Safety communication and its role in risk minimisation

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Introduction

New legislation in pharmacovigilance:

- Unprecedented focus on (safety) communication by regulatory authorities
- Openness
- Transparency
- Involvement of users of medicines in its preparation

***Guideline on good pharmacovigilance practices* (GVP) - Module XV defines safety communication** as:

- new or emerging information on an authorised medicine which has an impact on its benefit-risk
- facilitates informed decisions on the rationale use of medicines and to support risk minimisation behaviour.
  - two-way process
  - communication *vs* transparency
  - complement to statutory product information (i.e. package leaflet)
  - its coordination is essential

Transparency

- ‘one size fits all’
- creates environment for information on decisions and their rationale is provided in understandable, accessible, timely manner
- serves democratic decision making

Communication

- tailored message
- Involves a sender transmitting information to a receiver with a declared intention or expectation
- Aims at behavioural changes

Public pharmacovigilance communication: a process calling for evidence-based strategies *Bahri P, 2010* Drug Safety 1;33(12):1065-79

Principles of safety communication

- Safety communication is part of risk assessment of medicines (throughout the entire evaluation process)
- Need to deliver clear messages to right audience at right time
- Should be tailored to the appropriate audience and should use appropriate language
- Information on the risk to be put always in context of benefit
- Always address uncertainties
- Use of adequate quantitative measures
- Involve civil society (users of medicines)
- Effectiveness of communication should be measured
- Primary target audience: **patients and health professionals**

Content of safety communication

- Clear and concise information
- New (emerging) *important* information
- Explain reason for its publication/dissemination
- Include any recommendations to patient/healthcare professionals
- Avoid subjective, misleading, promotional information or advertisement

Means of (safety) communication

Tools & channels currently used by EU Network:

- Direct healthcare professional communication (DHPC)
- Documents in lay language (e.g. Q&A)
- Press communication
- Website and web-based communications
- Inter-authority communication (LTT)
- Public enquiries
- Bulletins and newsletters
- Others (e.g. scientific journals, etc)

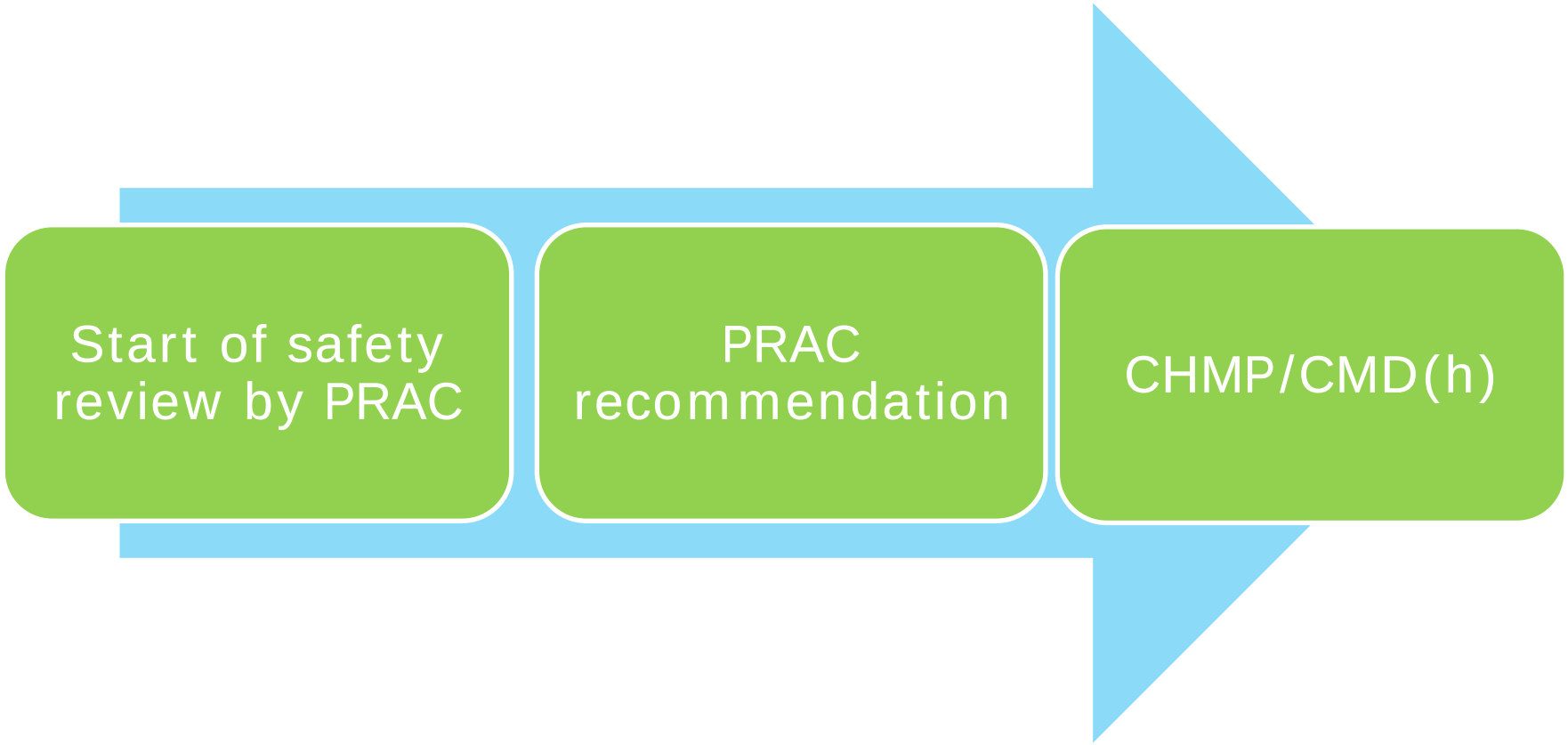
Direct healthcare professional communication (DHPC)

- Specific tool which involves both industry and regulators for the purpose of protecting public health.
- Defined as a '***communication intervention by which important safety information is delivered directly to individual healthcare professionals to inform them of the need to take certain actions or adapt their practices in the interest of public health***'
- Process has been streamlined - **criteria** identifies the need for a DHPC
- DHPCs agreed at EU level involve PRAC

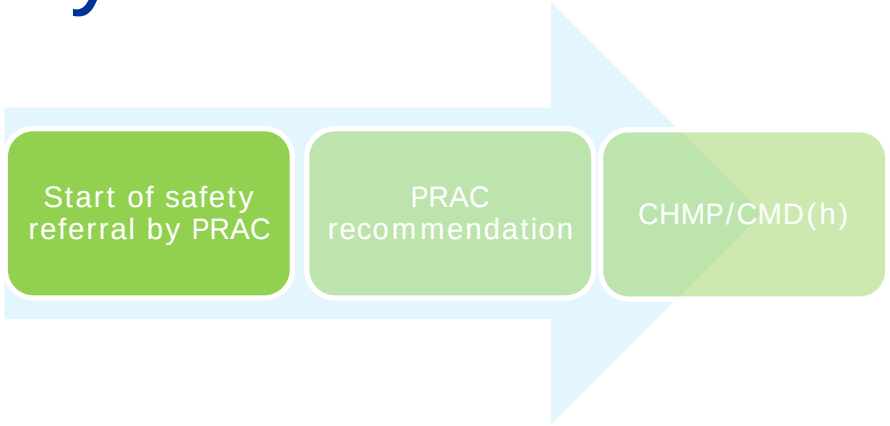
Coordination of safety announcements in EU

- Good level of coordination – clear, consistent messages for patients and healthcare professionals
- Prior to the publication of a safety announcement, the Member States, the EMA or the European Commission inform each other not less then 24 hours in advance.
- Criteria for coordination has been defined
- EMA is responsible for this coordination **‘Early Notification System’**

EMA safety communication



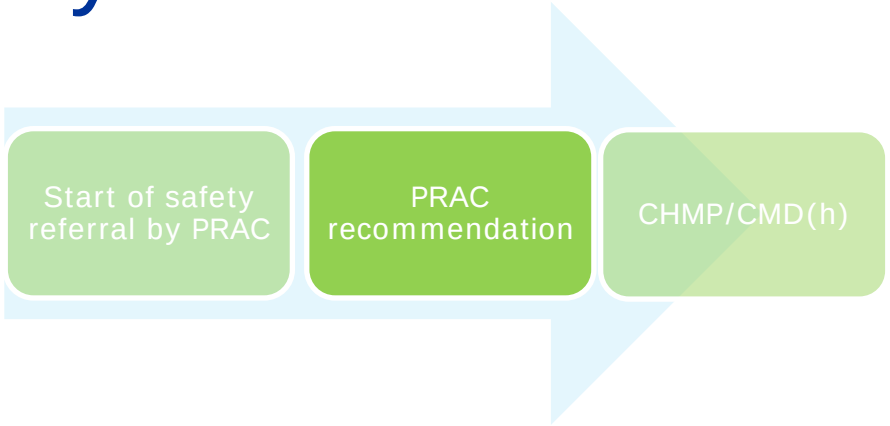
EMA safety communication



- *'EMA announcement of start of referral'*
- Notification
- List of Questions
- Timetable

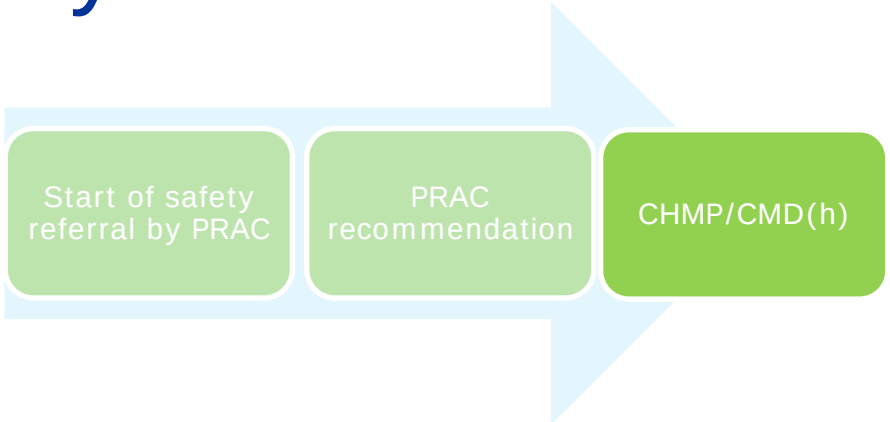
Example: Ibuprofen

EMA safety communication



- *'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: Domperidone

EMA safety communication



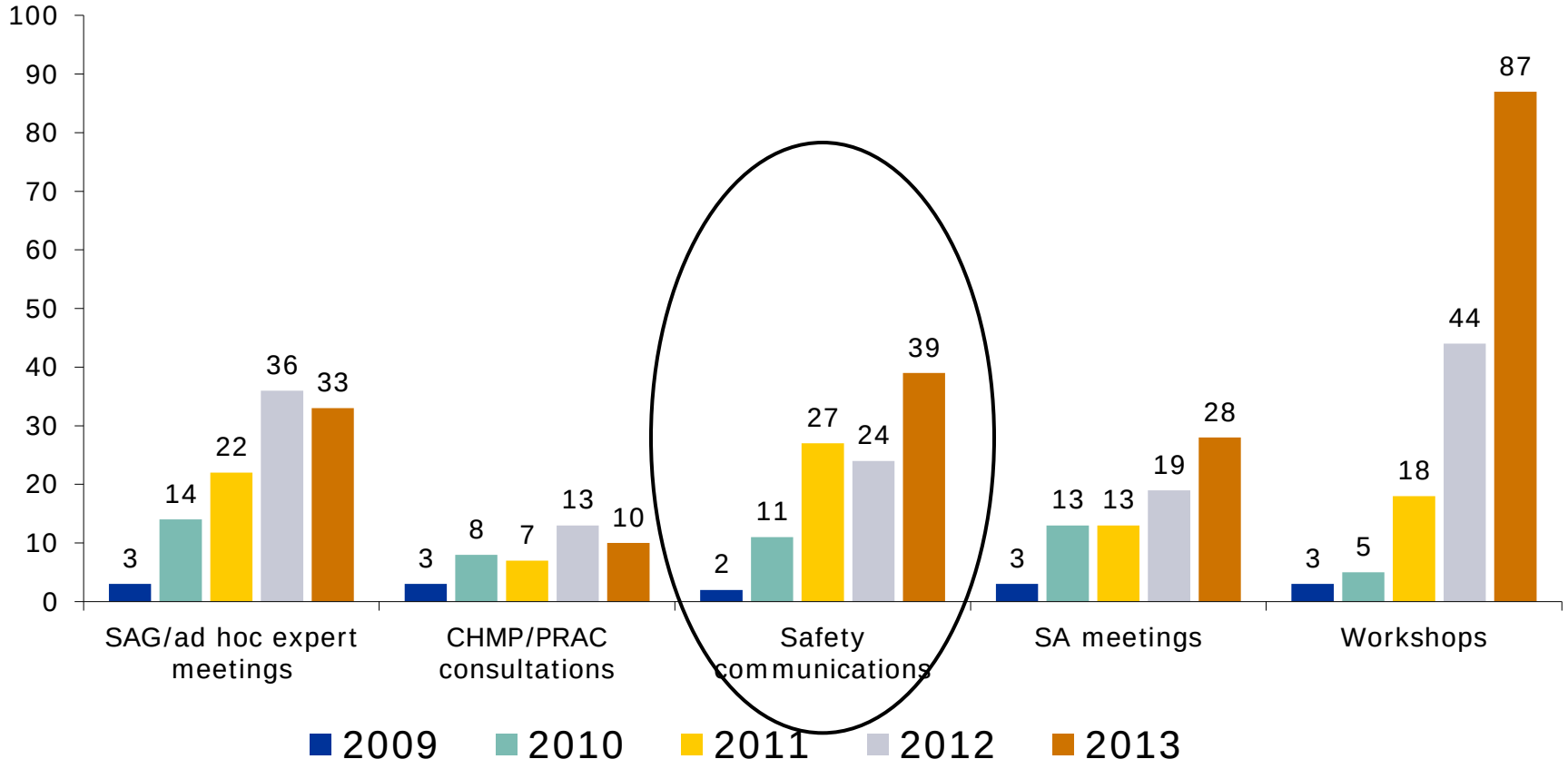
- *'EMA public health communication'*
- Single piece of information (composed of three sections, targeting 3 different audience groups):
  - Summary of the issue (for press and general public)
  - Information to patients
  - Information to healthcare professionals
- Syndicated to press, patients and healthcare professionals contacts
- *Example: Domperidone*

Collaboration with EU network of patients and healthcare professionals

- **Collaboration with individuals nominated by 'EU-eligible organisations':**
  - Actively through and with PCWP and HCP WP (EMA working parties with patients, consumer and healthcare professionals);
  - No financial support available.
- **Help us in:**
  - Designing and adapting communication tools;
  - Preparation of documents;
  - Dissemination of key information timely among members.
- **Excellent feedback and experience.**

Patient involvement – safety communication

Comparison of involvement in core activities 2009–2013



Patient input on EMA safety communication

Example 1: Metoclopramide

Review of metoclopramide

FINAL

...If you are taking metoclopramide (especially for long-term conditions) you will have your treatment reviewed by your doctor at your next scheduled appointment, and in some cases you may be recommended a different treatment. Patients who have any questions should discuss them with their doctor or pharmacist.

Patient input on EMA safety communication

Example 2: Almitrine

FINAL

Review of almitrine

As the PRAC recommendation was endorsed by consensus by the CMDh, it will now be implemented directly by the Member States where oral almitrine is authorised, according to an agreed timetable which should be completed by 25 July 2013.

Patient input on EMA safety communication

Example 3: Combined hormonal contraceptives (CHC)

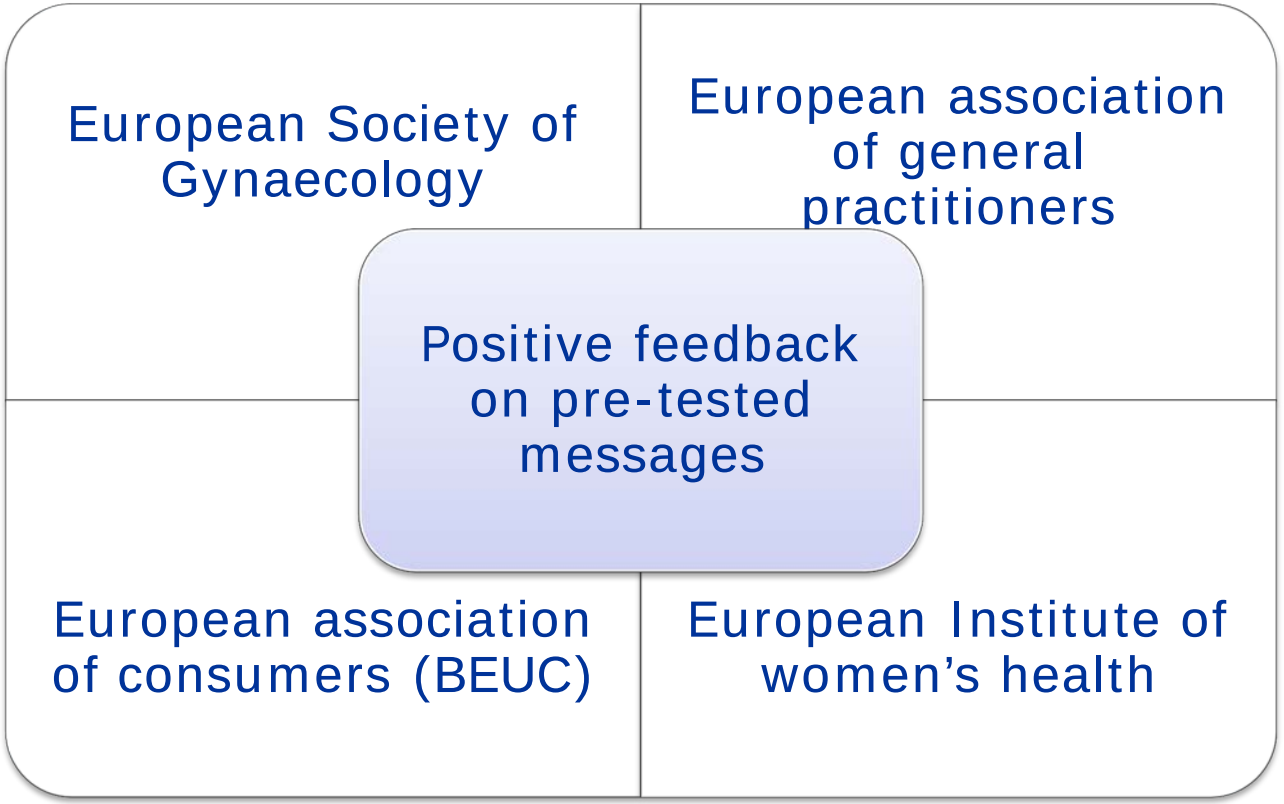
Review of Combined Hormonal Contraceptives (CHC)

FINAL

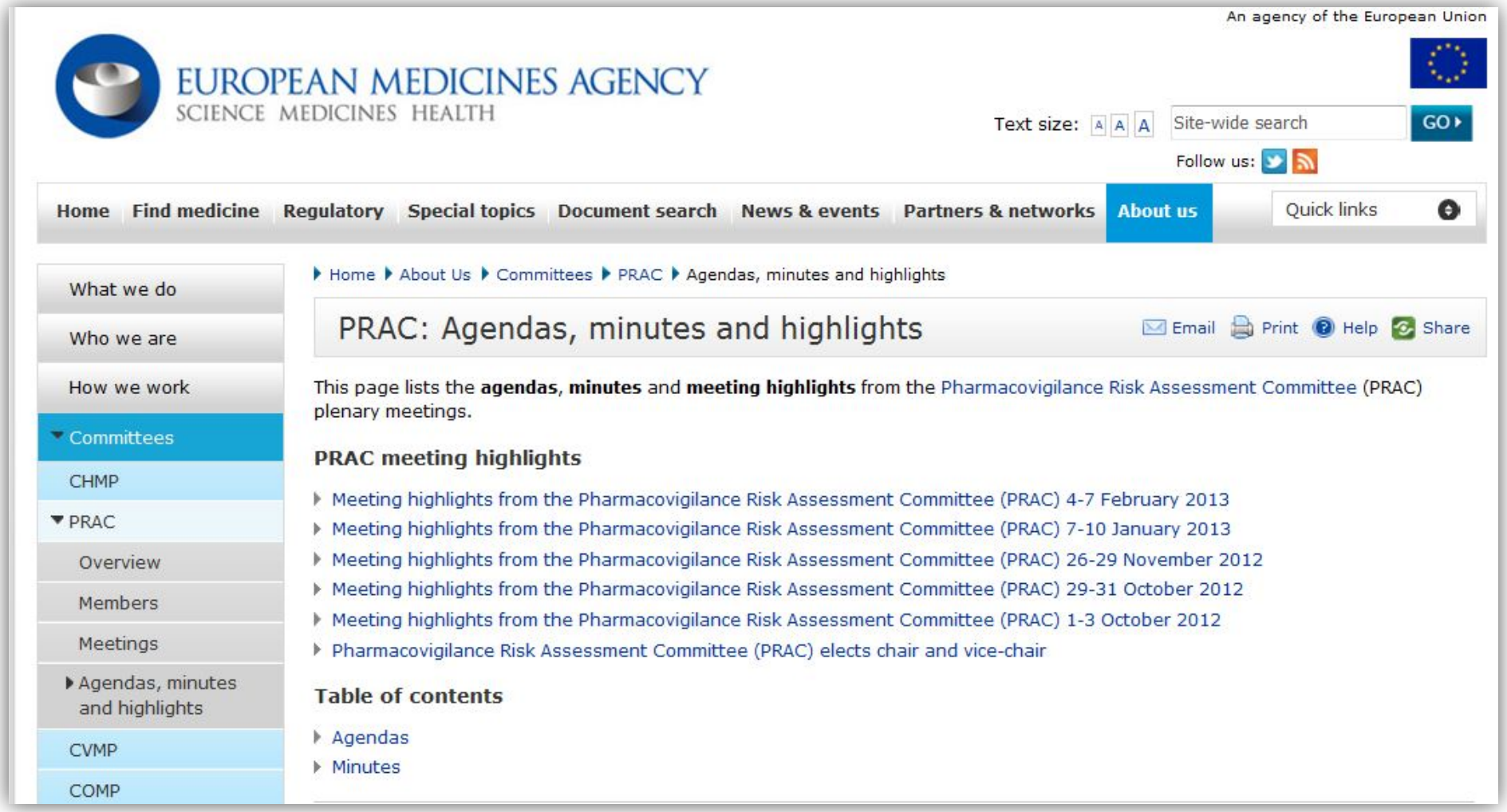
For CHCs containing chlormadinone, dienogest and nomegestrol, the available data are insufficient to know how the risk compares with the other CHCs, but further studies are ongoing or planned.

Patient/healthcare professional involvement

Example: Combined Hormonal Contraceptives (CHCs)



More information on safety

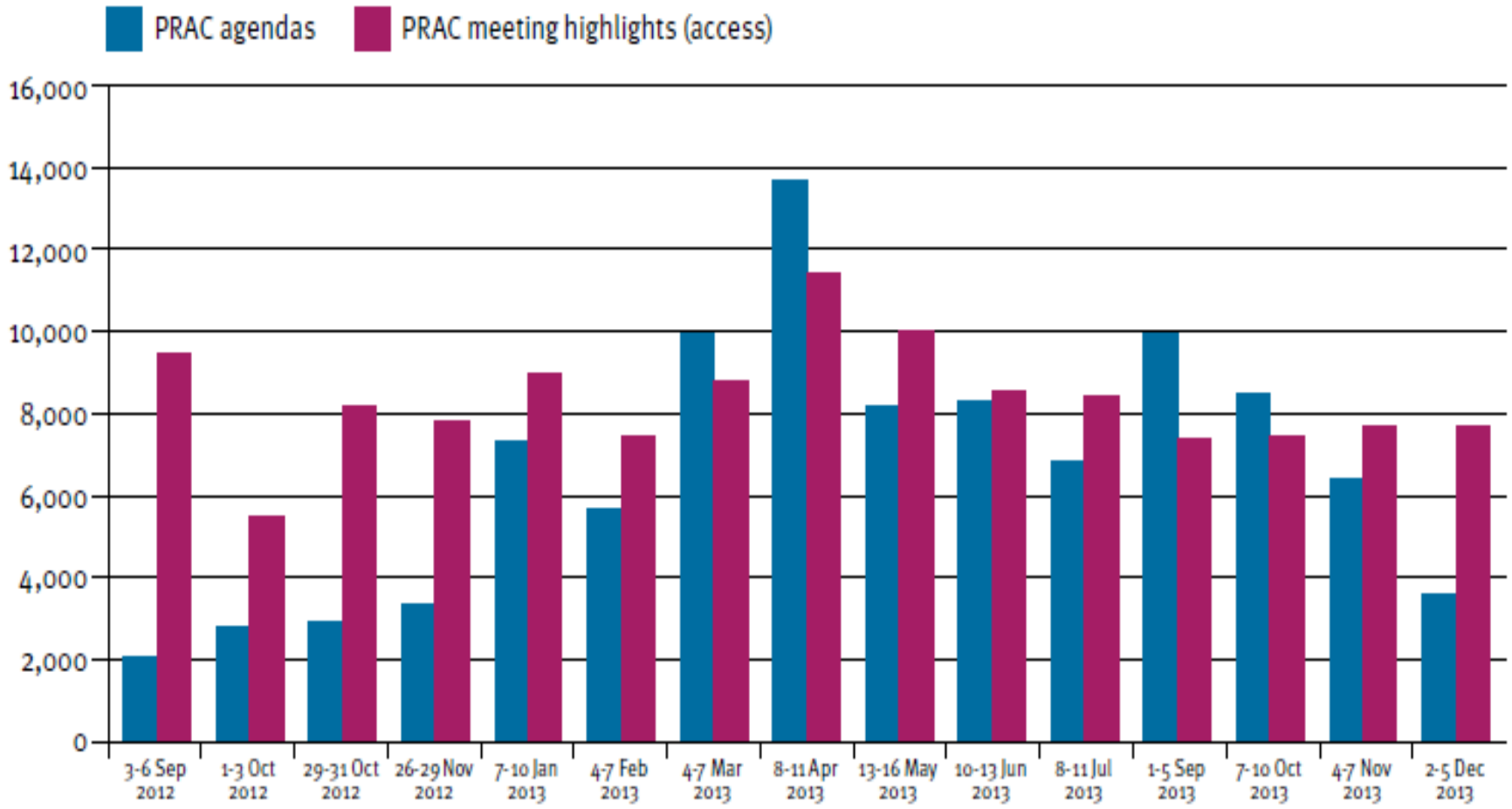


More information on safety

PRAC related information – publication schedule

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

Figure 1: Web access to PRAC agendas and meeting highlights in the month of publication.



A member state perspective

Member states are obliged to make available to public important information on pharmacovigilance concerns

Co-ordinated safety communication

Art 106a 2001/83/EC

"For active substances contained in medicinal products authorised in more than one Member State ***the Agency shall be responsible for the coordination between national competent authorities of safety announcements***

Under the coordination of the Agency, ***the Member States shall make all reasonable efforts to agree on a common message***

The ***PRAC shall at the request of the Agency provide advice on those safety announcements****"*

Risk communication in member states National Web-Portals

National web-portal to contain:

- Public assessment Reports and Summaries
- SPCs and PILs
- Summary Risk Management Plans
- List of substances under additional monitoring
- Information on how to report and electronic reporting forms
- ***Important information for the public***

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Aims of communication at national level

Timeliness

Comprehensibility

- Explanatory notes
- reader-friendly text

Accessibility

- Linkages at national level to EMA Web-portal

Impact on medicines use behaviour

Risk minimisation

Transparency Benefits & Challenges

Supporting prompt evaluation of signals

PRAC outcome is immediately publicly available

Building greater trust & confidence in regulation

HCPs and patients informed via Agenda publication

PRAC outcome is a recommendation not final advice

Risk amplification, if experts don't agree

How are challenges addressed?

Contextualisation of safety signals, clarity on PRAC's role

Clarity on status of information released during decision-making process

Supporting public and patients' understanding

Example – patient information on statins

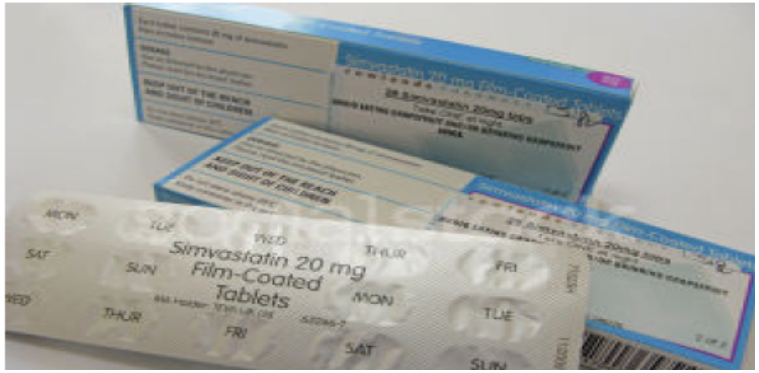
Simvastatin: why your dose or treatment may have recently changed

Article date: October 29th 2012

Key messages

Simvastatin is a medicine used to lower cholesterol and reduce the risk of heart problems and strokes.

- As with any medicine, simvastatin may cause side effects in some people. Most side effects are mild, but very rarely they can be serious



What is the new safety information for simvastatin?

As with any medicine, simvastatin may cause side effects (adverse drug reactions) in some people. Muscle problems such as pain, tenderness, weakness and cramps are one known side effect of simvastatin. On rare occasions (occurring in less than 1 out of 1000 patients), these muscle problems may be serious, including muscle breakdown leading to kidney damage.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2013
EMA/709120/2013

Benefits of combined hormonal contraceptives (CHCs) continue to outweigh risks – CHMP endorses PRAC recommendation

Product information to be updated to help women make informed decisions about their choice of contraception

Example
– combined hormonal contraceptives and thromboembolism

Drug Safety Update

MHRA

Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

Volume 7, Issue 7, **February 2014**

Contents

A2 Combined hormonal contraceptives and venous thromboembolism: review confirms risk is small—consider risk factors and remain vigilant for signs and symptoms

A review of the latest evidence on the risk of thromboembolism in association with combined hormonal contraceptives (CHCs) has concluded that:

- the risk of blood clots with all low-dose CHCs is small
- there is good evidence that the risk of venous thromboembolism (VTE) may vary between products, depending on the progestogen
- CHCs that contain levonorgestrel, norethisterone, or norgestimate have the lowest risk of VTE
- the benefits of any CHC far outweigh the risk of serious side effects
- prescribers and women should be aware of the major risk factors for thromboembolism, and of the key signs and symptoms

Deadly risk of pill used by 1m women: Every GP in Britain told to warn about threat from popular contraceptive

- Bestselling brands of birth control tablets linked to fatal blood clots
- They are believed to double the risk compared to older varieties
- 'Third-generation' contraceptives caused 14 deaths a year in France
- UK doctors have been ordered to alert women to the alarming dangers

NHS choices Your health, your choices

Health A-Z | Live Well | Care and support | Health

Media hype blood clot risk of birth control pills

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Monday February 3 2014

Categories

All Headlines

Lifestyle/exercise (729)
Food/diet (637)
Pregnancy/child (636)
Medical practice (572)
Cancer (564)
Medication (544)
Heart/lungs (461)
Neurology (431)
QA articles (335)
Genetics/stem cells (303)
Mental health (303)

"Deadly risk of pill used by 1m women: Every GP in Britain told to warn about threat from popular contraceptive," reports the Mail Online.

Combined hormonal contraceptives (or "the pill") are in the news after letters were sent to doctors to tell them about the latest evidence on the risk of thromboembolism (blood clots) associated with combined

Contraceptive pills are both safe and effective

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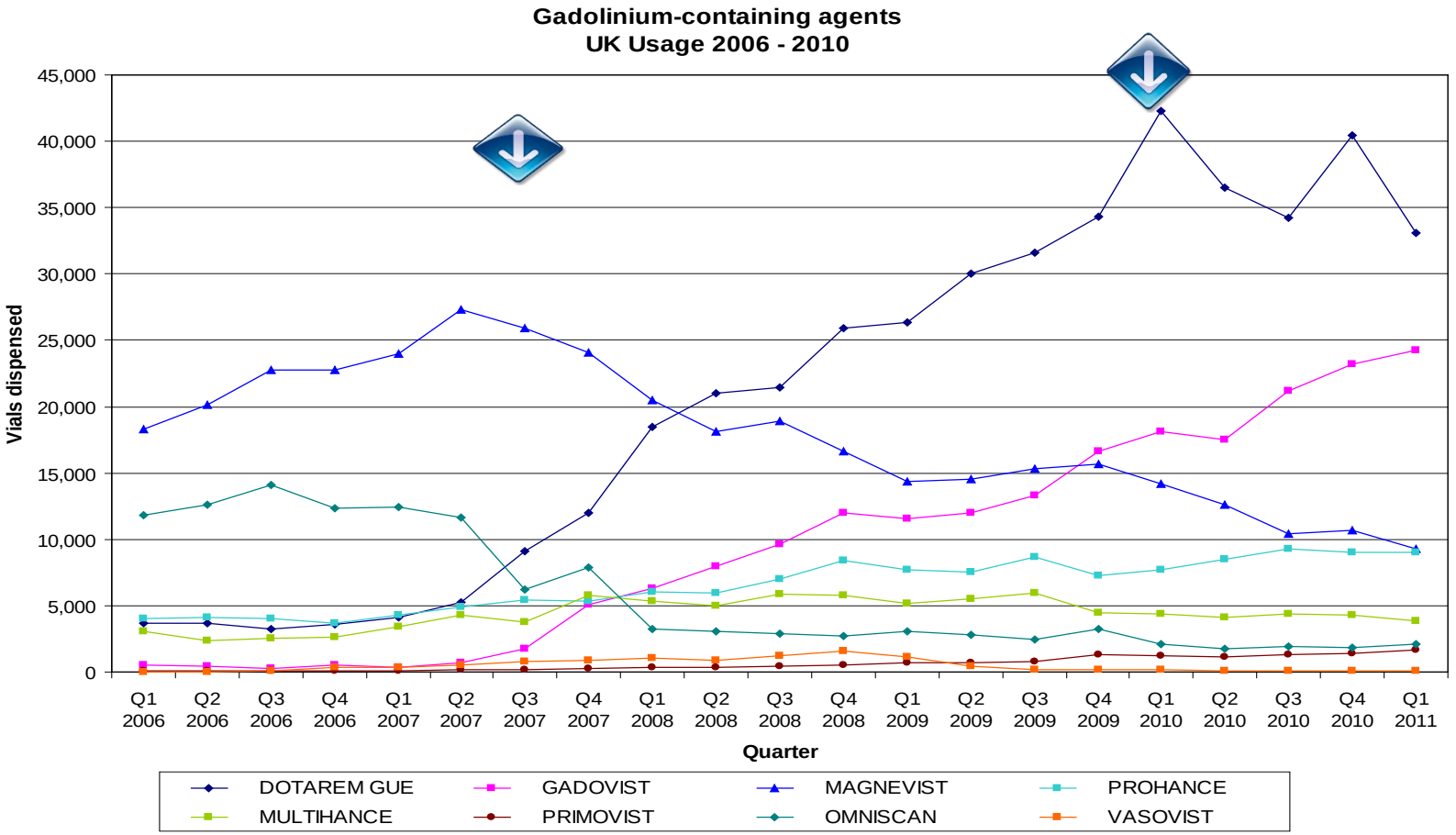
Effectiveness of Risk Minimisation

Use of Gadolinium contrast agents after nephrogenic systemic fibrosis



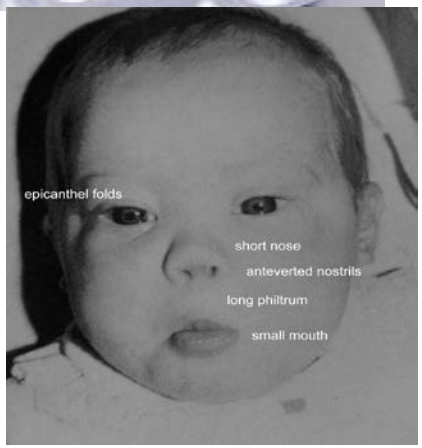
Example - Sodium valproate in pregnancy

Indications in EU include epilepsy, bipolar disorder & migraine

Use in women of child bearing potential varies across Europe

Nature and magnitude of developmental risk needs to be better understood

Patient representatives contributing to decision



Conclusions

Risk communication is a key element of the pharmacovigilance process

Co-ordination of communication by EMA and member states on drug safety is vitally important

Timely access to pharmacovigilance information and decisions is basis of stakeholder engagement

Involvement of stakeholders in safety communication is essential to effective risk minimisation

Measurement of impact of safety communications on how risk is managed is vitally important