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Overview of key improvements

9th Stakeholder forum on the Pharmacovigilance legislation, 15 September 2015

Presented by Dr June Raine
Chair, Pharmacovigilance Risk Assessment Committee

Looking ahead to ongoing improvement

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In this presentation:

- Key pharmacovigilance improvement themes
- Highlights of PRAC work plan 2015
- Challenges and some approaches to solutions

Ongoing improvement

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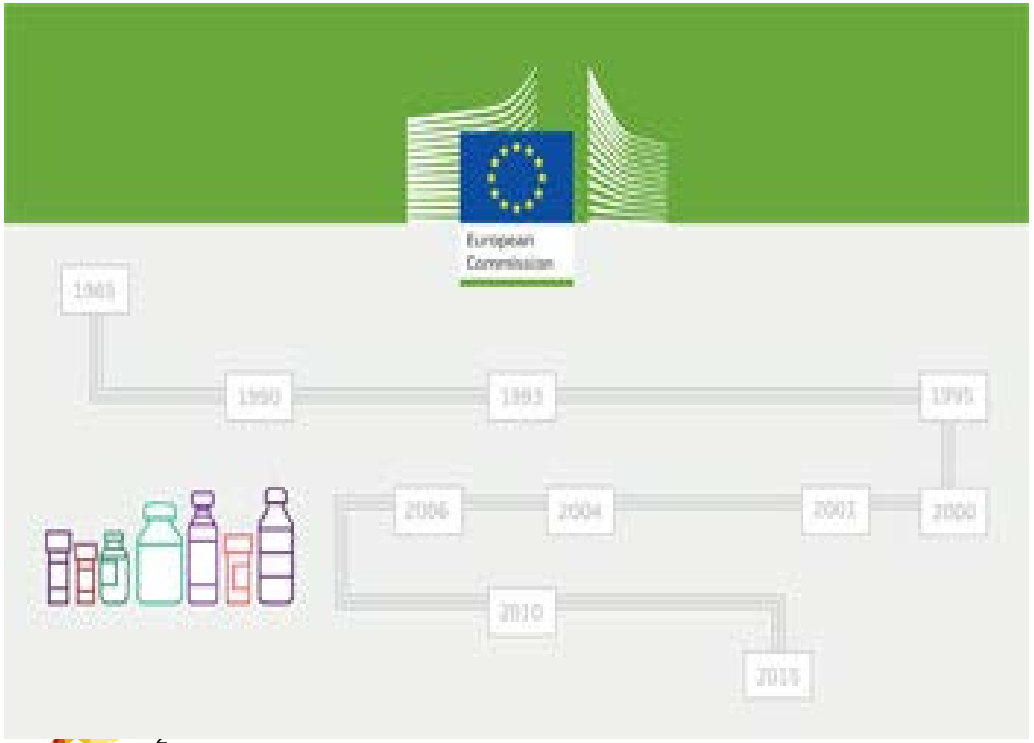
European Anniversary year 2015:



50 years of EU regulation

20 years of EMA

5 years since adoption of Phvig legislation

3 years of PRAC

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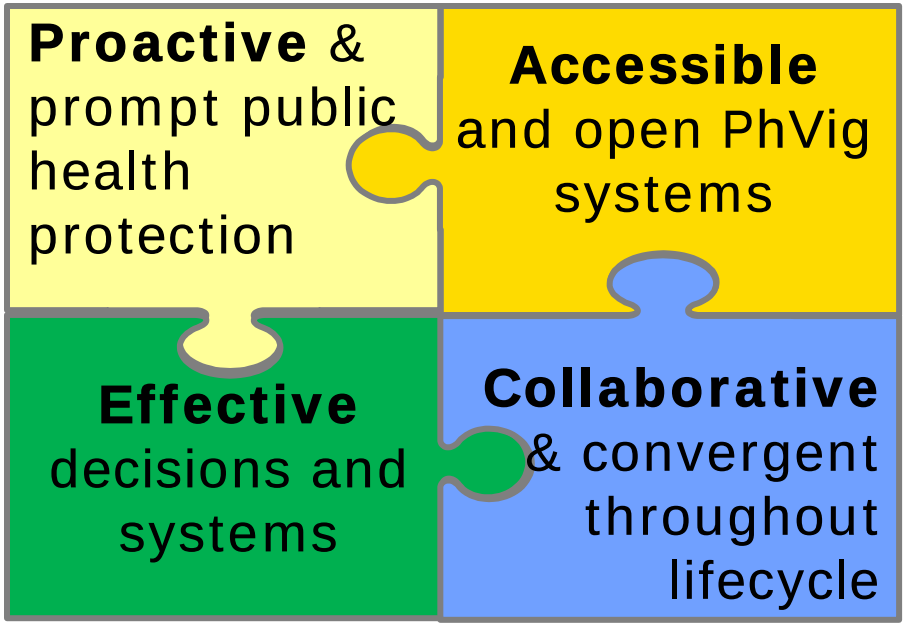
Keeping up the PACE

Making a difference

Keeping up the PACE



The 2015 PRAC Work Plan

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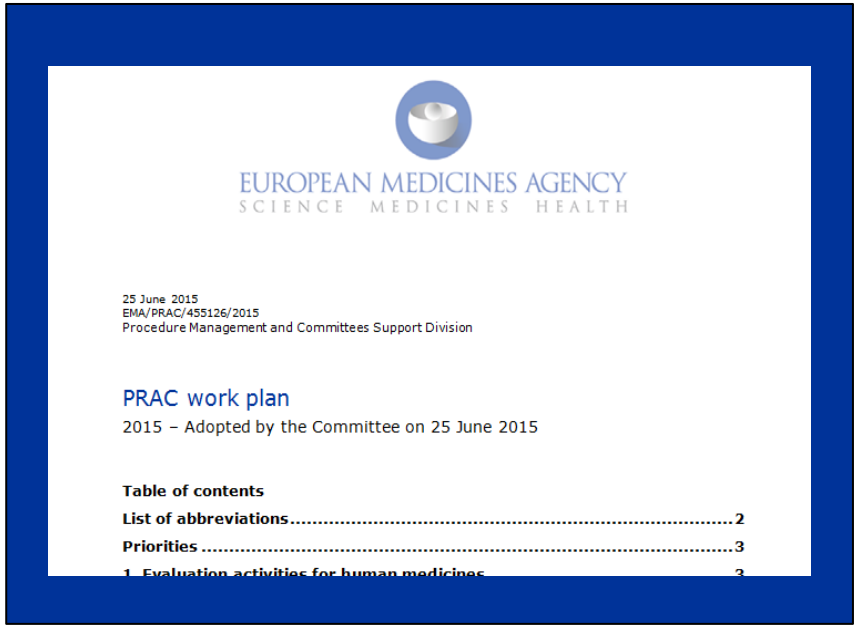
Comprehensive activity- focussed plan to utilise potential of all new legislative tools

Priorities include:

- Enhanced quality and consistency of PRAC reviews
- Lifecycle management
- Use of new tools

Focus on developing new guidance where needed

Strengthened collaboration with other EMA committees



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25 June 2015
EMA/PRAC/455126/2015
Procedure Management and Committees Support Division

PRAC work plan

2015 – Adopted by the Committee on 25 June 2015

Table of contents

List of abbreviations 2
Priorities 3
1. Evaluation activities for human medicines 3

Proactive public health protection

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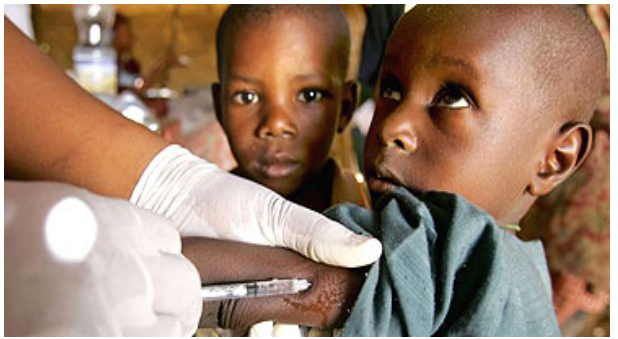
Proactive & prompt public health protection

- Strengthening evidence and science base
- Investigating use of benefit risk decision methodologies
- Focus on Post Authorisation studies – PASS and PAES
- SMART signal detection methodologies
- Best Practice for referrals
- New GVP guidance
  - Special populations
  - Biologics and vaccines
  - Pregnancy
  - Medication errors



The IMI PROTECT project

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To strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods

To enhance early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies)

To enable the integration and presentation of data on benefits and risks

20 1995 2015 EMA

Use of pharmacogenomic evidence

Using pharmacogenomics to define populations at risk of ADRs

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1 10 January 2014
2 EMA/281371/2013
3 Committee for Medicinal Products for Human Use (CHMP)

4 **Guideline on key aspects for the use of pharmacogenomic**
5 **methodologies in the pharmacovigilance evaluation of**
6 **medicinal products**
7 Draft

Draft Agreed by Pharmacogenomics Working Party	April 2013
Adoption by CHMP for release for consultation	20 December 2013
Start of public consultation	30 January 2014
End of consultation (deadline for comments)	30 July 2014

8

Transformative medicines

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Early access to medicines in areas of high unmet need

PRIME medicines procedures under development

Focus on real-world real-time evaluation

ADA-SCID gene therapy

1995 2015 EMA

Accessible pharmacovigilance systems

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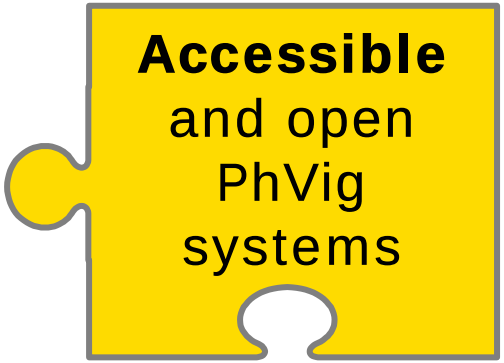
Optimising safety communications – update of GVP XV

Criteria for PRAC communication other than on referrals

Report on experience with co-ordination of EU communications

Introducing public hearings



Optimising pharmacovigilance communications

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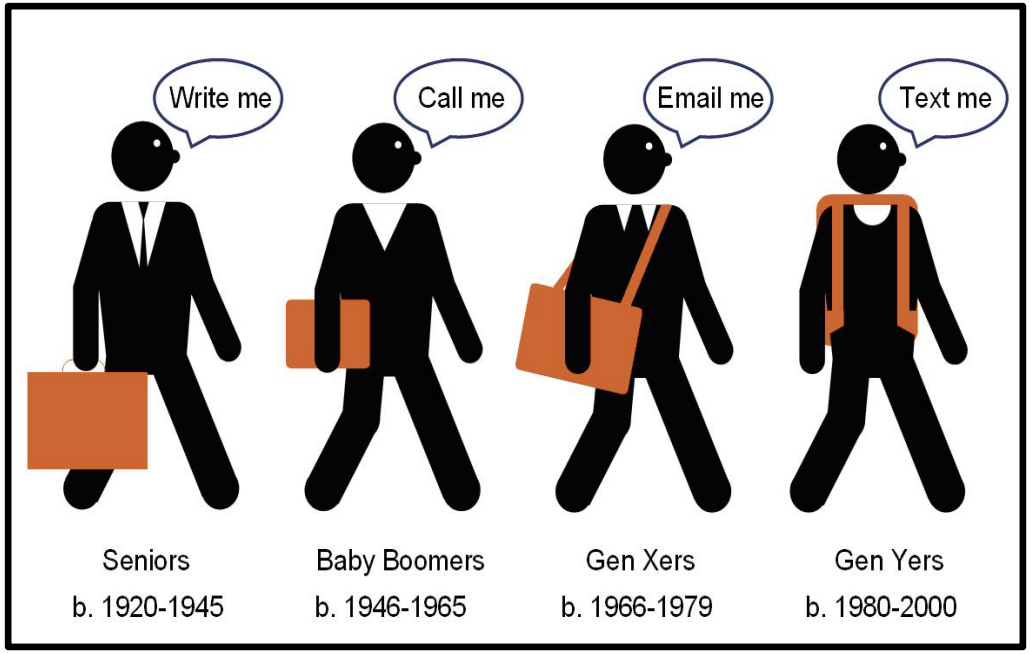
PRAC is supporting work by EMA, PCWP & HCPWP

Workshop on risk minimisation 16th Sept



Engaging with patients and the public

Interaction with patient and healthcare professional organisations so far during formal European reviews

Rules of procedure for conduct of public hearings being finalised

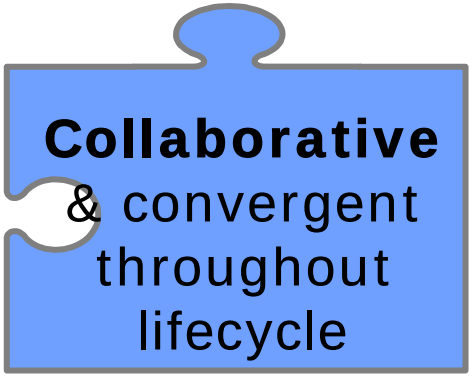
Collaborative pharmacovigilance

Working with internal and external stakeholders – building effective inter-committee collaboration

Context of EU Network Plan

SCOPE Joint Action project

Innovative Medicines Initiative WEB-RADR



Collaboration between committees

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Informal PRAC and Paediatric Committee meeting 28-9 May

SCOPE EU Joint Action

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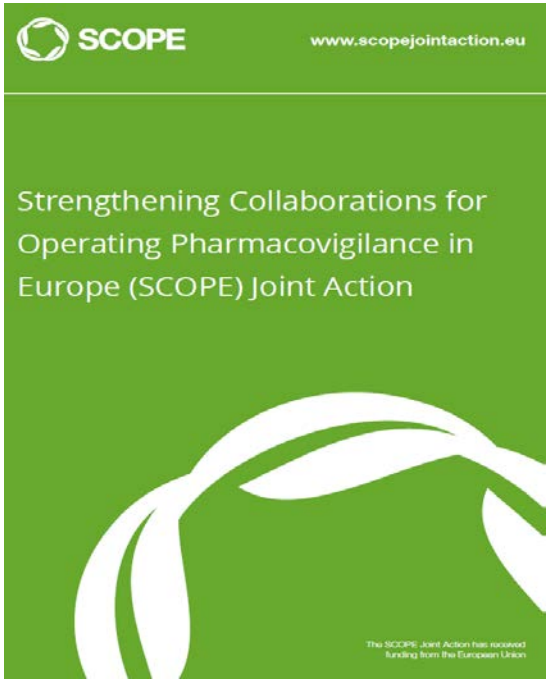
Strengthening pharmacovigilance collaboration:

- ADR reporting
- Signal detection
- Risk communications
- Pharmacovigilance assessment
- Quality management



Project due for completion October 2017

1995 2015 EMA

Development of a mobile app for

–ADR reporting

–Provision of information to users

Scientific evaluation of using social media data to identify ADRs, propose policy guidance

Effective pharmacovigilance systems

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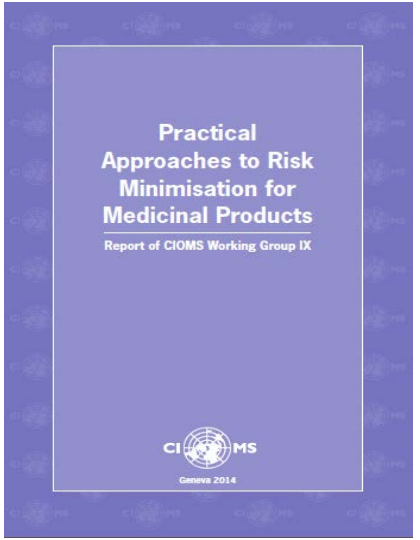
Developing GVP module XII on regulatory options

Developing strategy to strengthen evaluation of risk minimisation proposals

Developing a strategy to measure impact of pharmacovigilance

Effective decisions and systems



Impact of regulatory action

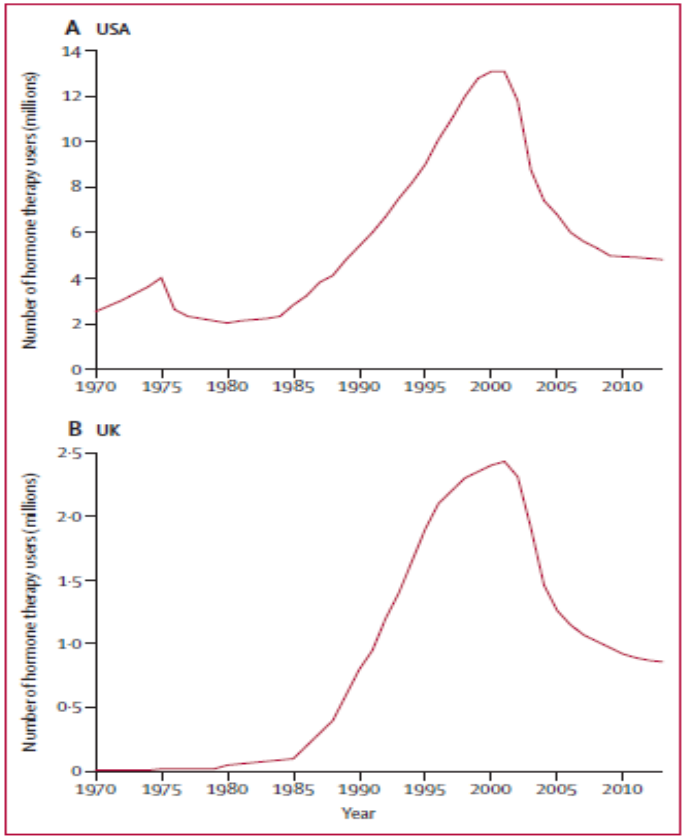


Figure 1: **Trends in hormone therapy use in the USA and the UK since 1970**
For source of data, see appendix p 4.

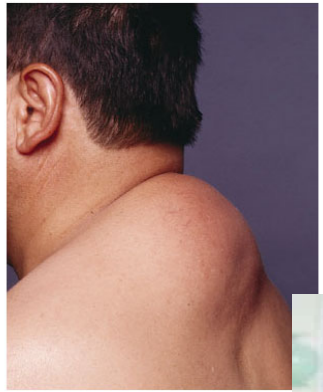
Removal of first-line indication in osteoporosis for HRT after WHI study showed harms

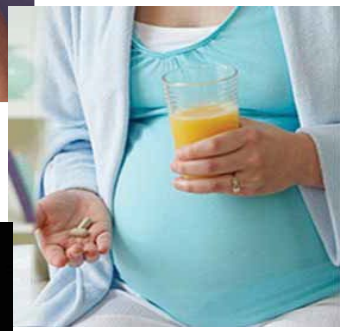
Followed by fall in incidence of breast cancer in women over 50 eg 7% in Australia

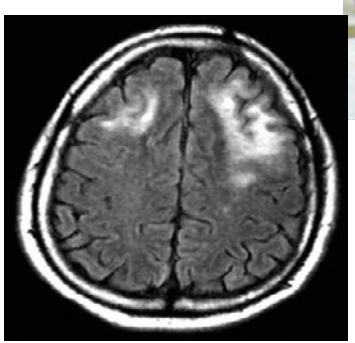
Trends in use of hormone therapy for the menopause since 1970

Some key challenges

- Workload, resources and prioritisation
- Optimising benefit risk of “mature” products
- Medicines in pregnancy
- Long term safety (biologics)







Some approaches and solutions

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Maximising use of new methodologies from collaborative projects in particular PROTECT

Building capacity for PASS and PAES studies by maximising use of European Network of Centres for Pharmacovig & Pharmacoepi

Better use of real-world data eg registries

Optimising IT to support and streamline pharmacovigilance systems

Benefits of international collaboration

Conclusions

Last three years have seen **great progress** in realising potential of EU Pharmacovigilance legislation & role of PRAC

Experience has demonstrated areas where a **strengthened**, **clarified** or **simplified** approach needed

This will be the basis for developing a **focussed work plan** for 2016

Ongoing **collaboration between all stakeholders** essential to achieve highest standards of public health protection in EU

With thanks to:

Jolanta Palepsaitiene for help with this presentation

All members and secretariat of PRAC

Thank you

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