

# SCOPE Work Package 8 (WP8) - Lifecycle Pharmacovigilance – training course

*20<sup>th</sup> – 21<sup>st</sup> September 2016, Lisbon, Portugal*



WP Lead Italian Medicines Agency (AIFA)

Topic Leads: AIFA (IT), Norwegian Medicines Agency (NO) and MPA (SE)

Active Contributors AEMPS (ES), National Organization for Medicines (GR), HPRA (IE), MEB (NL), INFARMED (PT) and MHRA (UK)

*Organised in co-operation with INFARMED I.P*

*Venue : INFARMED, I.P Parque de Saúde de Lisboa (Lisbon Health Park)*

*Av. do Brasil, 53 1749-004 Lisbon, Tomé Pires Building, Room A*





SCOPE is developing recommendations, guidance and training for regulators to support the EU pharmacovigilance network

Work Package 8 aims to explore existing standards for pharmacovigilance assessments and a good practices useful to ensure that National Competent Authorities (NCAs) are able to support the Pharmacovigilance Risk Assessment Committee (PRAC) with high-quality assessment and advice on: risk management plans; post authorisation studies, periodic safety update reports and referral procedures.

#### Learning Objectives of the training course :

**Session 1: RMP** - How to perform an RMP assessment and overcome the related challenges

**Session 2: PASS** – How to identify the objectives and design of the PASS and to be able to evaluate a PASS protocol

**Session 3: PSUR/PSUSA** - How to perform a PSUR/PSUSA assessment and overcome the related challenges

**Session 4: referral** - How to successfully trigger and manage a safety referral procedure

**Session 5: Additional Data Sources (ADSs)** outside spontaneous reporting – To understand the potential role of ADSs in the context of PV procedures evaluation and to recognise the added value for the best evidence in PV decision-making

**Session 6: competency** – To understand a basics of quality management, the quality standards of assessment reports (ARs) and how to use a quality assessment checklist while performing PV procedures' ARs

| 8.00 - 9.00 Registration              |                                                                                                                                                                              |                                                     |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Introductory session                  |                                                                                                                                                                              |                                                     |
| 9.00 – 9.40                           | Introduction to the SCOPE WP8 and to training course (10 min)                                                                                                                | Jelena Ivanovic (WP8 Lead) - AIFA IT                |
|                                       | WP8 deliverables in the context of overall SCOPE JA programme (10 min)                                                                                                       | Mick Foy (SCOPE Coordinator) - MHRA UK              |
|                                       | Building-up competency to support the Pharmacovigilance Risk Assessment Committee (PRAC) with high-quality assessments and advices – a point of view from SCOPE GAB (15 min) | June Raine (PRAC Chair and SCOPE GAB ) - MHRA UK    |
|                                       | Welcome address by CHAFEA (5 min)                                                                                                                                            | Georgios Margetidis (CHAFEA-European Commission)    |
| Session 1 Risk Management Plan ( RMP) |                                                                                                                                                                              | Moderator: Qun-Ying Yue - MPA SE                    |
| 9.40 – 10.00                          | Practical Guide for assessors - RMP                                                                                                                                          | Ingebjørg Buajordet - Norwegian Medicines Agency NO |
| 10.00 – 10.10                         | Discussion                                                                                                                                                                   | All                                                 |
| 10.10 – 10.40                         | Pharmacovigilance Plan - Additional PV activities                                                                                                                            | Menno van der Elst - MEB NL                         |
| 10.40 – 10.50                         | Discussion                                                                                                                                                                   | All                                                 |
| <b>10.50 – 11.10</b>                  | <b>Coffee break</b>                                                                                                                                                          |                                                     |
| 11.10 – 11.30                         | Risk Minimisation Plan (RMP) - Effectiveness of a RMMs                                                                                                                       | Inge Zomerdijk - MEB NL                             |
| 11.30 - 11.40                         | Discussion                                                                                                                                                                   | All                                                 |
| 11.40 - 12.10                         | RMP – case study                                                                                                                                                             | Ingebjørg Buajordet - Norwegian Medicines Agency NO |
| 12.10 -12.20                          | Discussion                                                                                                                                                                   | All                                                 |

| <b>Session 2 Post Authorisation Safety Studies (PASS)</b> |                                                                                   | <i>Moderator: Ingebjørg Buajordet- NOMA NO</i> |
|-----------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------|
| 12.20 - 12.35                                             | PRAC experience on protocol evaluation for imposed PASS – part 1: general aspects | Qun-Ying Yue - MPA SE                          |
| 12.35- 12.40                                              | Discussion                                                                        | All                                            |
| 12.40 – 13.00                                             | Epidemiology methodology and PASS in practice (part 1)                            | Marieke De Bruin - MEB NL                      |
| 13.00-13.10                                               | Discussion                                                                        | All                                            |
| <b>13.10 – 14.00</b>                                      | <b>Lunch</b>                                                                      |                                                |
| 14.00– 14.20                                              | Epidemiology methodology and PASS in practice (part 2)                            | Marieke De Bruin - MEB NL                      |
| 14.20 – 14.30                                             | Discussion                                                                        | All                                            |
| 14.30 – 14.55                                             | Practical Guide for the evaluation of PASS protocols                              | Diego Macias - AEMPS ES                        |
| 14.55 - 15.05                                             | Discussion                                                                        | All                                            |
| 15.05 - 15.20                                             | PRAC experience on protocol evaluation for imposed PASS – part 2: case assessment | Qun-Ying Yue - MPA SE                          |
| 15.20 - 15.30                                             | Discussion                                                                        | All                                            |
| <b>15.30- 15.50</b>                                       | <b>Coffee break</b>                                                               |                                                |
| <b>Session 3 PSUR/PSUSA</b>                               |                                                                                   | <i>Moderator: Alison Shaw - MHRA UK</i>        |
| 15.50 – 16.10                                             | Practical Guide for the evaluation of PSUR/PSUSA                                  | Eleanor Carey - HPRA IE                        |
| 16.10-16.20                                               | Discussion                                                                        | All                                            |
| 16.20 – 16.40                                             | Case study: PSUSA of ticlopidine                                                  | Amelia Cupelli - AIFA IT                       |
| 16.40 - 16.50                                             | Discussion                                                                        | All                                            |
| 16.50 – 17.05                                             | PRAC experience on evaluation of PSUR/PSUSA                                       | Leonor Chambel - INFARMED PT                   |
| 17.05 – 17.15                                             | Discussion                                                                        | All                                            |

**Session 4 Referrals**

*Moderator: Eleanor Carey - HPRA IE*

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|----------------------|-------------------------------------------------------------------------------------------|----------------------------------------|
| 9.00 – 9.30          | Practical Guide for assessors - referrals                                                 | Jane Woolley and Alison Shaw - MHRA UK |
| 9.30 – 9.40          | Discussion                                                                                | All                                    |
| 9.40 - 10.00         | Case study on referral art 107i excipient povidone - assessor's perspective as rapporteur | Qun-Ying Yue - MPA SE                  |
| 10.00 – 10.10        | Discussion                                                                                | All                                    |
| 10.10 - 10.30        | Case study on referral art. 31 valproate - assessor's perspective as non-rapporteur       | Ana Sofia Martins - INFARMED PT        |
| 10.30- 10.40         | Discussion                                                                                | All                                    |
| 10.40 – 11.00        | The PRAC perspective on referrals                                                         | Julie Williams - MHRA UK               |
| 11.00 – 11.10        | Discussion                                                                                | All                                    |
| 11.10 – 11.20        | Conclusions and “Top 10 tips”                                                             | Alison Shaw, Jane Woolley - MHRA UK    |
| <b>11.20 – 11.40</b> | <b>Coffee break</b>                                                                       |                                        |

**Session 5 ADSs outside spontaneous reporting**

*Moderator: Jane Woolley - MHRA UK*

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|----------------------|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| 11.40 – 11.50        | WP8 recommendations on ADSs                                                                  | Jelena Ivanovic - AIFA IT                                                 |
| 11.50 – 12.10        | Use of Electronic Healthcare Records                                                         | Gianluca Trifirò - University of Messina IT; Medical Centre, Rotterdam NL |
| 12.10– 12.30         | Electronic healthcare records and their role in vaccine pharmacovigilance – a case study     | Katherine Donegan - MHRA UK                                               |
| 12.30 – 12.55        | Data sources for Pharmacovigilance of pregnancy exposures: the role and principal challenges | Jelena Ivanovic - AIFA IT                                                 |
| 12.55 – 13.10        | Case study on isotretinoin                                                                   | Inge Zomerdijk - MEB NL                                                   |
| 13.10 – 13.25        | Discussion                                                                                   | All                                                                       |
| <b>13.25 – 14.25</b> | <b>Lunch</b>                                                                                 |                                                                           |

**Session 6 Competency**

*Moderator: Jelena Ivanovic – AIFA IT*

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|---------------|---------------------------------------------------------------|--------------------------------------|
| 14.25- 14.40  | WP8 recommendations on competency                             | Jelena Ivanovic - AIFA IT            |
| 14.40 – 15.00 | WP7- Quality management? Not my business...                   | Melinda Pálfi - OGYEI HU             |
| 15.00 – 15.20 | WP7-Quality standards of pharmacovigilance assessment reports | Ana Sofia Martins - INFARMED PT      |
| 15.20 – 15.30 | Discussion                                                    | All                                  |
| 15.30 – 15.40 | Closure of the training course and final conclusions          | Jelena Ivanovic (WP8 Lead) - AIFA IT |

## *Technical instructions:*



Participation in this training course is available also via webinar.

Instructions will be communicated by WP3 Team.

