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SCIENCE MEDICINES HEALTH

The PRAC in PRACtice

5th Stakeholders Forum – 25th May 2012

➔ Nominations update

- 2 Member States still outstanding
- Lichtenstein has delegated its pharmacovigilance tasks to Austria
- EC in process of selecting their experts – process should be finalised in the next few weeks
- HCP/patients representatives – nominations may be facing further delays due to European Parliament concerns
- MB should be consulted on the final composition of PRAC
- High overlap of PRAC members/alternates with existing PhVWP members *(21 Member States (+ Iceland and Norway) having either a future member or alternate currently participating in the PhVWP)*

Amended legislations define new tasks for PRAC that were within CHMP/MS remit before and give additional responsibilities to CMDh

*"The mandate of the PRAC shall cover all aspects of the **risk management** of the use of medicinal products for human use including the **detection, assessment, minimisation and communication relating to the risk of adverse reactions**, **having due regard to the therapeutic effect** of the medicinal product for human use, **the design and evaluation of post-authorisation safety studies and pharmacovigilance audit**"*

➔ PRAC will evaluate risks in the context of identified benefits

PRAC tasks lead by specific appointed Rapporteur

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—**Urgent union procedures** (Art 107i)

—Individual **PSUR assessment** (CAPs) and single PSURs assessment

—**PASS** (review study protocol/amendments, evaluation of results)

—**Pharmacovigilance inspections** related to medicinal products of Community interest; **Pharmacovigilance audit**

—**RMP** (approval, updating and monitoring of effectiveness)

—**Art 31, Art 20 referrals for safety reasons**

—**Signal detection** responsibilities (analysis and prioritisation)

— **Renewals, annual reassessments**

— **Safety type II variations**

PRAC outputs

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PRAC issues **recommendations/advice** to CHMP/CMDh on any question relating to pharmacovigilance activities in respect of medicinal products for human use and on risk management systems, including the monitoring of the effectiveness of those risk management systems

If CHMP/CMDh have **divergent views** than those expressed by the PRAC these should be duly justified

PRAC outputs

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PRAC outputs	Relevant processes	Types of products
Explicit mandate in the legislation with formal decision making phase ➔ **PRAC recommendation**	Pharmacovigiance referrals PSURs assessments Non interventional PASS	NAPs, CAPs and mixture of NAPs/CAPs
Explicit mandate in the legislation without formal decision making phase ➔ **PRAC advice**	RMP Renewal Type II safety variation Annual reassessment Signal PhV inspections requests and results PhV audits	NAPs, CAPs and mixture of NAPs/CAPs
Explicit mandate in the legislation without formal decision making phase ➔ **PRAC advice with adoption of assessment report**	RMP for CAPs Renewal for CAPs where PSURs included	CAPs
Directly applicable **PRAC decision**	PASS protocols and substantial amendments PASS study results	NAPs, CAPs and mixture of NAPs/CAPs
Lists	EURD list List of products requiring additional monitoring *(published by EMA)*	For EURD list PRAC output to be adopted by CHMP/CMDh
PRAC advice not going to CHMP/CMDh	Advice to MB on functionality of PSURs repository and EudraV; advice to EC on black symbol; advice to EMA on literature monitoring	NAPs, CAPs and mixture of NAPs/CAPs

PRAC Rapporteurs – where are we?

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— EMA in collaboration with MS is developing a workable proposal to be endorsed by MB (June)

— Appointments should be **based on best existing scientific expertise and where possible provide a "fresh pair of eyes"**

➔ PRAC Rapporteur shall closely collaborate with CHMP Rapporteur or RMS for nationally authorised products

Role of PRAC in decision making process

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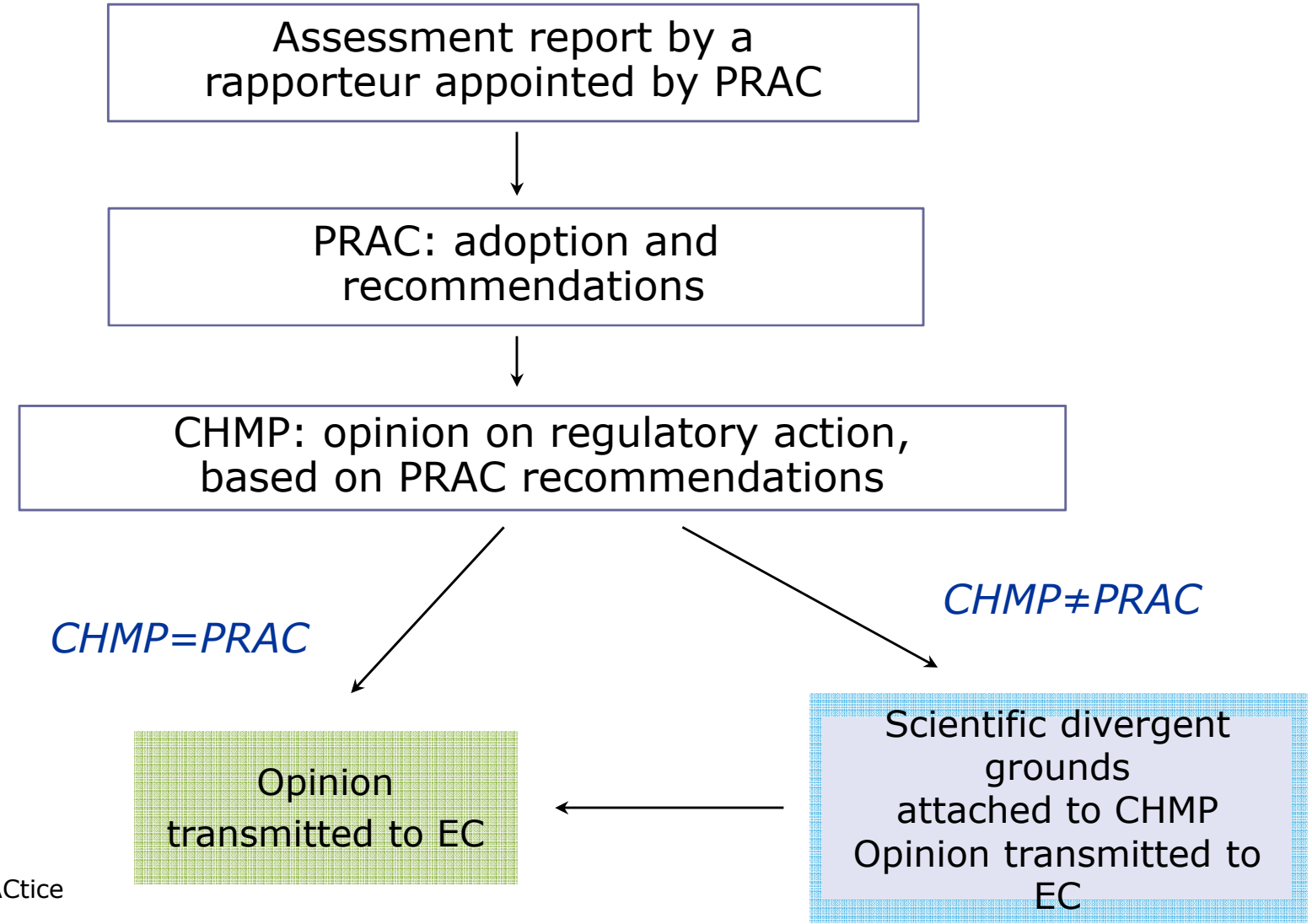
When at least one CAP is involved…



Role of PRAC in decision making process

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Only NAPs are involved…

New!! CMDh will vote

Assessment report by a rapporteur

↓

PRAC: adoption and recommendations

↓

CMDh: opinion on regulatory action, based on PRAC recommendations

CMDh=PRAC

consensus → Agreement sent to MS and MAH

no consensus ➔ majority position → Transmitted to EC

CMDh≠PRAC

consensus → Agreement sent to MS and MAH together with scientific divergent grounds

no consensus ➔ majority position → Transmitted to EC together with scientific divergent grounds

Meeting's organisation

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- PRAC normally meets at the Agency 2 weeks before CHMP/CMDh

19/20 July Brussels *(inaugural meeting)*
3, 4, 5, 6 September *(this is it!)*
1, 2, 3, 4 October
29, 30, 31 October
26, 27, 28, 29 November
…

- PRAC meetings occur Monday 1pm to Thursday

- Oral explanations possible in front of PRAC

- For Article 107i procedures, public hearings can take place at the PRAC *(of note MAHs or any other person intending to submit confidential data may ask to present data in a non public part of the hearing).*

Meeting's organisation

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PRAC agenda

Referrals, matters resulting from PSURs (CAPs/single assessment), advice on safety issues (variations), matters relating to signal management, matters relating to RMP/PASS, PhV inspections, safety communications, controversial renewals, re-examinations and ORGAM

Made public prior to meeting start (confidential information will be deleted)

PRAC minutes

Mirror agenda

Reflect background of issue, summary of questions raised by PRAC and conclusions reached together with action to be taken.

Made public once adopted

Transparency

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- Names of PRAC members, qualifications and Declaration of Interests publicly available
- PRAC agendas and minutes made public at pre-defined time points
- High level PRAC outcomes publicly available once meeting is over *(format/content/timing still under internal discussion)*
- Final PRAC recommendations/advice fully available once CHMP/CMDh have concluded relevant procedures

In summary

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- Most challenging piece of legislation for the Agency in years
- Only 8 weeks to go, work is on-going to finalise key documents / issues, to ensure we are ready
- Learning curve will be steep for all parties involved

…. Together we will get there!