EMA
EUROPEAN MEDICINES AGENCY

A new communication approach on medicines safety monitoring in the EU

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Context

- High demand for information **on how safety of medicines is monitored** and ensured in the EU
- **Questions, concerns** – sometimes misunderstandings – **constantly received**
- Safety monitoring information is **fragmented** on EMA website

Need for clear and easy to understand narrative for the public and other EMA stakeholders

What’s coming up?

- New **communication package** with materials dedicated on medicines safety monitoring, including vaccines.
- Materials in **lay language** and easily **accessible.**
- Content in **various formats** and for **various platforms**.
- **Translations** into all EU languages envisaged.

New approach in a nutshell

What?

- Explain how EMA and the EU Member States continuously monitor safety and take measures when needed

Who?

- General public
- Patients, caregivers, consumers and their organisations
- Healthcare professionals and their organisations
- Media

How?

- Booklet
- Videos
- Visuals
- And more…

Where?

- EMA corporate website
- Social media platforms
- Partners' channels (tbc)

Where are we now?

- Booklet outline developed
- Key topics identified
  - How medicines' side effects are identified and managed at time of authorisation
    - Importance of **Summary of Product Characteristics (SmPC)** and **package leaflet**
  - How safety is **continuously monitored** after authorisation
    - Focus on reporting of suspected adverse reactions: How? What? Why?
    - Explain how causality is established
  - Taking **measures** to minimise risks when needed
  - Integrating **patients and healthcare professionals' voices**
  - Transparency and communication
- Content production is in progress
- A few patients and HCPs provided further insights; comments taken on board

What people say

"The document is very comprehensive and easy to understand and follow"

Healthcare professional

"In the booklet I would explain deeper the proactive pharmacovigilance"

Patient

"Congratulations on this interesting document, which I think is very important for patients"

Patient

"It is important to emphasize how patients can report undescribed adverse drug reaction and adverse drug event through the reporting systems of national regulatory agencies."

Patient

"Very well organized overall and, if explored from a visual point of view with simple content, it covers everything that is really necessary"

Healthcare professional

What’s next?

- Content of booklet progressing well
- Target publication date: around #MedSafetyWeek (3-9 November 2025)
- Booklet forms basis for further content (videos and materials for social media)
- Foreseen videos on:
  - The package leaflet of a medicine; and
  - What happens when a signal is raised

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Thank you

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