EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How we communicate the outcome of safety reviews

PCWP/HCPWG joint meeting – 27-28 February 2013

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Directorate/Communications Sector

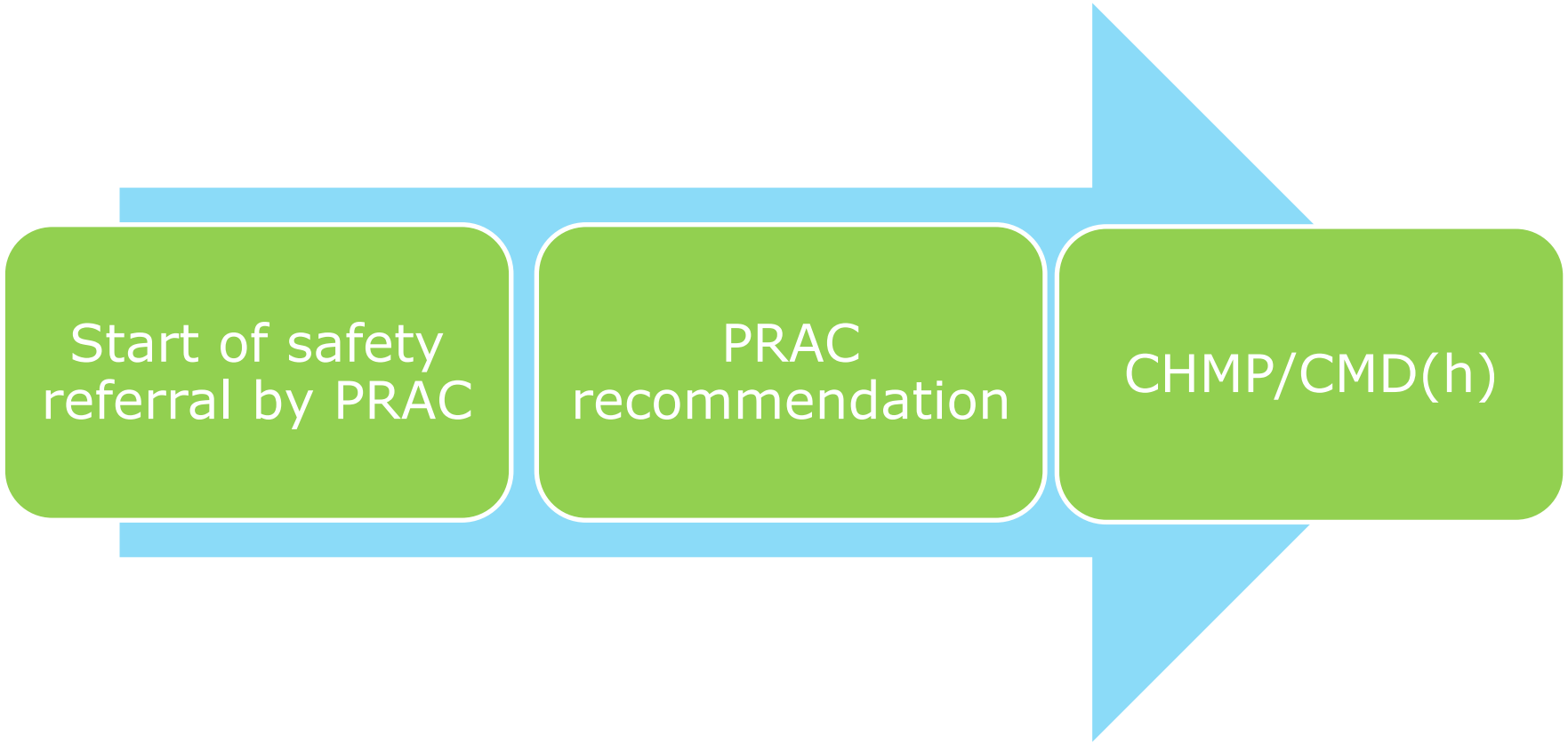
Transparency and communication – key objectives of the new legislation

Good information

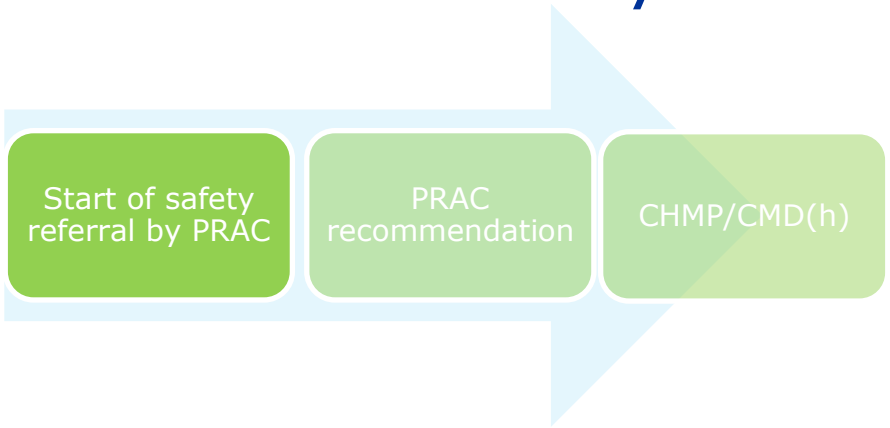
- Provides timely evidence-based information on the appropriate, safe and effective use of medicines;
- Facilitates changes to healthcare practices (including self-medication practices) where necessary;
- Improves attitudes, decisions and behaviours in relation to the use of medicines;
- Supports risk minimisation behaviour;
- Facilitates informed decisions on the rational use of medicines.

Communication about safety referrals

Procedure



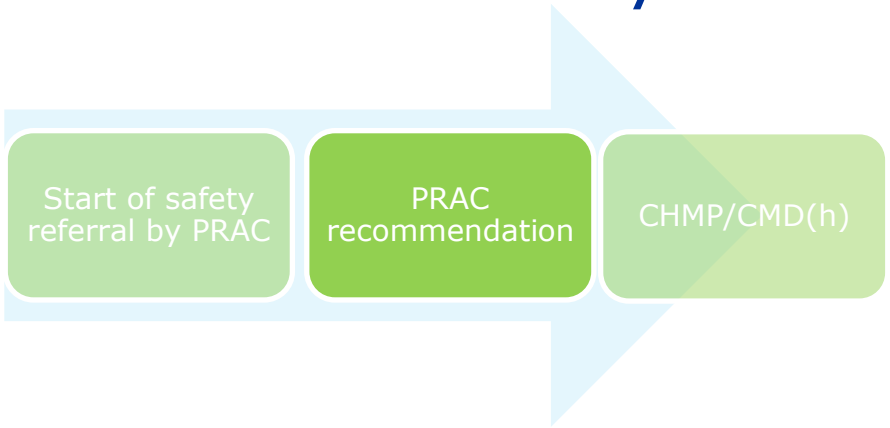
Communication about safety referrals



- *'EMA announcement of start of referral'*
- Notification
- PRAC List of Questions for marketing authorisation holders
- PRAC List of Questions for stakeholders
- Timetable
- List of medicines concerned by the referral

Example: DIANE 35

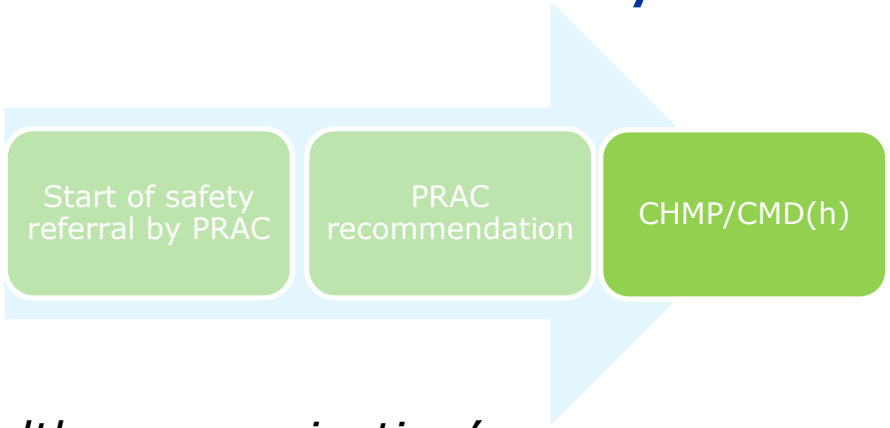
Communication about safety referrals



- *'Summary of PRAC recommendation'*
- *Format: Q&A*
- Written for lay readers
- Should ensure that the public understands the process and what 'PRAC recommendation' means (not the final EMA opinion) and what happens next.

Example: Tredaptive

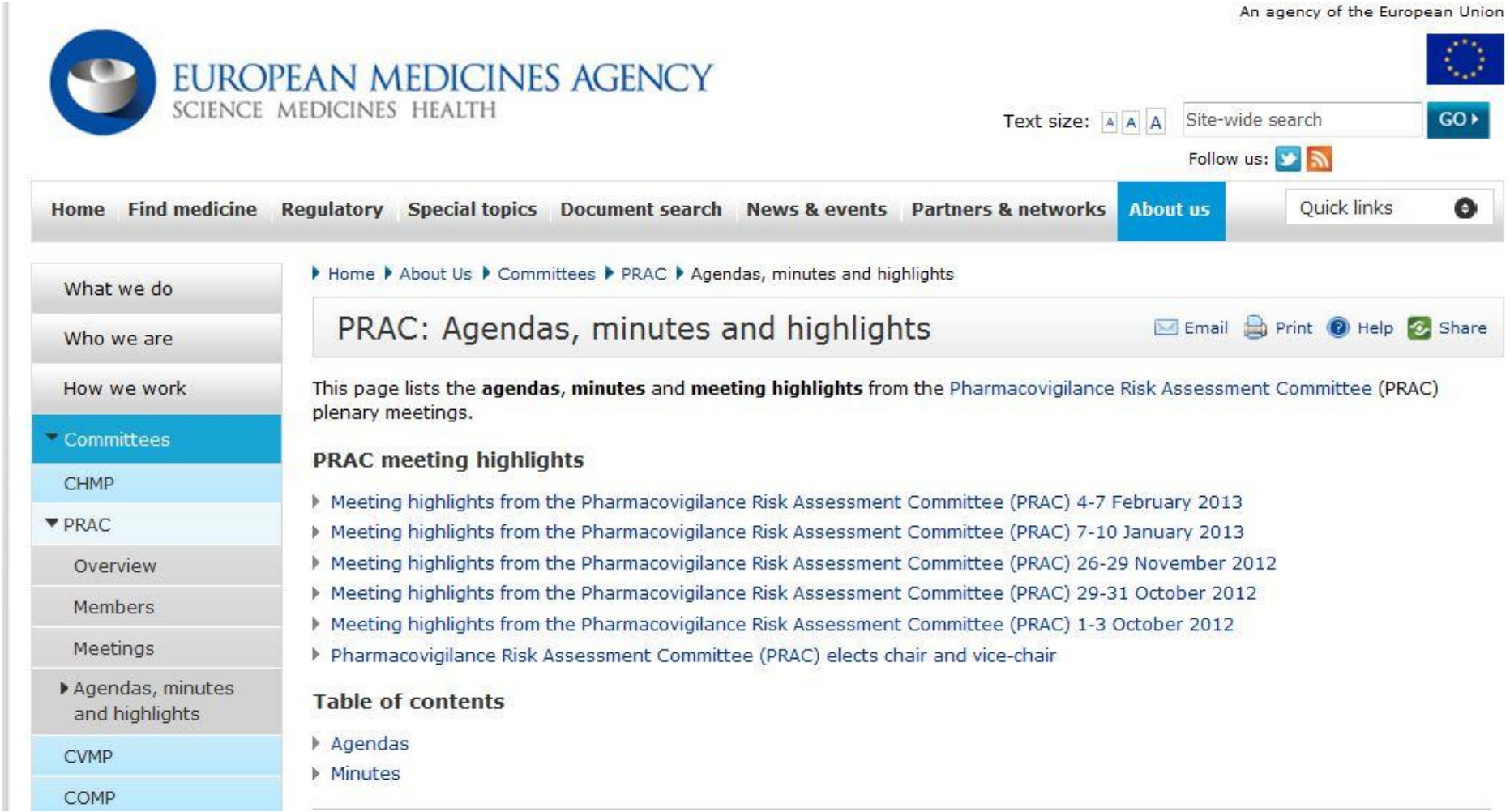
Communication about safety referrals



- *'EMA public health communication'*
- Single piece of information (integrates PR+Q&A into one document), composed of three sections:
  - Summary of the issue (for press and general public)
  - Information to patients
  - Information to healthcare professionals
- Explain any divergence with PRAC recommendation if applicable
- Syndicated to press, patients and healthcare professionals contacts

Example: Tredaptive

More information on PRAC outcomes



More information on PRAC outcomes
Agendas, minutes and highlights

Publication schedule

Agendas	First day of the PRAC by midday
Highlights	Friday of the PRAC week
Minutes	Friday of the PRAC week, in the following month

Thank you for your attention.