



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How we communicate the outcome of safety reviews

PCWP/HCPWG joint meeting – 27-28 February 2013

Presented by: Rebecca Harding
Directorate/Communications Sector

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Transparency and communication – key objectives of the new legislation

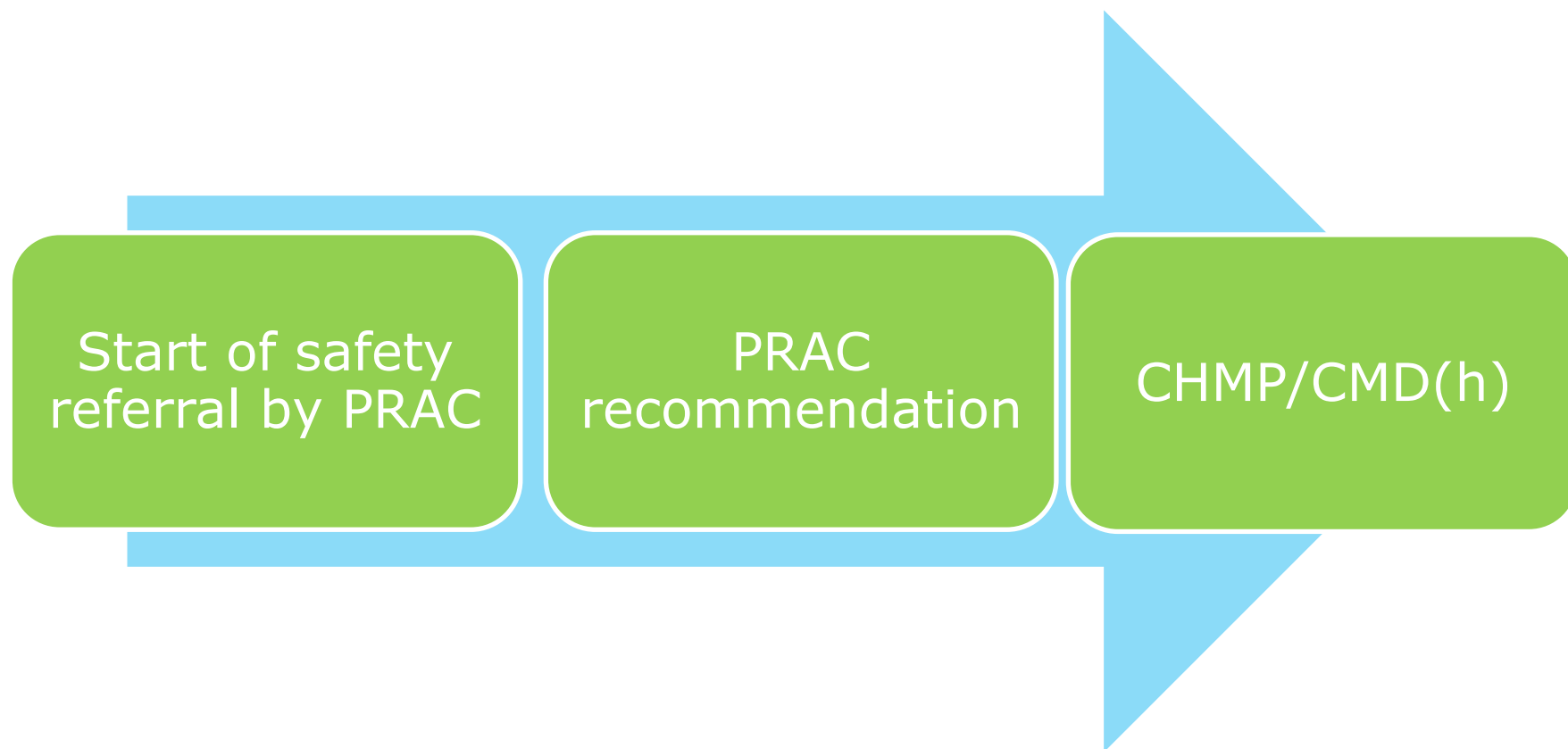
Good information

- 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.



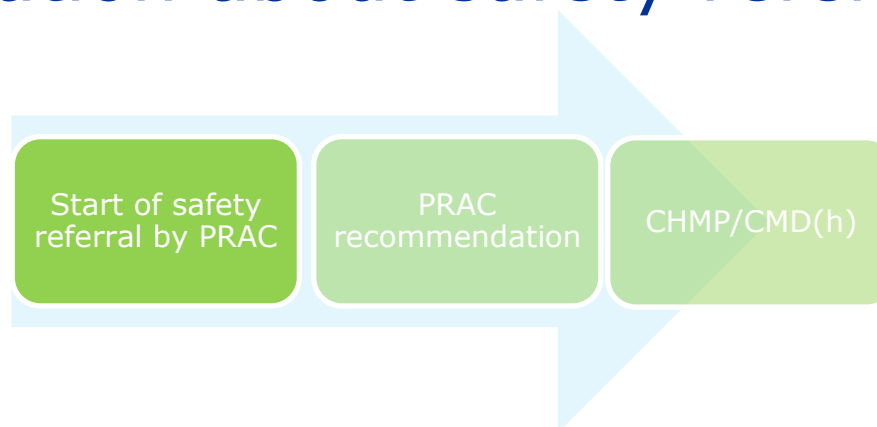
Communication about safety referrals

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

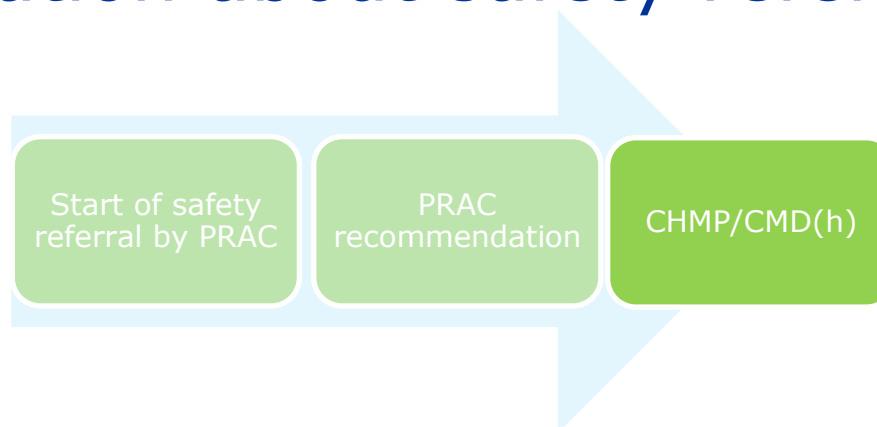


- *'Summary of PRAC recommendation'*
- *Format: Q&A*
- Written for lay readers
- Should ensure that the public understands the process and what 'PRAC recommendation' means (not the final EMA opinion) and what happens next.

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



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PRAC: Agendas, minutes and highlights

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This page lists the **agendas, minutes** and **meeting highlights** from the Pharmacovigilance Risk Assessment Committee (PRAC) plenary meetings.

PRAC meeting highlights

- ▶ Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 February 2013
- ▶ Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7-10 January 2013
- ▶ Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 26-29 November 2012
- ▶ Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29-31 October 2012
- ▶ Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 1-3 October 2012
- ▶ Pharmacovigilance Risk Assessment Committee (PRAC) elects chair and vice-chair

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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.