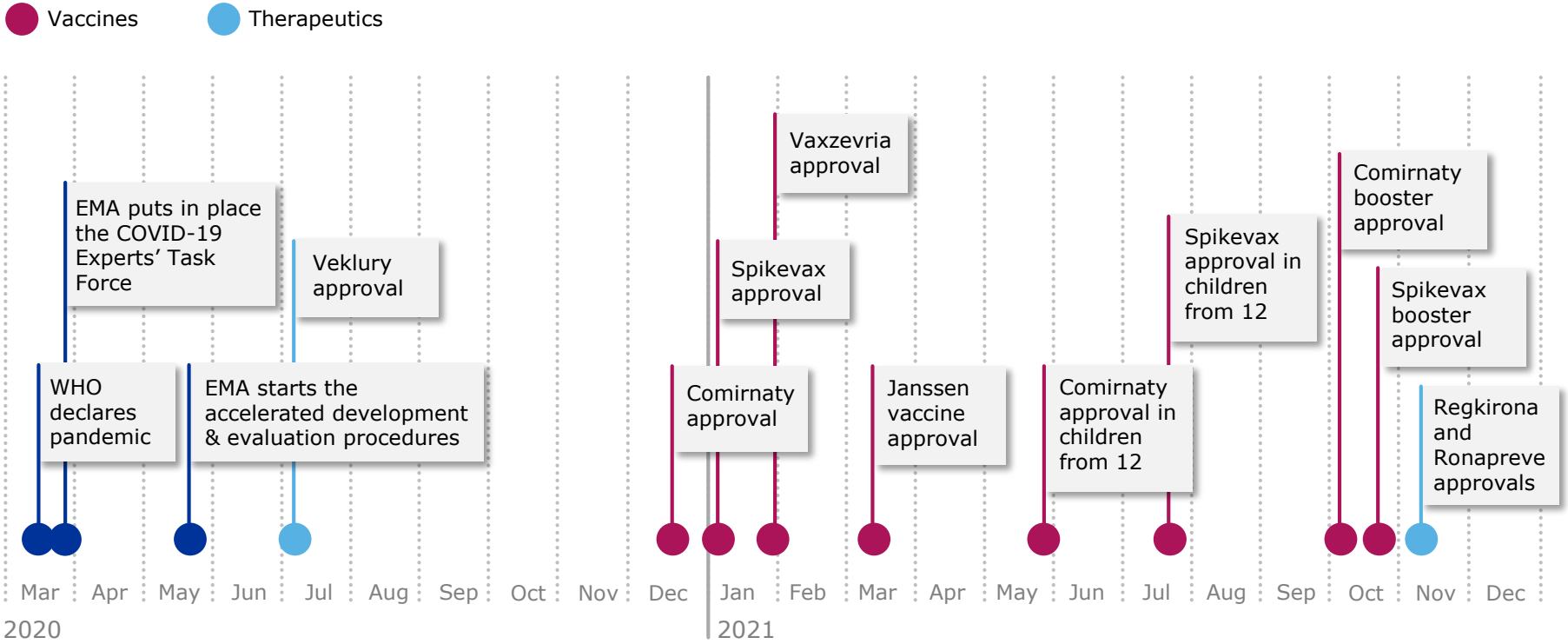
EMA response to COVID-19 pandemic

MILESTONES



Effectiveness of COVID-19 vaccines

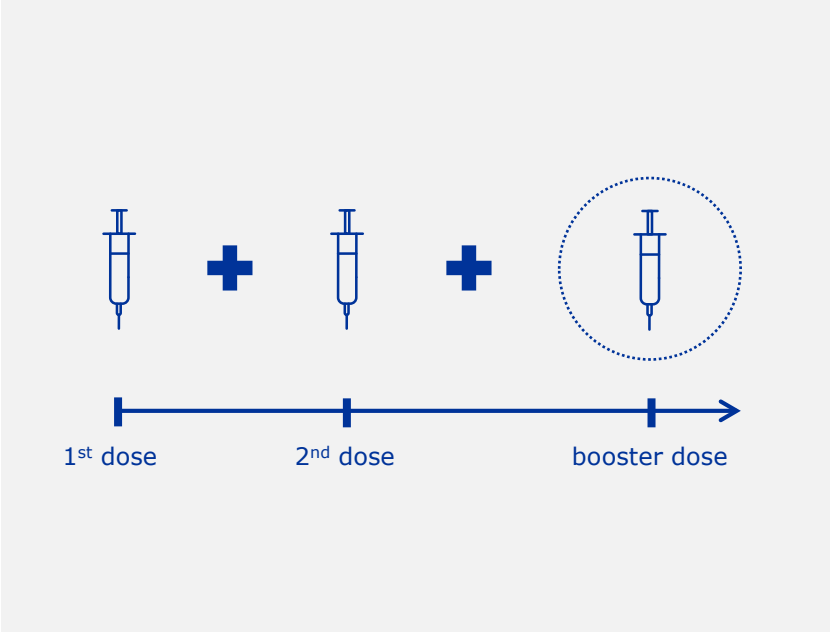
Vaccines have reduced the impact of the virus and remain the key tools to combat the pandemic

- Despite the Delta variant, vaccines remain effective, saving thousands from hospitalisation and death. However, there is still more to do:
  - Cases of infection are **rising in Europe**, and hospitalisations are growing
  - Most hospitalisations and deaths are **seen in unvaccinated people, but some are also vaccinated**
- There is evidence that protection is **waning over time**
- This is not unexpected, and people may need to restore their protection with a **booster**

Need for booster doses

Data show booster doses restore protection against infection and disease and confer high levels of antibodies

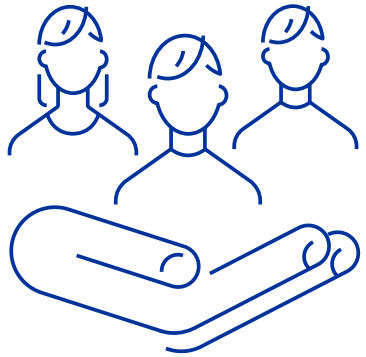
- Most EU Member States are **already giving boosters**
- **Comirnaty and Spikevax**: booster approved from 6 months after second dose in adults
- **Janssen**: evaluation ongoing for booster from 2 months after first dose in adults
- **Extra dose of Comirnaty and Spikevax** approved for people with severely weakened immune systems aged 12 and older



Safety of booster doses

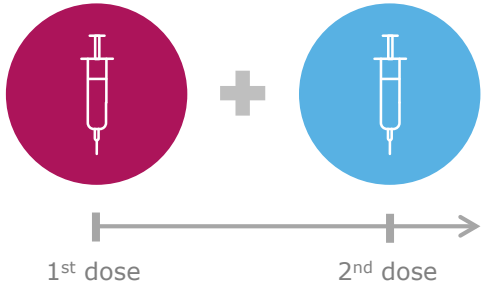
This is the largest vaccination campaign ever and the safety profile of the vaccines is very reassuring

- 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 booster are **carefully monitored**

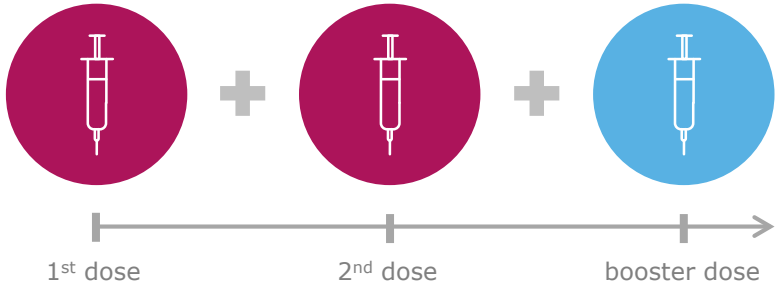


Heterologous or mix-and-match vaccination

Heterologous primary vaccination



Heterologous booster



- Heterologous primary vaccination used by several Member States. Data show **good immune response** and **relevant protection**
- Heterologous boosting shown in studies to provide **good immune response**
- EMA is preparing recommendations with respect to mix-and-match approach

COVID-19 vaccines in children

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

- High transmission results in increased hospitalisations in **children of all ages**
- Although children with underlying conditions are more vulnerable, healthy children represent **most pediatric hospitalisations** in the EU
- After COVID-19, children can suffer from **Multisystem Inflammatory Syndrome**. This can be severe with admission to intensive care in up to 70% of cases
- Children can also be exposed to the **long-term consequences** of COVID-19, currently poorly understood

COVID-19 vaccines in children

- Comirnaty and Spikevax approved for use in **children from 12 years old**
- **For younger children:**
  - **Comirnaty** from today also approved in **5-11 year olds**
  - **Spikevax** under review in **6-11 year olds**
- Member States to decide on vaccines in children as part of their vaccination campaigns, but EMA is evaluating data to support national authorities

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

Rapid regulatory processes used in EU

Same quality, safety and efficacy standards

Rolling review

Application for (conditional) marketing authorisation

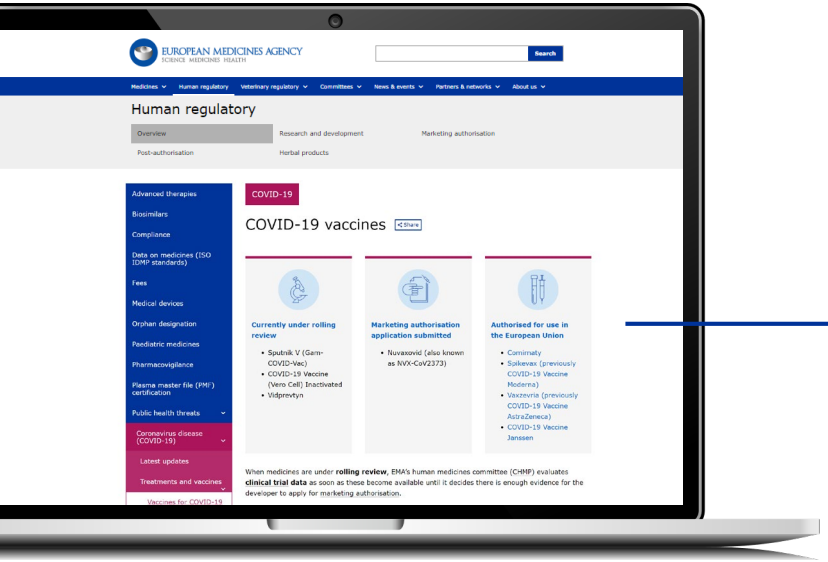
EMA opinion

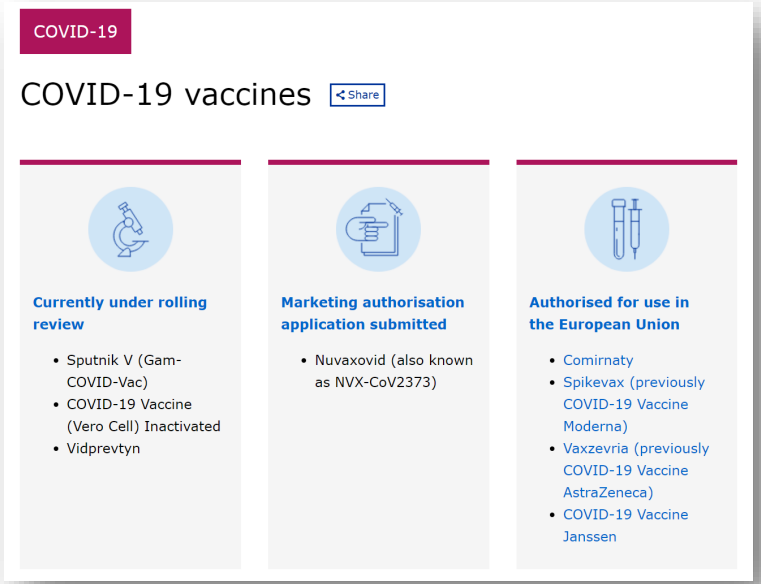
(Conditional) marketing authorisation

CMA for **Spikevax, Comirnaty, Vaxzevria** recently renewed for **another year**

Overview of COVID-19 vaccines in the EU

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





Nuvaxovid (NVX-CoV2373)

- **First protein-based** vaccine undergoing evaluation for marketing authorisation
- Contains tiny particles made from a laboratory-grown version of the spike (S) protein found on the surface of SARS-CoV-2 coronavirus
- Also contains an **adjuvant** to help strengthen the immune response to the vaccine
- Start of **final assessment** after rolling review completed: 17/11/2021
- Company: Novavax

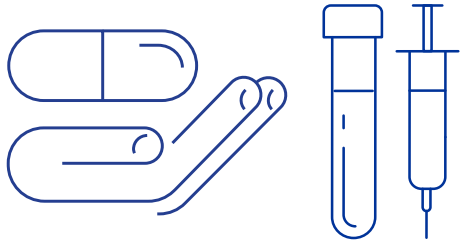
Under rolling review by EMA

	Start of rolling review	Type	Company
Sputnik V	4 March 2021	Adenovirus vaccine	Gamaleya National Centre of Epidemiology and Microbiology
COVID-19 Vaccine (Vero Cell) Inactivated	4 May 2021	Inactivated (killed) vaccine	Sinovac Life Sciences Co. Ltd
Vidprevtyn	20 July 2021	Protein-based vaccine	Sanofi Pasteur

The role of COVID-19 therapeutics

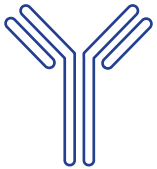
Therapeutics are being approved which will complement, but not replace, vaccines in the fight against COVID-19

- New/repurposed therapeutics could **treat or prevent COVID-19**
- They are expected to provide an **additional tool** to reduce the burden of disease associated with COVID-19
- Therapeutics are particularly relevant for **vulnerable groups** and people who **do not respond adequately to vaccination**



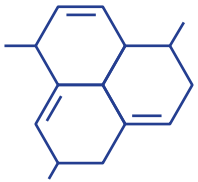
Overview of COVID-19 therapeutics in the EU

What are they and how do they work?



Biological medicines

- Neutralizing monoclonal antibodies: made of proteins that attach to the virus, stopping it from entering the body's cells thus preventing spread of the virus and severe symptoms
- Others work as immunomodulatory agents, they reduce the activity of the body's immune system, reducing inflammation and respiratory failure



Chemical medicines

- Antiviral enzyme or polymerase inhibitors: block cell processes that can prevent and disrupt multiplication of the virus inside the cells
- Some work as immunomodulatory agents helping to stabilise abnormal immune responses

Overview of COVID-19 therapeutics in the EU

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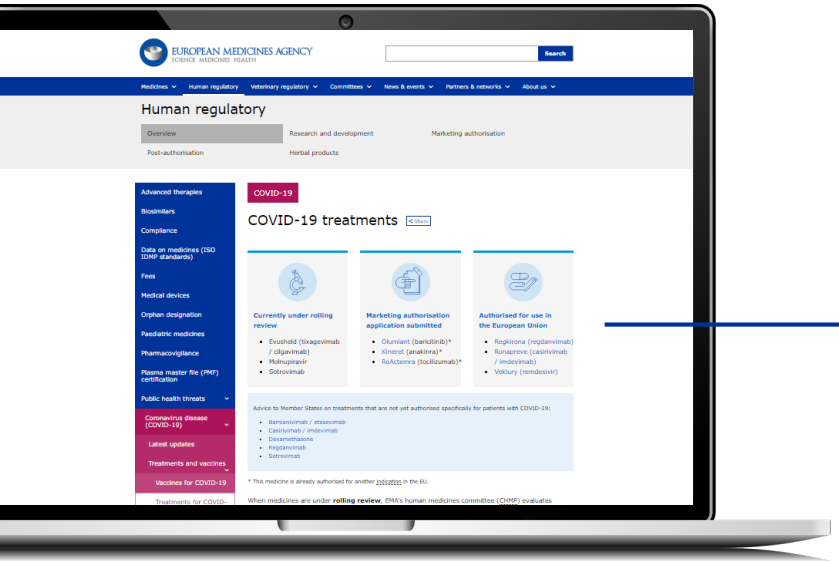

COVID-19

COVID-19 treatments

Share

Currently under rolling review

- Evusheld (tixagevimab / cilgavimab)
- Molnupiravir
- Sotrovimab

Marketing authorisation application submitted

- Olumiant (baricitinib)*
- Kineret (anakinra)*
- RoActemra (tocilizumab)*

Authorised for use in the European Union

- Regkirona (regdanvimab)
- Ronapreve (casirivimab / imdevimab)
- Veklury (remdesivir)

Advice to Member States on treatments that are not yet authorised specifically for patients with COVID-19:

- Bamlanivimab / etesevimab
- Casirivimab / imdevimab
- Dexamethasone
- Regdanvimab
- Sotrovimab

* This medicine is already authorised for another indication in the EU.

COVID-19 therapeutics approved in the EU

3 therapeutics **authorised in the EU**

- **Veklury (remdesivir)** - approved for the **treatment of COVID-19** in people from 12 years of age with pneumonia requiring extra oxygen
- **Regkirona (regdanvimab)** – approved for the **treatment of COVID-19** in adults at increased risk of severe disease
- **Ronapreve (casirivimab / imdevimab)** – approved for the **prevention of COVID-19** in people from 12 years of age, and the **treatment of the disease** in people from 12 years of age at increased risk of severe disease

Marketing authorisations under evaluation

Repurposed therapeutics

	Start of evaluation	New / Repurposed	COVID-19 indication
Olumiant (baricitinib)	29 April 2021	Repurposed	**To treat COVID-19** in hospitalised patients from 10 years of age who require extra oxygen
Kineret (anakinra)	19 July 2021	Repurposed	**To treat COVID-19** in adults with pneumonia at increased risk of developing severe respiratory failure
RoActemra (tocilizumab)	16 August 2021	Repurposed	**To treat COVID-19** in hospitalised adults already receiving corticosteroids, needing extra oxygen or mechanical ventilation

Marketing authorisations under evaluation

New therapeutics

	Start of evaluation	New / Repurposed	COVID-19 indication
Xevudy (sotrovimab)	18 November 2021	New	**To treat COVID-19** in people from 12 years of age at increased risk of severe disease
Lagevrio (molnupiravir)	23 November 2021	New	**To treat COVID-19** in adults at increased risk of severe disease

Under rolling review by EMA

	Start of rolling review	New / Repurposed	COVID-19 indication
Tixagevimab/ cilgavimab	14 October 2021	New	**To prevent COVID-19** in adults

Lagevrio / Paxlovid

- While a more comprehensive rolling review is ongoing, EMA has provided advice on the **use of Lagevrio (molnupiravir)** for the treatment of COVID-19 in adults who do not require extra oxygen and who are at increased risk of severe COVID-19
- EMA is also reviewing currently available data on the **use of Paxlovid** for the treatment of COVID-19
- These reviews will support national authorities who may decide on early use of these treatments, for example in emergency settings, prior to marketing authorisation

Conclusions

- Vaccines protect against the heavy burden of disease and death. **They remain the crucial tool in the fight against COVID-19**
- **Infections are growing in Europe** as a result of factors such as spread of the Delta 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** can help restore the protection of people who already had their primary cycle
- 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