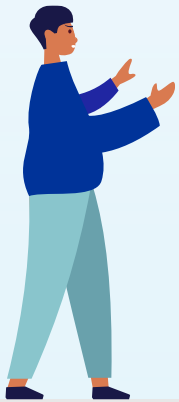
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

THE LIVE STREAMING WILL START SHORTLY

EMA public stakeholder meeting

on the approval and roll-out of COVID-19 vaccines in the EU



13:00 – 13:10	Introduction
13:10 – 14:10	Approval and roll-out of COVID-19 vaccines in the EU
14:10 – 14:15	Break
14:15 – 15:05	Public session with panel experts
15:05 – 15:15	Conclusions

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Basis for the EU approval of new vaccines

Presented by Harald Enzmann on behalf of EMA, as
Chair of Committee for Medicinal Products for Human Use (CHMP)

An agency of the European Union

Objective

- This presentation has been prepared by EMA to inform the general public and non-technical audiences of the basis for **approval and use of COVID-19 mRNA vaccines in the EU**
- It uses public-friendly language and summarises the evaluation of COVID-19 vaccines
- The **full scientific details and product information** are available here:
  - Comirnaty
  - COVID-19 Vaccine Moderna

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Outline

1. Which COVID-19 vaccines are authorised in the EU?
2. How are the mRNA COVID-19 vaccines used?
3. How do mRNA vaccines work?
4. How was efficacy of COVID-19 mRNA vaccines studied?
5. What benefits have been shown in studies?
6. Benefits and risks for Comirnaty and COVID-19 Vaccine Moderna
7. Can the vaccines reduce transmission of the virus from one person to another?
8. What about special populations?
9. Why are the vaccines approved in the EU?

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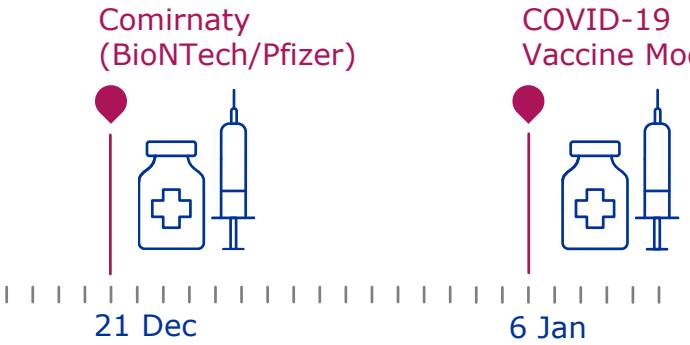
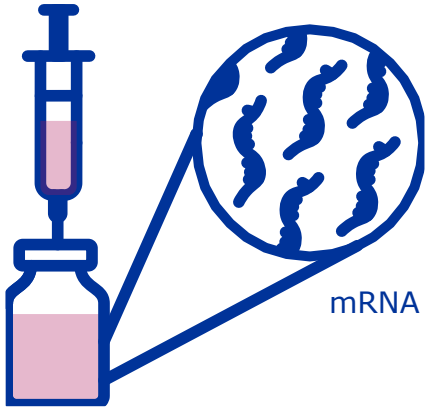
Which COVID-19 vaccines are authorised in the EU?





- Currently 2 COVID-19 vaccines are **authorised in the EU**
- Both contain a molecule called **messenger RNA (mRNA)** with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19
- The vaccines do not contain the virus itself and cannot cause COVID-19

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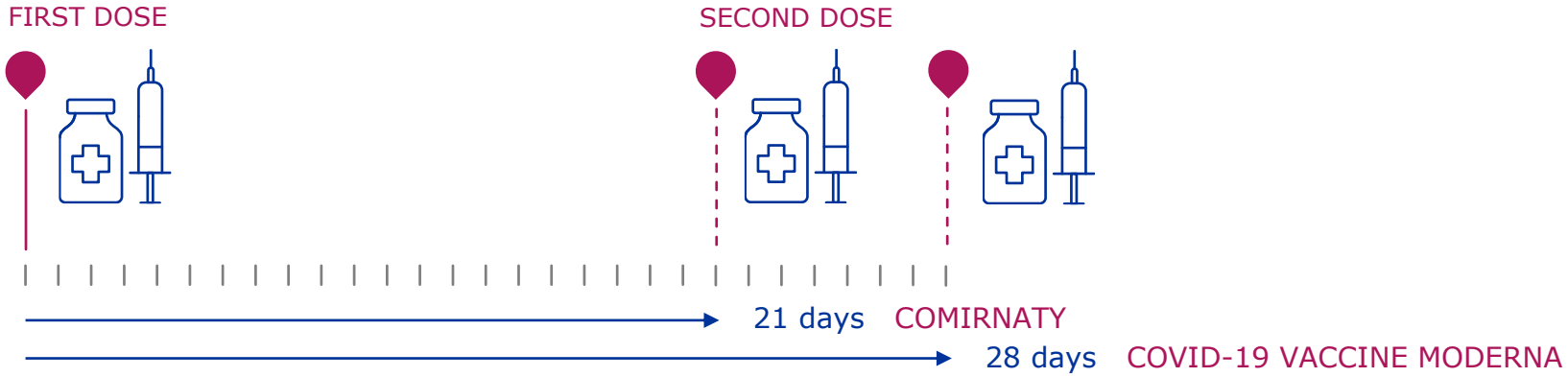
How are the mRNA COVID-19 vaccines used?



- Both vaccines are given as **two injections**, usually into the muscle of the upper arm
  - Comirnaty (BioNTech/Pfizer) is given **at least 21 days apart**
  - COVID-19 vaccine Moderna (Moderna Biotech Spain, S.L.) is given **28 days apart**
- You can check the specific conditions of use for Comirnaty or COVID-19 vaccine Moderna, **in the package leaflet or in the prescribing information**

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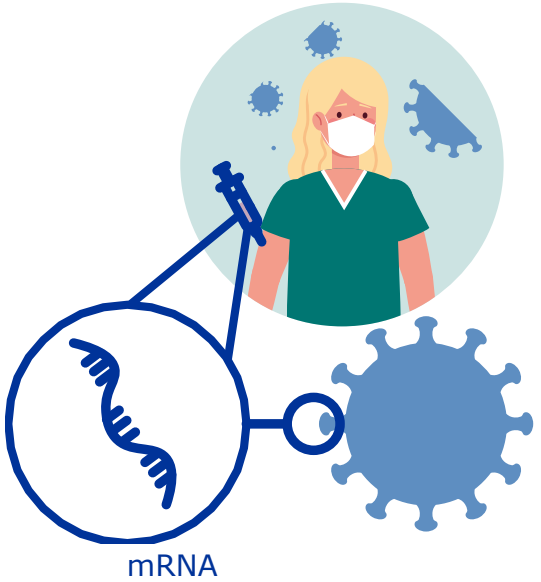
How do mRNA vaccines work?

- The vaccines **prepare the body to defend itself** against COVID-19
- The mRNA has **instructions for making the spike protein –** needed for SARS-CoV-2 virus to enter the body's cells
- When a person is given the vaccine, some of their cells 'read' the mRNA instructions and **temporarily** produce the spike protein
- The person's immune system recognise this protein as foreign and produce antibodies and white blood cells to attack it. If, later on, the person comes into contact with SARS-CoV-2 virus, their **immune system will recognise it and be ready to defend** the body against it
- The mRNA from the vaccine **does not stay in the body** but is broken down shortly after vaccination



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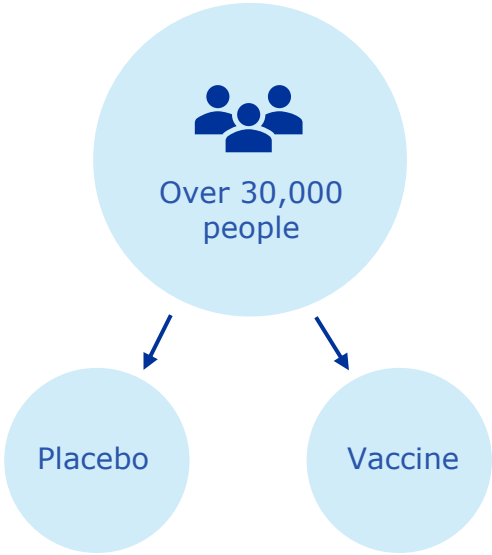
How was efficacy of COVID-19 mRNA vaccines studied?

- **Very large trials** showed that the mRNA vaccines are effective at preventing COVID-19
- The main trials involved **very large numbers of people**:
  - around **44,000** for Comirnaty
  - around **30,000** for Moderna vaccine
- Half received the vaccine and half were given a placebo (dummy injection)
- People did not know whether they received the vaccine or the placebo



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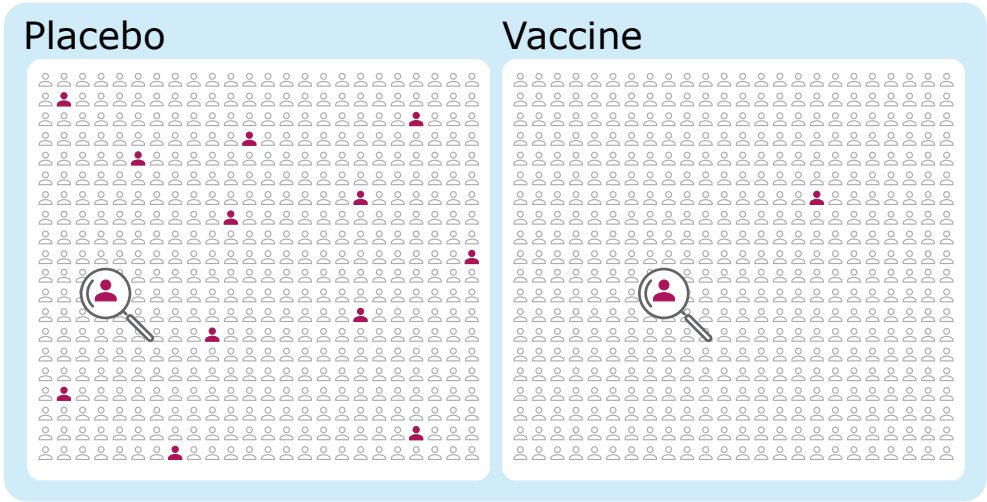
How was efficacy of COVID-19 mRNA vaccines studied?

- Some people in each group developed COVID-19 with symptoms
- The study identified whether these people with COVID-19 symptoms had got the vaccine or placebo

More cases of COVID-19 disease with symptoms were found in the placebo group



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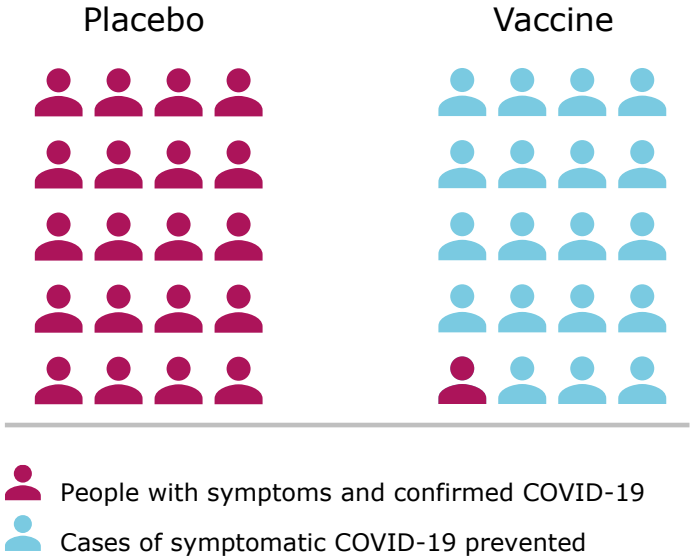
What benefits have been shown in studies?

95% vaccine efficacy for every 20 people in the trial who developed symptomatic COVID-19



- **For each vaccine**, the main study showed **around 95% reduction** in the number of symptomatic COVID-19 cases in the people who received the vaccine compared with people who received placebo
- This means that the **mRNA vaccines demonstrated around 95% efficacy** in the respective trials

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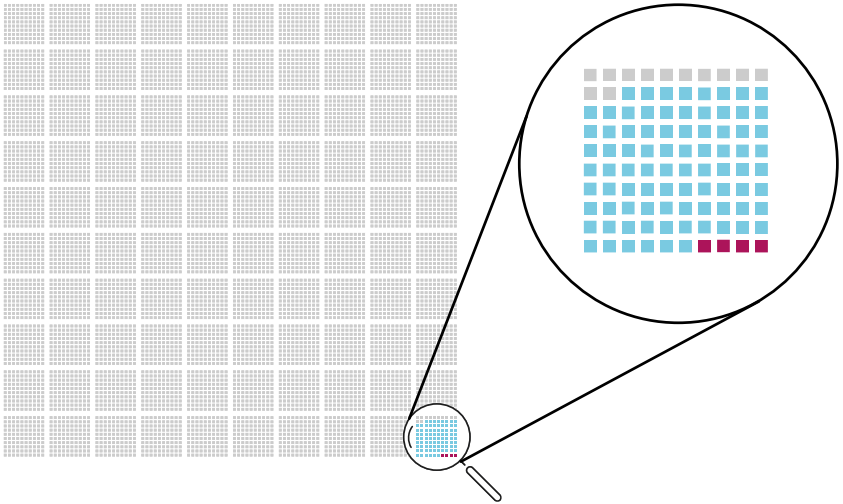
What benefits have been shown in studies?

For every 10,000 participants who received the vaccine, this is what happened compared to placebo



- 84 cases of symptomatic COVID-19 were **prevented by the vaccine (95% of all cases)**
- 4 cases of symptomatic COVID-19 occurred despite the vaccine (5% of all cases)
- 9,912 participants did not have COVID-19 symptoms

- **Snapshot of symptomatic COVID-19 cases** prevented at the time of analysis – around 1.5 months after 2nd dose
- **COVID-19 spreads quickly** and causes severe disease, death and large burden to healthcare systems
- Vaccines offer **individual benefit**
- Fewer people expected to go to hospital, **reducing the burden on healthcare** and freeing up resources to treat other illnesses

Comirnaty – main benefit identified in study

Vaccinated in the clinical trial

VACCINE EFFICACY 95%

How many people developed COVID-19 with symptoms?

18,325 people given placebo	→	**162**
18,198 people given Comirnaty	→	**8**

Full information on the benefit-risk assessment for Comirnaty

Comirnaty – main side effects identified in main study

MAIN SIDE EFFECTS

- Most common side effects **(more than 1 in 10 people)** usually mild or moderate and temporary, including pain and swelling at injection site, tiredness, headache, muscle and joint pain, chills and fever
- Redness at the injection site and nausea occurred in **less than 1 in 10 people**
- Itching at the injection site, pain in the limb, enlarged lymph nodes, difficulty sleeping and feeling unwell were uncommon side effects **(less than 1 in 100 people)**
- Weakness in muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely in **less than 1 in 1,000 people**
- **Very small number of cases of severe allergic reactions** (anaphylaxis) seen in vaccination campaigns

Full list of side effects for Comirnaty

COVID-19 Vaccine Moderna – main benefit identified in study

Vaccinated in the clinical trial

VACCINE EFFICACY 94,1%

How many people developed COVID-19 with symptoms?

14,073 people given placebo → **185**

14,134 people given Moderna → **11**

Full information on the benefit-risk assessment for COVID-19 vaccine Moderna

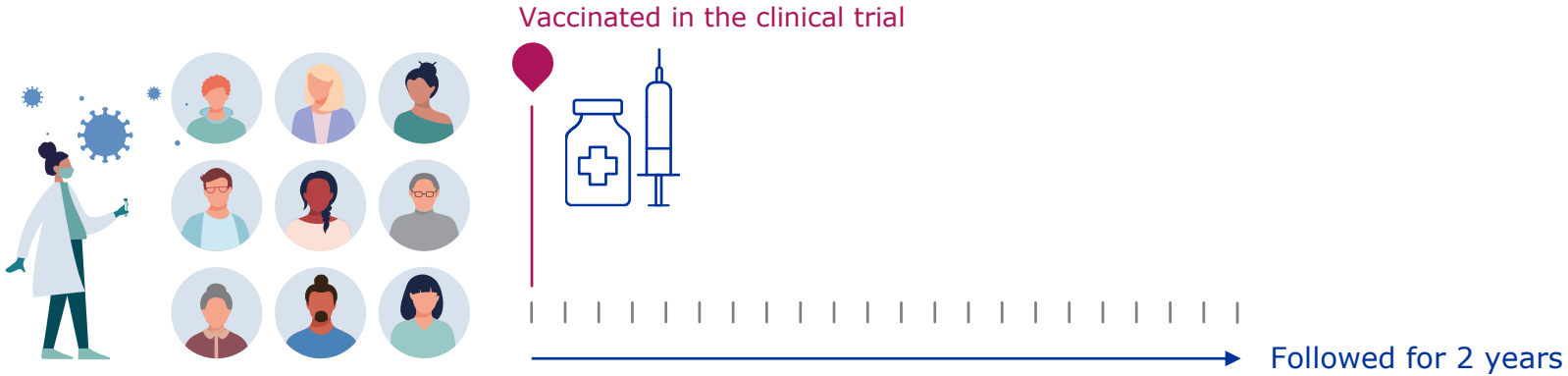
COVID-19 Vaccine Moderna – main side effects identified in study

MAIN SIDE EFFECTS

- Most common side effects **(more than 1 in 10 people)** usually mild or moderate and temporary, including pain and swelling at injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea and vomiting.
- Redness, hives and rash at the injection site and rash occurred in **less than 1 in 10 people**.
- Itching at the injection site occurred in **less than 1 in 100 people**.
- Swelling of the face, which may affect people who had facial cosmetic injections in the past, and weakness in muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely **(less than 1 in 1000)**.
- **Very small number of cases of severe allergic reactions** (anaphylaxis) seen in vaccination campaigns.

Full list of side effects for COVID-19 vaccine Moderna

How long does protection from the vaccines last?



- It is not currently known **how long protection given by the vaccines lasts**
- The people vaccinated in the clinical trial will **continue to be followed for 2 years** to gather more information on the duration of protection

Can the vaccines reduce transmission of the virus from one person to another?

- It is too soon to know the wider **impact of vaccination** with Comirnaty or Moderna vaccine on the spread of the SARS-CoV-2 virus in the community
- It is not yet known to which extent vaccinated people may still be able to carry and spread the virus – trials ongoing
- **The precautions must not be relaxed even after vaccination**: people should continue to **keep distance** from other people, **wear face masks and wash hands**
- It is important to **continue following national and regional guidelines**, which will be determined by the level of transmission locally

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Can vaccines return us to normal life?

- **Immediate benefit** for people who will be protected against COVID-19 symptoms
- **If fewer people are getting sick** (develop symptoms of COVID-19), particularly among high risk individuals such as older people, this will also **alleviate the huge burden of COVID-19 disease on healthcare systems**
- COVID-19 vaccines that reduce symptomatic disease will be an **important step towards beating the pandemic**
- At least initially, vaccines alone will not allow us immediately to return to 'normal' life, and other public health measures such as **face masks and social distancing will remain essential**

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Can people who have already had COVID-19 be vaccinated?

- **Not enough data from the trials** to conclude on how well the COVID-19 vaccines work for people who already had COVID-19
- **Trials included few people** who had previously had COVID-19
- There were no additional side effects in these people

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SPECIAL POPULATIONS

Can children / immunocompromised patients be vaccinated?

- The vaccines are currently **not approved for younger children:**
  - **Comirnaty** can be given above **16 years of age**
  - **Moderna** can be given above **18 years of age**

- There are limited data on **immunocompromised people** (people with weakened immune systems):
  - Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19

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Can pregnant or breast-feeding women be vaccinated?

- Data on the use of Comirnaty or COVID-19 Vaccine Moderna during pregnancy are **very limited**
- Non-clinical studies (e.g. animal studies) do not show any harmful effects in pregnancy
- Although there are no studies on breast-feeding, **no risk for breast-feeding is expected**
- The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks

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How well do COVID-19 vaccines work for people of different ethnicities and genders?

- **The main trials** included people of different ethnicities and genders
- **High efficacy** levels were maintained across genders, racial and ethnic groups

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Why are the vaccines approved in the EU?

- **The vaccines offer a high level of protection** (around 95%) against COVID-19 which is a critical need in the current pandemic
- **Most side effects are mild to moderate** in severity and are gone within a few days
- The Agency therefore decided that, for both vaccines, **the benefits are greater than its risks** and that they can be authorised for use in the EU
- The vaccines have been granted a conditional marketing authorisation
- This means that the company must provide more evidence which EMA will review

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What information is still awaited for the COVID-19 vaccines?

- The companies that market COVID-19 vaccines will continue to provide results from the **main studies, which are ongoing for 2 years**
- This trial and additional studies will provide information on how long protection lasts, how well the vaccine prevents severe COVID-19, how well it protects immunocompromised people, children and pregnant women, and whether it prevents asymptomatic cases
- In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also give more information on the **vaccine's long-term safety and benefit in the general population**
- The companies will also carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine

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Conclusions

- **First COVID-19 vaccines approved in the EU** – robust and efficient scientific assessment
- mRNA vaccines were **studied in large clinical trials**, involving many thousands of participants and including older people
- **Both vaccines show high efficacy** protecting against symptomatic COVID-19 disease and adequate safety profile
- It is still too soon to know the wider impact on preventing infection, asymptomatic transmission and viral spread in the community – until then measures like masks and social distancing are important
- **Vaccination is important** to prevent people getting sick with COVID-19 disease

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How the safety of the new COVID-19 vaccines will be monitored

Presented by Sabine Straus on behalf of EMA, as
Chair of Pharmacovigilance Risk Assessment Committee (PRAC)

Outline

1. Why do we need to monitor the safety of medicines after approval?
2. Who does the safety monitoring in the EU?
3. Are there different safety requirements for COVID-19 vaccines?
4. How is safety of vaccines studied from the development stage to use in real life?
5. How will the safety of vaccines continue to be monitored after approval?
6. What studies will be undertaken by regulators in the context of the COVID-19 pandemic?
7. How can I report side effects?
8. How will I know if side effects are caused by the vaccine?
9. Where can I find more information about Comirnaty and Moderna?

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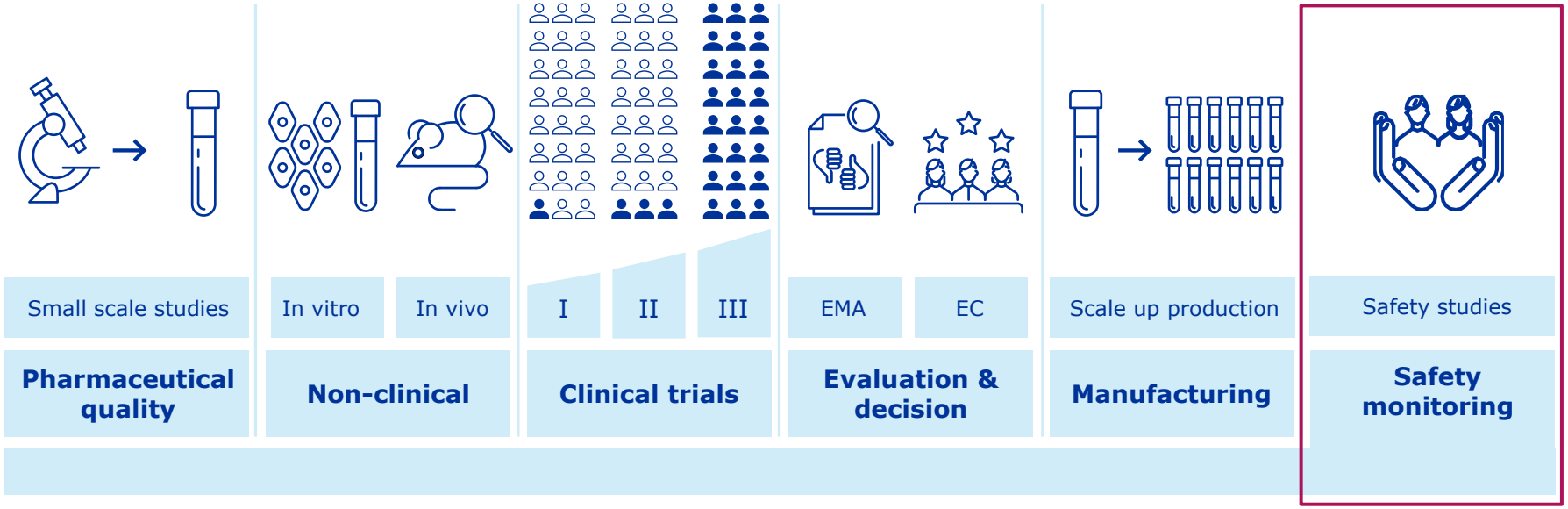
Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING



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Why do we need to monitor the safety of medicines 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
- Post-marketing **safety monitoring** is important **to identify** any new or changing risk as quickly as possible, and **take action**

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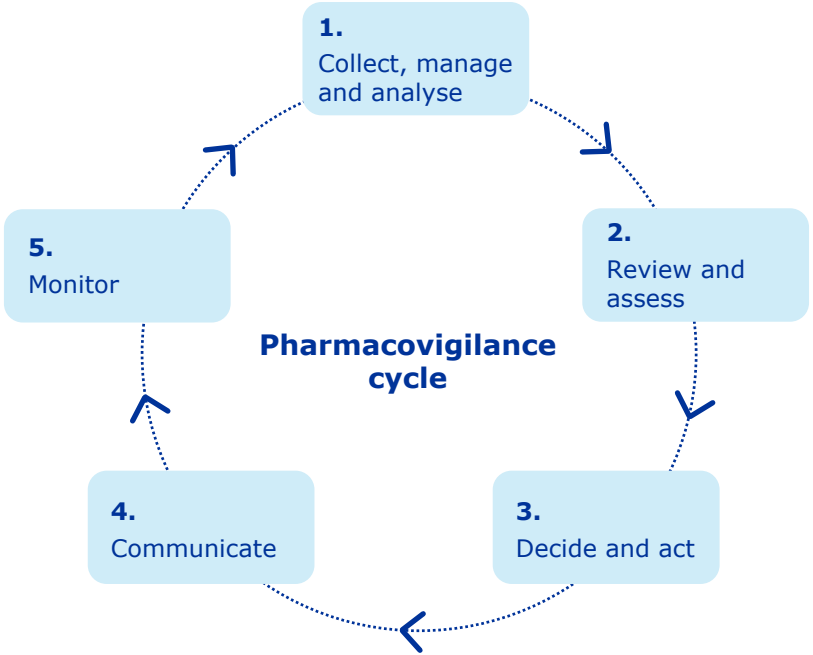
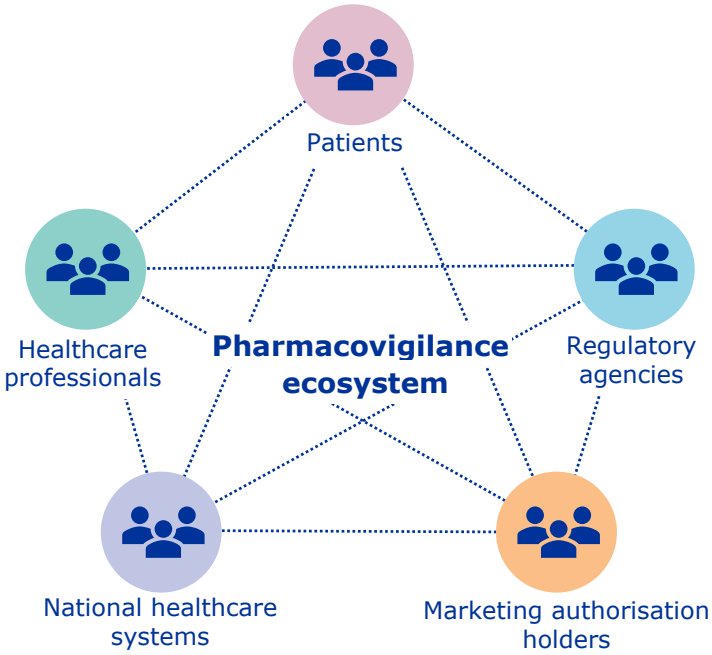
Who does the safety monitoring in the EU?

The EU has a comprehensive **safety monitoring** and **risk management** system known as the **EU pharmacovigilance system**





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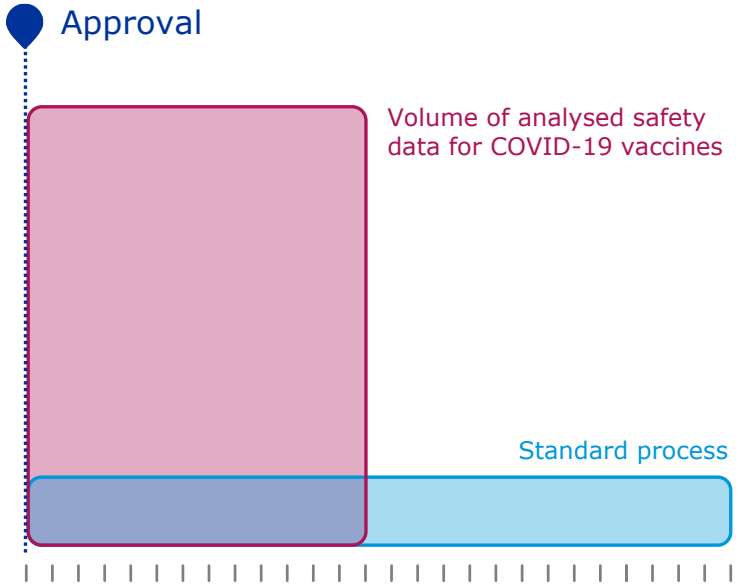
Are there different safety requirements for COVID-19 vaccines?

- The core safety requirements are the **same as** for any other vaccine in the EU
- Vaccines are **only approved if** overall benefits outweigh their risks
- COVID-19 vaccines to be used in millions of EU citizens in a short time;
  - Due to large number of vaccinated people we need to ensure safety monitoring **reacts quickly**
- **Additional resources** are being mobilised to closely monitor safety and assess new information



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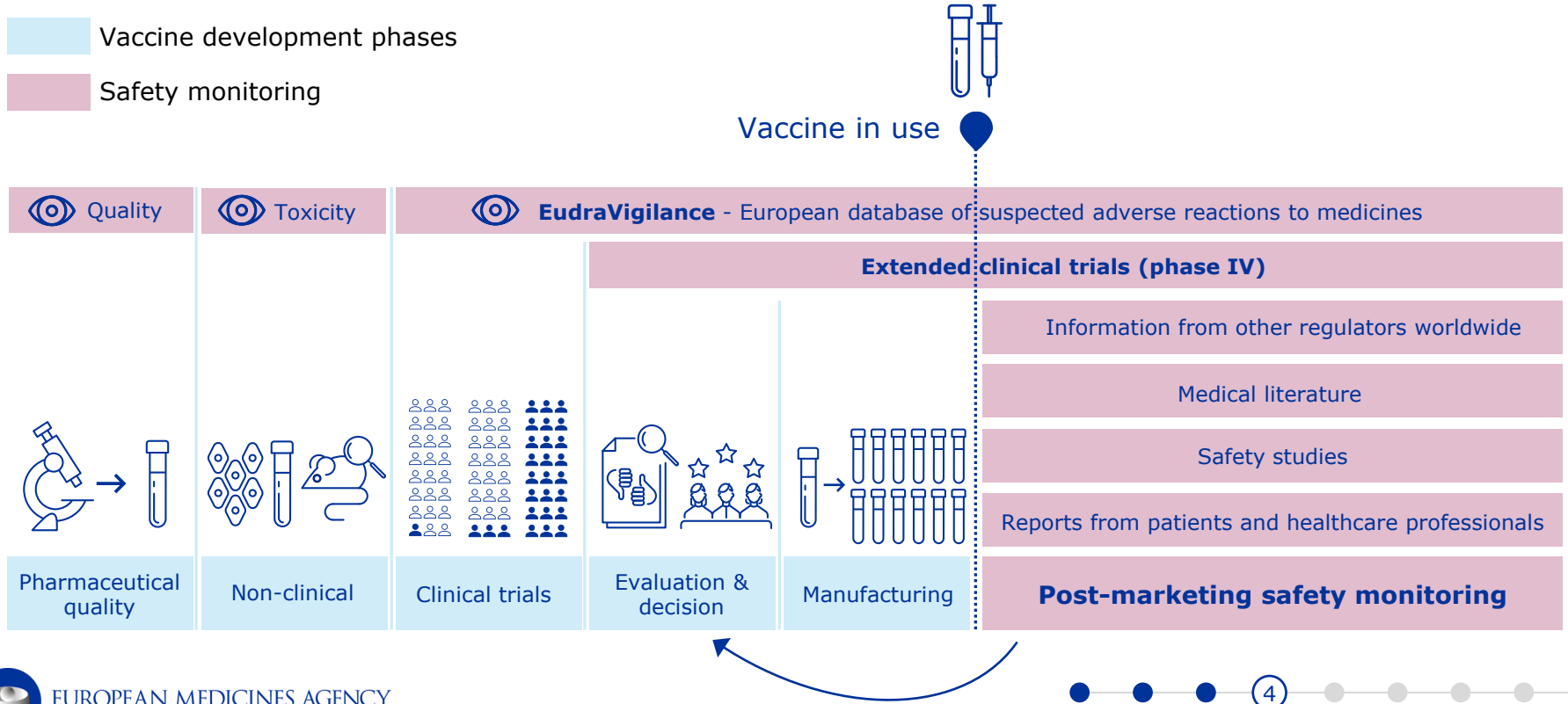
How is safety of vaccines studied from the development stage to use in real life?

Vaccine development phases

Safety monitoring



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How will the safety of vaccines continue to be monitored after approval?

Safety monitoring after approval is needed to detect any new or changing side effects. This includes:

- **Intensive analysis** of reports of suspected side effects from patients and healthcare professionals (also referred to as spontaneous reporting collected in EudraVigilance, the European database of suspected side effects)
- **Post-authorisation safety studies** conducted by the vaccines' manufacturers, as required by regulators
- **Additional studies** performed in Europe on the safety of vaccines when used in real life (also referred to as observational studies)
- **International collaboration** on COVID-19 vaccine monitoring

Risk management plan (RMP)

- Specifically developed for each approved vaccine, following EU guidelines
- Contains important information about the vaccine's safety, how to collect further information and how to minimise any risks
- Continually updated as more information becomes available

What studies will be undertaken by regulators in the context of the COVID-19 pandemic?

2020
ACCESS PROJECT

Set up a European infrastructure for vaccine monitoring

- Gather background information on key adverse events
- Establish an EU network of data sources
- Develop template protocols for vaccine coverage, effectiveness, and safety studies

2020/2021
BRIDGING STUDY

Additional early safety monitoring to complement spontaneous reporting systems

- Primary data collection using an app-based application to gather incidence rates of adverse events
- Complemented by secondary analysis of healthcare data for rapid signal assessment
- In priority groups, for one year, in at least 5 EU Member States

2021/2022
FUTURE STUDIES

Additional EMA-funded safety studies

- Active surveillance, building on the Bridging study
- Additional studies for rapid evaluation of any potential safety signals

How can I report side effects?

- **Reporting** suspected **side effects** following vaccination is critical
- **Anyone can report** a suspected side effect to their national authority or the vaccine manufacturer
- All reports are sent to **EudraVigilance, the European database** of suspected side effects where
  - the data are analysed to detect new side effects
  - and anonymised data are made public for all to review
- **Please report** suspected side effects
  - As vaccines are biologicals released in batches, the batch number is important for reporting purposes

http://www.adrreports.eu/

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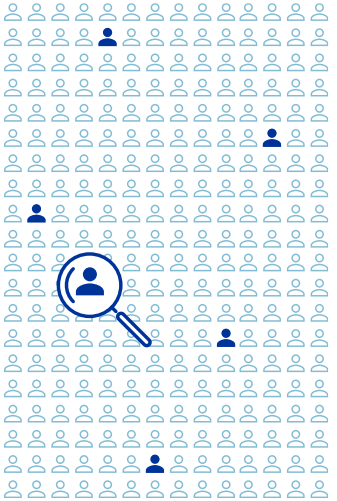
How will I know if side effects are caused by the vaccine?

- **Established analysis techniques** are in place to assess whether a side effect is likely to be caused by the vaccine
- Since millions of people will be getting the vaccine in a short time, many of them will develop illnesses for other reasons in close proximity to vaccination
- If these occur just after vaccination, they may be reported as suspected adverse reactions to the vaccine, when the **association** was just **due to chance**
- If analysis concludes that a **new** side effect is caused by a vaccine, it is included in the package leaflet
    - For example, a very small number of severe allergic reactions (anaphylaxis) have occurred in vaccination campaigns outside the EU an this new information was assessed and reflected in the package leaflet



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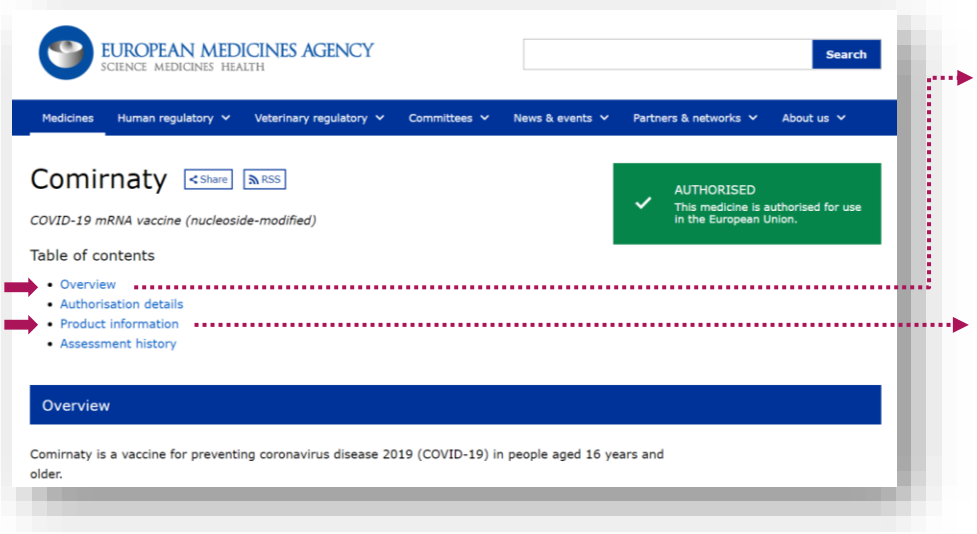
Where can I find more information about Comirnaty?

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty



- 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

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Where can I find more information about COVID-19 Vaccine Moderna?

https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-moderna

- Medicine overview addressing questions and answers in lay language
- Risk management plan (RMP)
- Product information with 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

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Conclusions

- **Vaccines are a key pillar** of public health and have been proven to **prevent serious diseases**
- No medicine is 100% safe so like any other medicines, vaccines can have side effects
- The majority are mild, and even rare, serious side effects must be balanced against the prevention of severe or even fatal disease like COVID-19
- A strong EU pharmacovigilance system is in place; **safety will not be compromised**
- **Unprecedented** steps are being taken to monitor safety in practice, to be transparent and to take action immediately
- Use of facemask, hand hygiene, physical distance **remain important**
- COVID-19 vaccine safety will be **stronger with your participation**
- **Please report suspected side effects**

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

John F. Ryan
Director, Public Health
European Commission – DG SANTE - Health security and vaccination

An agency of the European Union

Outline

1. EU vaccination strategy - objectives
2. Authorisation process – role of the Commission
3. Authorisation process – public information
4. Preparedness for COVID-19 vaccination strategies and vaccine deployment
5. COVID-19 vaccination strategies and vaccine deployment plans – survey among MS
6. Main concerns and issues affecting public confidence
7. Ongoing communication activities aimed at building public confidence
8. Additional resources

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EU Vaccination Strategy

OBJECTIVES

- **17 June 2020** – Endorsed by all Member States
- Accelerate **development**, **manufacturing** and **deployment** of vaccines against COVID-19
- Ensure **quality, safety** and **efficacy** of vaccines
- Secure **swift and equitable access** to them for Member States and their populations while leading the global solidarity effort

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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

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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

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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.

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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

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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

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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)

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Additional resources

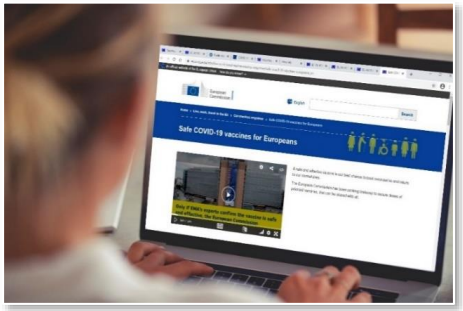
The Commission has just published a new website on safe and effective vaccination in the EU. The webpages are already translated in all EU languages

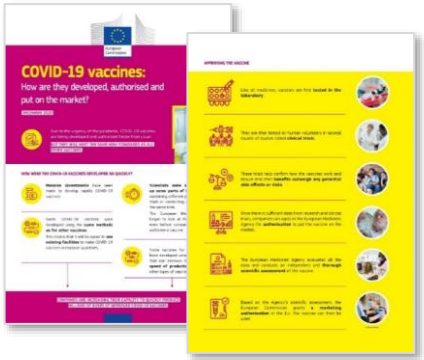
Factsheets: https://we.tl/t-MWKdIkt7d8

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

HMA
Heads of Medicines Agencies

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Ongoing actions for vaccine roll out at national level – Denmark as a Case

Nikolai C. Brun on behalf of Heads of Medicines Agencies (HMA)
Danish Medicines Agency, Director of Division, Chief Medical Officer

An agency of the European Union

Outline

1. Heads of Medicines Agencies (HMA): a short introduction
2. Organisation of vaccine roll out in Member States – an overview
3. Surveillance of side effects of COVID-19 vaccines
4. Knowledge of effectiveness and safety of COVID-19 vaccines
5. Promoting trust in Health Authorities through open and transparent communication

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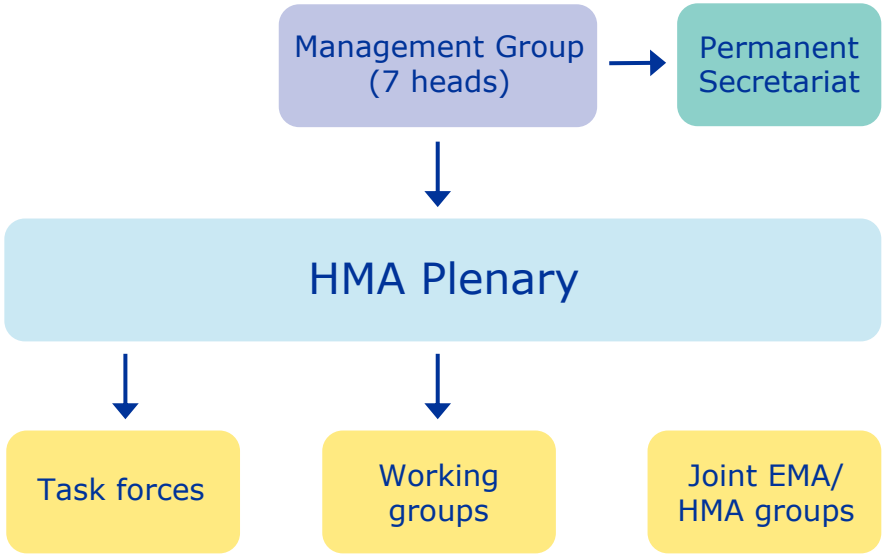
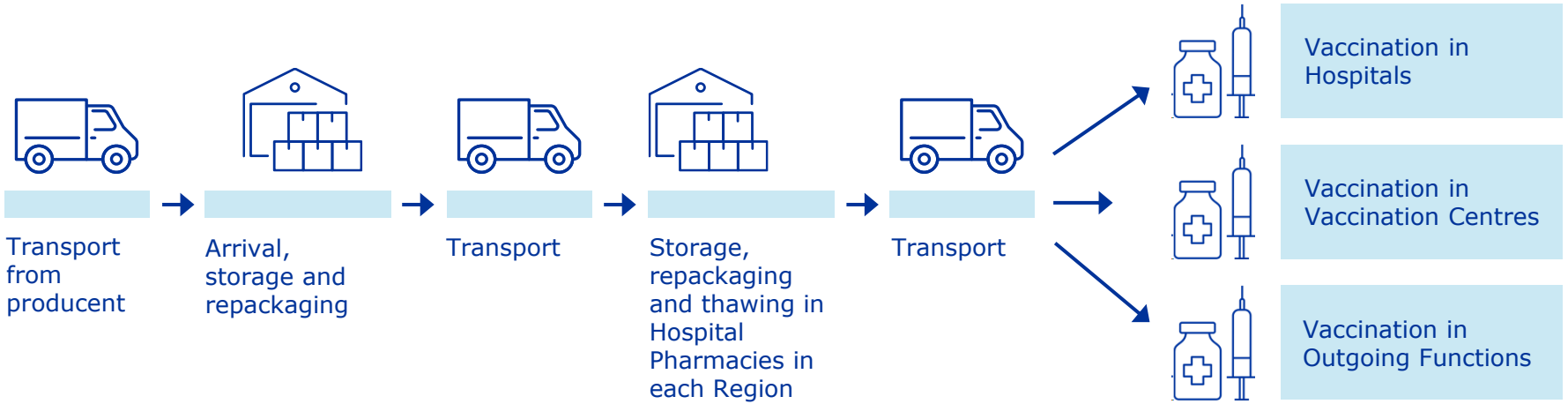
Heads of Medicines Agencies (HMA): a short introduction



- Coordinating role for National Competent Authorities (NCAs)
- Protecting and promoting public health in Europe
- Foster an effective and efficient European medicines regulatory system

Organisation of vaccine roll out in Member States

AN OVERVIEW USING DENMARK AS AN EXAMPLE



HMA Heads of Medicines Agencies

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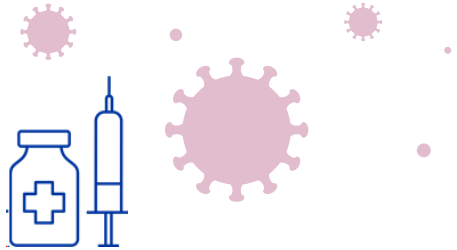
Organisation of vaccine roll out in Member States

AN OVERVIEW USING DENMARK AS AN EXAMPLE

Vaccines delivered to Member State



Distributed from Health Authorities to the Regions by selected target groups

- Selected citizens in nursing homes in areas with high incidence*
- Selected citizens > 65 at high risk of servere course with COVID-19*
- Selected front line staff at hospitals and nursing homes*

The vaccines assigned are distributed by regions according to target groups at the individual vaccination sites

- Hospitals
- Vaccination Centres
- Outgoing Functions

* Phase 1 in roll out

Surveillance of side effects of COVID-19

OBJECTIVES AND ACTIONS

- Ensure a strong set-up for reporting adverse reactions and monitoring the vaccines
- Healthcare professionals and citizens should be able to easily report suspected side effects at national level
- Healthcare professionals and citizens should have the necessary information to be able to report
- Focus on high quality of adverse reaction reports - crucial for signal monitoring
- Stricter reporting obligation to be considered at national level
- Studies to monitor the effectiveness and safety of vaccines

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Knowledge of effectiveness and safety of COVID-19 vaccines

- The companies will continue to provide study results and data as they continue to be generated
- In addition, independent studies of COVID-19 vaccines coordinated at EU level which will give more information on the vaccine's long-term safety and effectiveness
- Member States may also carry out their own additional studies at national level using national cohorts (e.g. in Denmark ENFORCE study)
- Member States may also use other means to gather data in real time and complement routine pharmacovigilance actions such as:
  - National Health Registries
  - electronic health records and
  - in future, use of AI based Signal Generation – early identification of unknown side effects and identification of unreported side effects

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Promoting trust in Health Authorities through open and transparent communication

OVERALL VISION

- Member States steping up communication efforts to support an informed debate on vaccines – an informed basis knowledge for everyone
- Everyone has a right to be informed – information on how the vaccines has been developed, approved and is being monitored
- Efforts are being made at national level to reach as many citizens as possible

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Everyone has a right
to be informed.

Thank you

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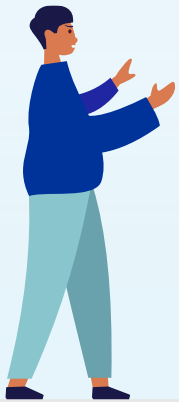
5’ break

EMA public stakeholder meeting

on the approval and roll-out of COVID-19 vaccines in the EU



13:00 – 13:10	Introduction
13:10 – 14:10	Approval and roll-out of COVID-19 vaccines in the EU
14:10 – 14:15	Break
14:15 – 15:05	Public session with panel experts
15:05 – 15:15	Conclusions

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Public session with panel experts

Comments and questions from the public

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