EMA
EUROPEAN MEDICINES AGENCY

Misinformation framework & Vaccine Outreach Strategy

Vaccine confidence advisory group

29 April 2026, kick-off meeting

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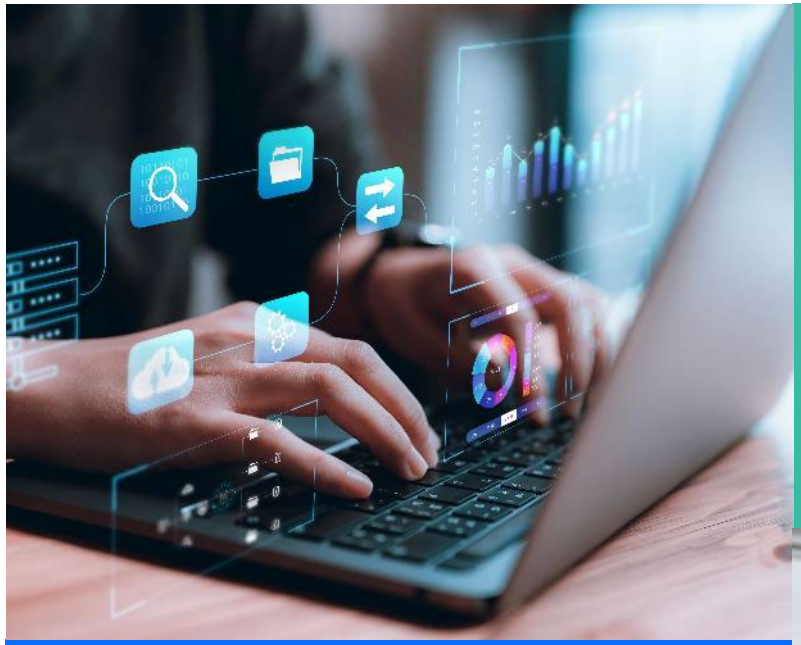
EMA’s framework against health misinformation



Collaboration

to share best practices, information and maximise impact

Insights

to drive proactive activities against misinformation

(Re)-build trust

Shift our communications approach to ensure visibility and influence of the scientific voice; increase community outreach

Insights into misinformation to guide action

EMA's listening process

- In 2025, EMA ran **two pilots** (RSV and long COVID) to better address misinformation, misconceptions, concerns, communication voids.
- Leading to a **listening process** which can be triggered on a needs-based, resource- and risk-appropriate way: with refined social listening methods, a catalogue of sources, an EMA template.
- But very resource-intensive

Focus in 2026

- Misinformation work focuses mainly on **vaccines**: list of issues and lines-to-take on vaccines regularly updated and shared internally.
- Specific social listening queries/insight reports considered as needed, in case of an acute issue
- Opportunities explored for a resource-appropriate collection of insights (partnerships, etc.)

Collaboration activities

Partners/network

Regular exchanges with EC/ECDC, with national competent authorities, to maximise impact

Specific focus on information integrity with EC/ECDC/MSs

HCPs, scientific academies and patient organisations

Engagement with healthcare professionals and patient/consumer organisations

Work on vaccine confidence and vaccine science literacy, incl. advisory group on vaccine confidence

Expertise-building

Collaboration with experts in infodemic management

Horizon scanning activities to build partnerships/expertise, and trainings

Re-build trust

- Reach new audiences, including young people (18-34 years olds): work with **content creators** (campaign on GLP-1 medicines).
- Diversify our reach on social media: EMA **ambassadors** and **thought leaders** relay science/facts, notably in areas of misinformation.
- Explain medicines regulation through its impact on citizens, showcase the people for relatable content: Inside EMA **podcast**
- Provide **accurate and evidence-based information** in areas of misinformation/misconceptions (e.g. Vaccines: concerns, questions and false claims, key facts on vaccine-preventable diseases).
- Close **engagement** with doctors, patients, and scientific academies: deliver joint, user-tested, communication tools (Vaccine Essentials).
- **Co-created awareness campaign** on shortages with healthcare professionals and consumer organisations (#ItTakesATeam).

EMA’s vaccine outreach strategy

Vaccine confidence - an ongoing challenge

2018

Global public health threat

- High scepticism– measles outbreaks
- Bad science > rumour ‘spreaders’ > general misinformation
- “Strategies must include listening and engagement”

COVID-19

Additional complexity

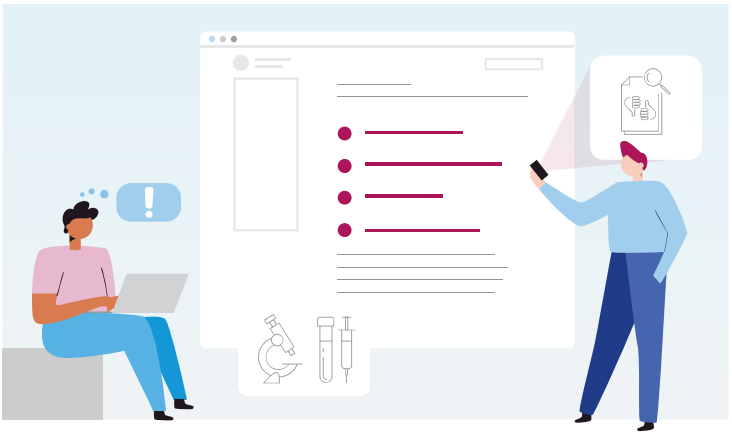
- New vaccine platforms
- Fast track development/approval
- Rare & new side effects
- COVID-19 denialism/Benefits of natural immunity
- Scale of misinformation spread in social media

Current context

Uncertainty on impact

- Geopolitical events
  - Public health leadership & ACIP Committee replacement
  - US Regulatory changes

EMA’s vaccine outreach strategy (VOS)



Goal

- Increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and empower the EU public and healthcare professionals to take well-informed vaccination decisions

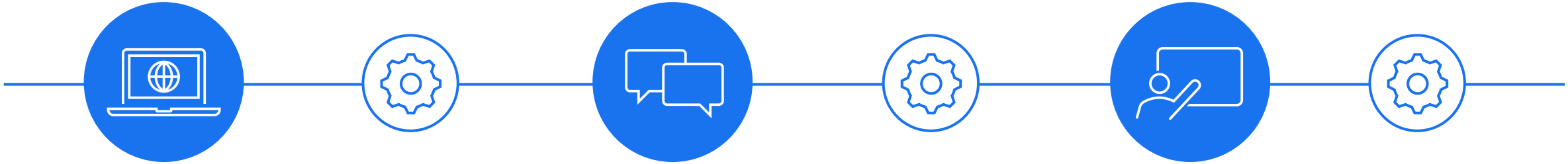
Vaccines Outreach Group (VOG)

- Set up in 2019
- Cross-Agency expertise
- Regular meetings
- Action plan with priorities

Objectives

- Monitoring & analysis of vaccine concerns
- Science outreach activities
- Collaborate with ongoing initiatives to improve information on vaccines
- Strengthen strategic collaboration with EU & international partners
- Expand evidence on the safety and effectiveness of vaccines, promote research and engagement

Strategy for enhancing vaccine science trust and addressing concerns/misinformation



Analysis of evidence/concerns

- **Regular listening + analysis**
  - Scientific evidence and concerns
- **Reporting** to relevant teams and Vaccine Outreach Group (VOG)
- **Focus on major concerns** (COVID-19)
- EMA's work on misinformation

Collaboration & building trust

- **Collaboration with HCPs** @ the frontline, as cornerstone of trust building
- **New Advisory Group on vaccine confidence** with HCPs/experts
- **New tool "Vaccine Essentials"**
- **New Joint social media campaigns** with HCPs
- **User-testing** new tools
- **Transparency**
- **Media/Social media** activities

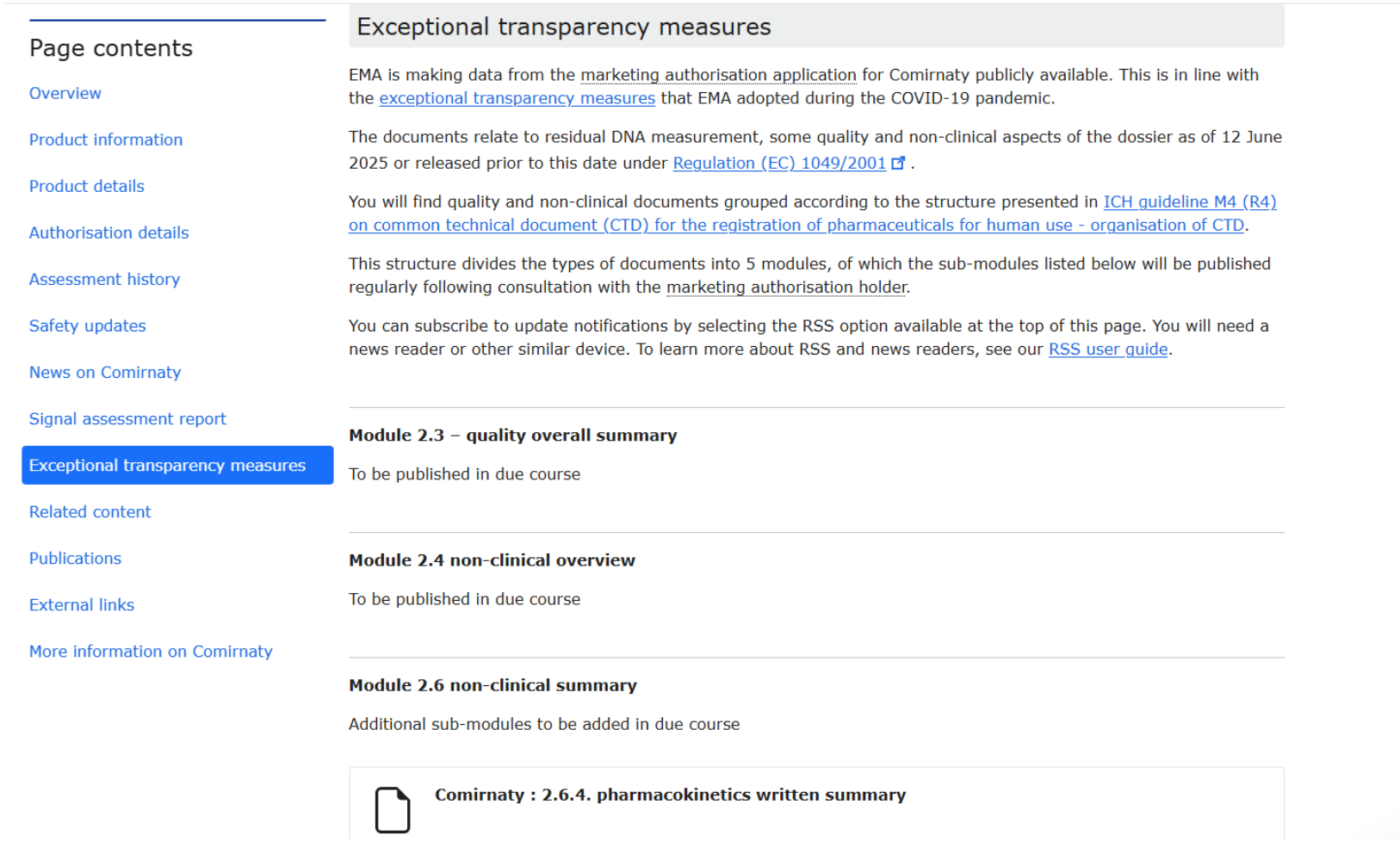
Evaluation

- **Feedback** from experts/partners
- **User-testing** and improvement
- Web/social media analytics

Increasing transparency

Addressing high demand

- Exceptional transparency measures throughout the pandemic
- More detailed landing pages for each COVID-19 vaccine
- Clinical data published for all COVID-19 medicines
- Additional measure: docs from Comirnaty and Spikevax initial applications published in response to high public interest
- Quality and non-clinical modules published



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More information on Comirnaty

Exceptional transparency measures

EMA is making data from the marketing authorisation application for Comirnaty publicly available. This is in line with the exceptional transparency measures that EMA adopted during the COVID-19 pandemic.

The documents relate to residual DNA measurement, some quality and non-clinical aspects of the dossier as of 12 June 2025 or released prior to this date under Regulation (EC) 1049/2001 .

You will find quality and non-clinical documents grouped according to the structure presented in ICH guideline M4 (R4) on common technical document (CTD) for the registration of pharmaceuticals for human use - organisation of CTD.

This structure divides the types of documents into 5 modules, of which the sub-modules listed below will be published regularly following consultation with the marketing authorisation holder.

You can subscribe to update notifications by selecting the RSS option available at the top of this page. You will need a news reader or other similar device. To learn more about RSS and news readers, see our RSS user guide.

Module 2.3 – quality overall summary

To be published in due course

Module 2.4 non-clinical overview

To be published in due course

Module 2.6 non-clinical summary

Additional sub-modules to be added in due course

Comirnaty : 2.6.4. pharmacokinetics written summary

Addressing concerns and false claims via EMA website

COVID-19 vaccines: key facts

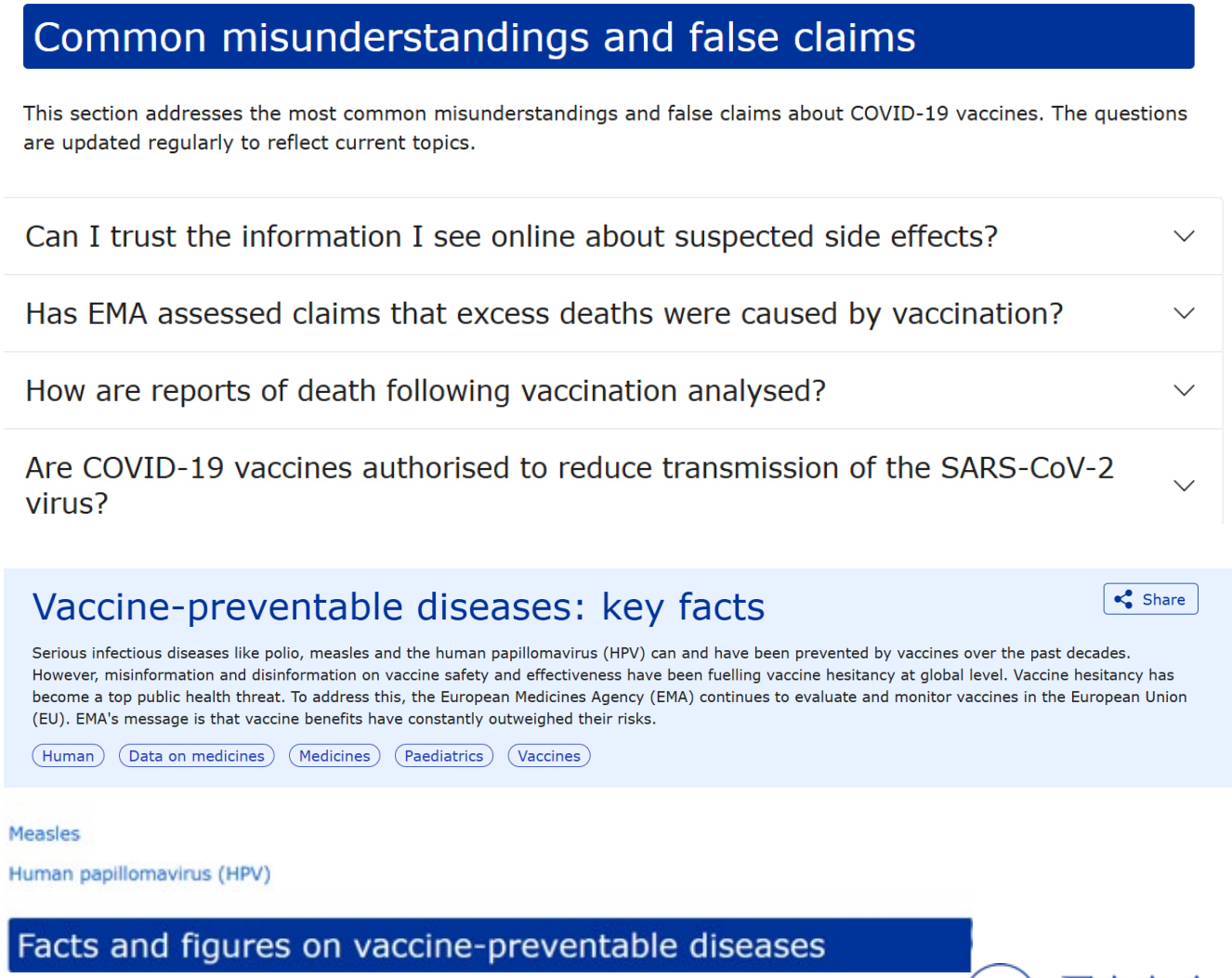
- Webpage live since 2020
- Regularly updated
  - Safety of self-amplifying mRNA, long-term side effects, residual DNA (Mar 2025)
  - Access to suspected side effects reports (Nov)

Vaccines safety with explainers

- How we monitor safety
- ADRs into context
- Specific side effects, e.g. TTS, myocarditis

Vaccines: concerns, questions and false claims

- Webpage live since spring 2025



Conclusions

Overall considerable efforts have been made and are ongoing to strengthen vaccine confidence, address misinformation and close knowledge gaps

- **Very difficult context** for vaccine confidence
- **Listening methodologies**, although time-consuming and resource-intensive, can **help identify topics faster in all areas**
    - for COVID-19 they helped us move quicker to address issues through clear messages and timely actions

More is needed

- **Collaborations** with medical societies/patient advocates, other public health institutions facing similar challenges are **key** to **delivering results** and **building trust**
- **Optimal IT tools, scientific input and assessment** are critical for addressing issues efficiently
- Uncertain future with **fast evolving AI tools and platforms**

Importance of strengthening efforts and being prepared to respond to new and increasingly sophisticated challenges

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Thank you

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