EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Emerging lessons on communication and engagement during the pandemic

Joint PEC – PCWP meeting

15 July 2022

- Rosa Gonzalez-Quevedo, PhD
- Stakeholders and Communication Division, EMA

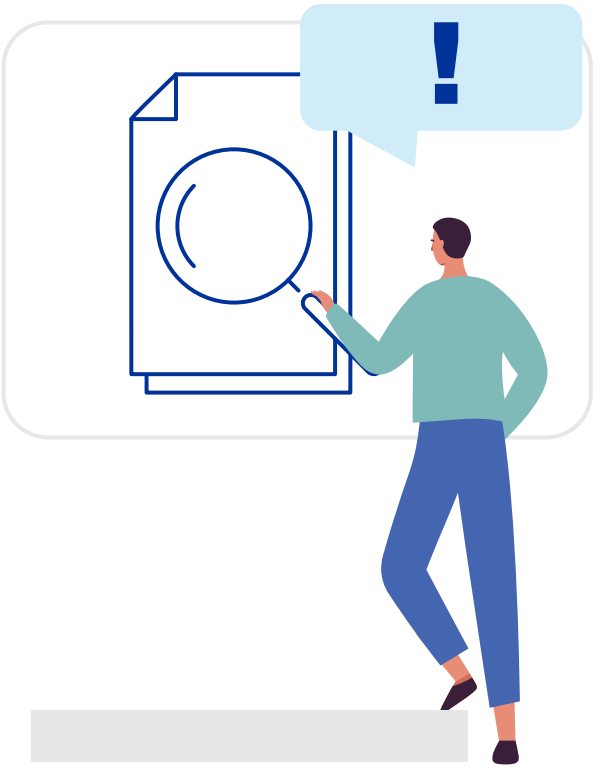
An agency of the European Union

Outline

1. Challenges communication during the COVID-19 pandemic
2. How is EMA communicating?
3. Transparency
4. How EMA tackles misinformation
5. Engagement and collaboration
6. Early learnings from the pandemic

Challenges communicating during the pandemic

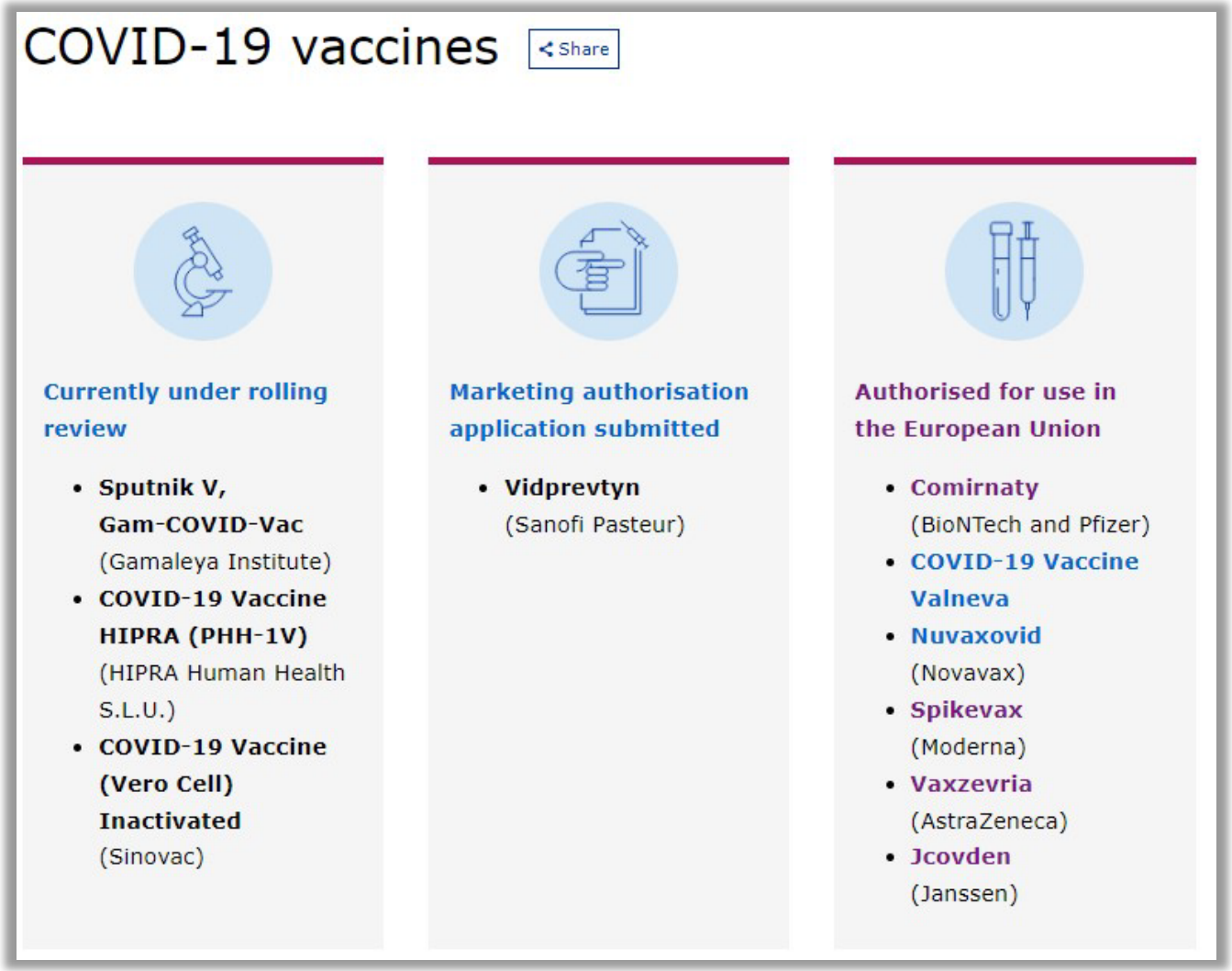
- Demand for **increased transparency and proactive communication**
- Constant request for information in a **context of uncertainty and evolving scientific evidence**
- Preliminary nature of interim results, needing to further collect and analyse data
- In some instances, **differences in public health policy decisions** (e.g., regarding age groups included in vaccination campaigns)
- **Urgent safety communications**
- Addressing **misinformation**
-



How is EMA communicating?

- **New information** on development & approval of COVID-19 vaccines – specifically targeting the general public
- **Responding to queries** from members of the public and media
- **Press, public meetings & social media** on key developments
- **Media interviews** with experts
- Providing content for European Vaccination Information Portal and supporting the European Commission
- EMA/Member States' **safety communications**

Status of COVID-19 vaccines



COVID-19 vaccines

Share

Currently under rolling review

- **Sputnik V, Gam-COVID-Vac** (Gamaleya Institute)
- **COVID-19 Vaccine HIPRA (PHH-1V)** (HIPRA Human Health S.L.U.)
- **COVID-19 Vaccine (Vero Cell) Inactivated** (Sinovac)

Marketing authorisation application submitted

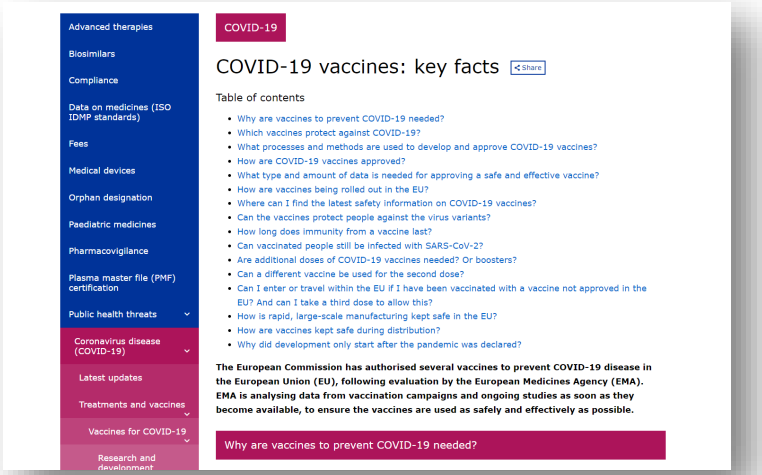
- **Vidprevtyn** (Sanofi Pasteur)

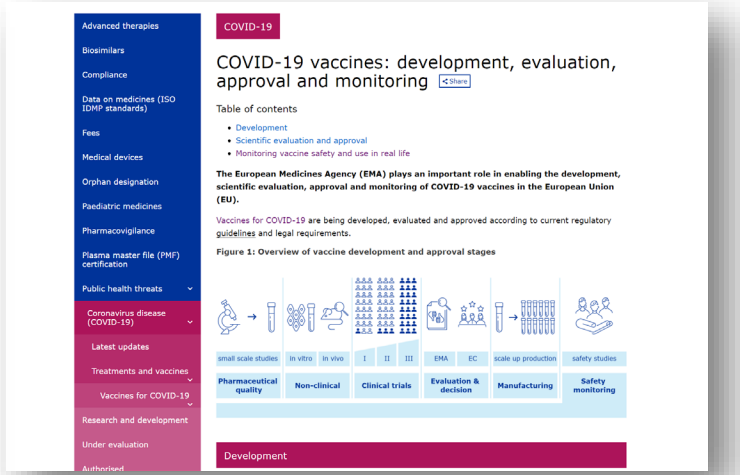
Authorised for use in the European Union

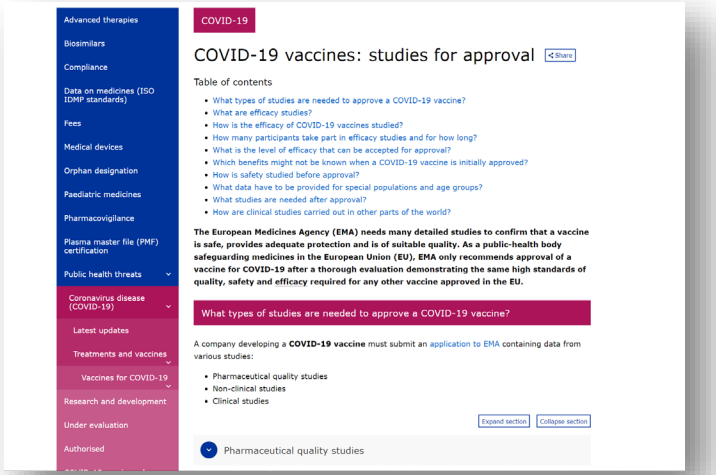
- **Comirnaty** (BioNTech and Pfizer)
- **COVID-19 Vaccine Valneva**
- **Nuvaxovid** (Novavax)
- **Spikevax** (Moderna)
- **Vaxzevria** (AstraZeneca)
- **Jcovden** (Janssen)

HOW IS EMA COMMUNICATING?

Proactive materials on COVID-19 vaccines







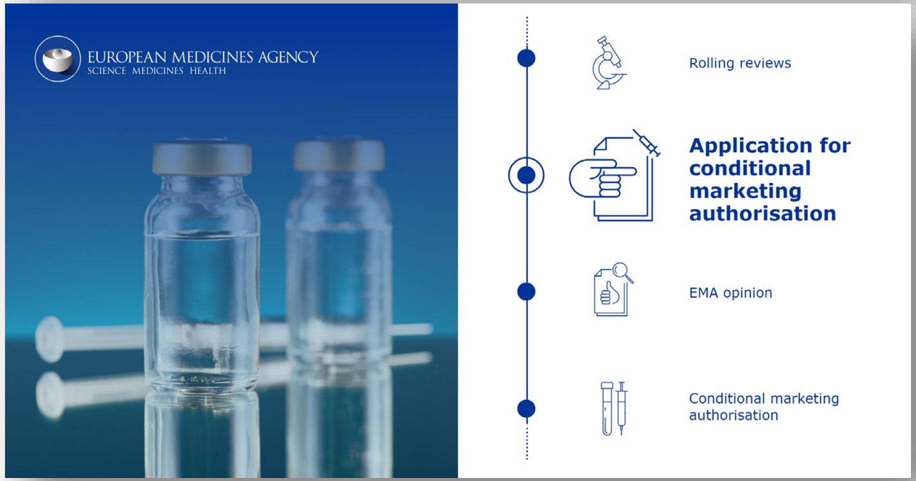
- Key facts
- For general public
- Addresses commonly received questions

- Explanation on how vaccines are developed and approved
- Use of graphics to explain key concepts

- Information on studies needed to approve a COVID-19 vaccine
  - Quality, Safety & Efficacy
- Professional audiences and general public

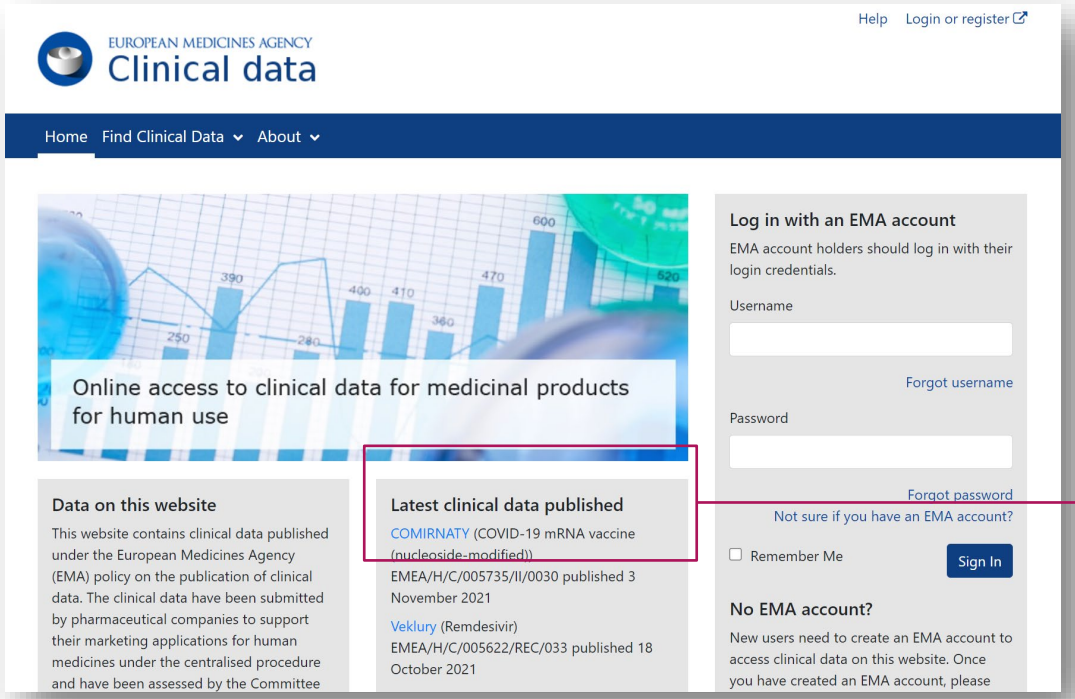
HOW IS EMA COMMUNICATING?

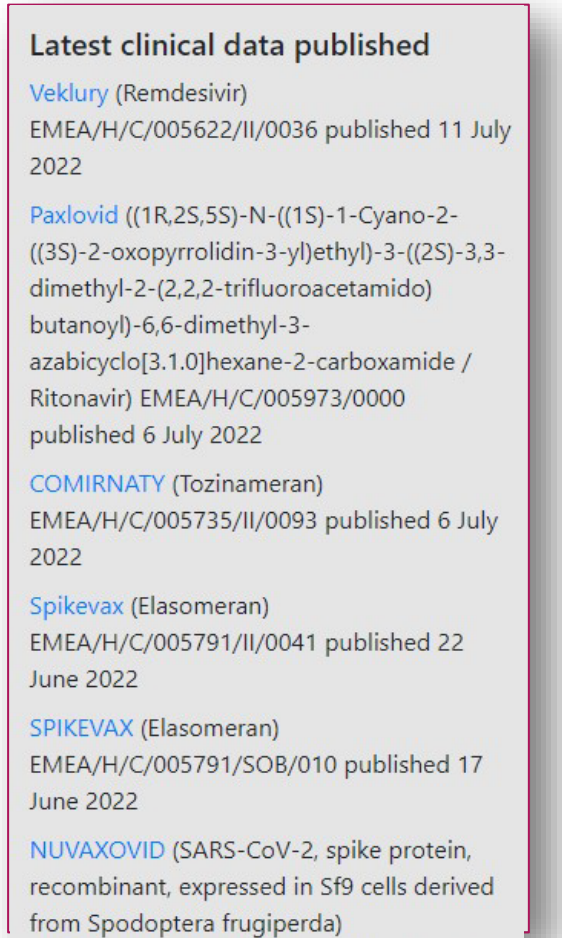
EMA social media channels



Publication of clinical data for all COVID-19 medicines

https://clinicaldata.ema.europa.eu/web/cdp/home





Misinformation during the COVID-19 pandemic

- Spreading of misinformation during the COVID-19 pandemic has **a large public health impact**
- It undermines trust in medicines – e.g. **limits uptake of life saving vaccines**
- **Social media** used to amplify an “infodemic” where massive amounts of information are shared and **disinformation and misinformation can easily spread**
- The spreading of false messages is also supporting the **polarisation of the public debate on topics related to COVID-19**
- It is critical to **address confusion or misleading information**

How EMA tackles misinformation

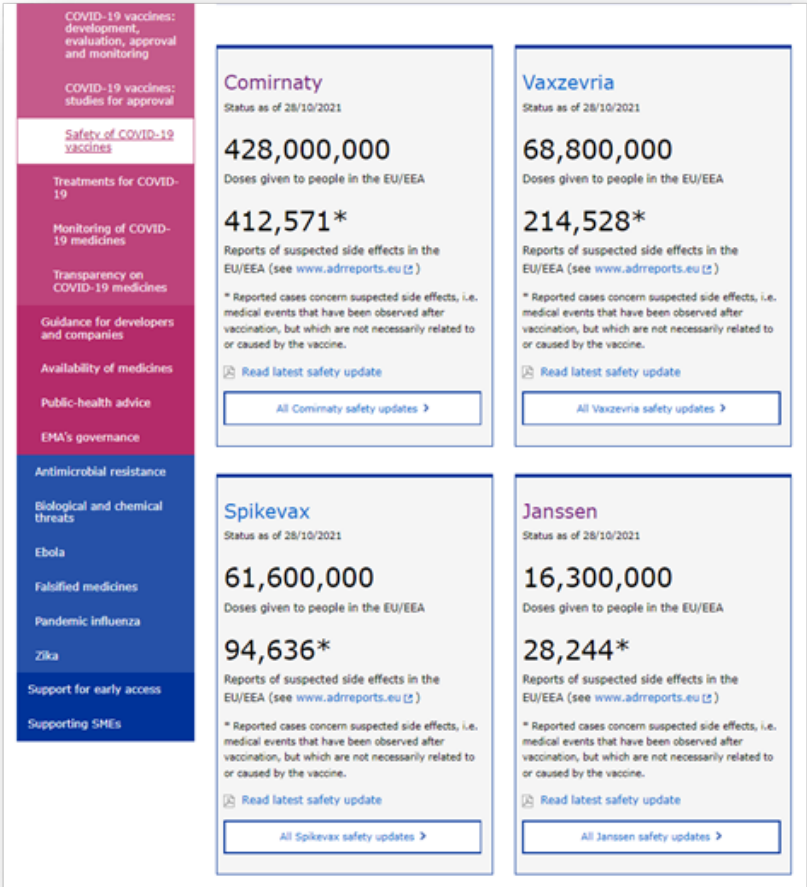
- **Identification**
  - (Social) Media monitoring
  - Queries from members of the public
  - Collaboration with EU & international public health bodies
- **Two-way dialogue** to listen to the public's concerns & engagement
- **Address concerns proactively** - 'pre-bunking' or trying to address concerns before these can take hold and proliferate
- Make EMA's voice **heard** – **e.g. social media**
- **Communicate the fact-based science** supporting EMA regulatory decisions
- **Ensure full transparency** on EMA actions and decisions, and on data supporting such regulatory outcomes

Addressing misinformation on vaccine safety

False reports relating to the number of side effects in Eudravigilance with COVID-19 vaccines

FALSE

- EMA is now producing an **overview of safety updates with statistics on reported side effects**:
  - contextualising number of suspected side effects with **doses given in the EU/EEA**
  - **response to stakeholders**' request for further transparency and enhancing visibility of safety updates

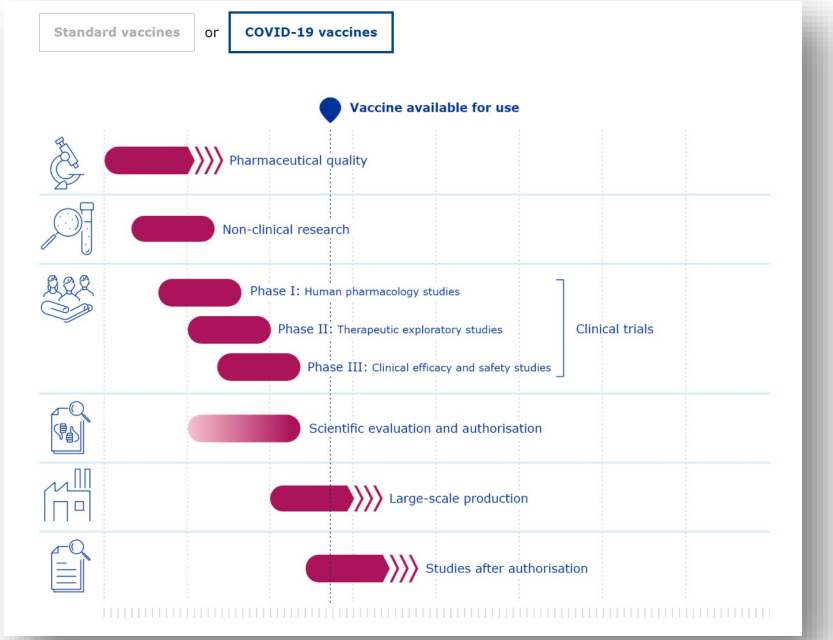


Addressing misconceptions about the pace of vaccine development and authorisation

INCORRECT

Misinformation circulating that there is insufficient data on the quality, safety and effectiveness on COVID-19 vaccines due to their rapid development and authorisation

- EMA has published information explaining how **development and authorisation can be condensed without compromising standards**
- There are **extensive study results** underpinning the authorisation of vaccines
- **Full transparency** on basis for authorisation (European Public Assessment Report & publication of clinical data)



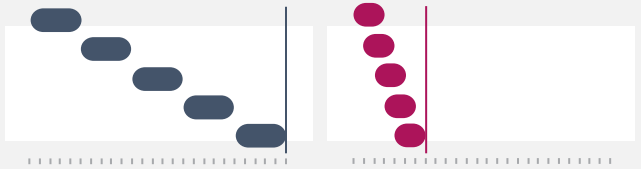
Engagement and collaboration

Who are we working with?

- Engaging with **patients and healthcare professionals** in EMA's pandemic task force, regular meetings, user testing information materials
- **Working together** with European Commission, ECDC, national medicines regulators
- Listening to **public concerns** on vaccines, to explain the science

EMA public meetings

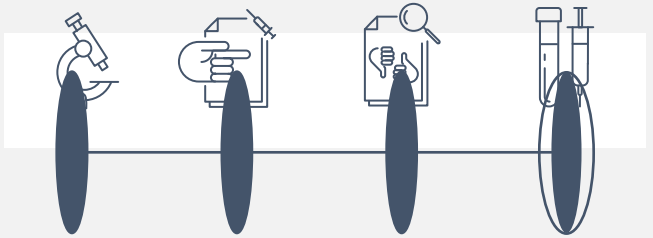
Listen to the public and stakeholder groups on their needs, questions and any concerns, so that these can be considered in the relevant regulatory processes.



#EMAPublicMeeting1

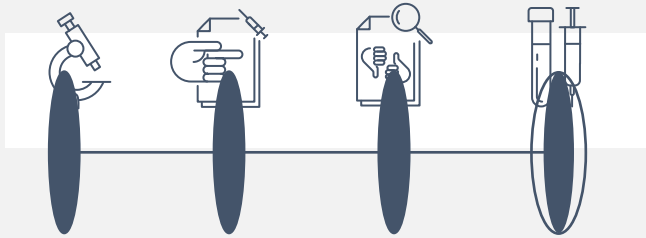
11 December 2020

EU regulatory process for approval of COVID-19 vaccines and EMA's role



#EMAPublicMeeting2

8 January 2021



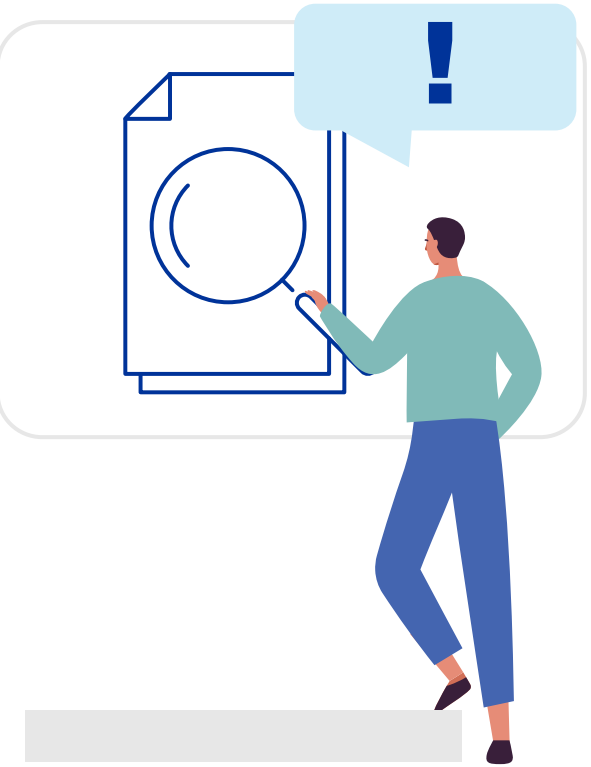
#EMAPublicMeeting3

26 March 2021

Early learnings from the pandemic

- **Opportunities**

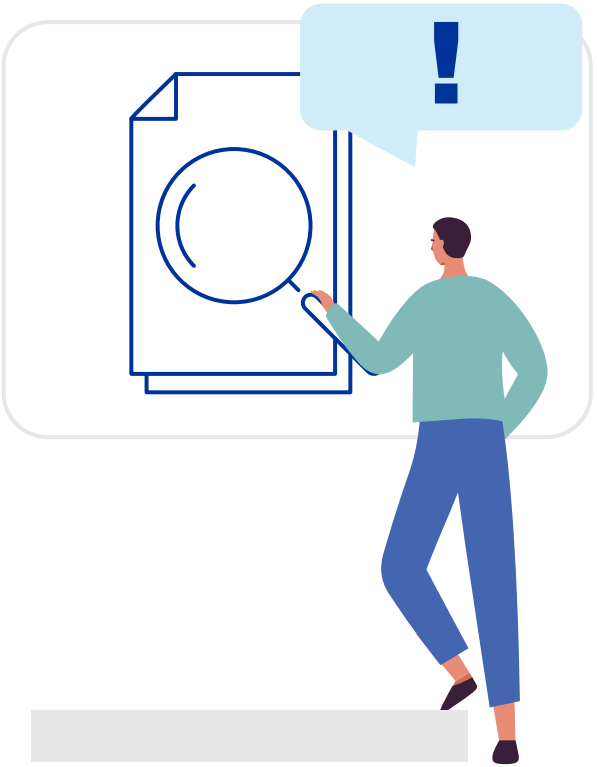
- **Increased visibility of the Agency and high demand for information** called for exceptional transparency and communication measures
- Regular press briefings and topic driven public stakeholder meetings **reinforced EMAs outreach**
- Increased transparency (e.g., prompt EPAR availability, publication of Risk Management Plans) **supported press enquiries and avoids escalating requests to Access to Documents**



Learnings from the pandemic

- **Remaining challenges**

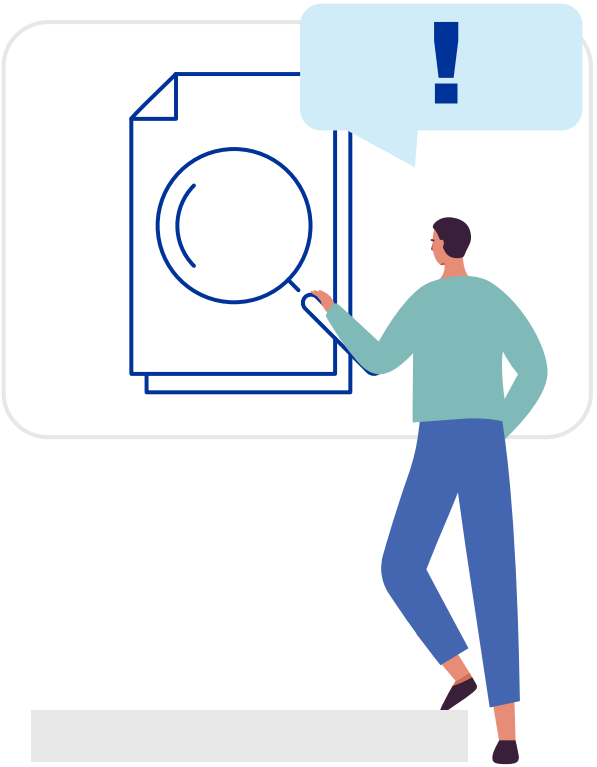
- **Timely communication** on the basis of evolving evidence
- External pressure to apply even **higher level of transparency**
- Need to address misunderstanding/lack of knowledge about the **role of regulators versus national policy makers**
- **Gathering up-to-date information** can be lengthy (e.g. gathering data from Member States)
- Reaching out to the public at national level (**24 official EU languages**)



Early learnings from the pandemic

- **Considerations**

- **Explore additional transparency measures**; some suitable for crisis situations only
- **More research needed** to define optimal tools for communication and data visualisation
- Explore **alternative routes to engage** regularly with the media, healthcare professionals and the public
- **Strengthen collaboration** and communication with ECDC and national public health authorities
- Explore options for a **more proactive approach to counteracting misinformation**



Conclusions

- **Reliable information, good** and **timely communication** and **transparency** are key
- **EMA provides transparency & access to clinical data** to understand the rationale behind important decisions
- **Engagement** is crucial:
  - ➢ actively listening to the public and our stakeholders
  - ➢ involving them in our activities
- **Misinformation has serious consequences** which we all need to combat
  - – get the facts from public health authorities

The Lancet Regional Health - Europe 9 (2021) 100192

Contents lists available at ScienceDirect

The Lancet Regional Health - Europe

journal homepage: www.elsevier.com/lanepe

Series Viewpoint

Shaping EU medicines regulation in the post COVID-19 era

Marco Cavaleri[1,*], Fergus Sweeney[2], Rosa Gonzalez-Quevedo[3], Melanie Carr[4]

[1] European Medicines Agency, Chair COVID-19 Task Force, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
[2] European Medicines Agency, Head of Clinical Studies and Manufacturing Task Force, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
[3] European Medicines Agency, Stakeholders and Communication Division, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
[4] European Medicines Agency, Head of Stakeholders and Communication Division, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

ARTICLE INFO

Article History:
Received 14 June 2021
Revised 20 July 2021
Accepted 29 July 2021
Available online xxx

ABSTRACT

The EU Medicines Regulatory Network (EMRN), comprised of the European Medicines Agency (EMA), the medicines regulatory authorities of the Member States and the European Commission (EC), is operating amid a complex crisis that has positioned regulators centre stage due to their key role in the development, approval and safety monitoring of vaccines and treatments for COVID-19. Here we consider the EMA's and EMRN's response to the pandemic and some of the early learnings that will help reshape medicines regulation in the post COVID-19 era. We also reflect on how some of these learnings will be formally followed up under revised EU legislation to extend EMA's mandate, reinforcing its role in crisis preparedness and response.

1. The role of the European Medicines Regulatory Network in medicines' regulation

The EU Medicines Regulatory Network (EMRN), comprised of the European Medicines Agency (EMA), the medicines regulatory authorities of the EU Member States (MSs) and the European Commission (EC), is operating in this pandemic, a complex crisis that has positioned medicines regulators centre stage. The EMRN is the cornerstone of medicines' approval and supervision in the EU. The European Union (EU)-wide centralised authorisation procedure, managed by EMA, relies on MS's experts, who form EMA's scientific committees, to issue a scientific opinion on the benefit-risk balance of medicines. This is then examined by the EC, who will subsequently issue a formal decision on whether to grant a marketing authorisation which is then valid throughout the EU. Working jointly as a network of experts across all MSs provides a unified scientific evaluation, and if successful, a single marketing authorisation for pharmaceuticals valid for the whole EU.

Here we reflect on the EMRN's response to the pandemic and some early learnings that will help reshape medicines regulation in the post COVID-19 era. We also consider how some learnings will be formally followed up under revised EU legislation to extend EMA's mandate, reinforcing its role in crisis preparedness and response.

2. The EMRN response during the COVID-19 public health emergency

The COVID-19 pandemic is placing a sustained and intense demand on the EMRN's resources, with multiple medicinal products subject to fast-track evaluation and safety monitoring [1], on top of regular work managing all other medicines in the regulatory system. The network's operation under these circumstances relies on the existing health threats preparedness plan [2], the mobilisation of experts from the EU Network in the COVID-19 EMA pandemic Task Force (COVID-ETF) [3], set up as soon as the pandemic was announced, and on close collaboration with international regulators. Furthermore, a quick mechanism for scientific advice on the development and evaluation of COVID-19 medicines for marketing authorisation was activated. These processes rely on the EMRN's and EMA's crisis and business continuity plans, which allow core activities to be maintained while addressing the health emergency.

The resilience of EU medicines regulators has never been tested to this extent. Challenges include the need for constantly adapting to emerging scientific data or communicating uncertainty in real time, as the pace and extent of research on COVID-19 disease and on medicine

DOI of original article: http://dx.doi.org/10.1016/j.lanepe.2021.100203, http://dx.doi.org/10.1016/j.lanepe.2021.100210, http://dx.doi.org/10.1016/j.lanepe.2021.100213, http://dx.doi.org/10.1016/j.lanepe.2021.100215, http://dx.doi.org/10.1016/j.lanepe.2021.100216, http://dx.doi.org/10.1016/j.lanepe.2021.100221, http://dx.doi.org/10.1016/j.lanepe.2021.100223, http://dx.doi.org/10.1016/j.lanepe.2021.100219, http://dx.doi.org/10.1016/j.lanepe.2021.100230, http://dx.doi.org/10.1016/j.lanepe.2021.100231.
* Corresponding author.
E-mail address: Marco.Cavaleri@ema.europa.eu (M. Cavaleri).

https://doi.org/10.1016/j.lanepe.2021.100192

Questions?

rosa.gonzalez-quevedo@ema.europa.eu

Latest updates on EMA's corporate website: COVID-19 pandemic

ema.europa.eu

@EMA_News

European Medicines Agency

Follow #COVID19vaccines