



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How we communicate the outcome of safety reviews

PCWP training session on the new pharmaceutical legislation

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An agency of the European Union





Transparency and communication – key objectives of the new legislation

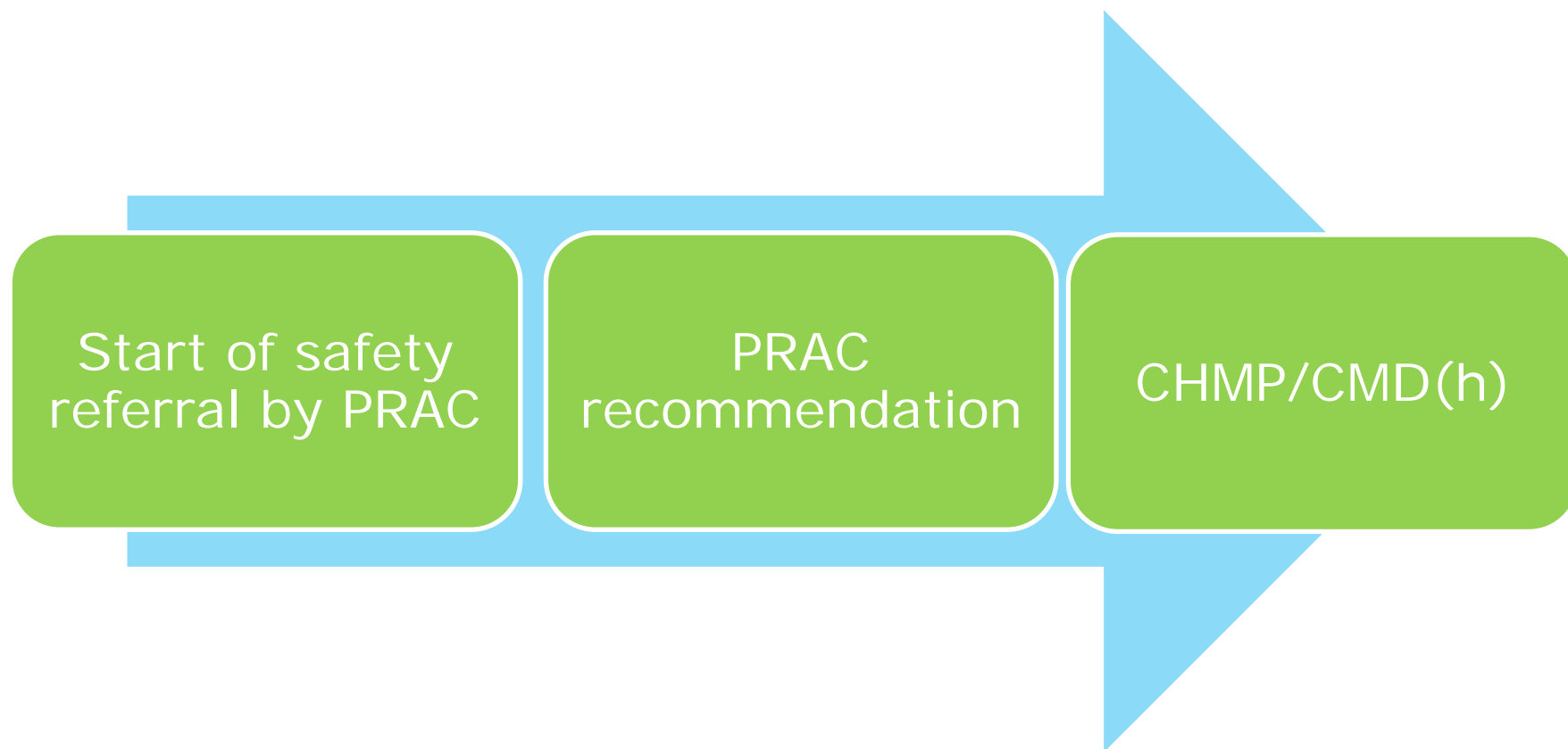
Good information

- 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
- List of Questions
- Timetable

Example: [diclofenac](#)



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.



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
- Syndicated to press, patients and healthcare professionals contacts



More information on PRAC outcomes



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CHMP

▼ PRAC

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Members

Meetings

▶ Agendas, minutes and highlights

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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 \(PRAC\) 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](#)

Table of contents

- ▶ [Agendas](#)
- ▶ [Minutes](#)



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



Looking ahead

Information resources still to come

- Summary of risk management plans for centrally authorised medicines
- List of medicines subject to additional monitoring
- Public hearings



Thank you for your attention.