EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

COVID-19 vaccines safety monitoring

Update on emerging data since EU authorisations

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An agency of the European Union

Outline

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Safety monitoring of vaccines – why?

WHY DO WE NEED TO MONITOR SAFETY AFTER APPROVAL?

- All medicines, including vaccines, have **benefits and risks**
- **At the time of approval:** evidence comes mainly from controlled, randomised clinical trials
- **After approval:** medicines will be used in real conditions by a far larger population
- **Safety monitoring** after approval is important **to identify** any new or changing risk as quickly as possible, and **take action**
- Due to large number of people vaccinated in a short time we need to ensure safety monitoring **reacts quickly**
- **Additional resources** are being mobilised to closely monitor safety and assess new information

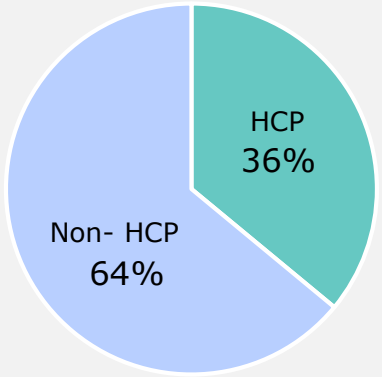
Safety monitoring of vaccines

HOW TO REPORT A SIDE EFFECT?

- **Anyone** can report a suspected side effect to their national authority or the vaccine manufacturer
- Consult the appropriate authority from the list of national medicines regulatory authorities in the EEA for information on how to report a side effect
- Reports are sent to **EudraVigilance, the European database** of suspected side effects

Who has reported?

Status as of 11.11.2021 – European Economic Area (EEA)



Healthcare professionals (**440,869 reports**)

Non-healthcare professionals (**783,257 reports**)

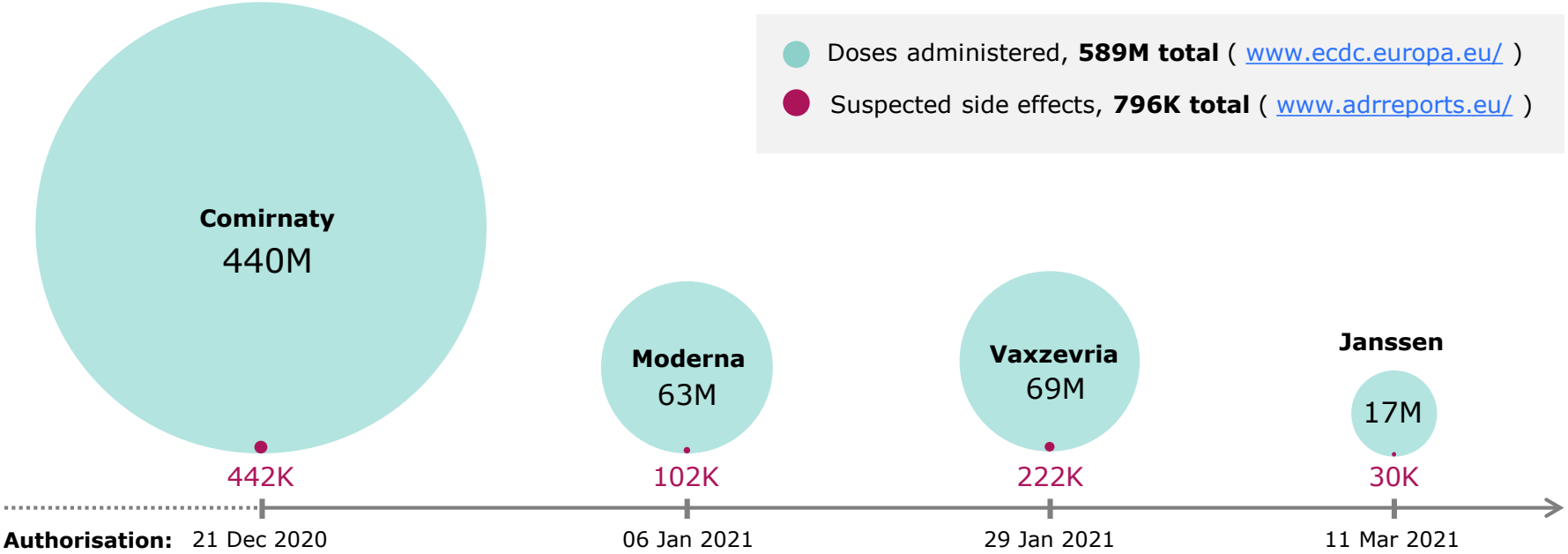
Source: EudraVigilance

What is EudraVigilance telling us?

REPORTS OF SUSPECTED SIDE EFFECTS IN THE CONTEXT OF USAGE

Status as of 11.11.2021 – European Economic Area (EEA)

Numbers of **suspected** side effects need to be put into context of **how many** people have been vaccinated and **how long** the vaccine has been on the market.

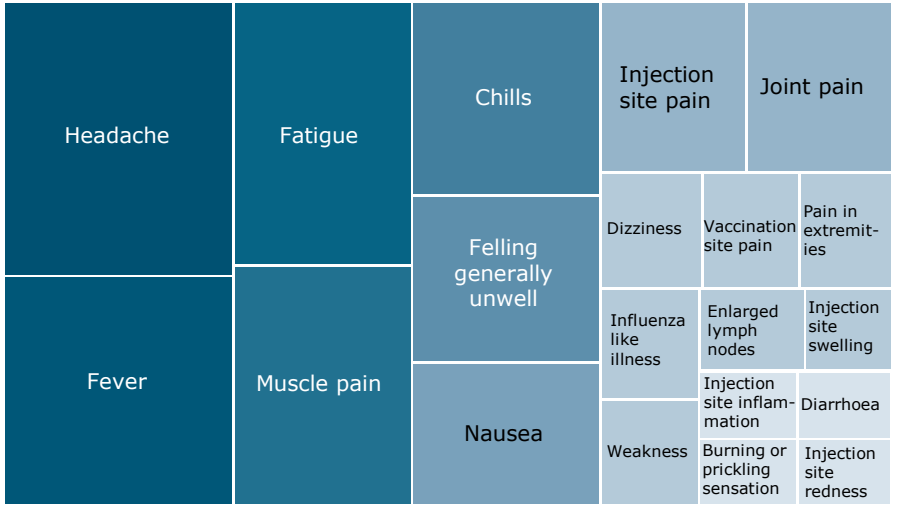


Do COVID-19 vaccines remain safe?

- The safety of vaccines is **continuously monitored**, with **safety updates** regularly provided to the public
- COVID-19 vaccines, with over 589 million doses administered in the EU/EEA, continue to show a **very reassuring safety profile**
- As with all medicines, **side effects do occur**, but these are **usually mild**, and are **outweighed** by far **by the benefits** that vaccines bring against severe disease and death
- EMA will take necessary action if any new safety issues are identified

The most common suspected side effects reported **are already known;** they are mild and moderate and improve within a few days from the vaccination

Status as of 11.11.2021



Are there new or changing risks?

FOR VAXZEVRIA AND JANSSEN

Unusual blood clots with low blood platelets
(thrombosis and thrombocytopenia, TTS):

- Through the EU pharmacovigilance system, this new risk was identified for Vaxzevria and prompted rapid action to mitigate the risk
- EMA's Safety Committee, PRAC, proactively assessed the same potential risk for Janssen, acting before its rollout in the EU
- TTS cases remain very rare

What you need to be aware of, after vaccination:

Go to a doctor immediately if you experience severe or persistent headache, blurred vision, confusion, seizures, shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain, unusual skin bruising or pinpoint round spots beyond the site of vaccination within three weeks of vaccination, as these could be signs of TTS.

Are there new or changing risks?

FOR mRNA VACCINES

Myocarditis and pericarditis:

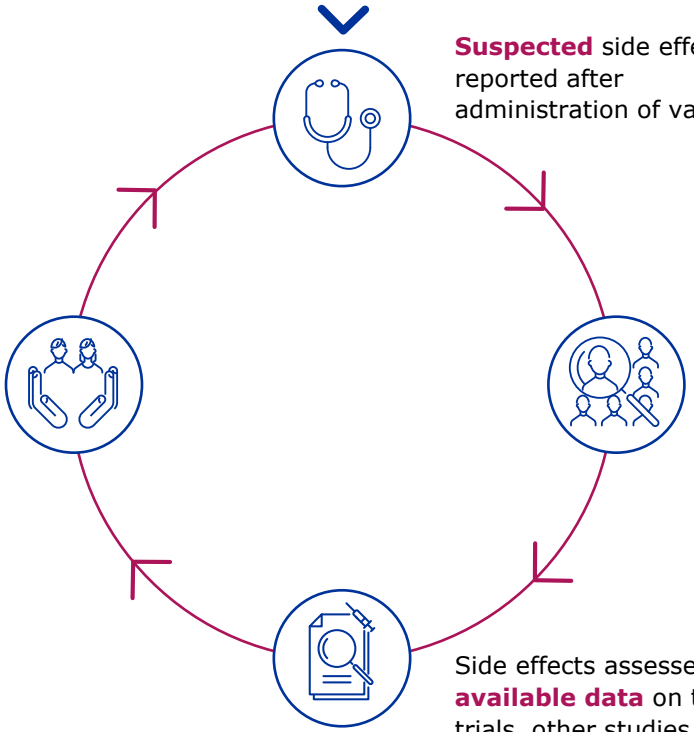
- Very rare cases of myocarditis and pericarditis (inflammatory conditions of the heart) observed following vaccination with mRNA vaccines
- These cases have primarily occurred within 14 days after vaccination, more often after the second dose and in younger male vaccinees
- The course of these conditions is generally mild and responding to treatment

What you need to be aware of, after vaccination:

- Go to a doctor immediately if breathlessness, strong heartbeat or chest pain occurs

How are regulators looking at reports?

CONTINUOUS MONITORING OF THE BENEFITS AND RISKS OF THE VACCINE



Suspected side effects reported after administration of vaccine

A **scientific assessment** looks at the suspected side effect in the context of the person's individual case to determine if it may be caused by the vaccine or occur for other reasons

Side effects assessed in the context of **all available data** on the vaccine, including clinical trials, other studies and the scientific literature

Conclusions are drawn on the **benefits and risks** of the vaccine:

Benefits continue to outweigh risks - new/ changing risks could lead to:

- Restrictions of use
- Contraindications
- Warnings or screenings/tests healthcare professionals should do before vaccination

Risks outweigh benefits – vaccine is removed from the market

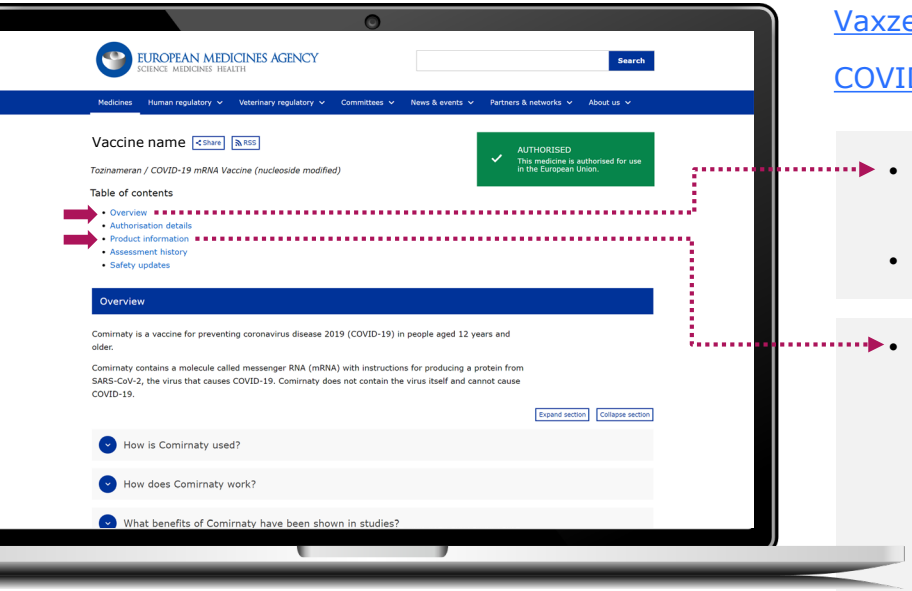
Where can I find more information about each COVID-19 vaccine?

[Comirnaty (BioNTech/Pifzer)]

[Spikevax (Moderna)]

[Vaxzevria (AstraZeneca)]

[COVID-19 Vaccine Janssen]

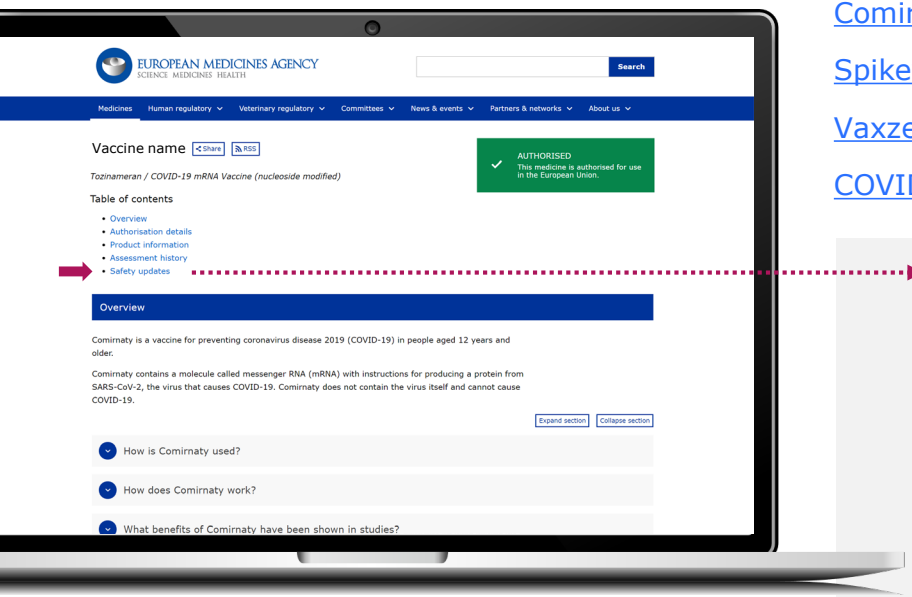


- Medicine overview addressing questions and answers in lay language; available in all EU languages
- Risk management plan (RMP)

- Recommendations and precautions to be followed by:
  - healthcare professionals (summary of product characteristics) and
  - patients (package leaflet)

  for the safe and effective use of each approved vaccine; available in all EU languages

Where can I find safety updates on COVID-19 vaccines?



[Comirnaty (BioNTech/Pifzer)]

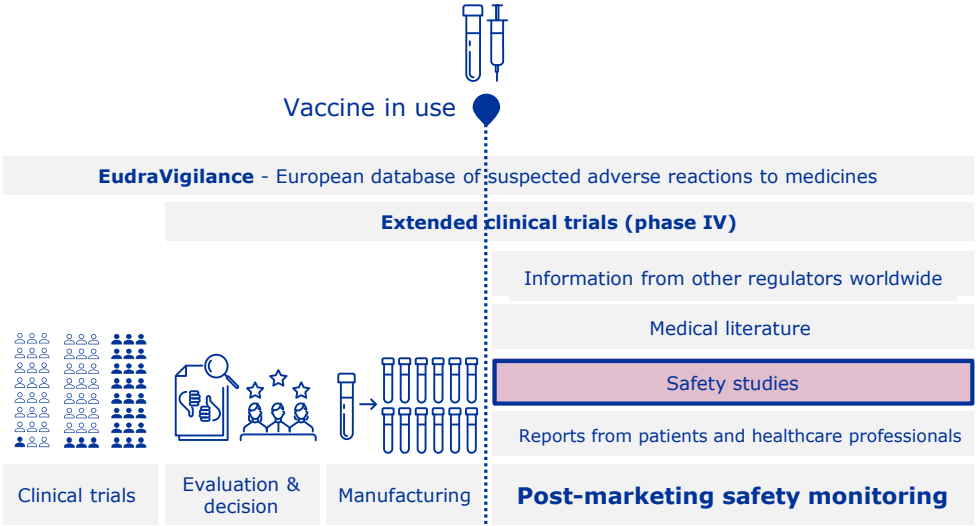
[Spikevax (Moderna)]

[Vaxzevria (AstraZeneca)]

[COVID-19 Vaccine Janssen]

- Published monthly
- Main outcomes from PRAC's latest safety assessment – what new information will be added to the product information
- Updates on assessments of new safety data
- Overall information on how safety is monitored
- Background information on the vaccine

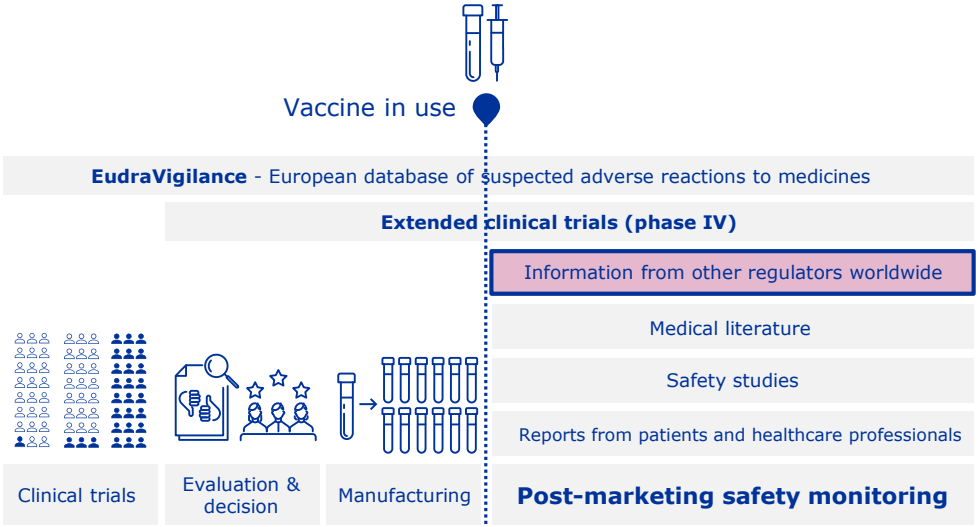
What studies are being undertaken by regulators in the context of the COVID-19 pandemic?



EMA–funded safety studies in people prioritised for vaccination and as vaccination campaigns expand to additional population groups

International collaboration on COVID-19 vaccine monitoring

International Coalition of Medicines Regulatory Authorities (ICMRA)



International Pharmacovigilance Network

Sharing experience and communications on vaccines

- Pharmacovigilance activities
- Emerging issues

Pregnancy research

Building international cohorts

Conclusions

- This is the largest vaccination campaign ever and the **safety profile** of the vaccines is **very reassuring**
- A strong EU pharmacovigilance system is in place; **safety is the priority**
- **Unprecedented** efforts have been made to manage the high volume of safety information
  - Very rare side effects, some serious, have been detected quickly, assessed promptly and acted upon - supported by continuous transparency and communication to the public
  - We have enhanced tools for safety monitoring and frameworks for risk communication and international collaboration
- COVID-19 vaccine safety is **stronger with your participation**
- **Please report suspected side effects**