EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New pharmacovigilance legislation: focus on first year of operation

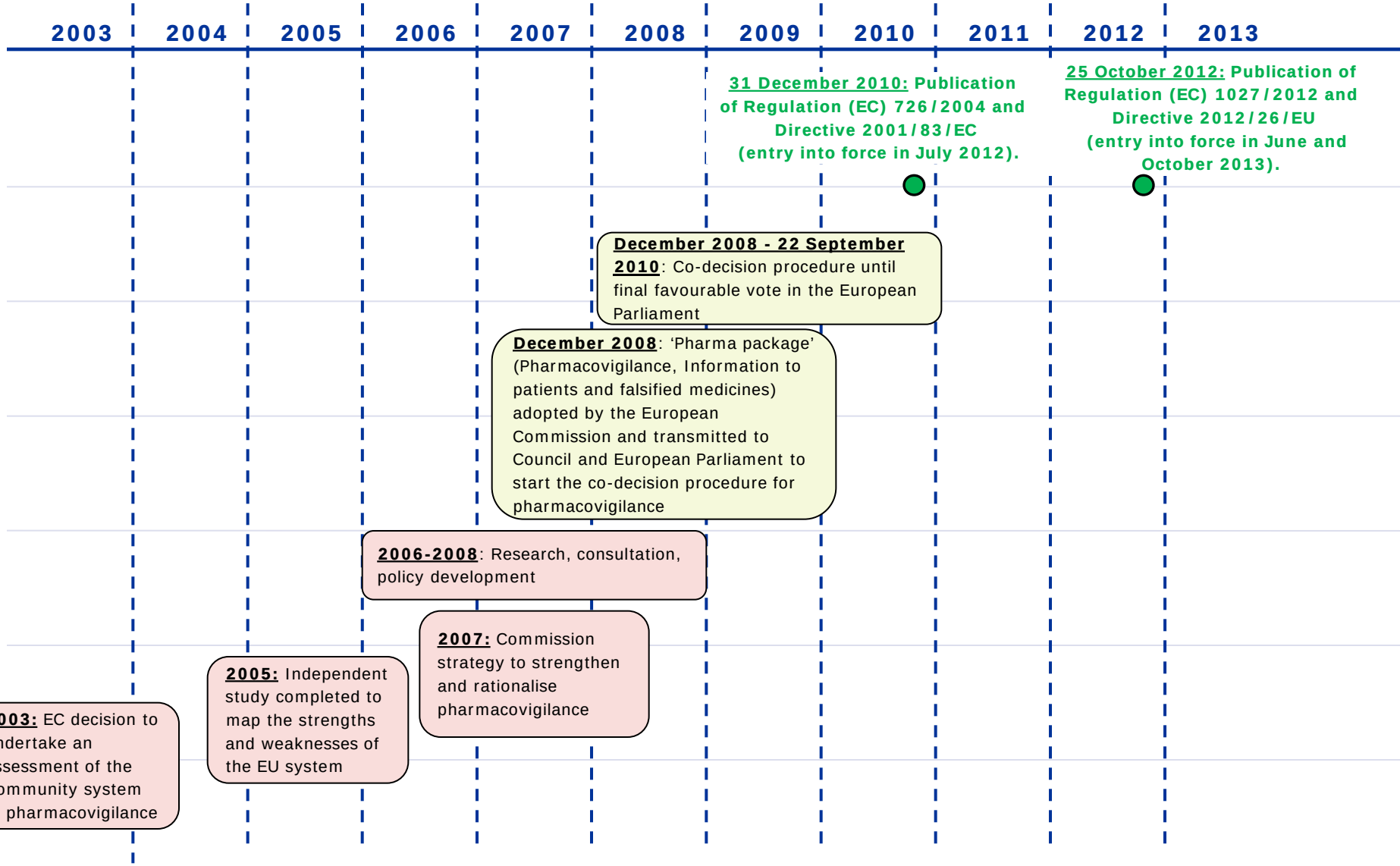
PCWP. December 2013

Dr Peter Arlett
EMA
December 2013

In this presentation

1. Objectives, where we have come from: where we are going
2. What has been delivered in 2012 – 2013 and what are now routine activities
3. What remains to be done
4. Moving forward together

Where we have come from



Where we are going: legislation objectives

Promote and protect public health by reducing burden of Adverse Drug Reactions and optimising the use of medicines:

- Clear roles and responsibilities
- Science based
- Risk based/proportionate
- Increased proactivity/planning
- Reduced duplication/redundancy
- Integrate benefit and risk
- Ensure robust and rapid EU decision-making
- Strengthen the EU Network
- Engage patients and healthcare professionals
- Increase transparency and accountability
- Provide better information on medicines

Challenges

- Major resource constraints
- Size of change
- Product lifecycle impacted
- Number of stakeholders impacted

What has been delivered and what is now routine

EUROPEAN MEDICINES AGENCY

Pharmacovigilance Risk Assessment Committee

Inaugural meeting

Brussels July 19-20th 2012

Membership of PRAC

Appointed by each Member State:

1 member + alternate

28 + EEA countries non voting members

Appointed by European Commission:

6 members - relevant expertise including clinical pharmacology and pharmacoepidemiology

1 member / alternate representing patient organisations

1 member / alternate representing healthcare professionals

HCP and patient representatives

HAS ADOPTED THIS DECISION:

Sole Article

1. The following are hereby appointed members and alternates of the Pharmacovigilance Risk Assessment Committee to represent healthcare professionals for a term of three years from 1 March 2013:

— Member: Filip Babylon,

— Alternate: Kirsten Myhr.

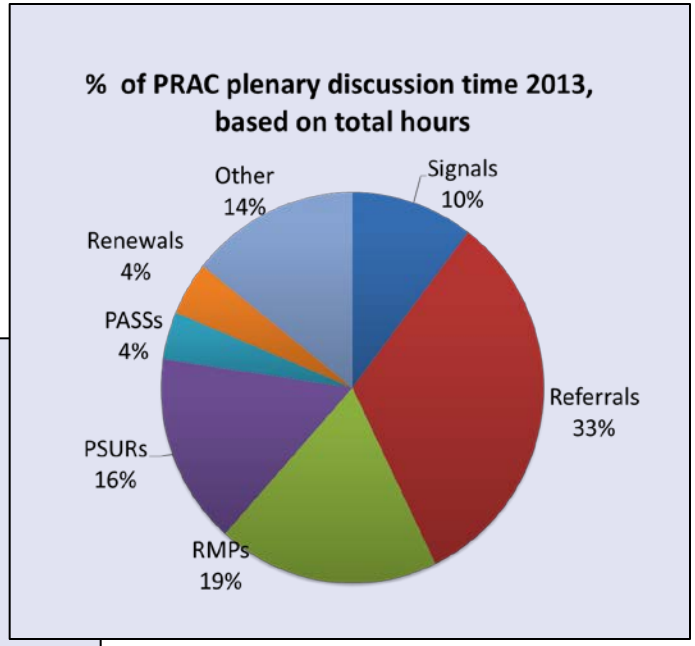
2. The following are hereby appointed members and alternates of the Committee to represent patient organisations for a term of three years from 1 March 2013:

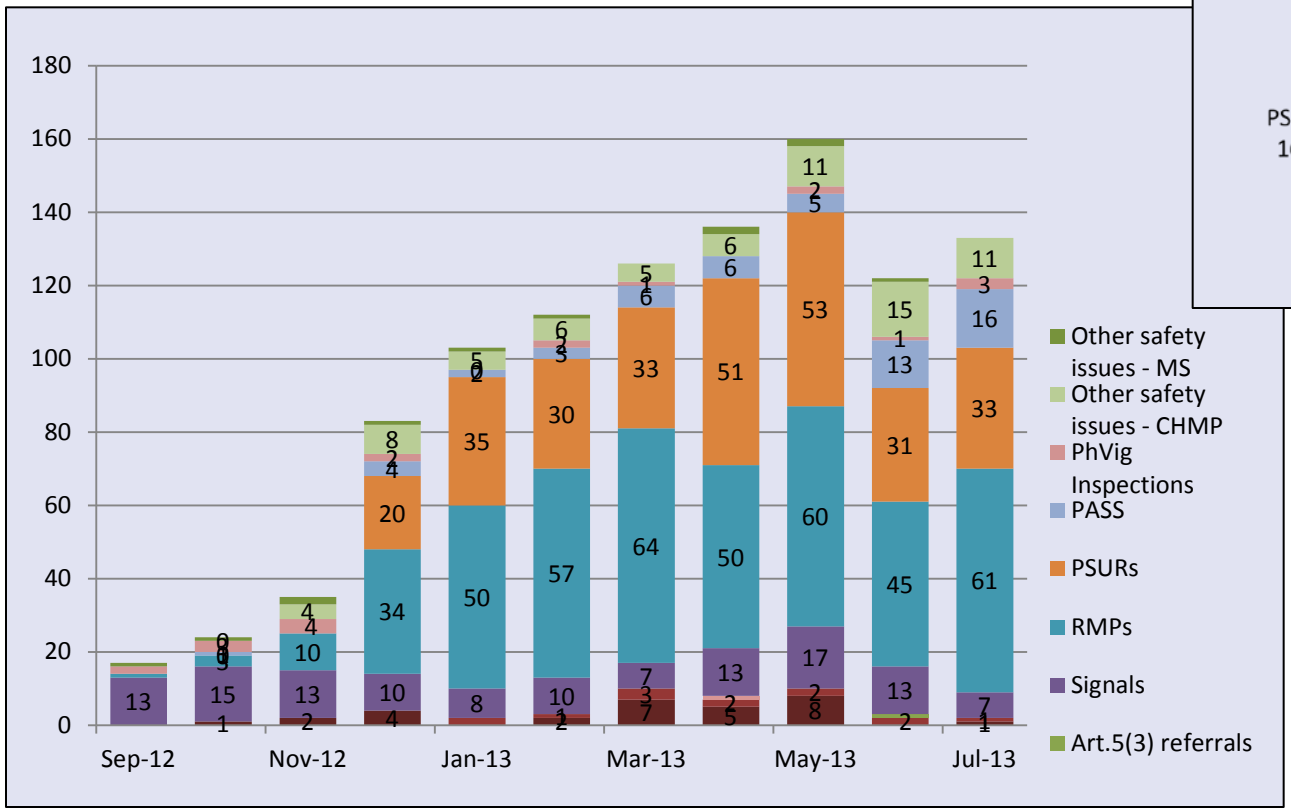
— Member: Albert van der Zeijden,

— Alternate: Marco Greco.

Done at Brussels, 28 February 2013.

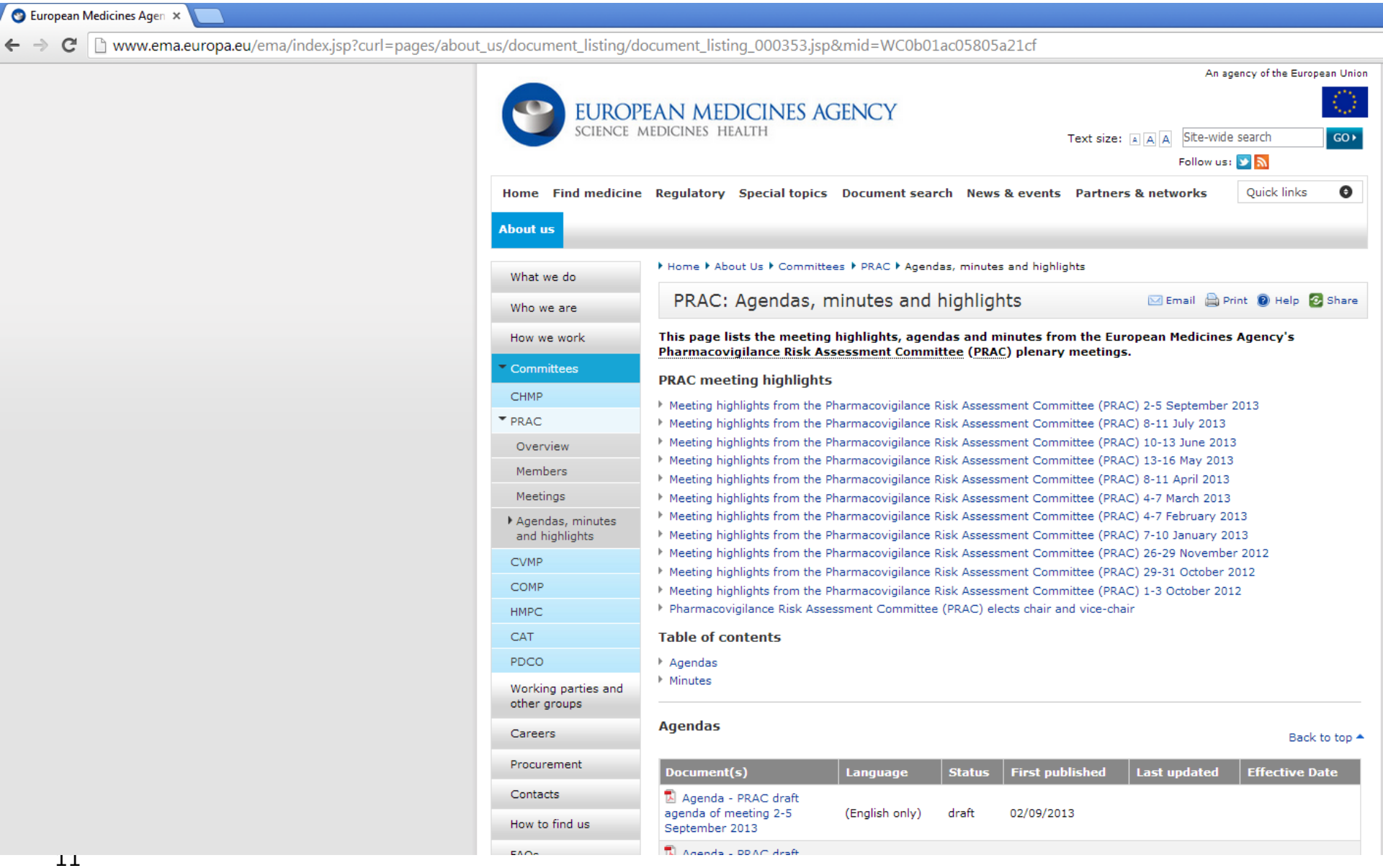
PRAC volumes (July 2012 – July 2013)





Transparency of activities for Pharmacovigilance Risk Assessment Committee

- **Agenda** is published on Day 1 of PRAC by mid-day
- **Meeting highlights** are published on Friday of PRAC week
- **Safety referrals** are published on Friday of PRAC week
- **Minutes** are published on the following month after adoption


European Medicines Agen
www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000353.jsp&mid=WC0b01ac05805a21cf
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This page lists the meeting highlights, agendas and minutes from the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) plenary meetings.
PRAC meeting highlights
Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 2-5 September 2013
Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 July 2013
Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 10-13 June 2013
Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 13-16 May 2013
Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 April 2013
Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 March 2013
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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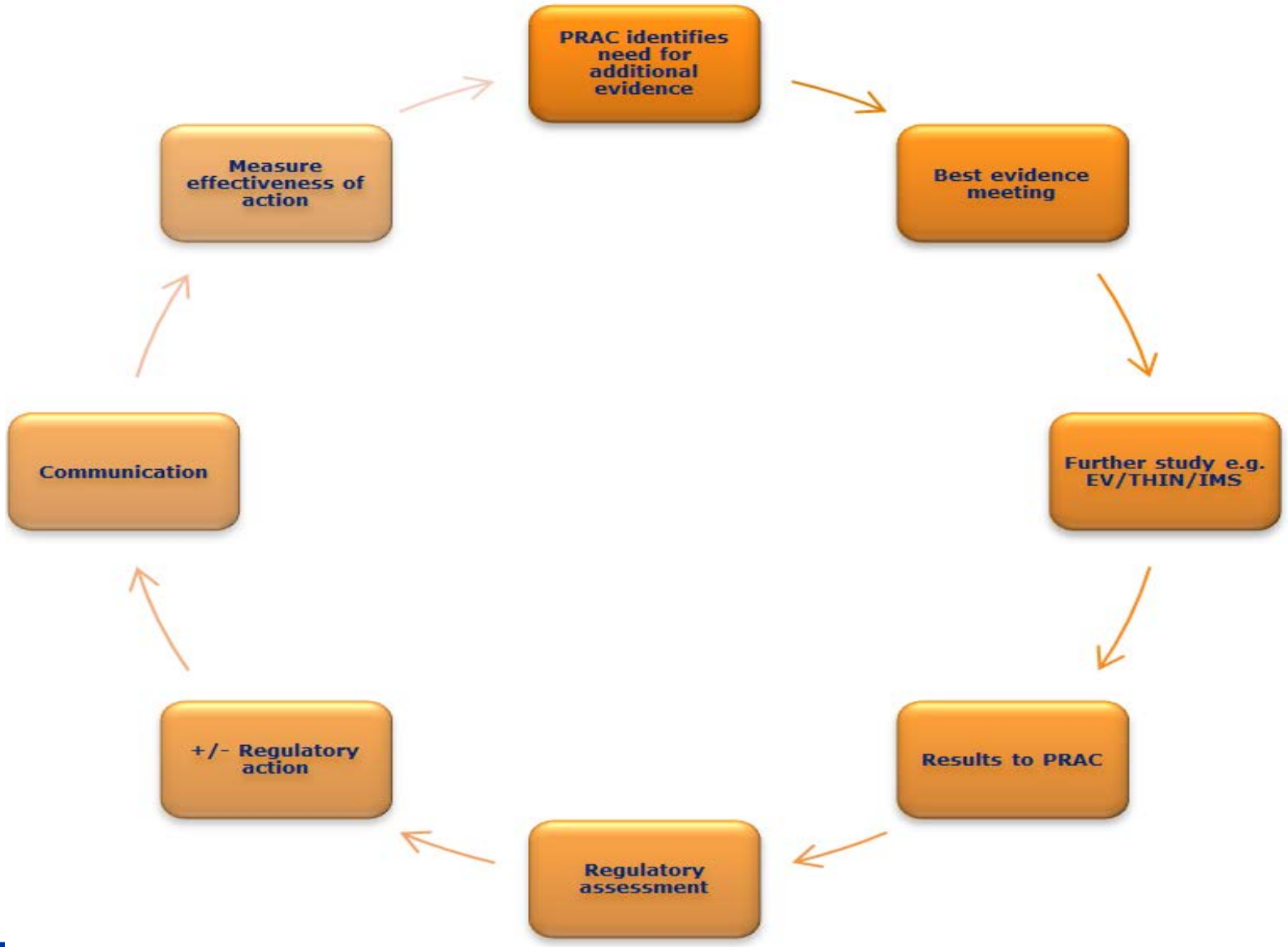
Document(s)
Language
Status
First published
Last updated
Effective Date
Agenda - PRAC draft agenda of meeting 2-5 September 2013
(English only)
draft
02/09/2013

Evidence – decision cycle



Strengthening the science base


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 January 2013
EMA/14946/2013
Patient Health Protection

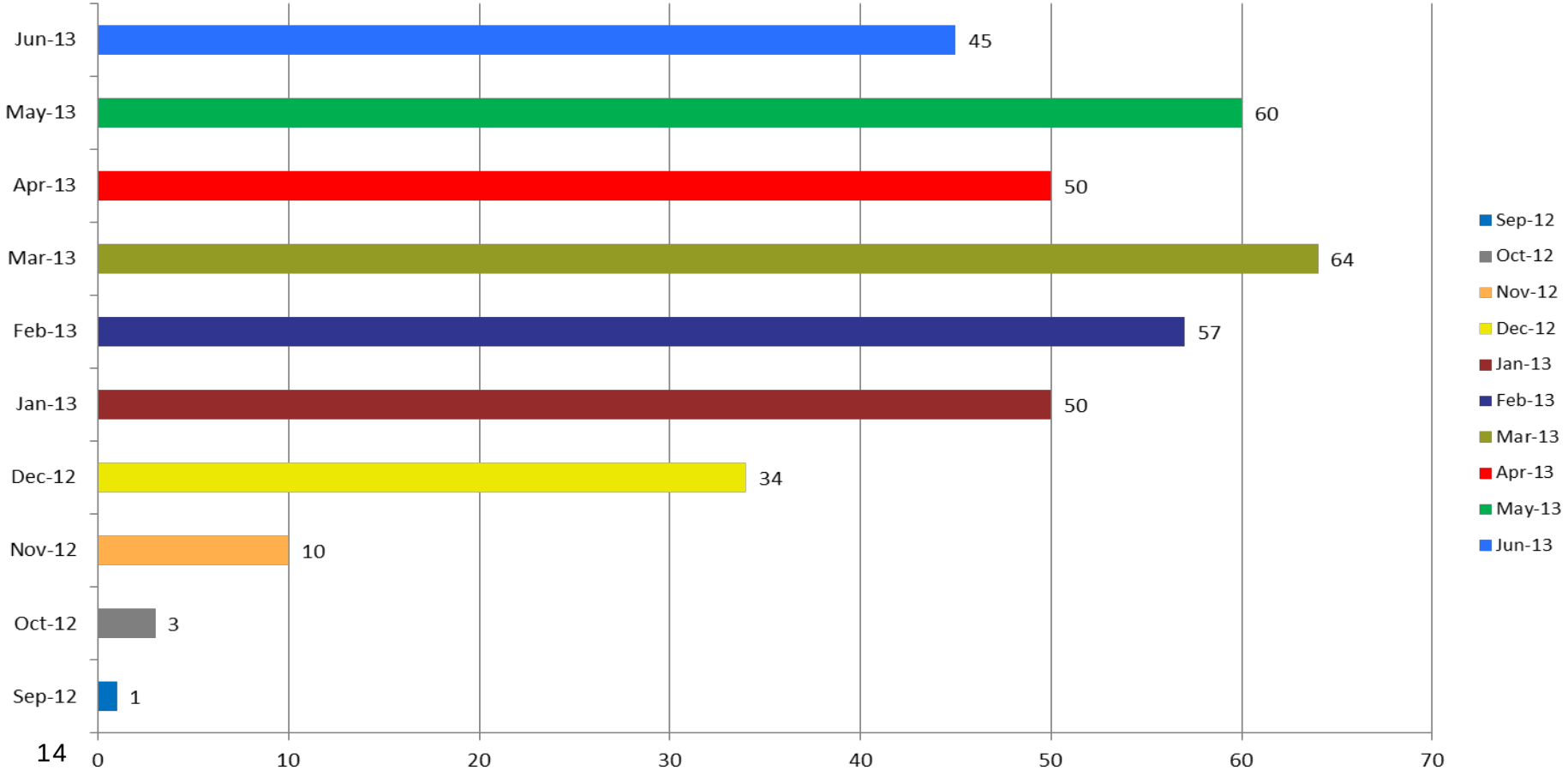
European Medicines Agency process for engaging in external regulatory sciences and process improvement research activities for public and animal health

Methods work – evidence based process improvement

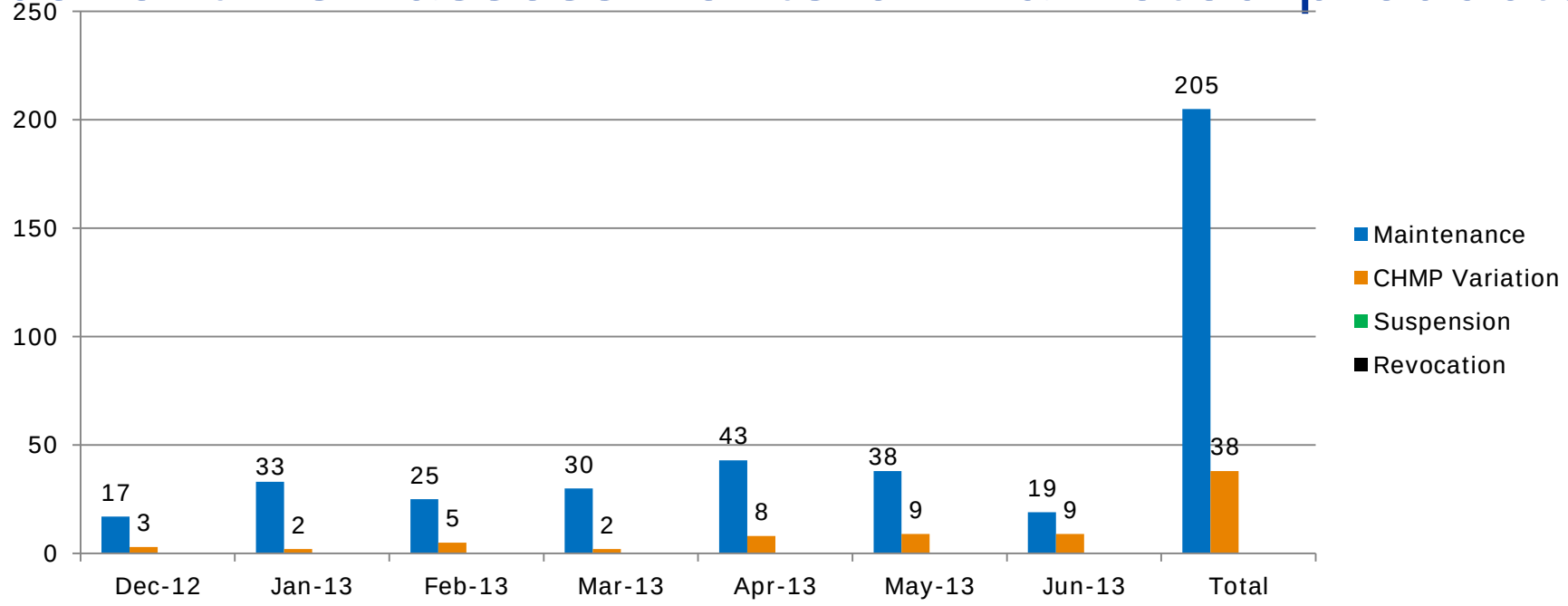
Strengthening evidence underpinning individual decisions - increases quality of Opinions

RMP Risk Management Plans – based on safety profile, plan the data collection and risk minimisation

Total Number of PRAC assessments/advice for RMPs - 374



PSURs: Periodic Safety Update Reports = benefit risk assessments of marketed products



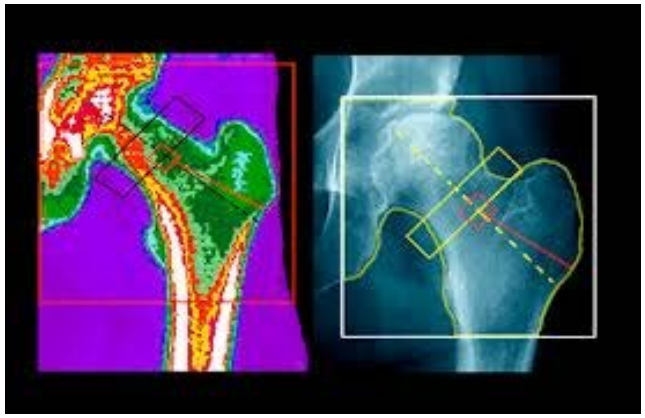
- 243 PSUR PRAC recommendations (single CAPs) from Dec 2012 till June 2013
- 38 (16%) PRAC recommendations to vary MA
- No suspensions, no revocations

Example –*Strontium ranelate*

Periodic safety update report identified increased risk of cardiac disorders including MI

PRAC advised urgent variation to restrict MA on safety grounds

Art 20 referral ongoing



heartwire

PREVENTION

CV risks prompt recommendations for EU strontium ranelate restrictions

APRIL 15, 2013 Deborah Flapan

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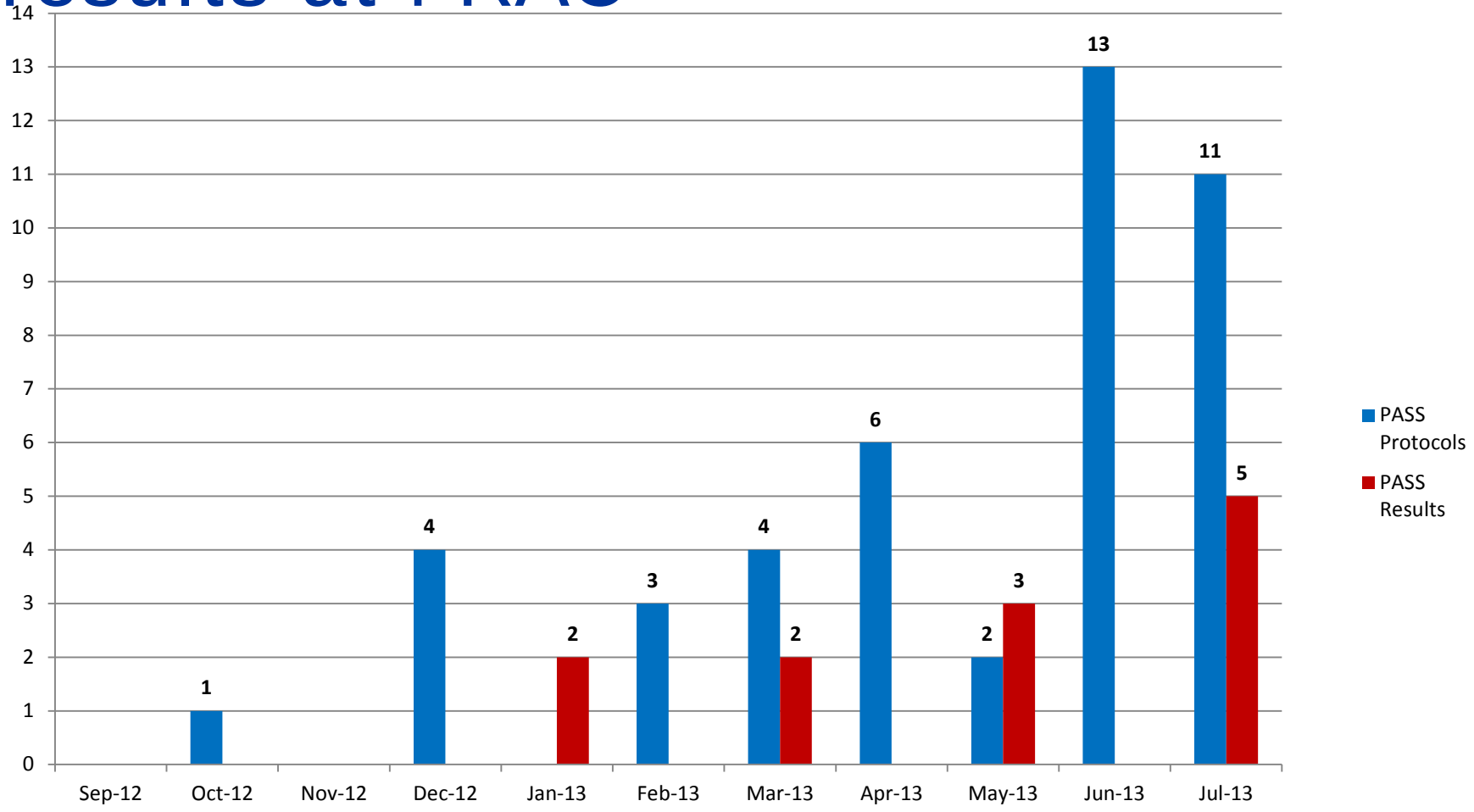
0 Comments Read later Print Font size A A A Cite

London, UK - The Pharmacovigilance Risk Assessment Committee (PRAC) of the **European Medicines Agency** (EMA) has recommended restrictions in the use of **strontium ranelate** (Protelos/Osseor, Servier) to reduce the risk for adverse cardiovascular events in postmenopausal women [1].

Safety Studies: protocols and results at PRAC



European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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- Standards & Guidances
- ENCePP Study Seal
- Public Consultation
- Glossary of terms
- Resources Database
- Partners Forum
- E-Register of Studies
- EU PAS Register

EU PAS Register

EU PAS Register Guide

One of the ENCePP guiding principles is transparency to the public of ongoing research relating to medicines used in clinical practice, in particular information on post-authorisation studies. Registration of protocols and study reports in the ENCePP E-Register of Studies is a means to achieve these objectives.

The 2010 pharmacovigilance legislation also requires the EMA to publish in a publicly available register the protocols and abstracts of results of **post-authorisation safety studies (PASS) imposed as an obligation** by a competent authority in accordance with Articles 10 or 10a of Regulation (EC) No 726/2004 or with Articles 21a or 22a of Directive 2001/83/EC. It also specifies that the final report of such studies must provide the date of registration in this register.

Information about PASS which are initiated, managed or financed **voluntarily** by a MAH and which are required in the **Risk Management Plan (RMP)** to further investigate safety concerns or to evaluate the **effectiveness of risk minimisation activities, or any other PASS** should also be entered into this register in order to support the same level of transparency, scientific and quality standards.

Further information about the requirements for the registration of PASS is available in the guideline on Good Pharmacovigilance Practices (GVP) module VIII, chapter VIII.B.4.

The publicly available register referred to as the 'EU PAS Register' in the GVP is to be maintained by the EMA and will be built as an upgrade of the ENCePP E-Register of Studies.

Before the EU PAS Register is fully operational, the E-Register of Studies, therefore, serves as the 'EU PAS Register' for all pharmacoepidemiological and pharmacovigilance studies regardless of whether they are initiated, managed or financed by a MAH, or whether they are conducted by a research centre that is a partner of the ENCePP network or any other research centre, including from outside the European Union.

For now, MAHs should therefore register their non-interventional PASS in the E-Register of Studies.

135 studies registered: most since July 2012

Article 57(2) data content

Substance Information:
- S1: Substance names
- S2: Substance Translations
- S3: Substance synonyms
- S4: Substance class
- S5: Reference source
- S6: International Codes

Business Service **Substance** — S

Reference Terminology:
- R1: Pharmaceutical form
- R2: Route of Administration
- R3: ATC codes
- R4: Units of Measurement
- R5: Units of presentation
- R6: Reference source

Business Service **Referentials** — R

Organisation information:
- O1: MAH (Legal Entity)
- O2: QPPV
- O3: PhV Enquiries
- O4: PhV System Master File

Business Service **Organisation** — O

Structured Medicinal Product Information:
- P1: MAH (Legal Entity)
- P2: QPPV
- P3: PhV Enquiries
- P4: PSMF
- P5: Authorisation country code
- P6: Authorisation procedure
- P7: Authorisation status
- P8: Authorisation number
- P9: Authorisation date
- P10: MRP/DCP/EU number
- P11: Date of withdrawal/revocation/suspension
- P12: Package description
- P13: Orphan drug designation
- P14: Comments (e.g. paediatric use)
- P15: Medicinal product name
- P16: Medicinal product invented name
- P17: Product generic name
- P18: Product company name
- P19: Product strength name
- P20: Product form name
- P21: Pharmaceutical Form
- P22: Route of administration(s)
- P23: Active ingredient(s), Adjuvant(s)
- P24: Excipients
- P25: Medical device(s)
- P26: Strength of active ingredient(s)/adjuvant(s)
- P27: Therapeutic Indication(s)
- P28: ATC code

Business Service **Product** — P

Unstructured Medicinal Product Information:
- P29: Summary of Medicinal Product Characteristics

Article 57(2) data: business case

- Better analysis and understanding of data/information
  - EudraVigilance data analysis, safety signal detection
- Regulatory action to safeguard public health
  - Support to referral procedures (e.g. interaction with MAHs)
  - Provision of other PRAC outputs to MAHs
  - Facilitation of PhV inspections
  - Longer term (ISO) – quality defects of medicines and counterfeits can be linked to the correct products
- Communication with stakeholders
  - European medicines web portal (search for medicines authorised in the EU)
  - Publication of lists (work-sharing purposes, products under additional monitoring, PSUR list, list of withdrawn products)
  - Access to EudraVigilance data (proactive and reactive)
  - EU/international data exchange

Article 57(2) Implementation status and next steps

- As of 23rd September, MAHs have submitted a total of **443,000** medicinal product entries to the Agency. New entries in the XEVMPD are received on a daily basis
- The next steps in the Art57 implementation, including strategy and timelines for the kick-off of the maintenance phase, will support the wider EU data architecture strategy…..

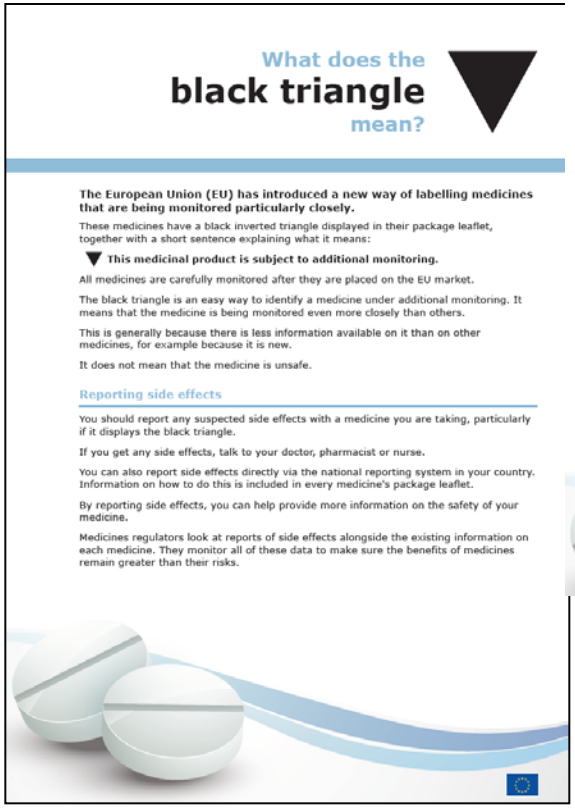
‘Black symbol’ for products under additional monitoring (1/2)

- Black symbol:
  - Selected by the European Commission following a recommendation of the PRAC (after involving stakeholders) on 7 March 2013
  - Inverted equilateral black triangle 
- New text in Product Information
  - *SPC text: <{Black symbol}> This medicinal product is subject to additional monitoring. This is to allow any safety information to be identified rapidly. Healthcare professionals are encouraged to report any suspected adverse reactions. See section 4.8.>*
  - *PL text: <{Black symbol} This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.*
- List of products under additional monitoring
  - initial list published on 25th April 2013 and updated every month

New communication material on additional monitoring (1/2)

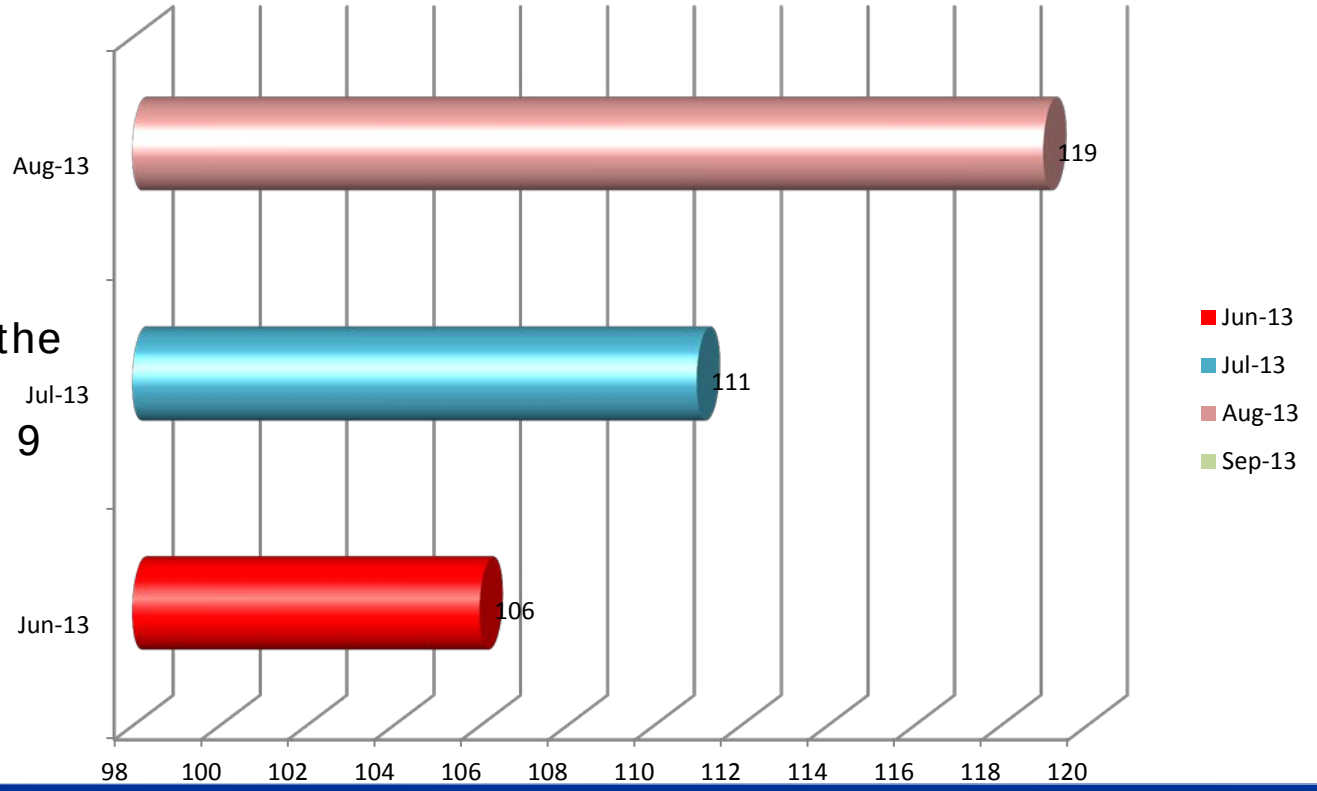
Factsheet + Video

- Consultation: EC, HMA WGCP and Project Team 3 involved in preparation
- PRAC informed at September meeting
- All EU languages
- Easily printable
- Based on already published information

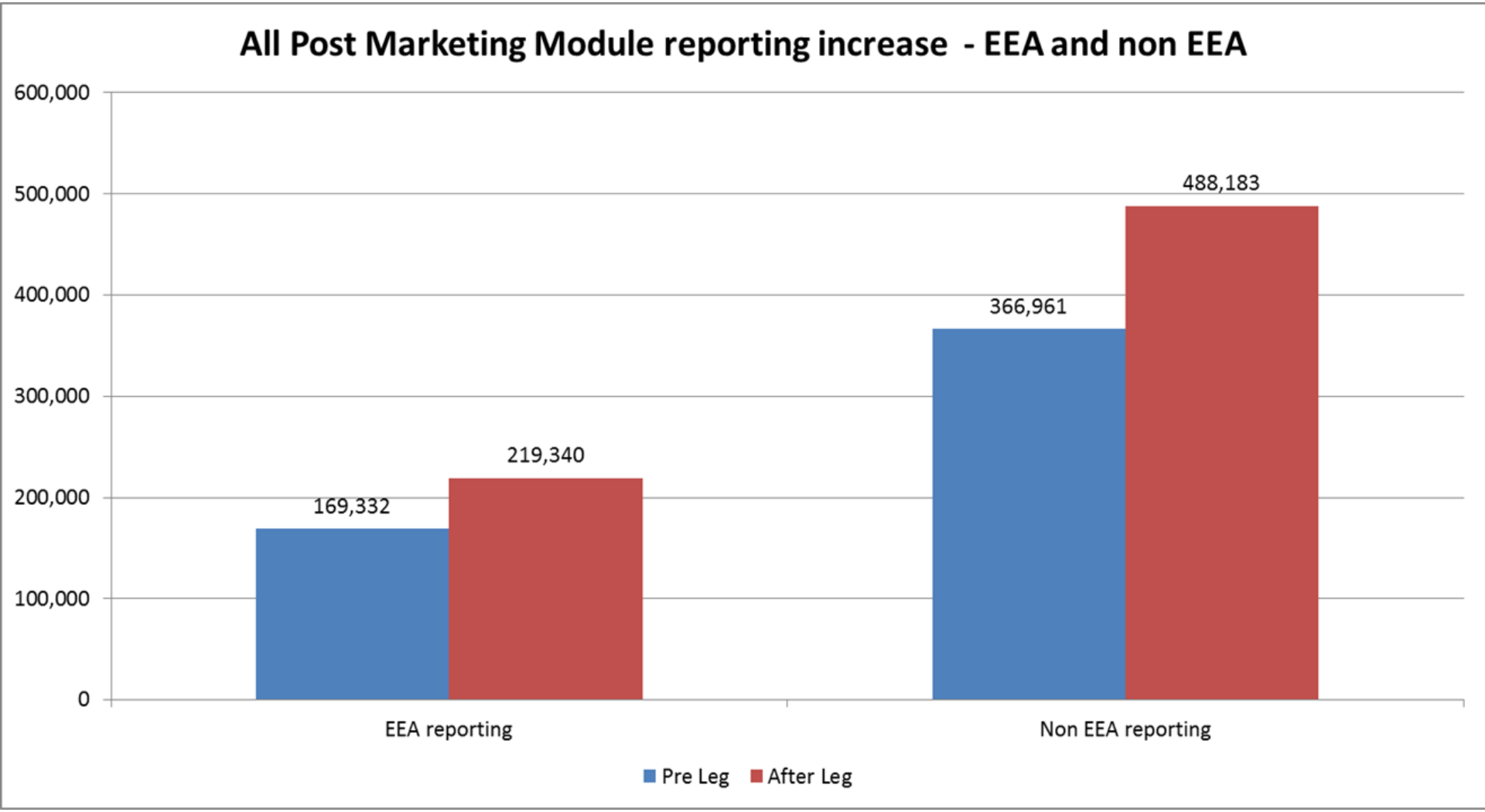


Prioritised implementation of the pharmacovigilance legislation

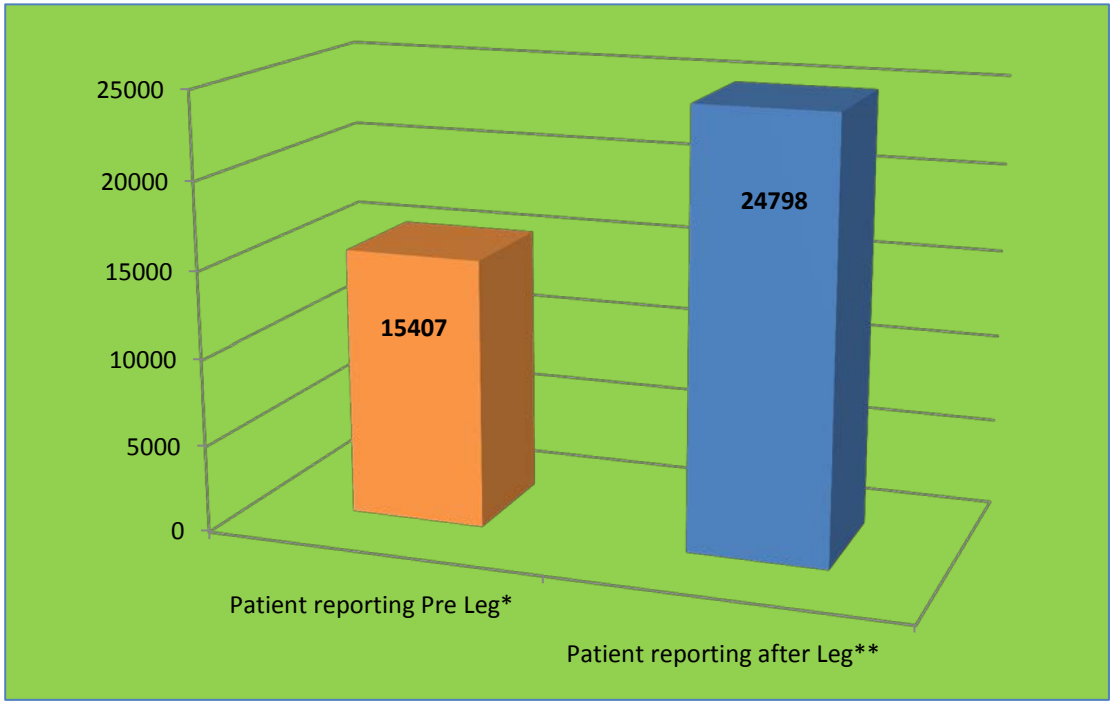
The current number of the additionally monitored drugs – **119** (published 9 August 2013)



Reporting numbers: Pre and Post legislation

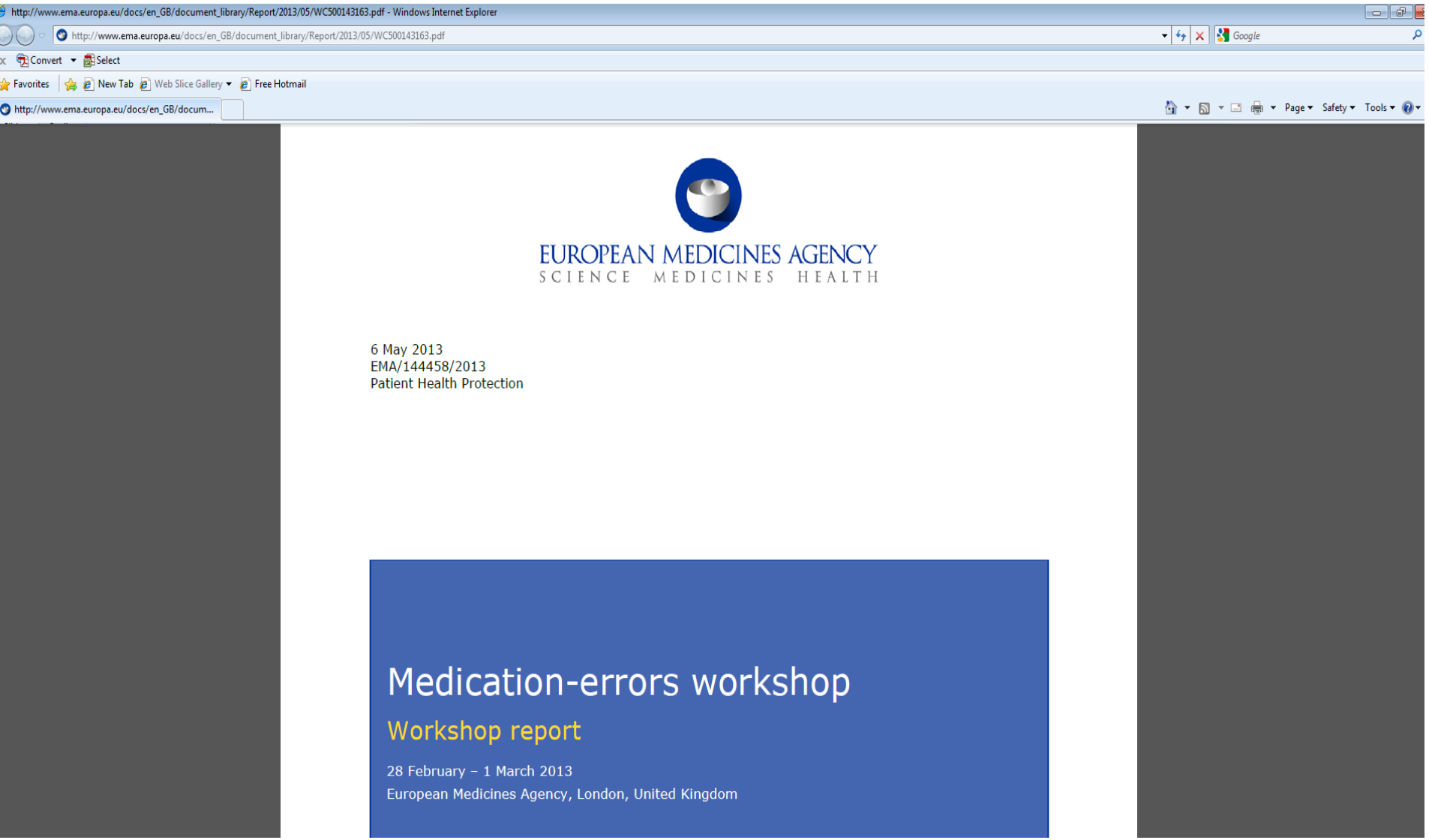


Spontaneous reporting by patients in EU



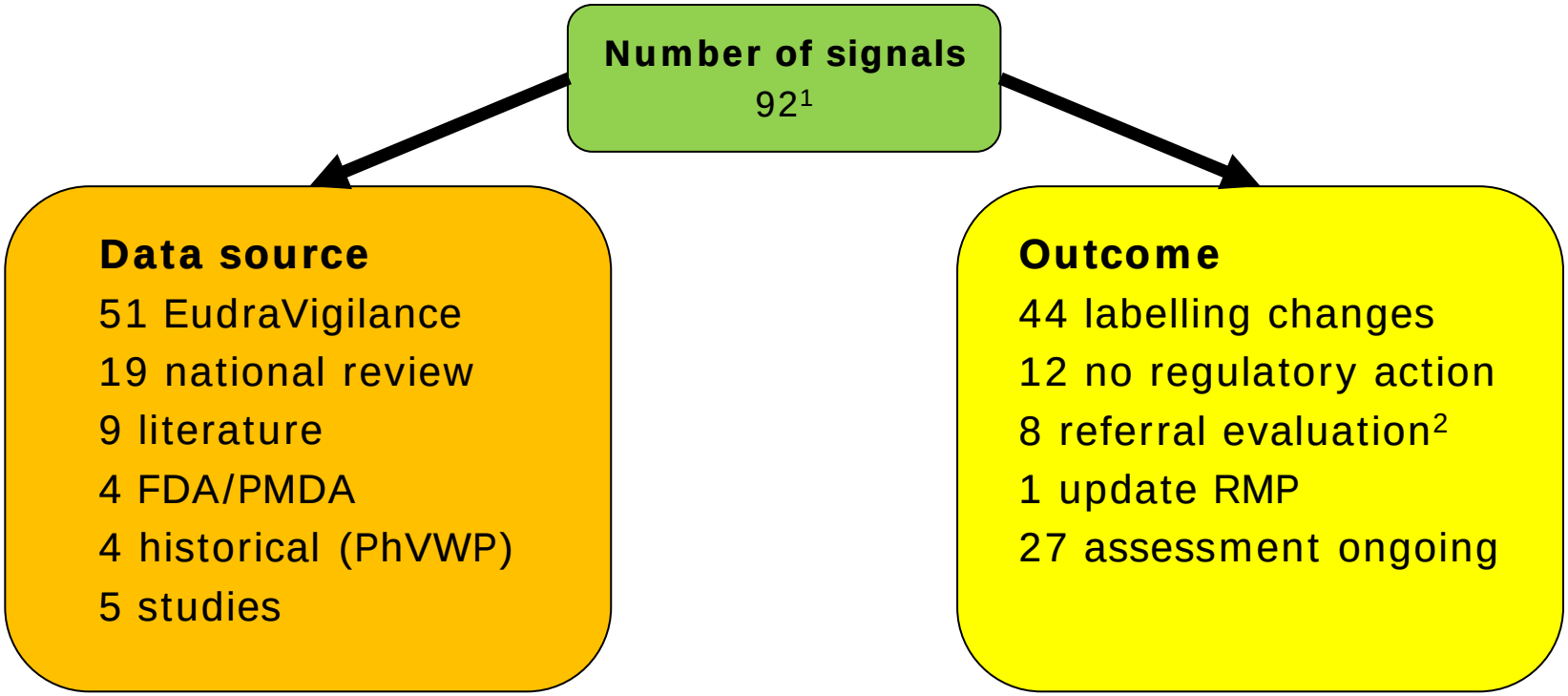
* Pre legislation data period - 02/07/2011 - 01/07/2012

** Post legislation data period -02/07/2012 - 01/07/2013



Implementation plan agreed at HMA in November

Proactive pharmacovigilance – signal detection



[1] 54 for CAPs (59%), 29 for NAPs (31%), 9 for both (10%)

[2] 6 referrals ongoing, 2 concluded: restriction of use (codeine) and suspension of MA (HES)

Signal descriptions – first publication in October 2013

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2013
EMA/550442/2013
Patient Health Protection

PRAC recommendations on signals

Adopted at the PRAC meeting of 2-5 September 2013

This document provides an overview of the recommendations adopted by the Pharmacovigilance Risk Assessment Committee (PRAC) on the signals discussed during the meeting of 2-5 September 2013.

PRAC recommendations to provide additional data are directly actionable by the concerned marketing authorisation holders (MAHs). PRAC recommendations for regulatory action (e.g. amendment of the product information) are submitted to the Committee for Medicinal Products for Human Use (CHMP) for endorsement when the signal concerns Centrally Authorised Products (CAPs), and to Member States and the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for information in the case of Nationally Authorised Products (NAPs). Thereafter, MAHs are expected to take action according to the PRAC recommendations.

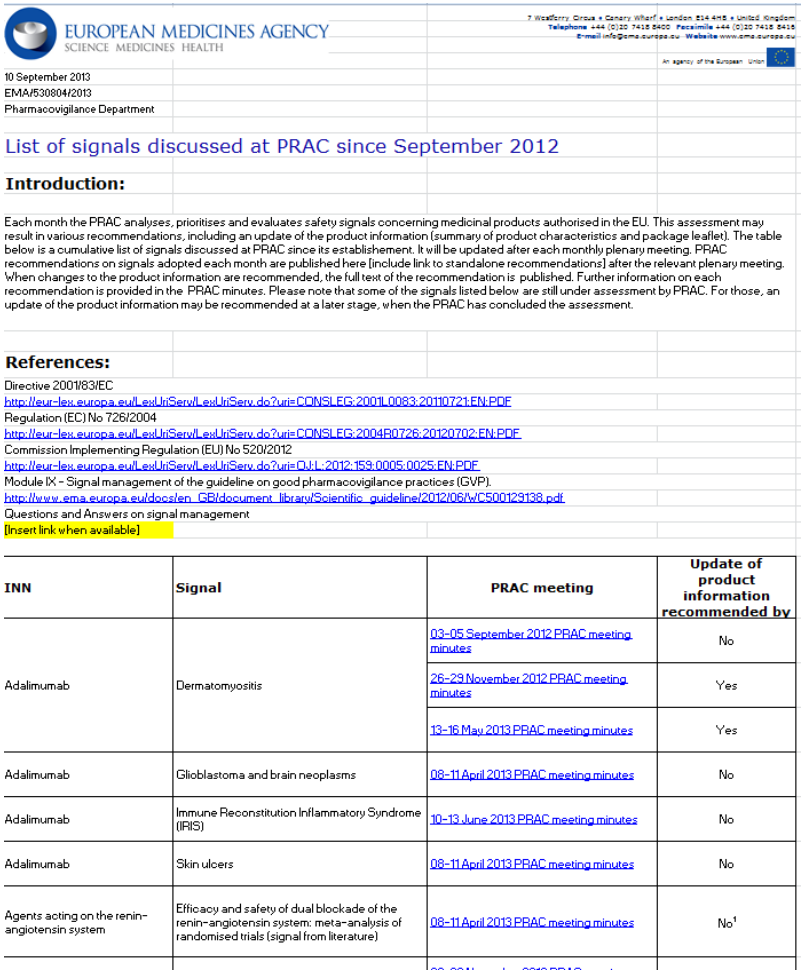
When appropriate, the PRAC may also recommend the conduct of additional analyses by the Agency or Member States.

MAHs are reminded that in line with Article 16(3) of Regulation No (EU) 726/2004 and Article 23(3) of Directive 2001/83/EC, they shall ensure that their product information is kept up to date with the current scientific knowledge including the conclusions of the assessment and recommendations published on the EMA website (currently acting as the EU medicines webportal).

For CAPs, at the time of publication, PRAC recommendations for update of product information have been agreed by the CHMP at their plenary meeting (16-19 September 2013) and corresponding variations will be assessed by the CHMP.

For nationally authorised medicinal products, it is the responsibility of the National Competent Authorities (NCAs) of the Member States to oversee that PRAC recommendations on signals are adhered to.

Variations for CAPs are handled according to established EMA procedures. MAHs are referred to the available guidance. Variations for NAPs (including via mutual recognition and decentralised procedures)



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An agency of the European Union

10 September 2013
EMA/530804/2013
Pharmacovigilance Department

List of signals discussed at PRAC since September 2012

Introduction:

Each month the PRAC analyses, prioritises and evaluates safety signals concerning medicinal products authorised in the EU. This assessment may result in various recommendations, including an update of the product information (summary of product characteristics and package leaflet). The table below is a cumulative list of signals discussed at PRAC since its establishement. It will be updated after each monthly plenary meeting. PRAC recommendations on signals adopted each month are published here [include link to standalone recommendations] after the relevant plenary meeting. When changes to the product information are recommended, the full text of the recommendation is published. Further information on each recommendation is provided in the PRAC minutes. Please note that some of the signals listed below are still under assessment by PRAC. For those, an update of the product information may be recommended at a later stage, when the PRAC has concluded the assessment.

References:

Directive 2001/83/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0083:20110721:EN:PDF
Regulation (EC) No 726/2004
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0726:20120702:EN:PDF
Commission Implementing Regulation (EU) No 520/2012
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:159:0005:0025:EN:PDF
Module IX - Signal management of the guideline on good pharmacovigilance practices (GVP).
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129138.pdf
Questions and Answers on signal management
[Insert link when available]

INN	Signal	PRAC meeting	Update of product information recommended by
Adalimumab	Dermatomyositis	03-05 September 2012 PRAC meeting minutes	No
		26-29 November 2012 PRAC meeting minutes	Yes
		13-16 May 2013 PRAC meeting minutes	Yes
Adalimumab	Glioblastoma and brain neoplasms	08-11 April 2013 PRAC meeting minutes	No
Adalimumab	Immune Reconstitution Inflammatory Syndrome (IRIS)	10-13 June 2013 PRAC meeting minutes	No
Adalimumab	Skin ulcers	08-11 April 2013 PRAC meeting minutes	No
Agents acting on the renin-angiotensin system	Efficacy and safety of dual blockade of the renin-angiotensin system: meta-analysis of randomised trials (signal from literature)	08-11 April 2013 PRAC meeting minutes	No[1]

Referrals: safety or benefit risk issues requiring a binding EU assessment

- Number of referrals (July 2012 – July 2013[1]):

Referral type	Started	Finalised
Art. 20	5	3
Art. 107i	5	3
Art. 31	11	3
Total	**21**[2]	**9**[3]

[1] Also includes procedures started and finalised by PRAC in July 2013

[2] In 6 procedures (29%) an ad-hoc expert meeting has been organised

[3] Finalised means final outcome obtained at either CHMP or CMDh

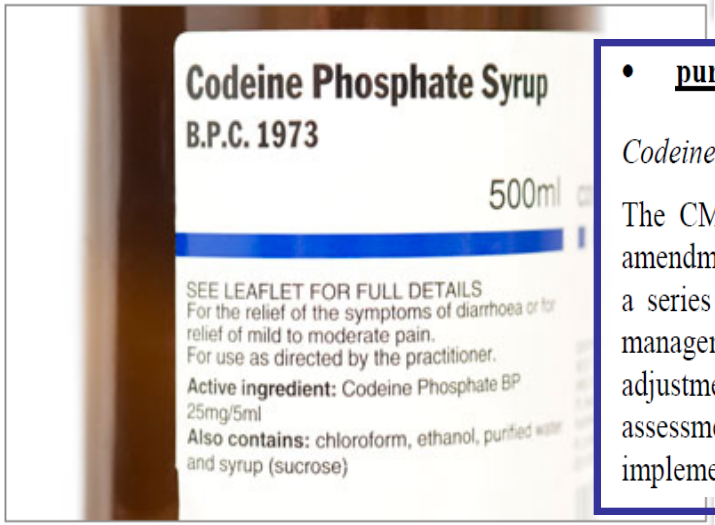
Referrals: Outcomes

- Overview of finalised referrals:

Procedure name	Article	Finalised	Committee	Grounds	Outcome	EC Decision	Duration (calender days)
Tredaptive	20	Jan-13	CHMP	B-R	Suspension	Yes	1 month
Trevaclyn	20	Jan-13	CHMP	B-R	Suspension	Yes	1 month
Pelzont	20	Jan-13	CHMP	B-R	Suspension	Yes	1 month
Tetrazepam	107i	Apr-13	CMDh	S	Suspension	Yes	3 months
Cyproterone, ethinylestradiol - DIANE 35 & other medicines containing cyproterone acetate 2mg and ethinylestradiol 35 micrograms	107i	May-13	CMDh	S	Variation	Yes	3 months
Almitrine	31PhV	May-13	CMDh	B-R	Revocation	No	7 months
Codeine-containing medicinal products	31PhV	Jun-13	CMDh	B-R	Variation	No	8 months
Diclofenac-containing medicinal products	31PhV	Jun-13	CMDh	B-R	Variation	Yes	8 months
Flupirtine	107i	Jun-13	CMDh	S	Variation	Yes	6 months

- Time taken: 1 to 8 months

Codeine analgesia in children



The risk of respiratory depression outweighs the benefits of using codeine for moderate pain in children under 12 years as there are safer alternatives | SCIENCE PHOTO LIBRARY

The Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA has recommended that use of codeine-containing medicines in children be restricted to those aged over 12 years with acute moderate pain that cannot be relieved by other analgesics, for example, paracetamol or ibuprofen.

In addition, codeine should never be used for children under 18 years undergoing tonsillectomy or adenoidectomy to treat obstructive sleep apnoea. The prescribing information will also be updated to contraindicate codeine in conditions associated with impaired breathing.

- **pursuant to Article 31 of Directive 2001/83/EC**

Codeine-containing medicines

The CMDh, having considered the PRAC assessment report and following a scientific discussion on amendments of the wording of the product information, has endorsed by consensus the recommendation for a series of measures to address safety concerns with codeine-containing medicines when used for the management of pain in children. Due to the wide range of marketing authorisations involved in the referral, adjustments to the wording of the product information will be needed on a case by case basis. As an assessment of the changed product information is needed, a Type IA variation will not be applicable for the implementation of the changes.

CMDh

Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

Report from the CMDh meeting held on 24-26 June 2013

CHCs and VTE

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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Combined hormonal contraceptives

Summary | Key facts | All documents

Procedure started → Under evaluation → PRAC recommendation → CHMP opinion → European Commission final decision

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

The European Medicines Agency has now completed its review of combined hormonal contraceptives (CHCs), particularly of the risk of venous thromboembolism (VTE or blood clots in veins) associated with their use. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of CHCs in preventing unwanted pregnancies continue to outweigh their risks, and that the well-known risk of VTE with all CHCs is small.

The review has reinforced the importance of ensuring that clear and up-to-date information is provided to women who use these medicines and to the healthcare professionals giving advice and clinical care.

Example 107i procedure – *Numeta 13%*

Numeta 13% parenteral nutrition for preterm babies

Signal of 14 reports of hypermagnesaemia – July 2013

Voluntary recall of Numeta 13%

PRAC concludes advice in 60 days to suspend Numeta 13%, introduce risk management for Numeta 16%

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Entertainment & Arts

30 May 2013 Last updated at 00:40

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Common painkillers 'pose heart risk'

By James Gallagher
Health and science reporter, BBC News

Two common painkillers, ibuprofen and diclofenac, can slightly increase the risk of heart problems if taken in high doses for a long time, data suggests.

People with severe arthritis often take the drugs, which also calm inflammation, to go about daily life.

The researchers said some patients would deem the risk acceptable, but they should be given the choice.

A study, **published in the Lancet**, showed the drugs posed even greater risks for smokers and the overweight.

The risks have been reported before, but a team of researchers at the University of Oxford analysed the issue in unprecedented detail in order to help patients make an informed choice.

Relate

Drug 'ov
despite

Painkill
heart ri

Q&A: Vi

Diclofenac & CVS risk

Legal status to be considered at national level

Referrals: Observations

- Positive experience:
  - High acceptance rate by CHMP/CMDh of PRAC outcome
  - Compliance with legal deadlines
  - Shortening of scientific review process for Art 31 procedures
  - Excellent teamwork EMA Secretariat – PRAC Rapporteurs (in terms of procedural, content and data support aspects)
- Issues requiring consideration:
  - Optimal use of referrals tools for public health
  - Workload for Network high and remains unpredictable
  - Communication and planning

Prioritised implementation of the pharmacovigilance legislation

Collection of key information on medicines

List of medicines withdrawn for safety reasons:	2012	2013	
Develop a business process for establishing, maintaining and publishing such list			Based on 2012 changes to pharmacovigilance legislation

Prioritised implementation of the pharmacovigilance legislation by the EMA

Communication with stakeholders

Coordination of safety messages:	2012	2013	
Operation of the coordination of Member States' safety announcements for non-CAPs.			- Started July 2012

Publication of RMP summaries

Pilot phase initiated in October 2013.

- Summary (Part VI.2 of RMP) to be published at the time of the EPAR publication.
- Summary to be updated in case of important changes to RMP.
- Summary is aligned with other information (EPAR summary, product information).
- For **all** newly - authorised CAPs;
- For other (not newly authorised) CAPs, RMP summary to be published when RMP is updated.

Prioritised implementation of the pharmacovigilance legislation by the EMA

Communication with stakeholders

European Medicines web-portal:	2012	2013	
Initiate research and design work			

Legal notice: EMA website serves as the EU Medicines Web-portal

Beyond 2013…what still needs to be done

Topics	Activities
Literature monitoring	EMA service to industry for population of EudraVigilance with case reports of old substances.
EudraVigilance	Delivery of enhanced functionalities and IT system audit results in centralised reporting for industry
Article 57(2) data submission and handling	Updates (variations) to the data can be submitted by industry and data fully used to support regulation, safety and stakeholder needs.
Periodic Safety Update Reports	Delivery of PSUR repository and single PSUR assessment process for NAPs allowing centralised reporting for industry and faster warnings for NAPs
Risk Management System	Implement risk-based system for measuring the effectiveness of risk minimisation
Transparency and communication	Delivery of EU Medicines web-portal and public hearings.

European Commission Joint Action

Strengthening Collaborations to Operate Pharmacovigilance in Europe

SCOPE

EUROPEAN COMMISSION
EXECUTIVE AGENCY FOR HEALTH AND CONSUMERS

Health Unit

Executive Agency for Health and Consumers

Luxembourg,
EAHC LB/IK Ares (2012)

2013 CALL FOR PROPOSALS FOR JOINT ACTIONS

SECOND PROGRAMME OF COMMUNITY ACTION IN THE FIELD OF HEALTH (2008-2013)

Facilitating collaboration among the Member States for the effective operation of the pharmacovigilance system in the EU

What have we achieved

A huge change has been delivered for better public health improvement:

- Better public participation
  - increase of patient reports by 10,000
  - Patients and HCPs voting on PRAC
- Better planning – risk management plans now routine
- Better evidence – routine identification of data needs for referrals
- Faster decision-making
  - Referrals finalised in 1 to 8 months
  - PSURs directly lead to label changes
- Greater transparency – agendas, minutes, signals
- Better information – black triangle, ADR reporting, warnings

But there is still more to do

Deliver on the simplifications:

- Further improve on the processes already implemented
- Centralised ADR reporting
- Centralised PSUR reporting
- Literature monitoring by EMA for industry

Full delivery on better information:

- EU medicines webportal

Process improvements based on experience to date:

- E.g. RMPs, PSURs etc

We will get there…..working together

Conclusions

Major change has been delivered:

- Collaboration
- Consultation
- Concentration

Public health has been improved:

- Better evidence
- Faster decisions and labelling
- Greater transparency
- Greater participation and empowerment

Further process improvements are underway!