



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSURs

5th industry stakeholder platform - operation of EU pharmacovigilance legislation



Presented by Irene Rager on 15 Sept 2015

An agency of the European Union





Understanding the issues for action

- Understand the points raised by Industry
- Setting them into the context of the regulatory framework
- Discussion
- Agreeing on the action items/ areas for improvement

→ Today

How will the points be addressed?

- Survey of the network to identify assessors' issues and expectations (Oct 2015)
 - Advisory Group for the EURD list (GPAG – established)
 - Development of a procedural guidance for assessors (started)
 - PRAC Assessors' training on 19/20 November with a focus on PSUSAs
 - Review and refinement of the assessment report template Q1 2016
 - SCOPE "Hints and Tips" document for PSUR/PSUSA Assessment
 - Revision of the regional part of GVP VII in 2016
- Review with Industry on success of measures



Thank you for your attention

Further information

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