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
ICH guideline E2C (R2) on periodic benefit-risk evaluation report (PBRER)
Step 5

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<tr>
<td>Transmission to CHMP</td>
<td>April 2012</td>
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<td>Adoption by CHMP for release for consultation</td>
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<td>End of consultation (deadline for comments)</td>
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<td>Final adoption by CHMP</td>
<td>December 2012</td>
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<td>Date for coming into effect</td>
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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
Dr. Arlett, 7th Stakeholder Forum on the Implementation of the new Pharmacovigilance Legislation
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

Dr. Arlett, 7th Stakeholder Forum on the Implementation of the new Pharmacovigilance Legislation
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.

Dr. Arlett, 7th Stakeholder Forum on the Implementation of the new Pharmacovigilance Legislation
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

Development → Review → Post-authorisation

DSUR → PBRER

ICH-E2E
Through life-cycle of products

**PBRER**

**DSUR**

- Data collection
- Data review
- Plan to further evidence
- Assessment of the action
- Communication with stakeholders
- Regulatory assessment
- Regulatory action
Work together!

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