EMA
EUROPEAN MEDICINES AGENCY

Communications on safety monitoring of medicines in the EU

Engagement with stakeholders

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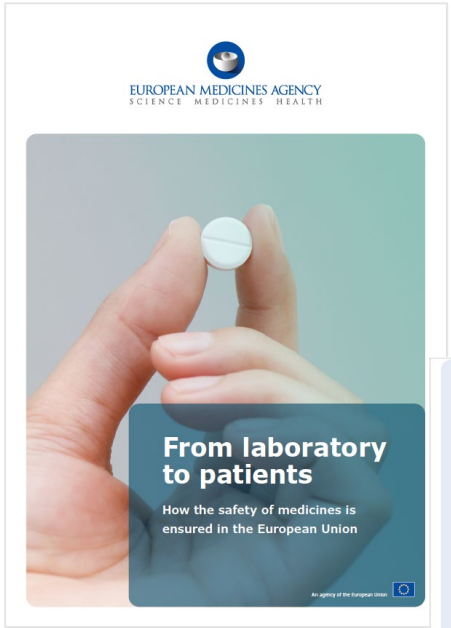
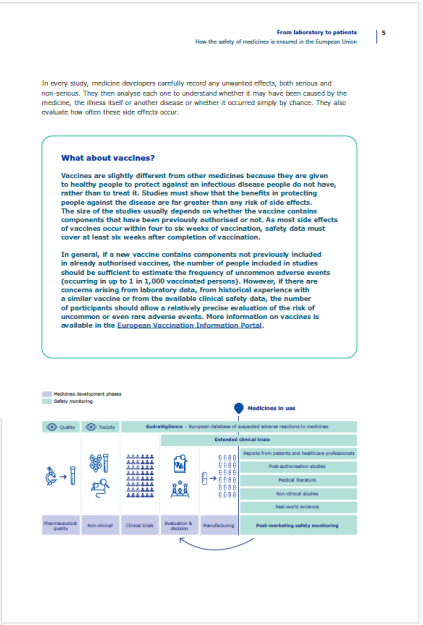
PCWP/HCPWP meeting – 19 November 2025

Communication materials on the safety monitoring of medicines





Importance of reporting suspected side effects

- Raise awareness of reporting tools at national level
- How to report?
- What to report?
- What happens afterwards?

Reporting side effects can make medicines safer for everyone

Anyone can report a suspected side effect on a medicine as long as they have the necessary details; this includes the patient, the patient's carer, a doctor, nurse or pharmacist. Patients can report a suspected side effect themselves, or talk with their healthcare professional during a consultation, who can submit a report on their behalf. Each EU country has a reporting tool and information about how to submit a report is available on the websites of national competent authorities. Information on how to report a suspected side effect can also be found in the package leaflet and the SmPC. Providing clear and detailed information is essential when reporting a suspected side effect. The following key details should be included:

information on the person who has experienced the side effect, including age and sex

the name of the medicine (brand name as well as active substance) suspected to have caused the side effect

dose and duration of treatment with the medicine

how long the treatment had lasted when the suspected side effect occurred

whether the person stopped taking the medicine after the side effect occurred and, if so, did the side effect stop

the batch number of the medicine (found on the packaging)

other medicines taken around the same time (including non-prescription, herbal or birth control medicines)

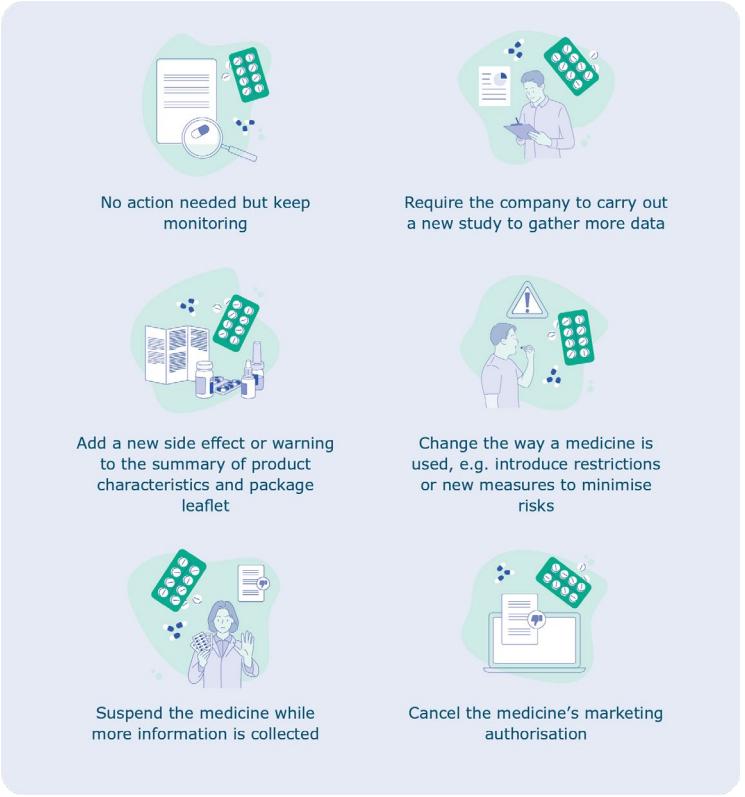
any other health condition that the person may have

Actions taken to address safety concerns

- Describe the range of data sources analysed
- Explain how new data are assessed
- Highlight the range of actions that EMA and the EU medicines network can take

4. Taking measures when needed

- **A key outcome of safety monitoring is action taken to prevent or minimise harm.**
- **The continuous evaluation of new data can lead to different actions.**
- **The choice of action depends on the seriousness of the concern and may take into account whether other treatment options exist.**



Consulting patients and healthcare professionals

- Consulted as experts in many ways
- Throughout the assessment of key safety issues
- Until final outcome and communication

5. Integrating patients' and healthcare professionals' voices

- **Patients and healthcare professionals are best placed to understand issues arising with medicines 'first hand'.**
- **They are consulted as experts and can share their views and insights during the evaluation of safety concerns in various ways.**

Patients and healthcare professionals are involved in the safety of medicines in many ways. Patients contribute by highlighting, for example, their experience of the disease, their needs and what risks they would consider acceptable in view of the expected benefits. Healthcare professionals may advise on the feasibility of measures proposed to minimise the risks associated with a medicine in clinical practice.

Did you know?

Patients and healthcare professionals review a number of EMA documents before they are published on the EMA website to ensure they are clear and understandable. They review, for example, public health communications when they include safety recommendations, medicine overviews, package leaflets and direct healthcare professional communications.

› They are full members of the PRAC.

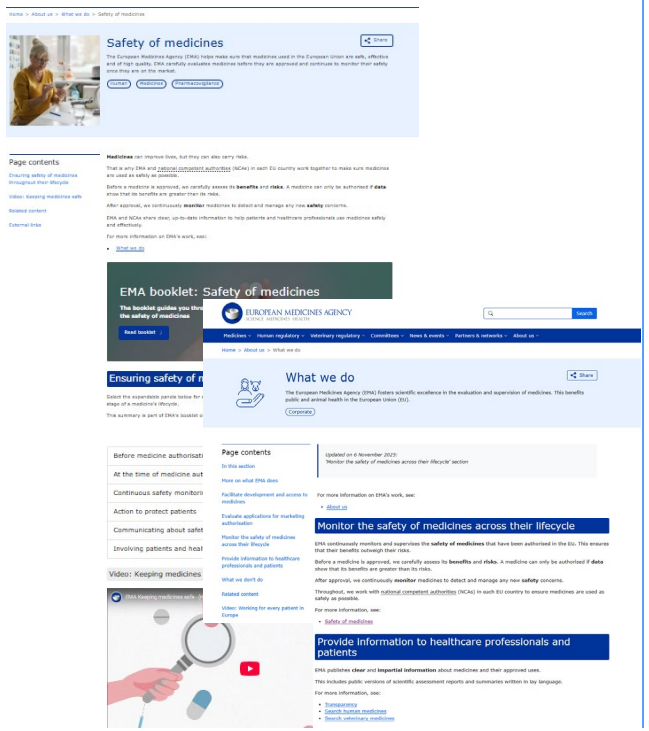
› They are involved as experts in scientific advisory groups or ad-hoc expert groups, and may be consulted during safety reviews.

› They can take part in public hearings, which EMA holds on a case-by-case basis before issuing major public health recommendations.

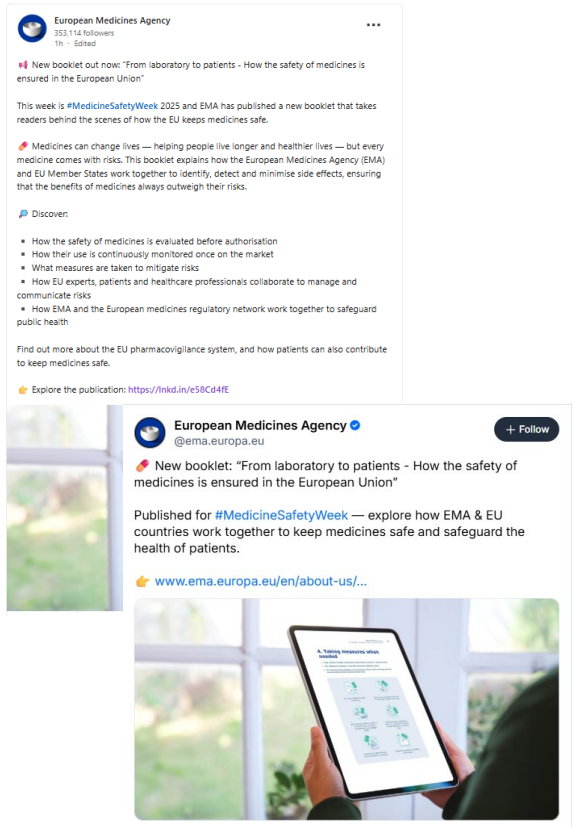
› They can send their input in writing for consideration during any ongoing review.

Joint efforts, shared success: Materials promoted during #MedSafetyWeek2025

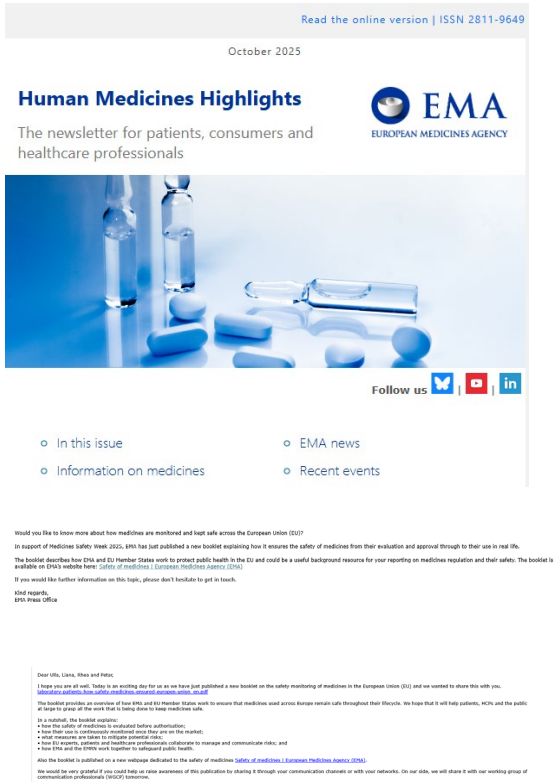
New webpages



Social media posts



Targeted mailing

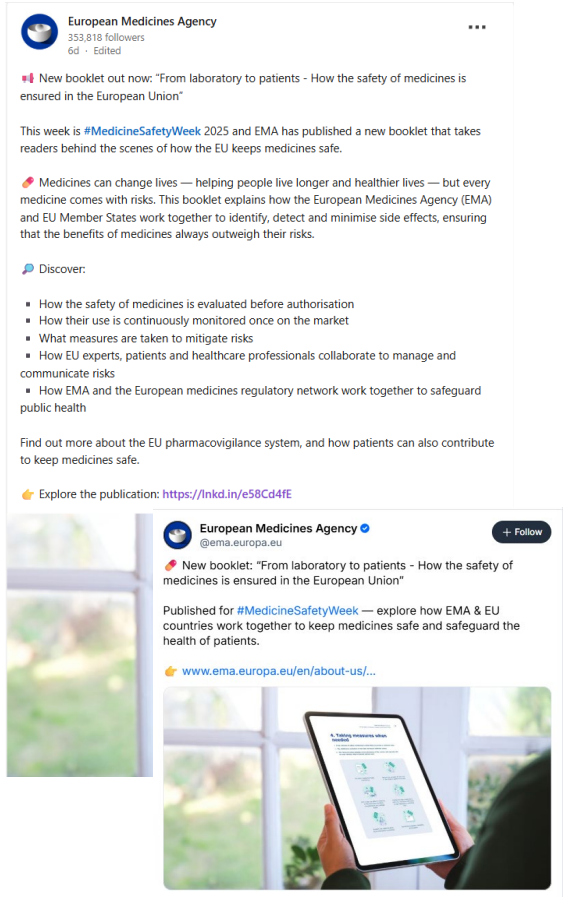


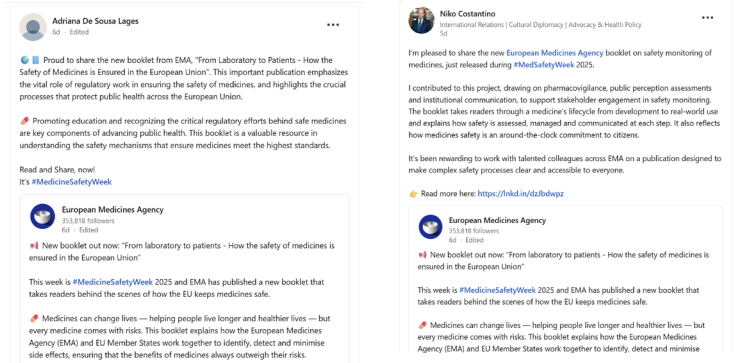
Key meetings

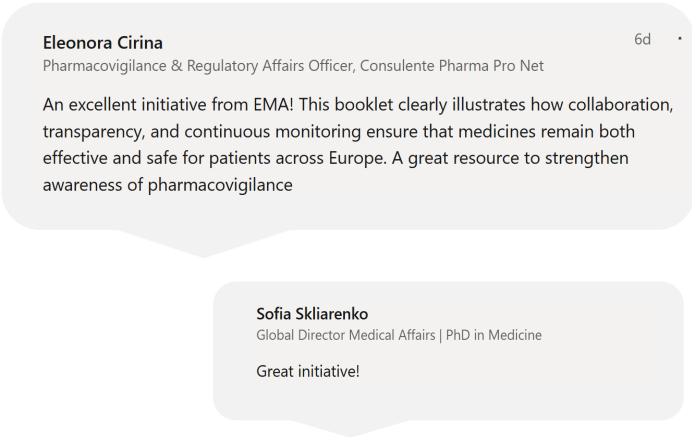
- Joint EMA/HMA communication group (7 Nov)
- International Coalition of Medicines Regulatory Authorities (ICMRA) Communications Group (26 Nov)
- PRAC lunchtime talk (26 Nov)
- ...and more

Joint efforts, shared success: Key results

- **Broad visibility and reach** with over 10,800 impressions on LinkedIn;
- **High engagement on LinkedIn** with 152 reactions, 29 shares and multiple reposts;
- **Moderate engagement on Bluesky** with 10 likes, 6 reposts and 3 saves;
- **Interest in featured content and good traffic generation** via LinkedIn (262 link clicks);
- Comments and saves on social media show **content relevance and meaningful interaction**.

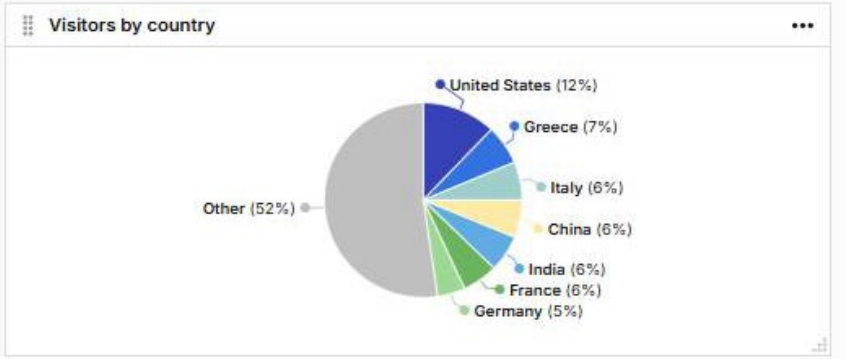


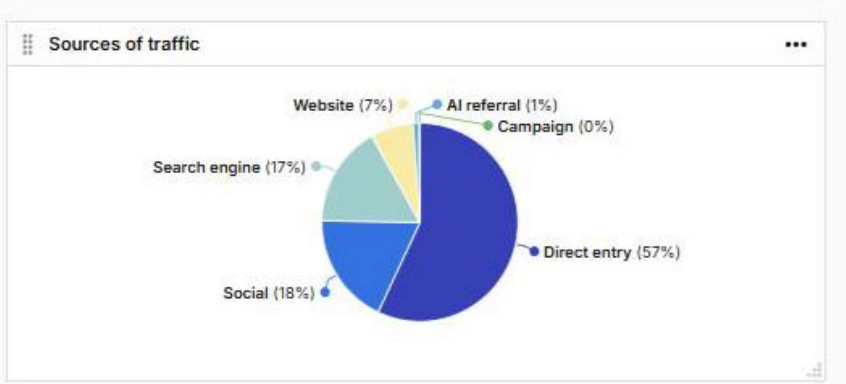




Joint efforts, shared success: Key results (cont.)

- **990 stakeholders** visited the new webpage within the first week after its publication. They **downloaded the booklet 381 times** during this period;
- **Almost 56%** of them were **returning visitors**, suggesting their **interest** in this topic;
- **Most web visitors** (63%) were based **in Europe** and 21% were in Asia;
- **More than half** of them (57%) **accessed the content directly** by using the link to the webpage, while only 17% found it through a search engine, such as Google.





What's next?

- Social media promotion:
    - Focus on safety messages (e.g. what information patients can report and the safety measures EMA can take) by the end of November;
    - Promotion of new videos about the package leaflet and the safety signals by the end of December;
- Interactive version of the booklet (to be developed in early 2026);
- Translation of booklet in all EU languages (planned for early 2026);
- Continuous monitoring of engagement and use of these materials should not stop!
    - Sustaining effort will help counter the public concerns around medicines safety.

Join us in sharing these materials and keep the conversation going!

EUROPEAN MEDICINES AGENCY
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Thank you

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