Expectation for PBRER and its foresight

- Insights from current situation both in EU and Japan

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PSUR to PBRER

- ICH-E2C
  - Periodic Safety Update Report
  - Periodic Benefit and Risk Evaluation Report

- PSUR still exists in EU legislation.

ICH-E2C (R2)

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

PERIODIC BENEFIT-RISK EVALUATION REPORT (PBRER)

E2C(R2)

Current *Step 4* version

dated 17 December 2012

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

January 2013
EMA/CHMP/ICH/544553/1998

ICH guideline E2C (R2) on periodic benefit-risk evaluation report (PBRER)

Step 5

Transmission to CHMP	April 2012
Adoption by CHMP for release for consultation	April 2012
End of consultation (deadline for comments)	May 2012
Final adoption by CHMP	December 2012
Date for coming into effect	January 2013

PSUR (PBRER) in EU

- Operation of new procedures related to PSURs of CAPs started in July 2012.
- Handling of PSURs for active substances contained in both CAPs and NAPs accordance with URD list started in June 2013.

Establishment of PRAC

- Pharmacovigilance Risk Assessment Committee （PRAC）
- Established in July 2012
- The experts from regulatory authorities in Member States and other specialised institutions

PRAC volumes (July 2012 – July 2013)

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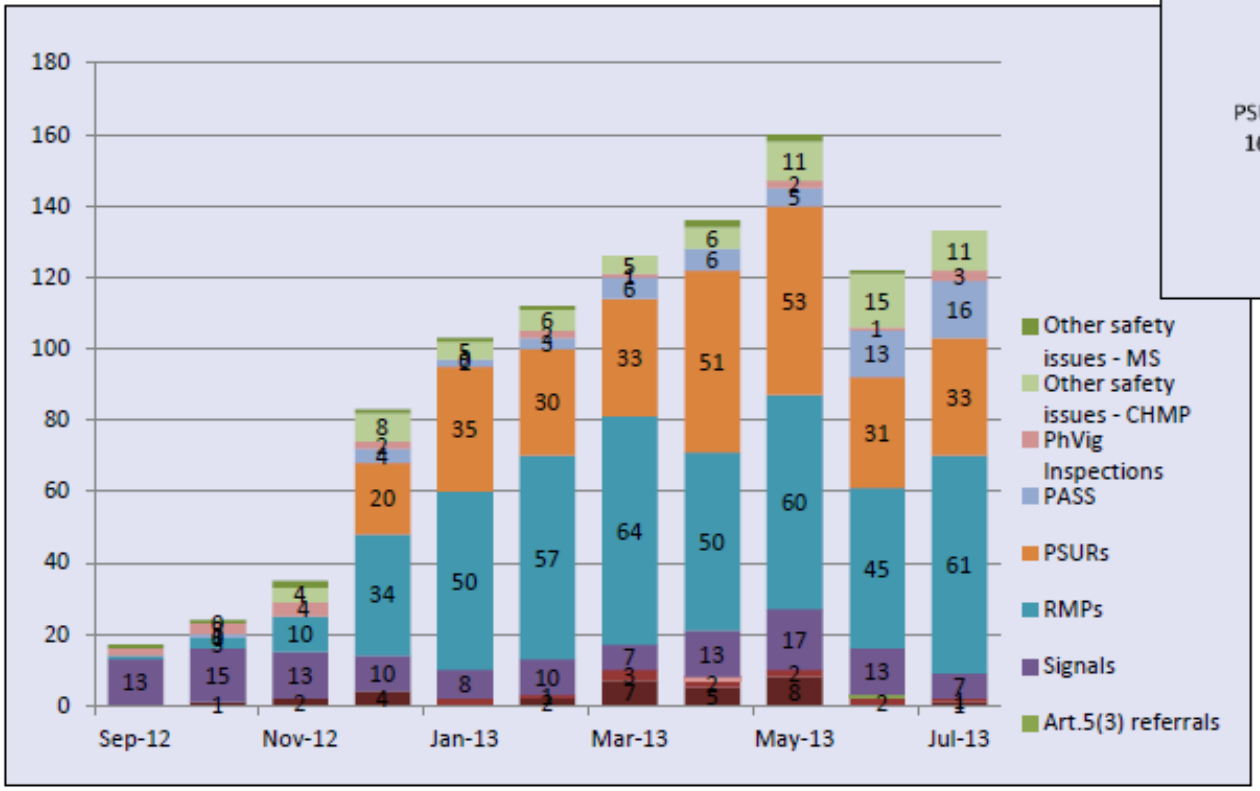
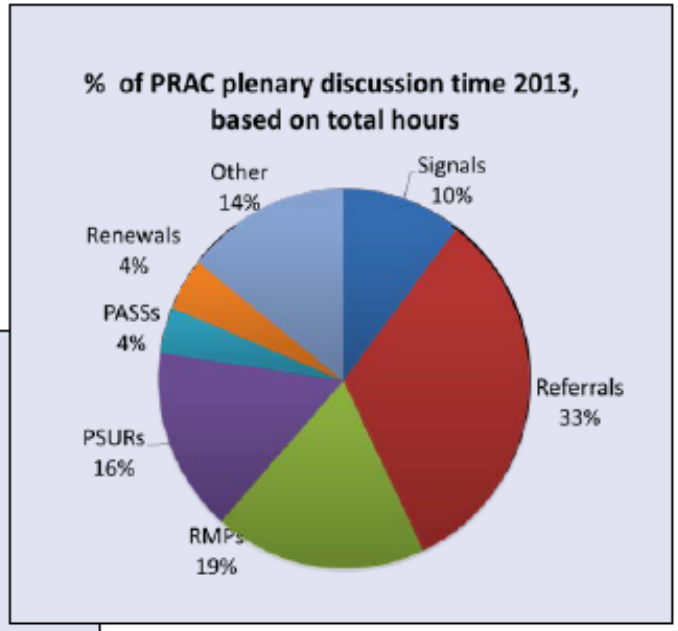
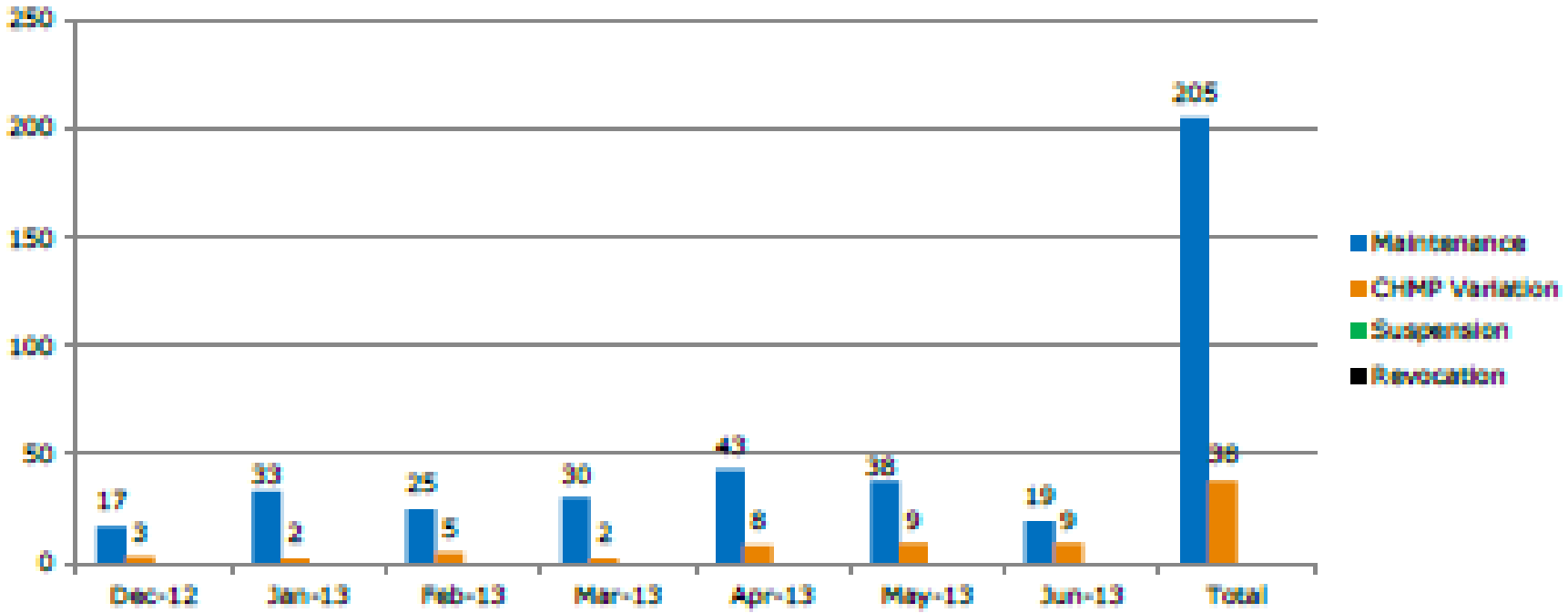




PSURs: Outcomes at PRAC



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

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PSURs: Observations (EU)

- Procedure now better understood by all concerned parties – clear improvements noted.
- Increasing number of PSUR procedures leading directly to MA variation – efficiency gains since no need for follow-up variation and health gains through rapid update of product information
- Still room for further improvement in terms of better understanding the new procedure:
  - For regulators:
    - requests for additional information to be more clearly phrased
    - requests for labelling to be explicit and clearly justified
  - For pharmaceutical industry: key success factor is the provision by companies of clear positions and proposals for regulatory action/follow-up

⇒ Further training to be provided

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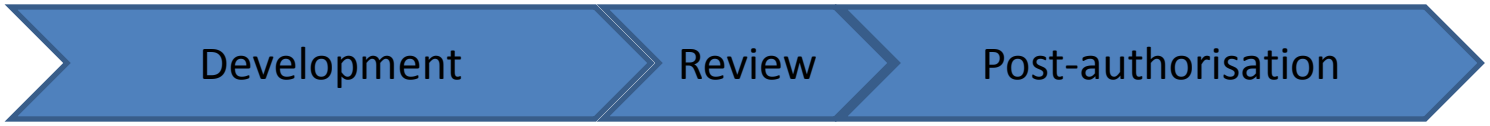
Expectation to DSUR/PBRER

- As benefit-risk decision-making tool
- To be more positive benefit-risk balance
  - Foster the product through the life-cycle
  - To accelerate to collect benefit data
    - more efficiently and more meaningfully
  - To identify risk factors
    - Minimise risks

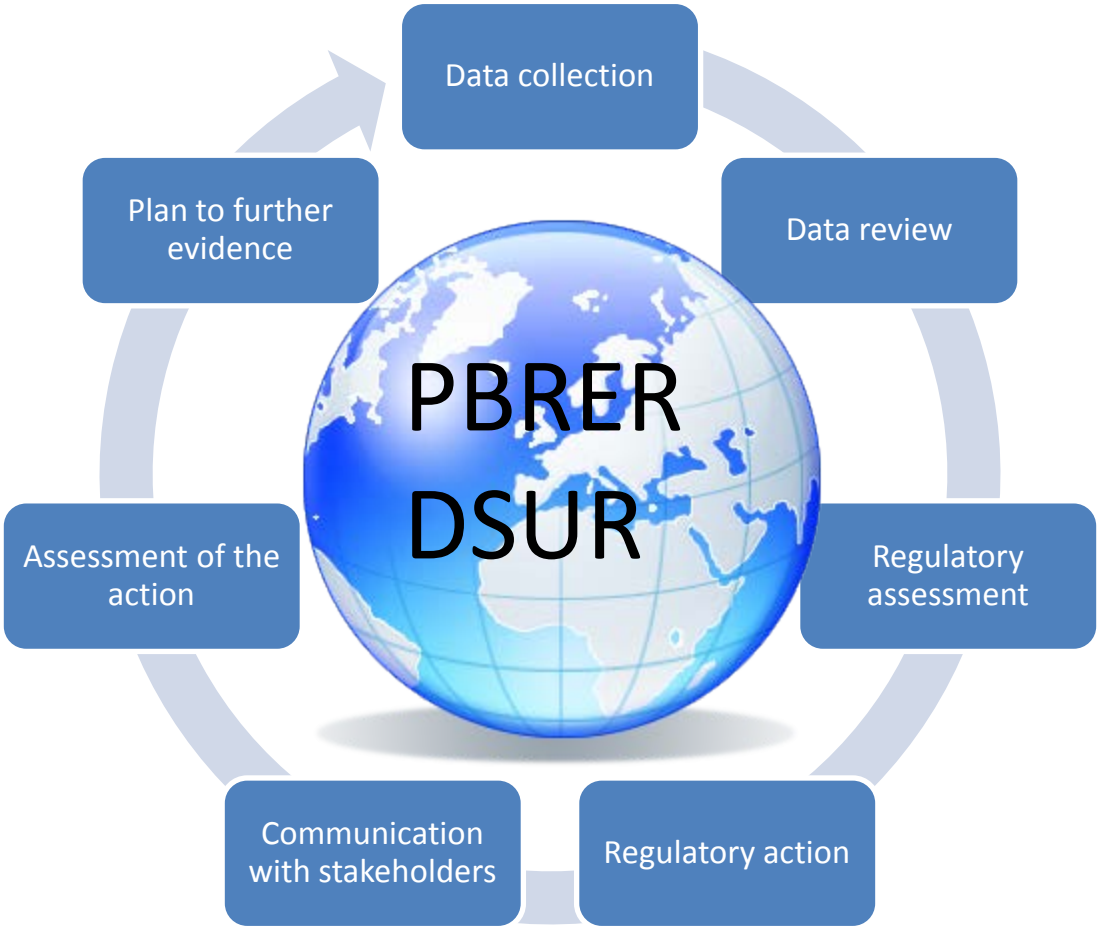
From DSUR to PBRER



DSUR → PBRER

ICH-E2E

Through life-cycle of products



Work together!

- For patients
- For more positive benefit-risk balance of products