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SCIENCE MEDICINES HEALTH

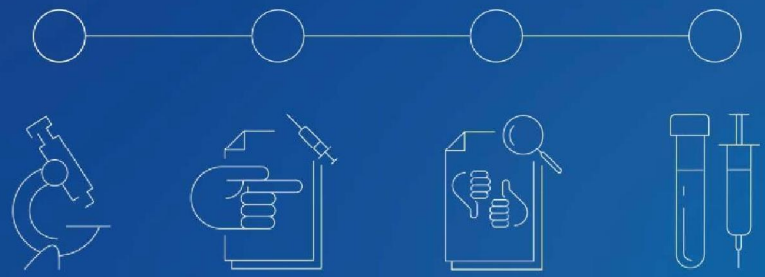
Update on COVID-19 vaccine development and evaluation - Part II

Fergus Sweeney, 3 December 2020

An agency of the European Union

Topics to be discussed

- How does EMA evaluate COVID-19 vaccines?
- What types of authorisation are available in the EU for COVID-19 vaccines?
- How do we monitor the safety of COVID-19 vaccines once a marketing authorisation is granted?



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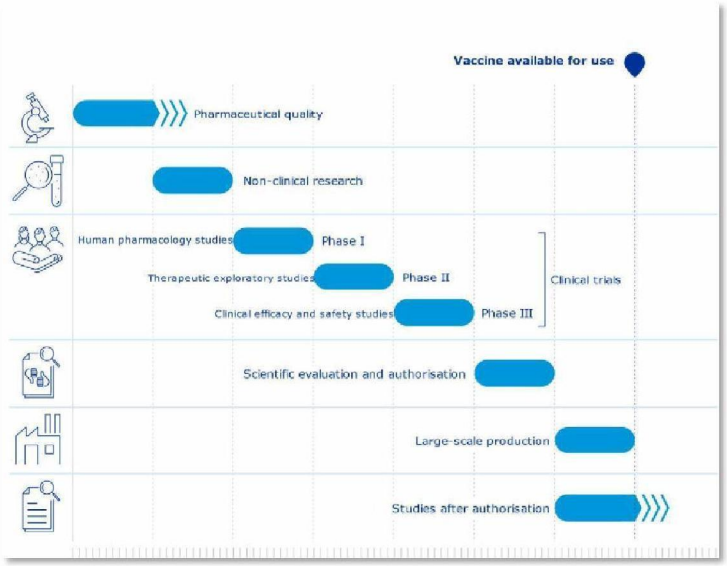
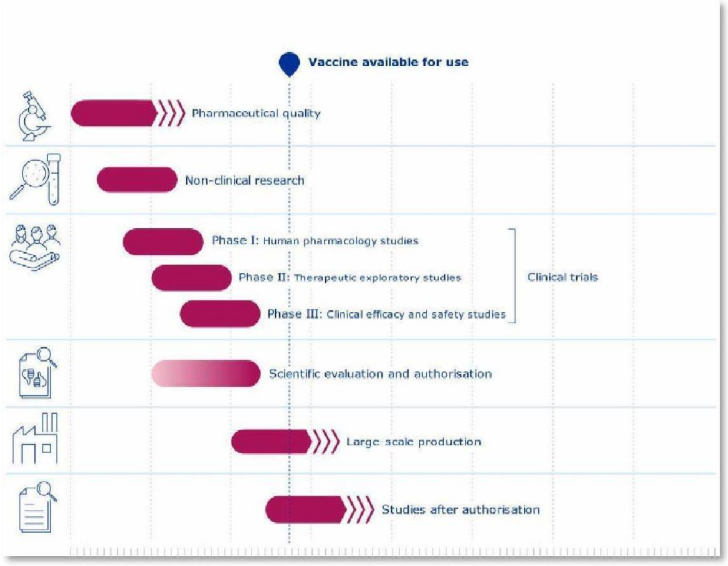
STANDARD
vaccine development



FAST-TRACK
development in a public health emergency context



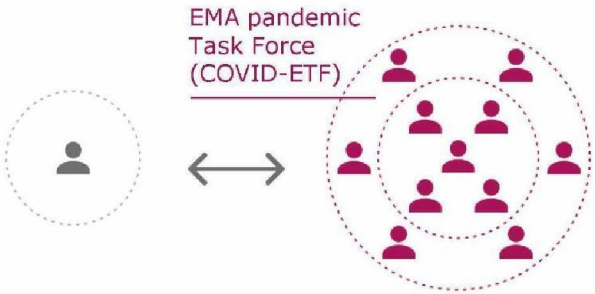
Regulatory standards are maintained

For approval of COVID-19 vaccines, **same high standards** of quality, safety and efficacy need to be met - as for all EU medicines

Speed of development and approval due to the public health emergency

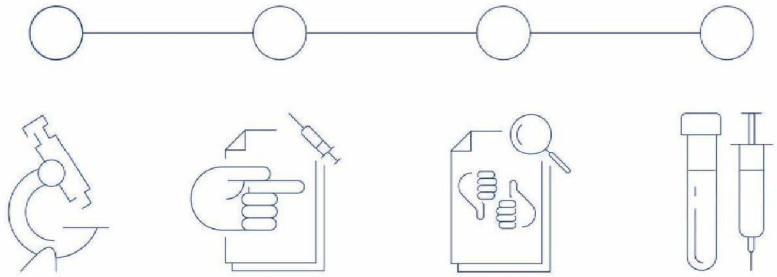
- Development is compressed in time
- Clinical trial phases combined or conducted in parallel
- Fast-track approval processes
- Scaled up manufacturing up front

Unprecedented mobilisation of human resources from the EU Network – **EMA Task Force (ETF)**



Rapid regulatory processes being used in EU

Early support for medicine and vaccine developers: thorough scientific advice and COVID-19 ETF



Rolling review

Leading to…

Conditional marketing authorisation

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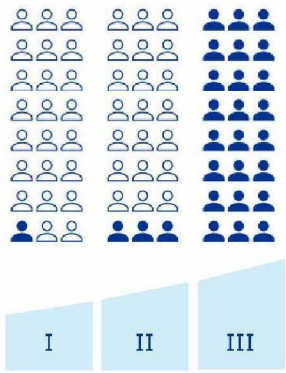
Rolling review to evaluate data as soon as available

- In a public health emergency, EMA can **evaluate data** for a promising medicine as soon as they **become available** on a rolling basis
- **Several** rolling review **cycles** can be done as data continue to emerge
- Once the data needed are ready to support all the **required Quality, Safety and Efficacy evidence**, a company can formally send a marketing authorisation application (MAA) to EMA
- This MAA may be for a standard Marketing Authorisation or for a Conditional Marketing Authorisation (CMA)



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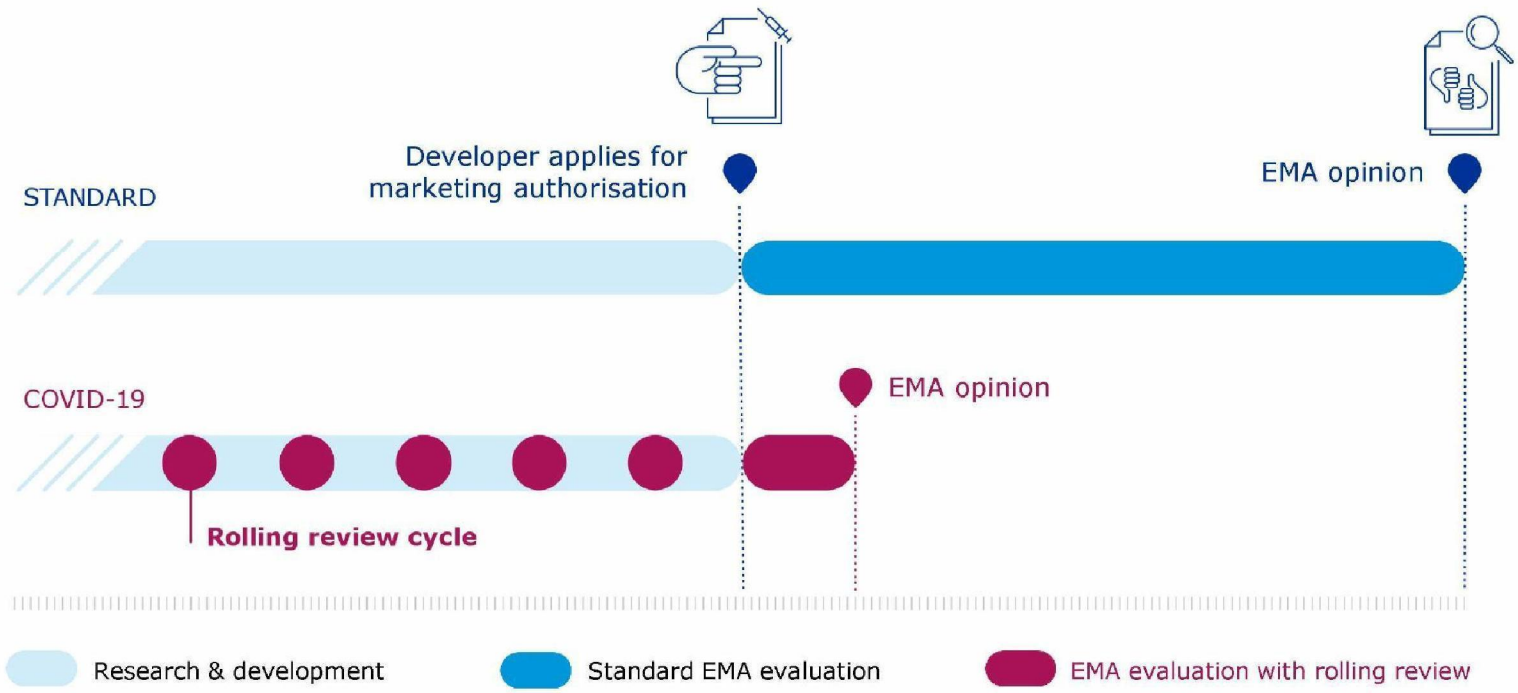
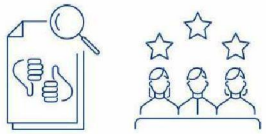


Conditional Marketing Authorisation (CMA)



- Foreseen in EU pharmaceutical legislation for use in public health emergencies
  - as soon as data available demonstrate that the **benefits outweigh the risks**
- CMA is an approval on **less data** than normally required
  - **necessary data** to show positive benefit-risk **must** be provided
  - **other data** must be provided by the company, **after marketing approval** (e.g. long term protection data)
  - these are the **"conditions"** set out in the conditional approval, **legally binding** and with defined **timelines**

Why is a CMA is the most appropriate tool in the EU?

- CMA provides a **robust framework** for accelerated approval
- It is a marketing authorisation with **all safeguards and controls** in place:
  - A robust risk-management and safety monitoring plan
  - Clear legal framework for evaluation of emerging efficacy data
  - Manufacturing controls including batch controls for vaccines
  - Full product information with defined conditions for storage and use of the vaccine
  - An investigation plan for use in children
  - Post-approval obligations (i.e. conditions) apply in a legally binding manner
- These are essential elements to ensure a **high level of protection to citizens** during the course of a mass vaccination campaign

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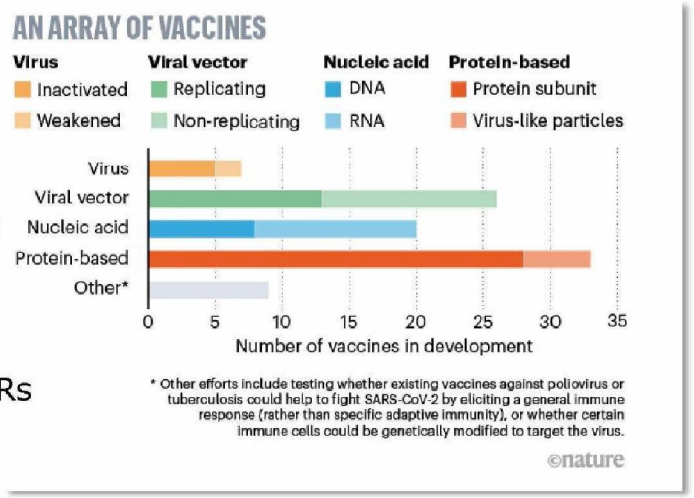
COVID-19 vaccines monitoring preparedness

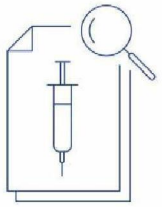
- Potentially many different vaccines, **new technologies**
- **Accelerated** development and approval
- **Rapid vaccination** to occur in millions or billions
- **Safety critical**: Systems need to be in place to rapidly detect and minimise serious risks to patients, including unexpected or rare serious ADRs
- **Transparency** and **communication** will be key
- **Rigorous regulatory system** is essential for public confidence in vaccines and vaccination



Enhanced safety monitoring of medicines used in treatment of COVID-19

- **Responsibilities** of marketing authorisation holders:
  - monitor the safety vaccines, report suspected adverse reactions to EMA, keep product information up to data
  - conduct safety and effectiveness studies looking at performance of their products on the market
  - submit regular safety and benefit risk reports to EMA which will be assessed by the PRAC
- **All reported suspected ADRs will be monitored** for new or changing safety issues and if detected these will be rapidly assessed by the PRAC and any necessary risk minimisation action taken:
  - Detailed guidance on individual case safety reports (ICSRs) in the context of COVID-19
  - CoreRMP19
  - Monthly summary safety reports from manufacturers post approval (in addition to 6 monthly PSUR)

Enhanced monitoring by regulators



- **COVID-19 specific guidance for safety monitoring**
- Dedicated **eRMRs** (EudraVigilance safety monitoring reports) with increased frequency
- Reduced timeframe for confirming **urgent COVID-19 related signals**

Observational safety monitoring study to complement safety studies being conducted at national level.

Enhanced transparency and communication is being put in place including the website www.adrreports.eu and regular safety updates on the EMA website.

Concluding remarks

- **A huge responsibility** – EC, Member States and EU citizens rely on the EMA's scientific assessment
- Unprecedented **mobilisation of scientific resources** across the EU to ensure robust assessment
- Standards for **quality, efficacy and safety** remain unchanged
- CMA provides **a robust framework** for accelerated approval and post-authorisation safeguards and controls
- **Post-approval commitments** will cover enhanced safety-monitoring, longer-term continuation of clinical trials, additional studies as needed and observational studies for effectiveness and safety

Any questions?

Further information

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