The development of COVID-19 vaccines

Dr. Julio Delgado
Seconded National Expert, Oncology Office, EMA
Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING
STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Indicative timeline
STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Indicative timeline

- Pharmaceutical quality
- Non-clinical research
- Phase I
- Phase II
- Phase III
- Scientific evaluation and authorisation
- Large-scale production
- Studies after authorisation

Vaccine available for use
Rolling review

• In public health emergency - EMA can **evaluate data** for a promising medicine **as soon as available**

• **Several** rolling review **cycles** can be done as data continue to emerge

• Once all **Quality, Safety and Efficacy** data are ready, the company can formally apply for marketing authorisation application to EMA

---

**STANDARD**

**COVID-19**

**Rolling review cycle**

Developer applies for marketing authorisation

EMA opinion
STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Regulatory standards

COVID-19 vaccines must be approved according to the **same standards** that apply to all medicines in the EU

<table>
<thead>
<tr>
<th>Quality</th>
<th>Safety</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>✅</strong> Safety</td>
<td><strong>✅</strong> Quality</td>
<td><strong>✅</strong> Efficacy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19</th>
<th>Quality</th>
<th>Safety</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>✅</strong> Safety</td>
<td><strong>✅</strong> Quality</td>
<td><strong>✅</strong> Efficacy</td>
<td></td>
</tr>
</tbody>
</table>
Overview
COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING
Conditional Marketing Authorisation

- Medicines that address unmet medical needs
- The benefit of immediate availability of the medicine outweighs the risks
- Medicines intended for
  - treating, preventing or diagnosing seriously debilitating or life-threatening diseases
  - public health emergencies
- Other data must be provided by the company, after approval (e.g. long-term safety data)
Conditional Marketing Authorisation

WHY CONDITIONAL APPROVAL IS THE MOST APPROPRIATE TOOL IN THE EU?

- **Formal approval** of a medicine across the EU: **all member states benefit** from the joint scientific assessment and approval

- It has **all safeguards and controls** in place to ensure high level of protection to citizens during a mass vaccination campaign:
  - A robust **monitoring plan** for managing **safety**
  - Clear **legal framework** for evaluation of **emerging efficacy data**
  - **Manufacturing** controls including **batch controls** for vaccines
  - Full **prescribing information** and **package leaflet** with defined conditions for storage and use of the vaccine
  - A **plan** for **use** of the vaccine **in children**
  - **Additional studies or other data** (‘conditions’) that the company is **legally obliged** to provide with defined **timelines**
Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING
Companies are expanding manufacturing and production capacity to ensure efficient vaccine deployment.
Overview

COVID-19 VACCINE DEVELOPMENT, EVALUATION, APPROVAL AND MONITORING

Small scale studies → In vitro → In vivo → I II III → EMA EC → Scale up production → Safety studies

Pharmaceutical quality → Non-clinical → Clinical trials → Evaluation & decision → Manufacturing → Safety monitoring

Classified as public by the European Medicines Agency
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**.
Why and how is the safety monitored after approval?

- Detection of previously unrecognised or changing side effects to **optimise safe and effective use**
- **Intensive analysis** of reports of suspected side effects from patients and healthcare professionals
- Manufacturers obliged to conduct **safety studies** (as part of the **conditional marketing authorisation**)
- **Additional studies** will be performed in Europe on the safety of vaccines when used in real life
- **International collaboration** on COVID-19 vaccine monitoring
COVID-19 vaccination in patients with cancer

- Patients with cancer requiring active therapy and immunocompromised patients were excluded from pivotal trials.


- Although these people may not respond as well to the vaccine, no particular safety concerns are anticipated.

- The benefit-risk ratio for patients with cancer is positive and they may be at higher risk from COVID-19.
Conclusions

- **Same types of studies** as for other medicines - timelines shortened
- Expected benefits at time of initial approval:
  - Demonstrated **reduction in COVID-19 disease**
  - Some **uncertainties: long term protection** and **community transmission**
    - Use of facemask, hand hygiene, physical distance **remain important**
- **High regulatory standards** for Quality, Safety and Efficacy
- 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
- COVID-19 vaccine safety will be **stronger with your participation**