

Strengthening Collaborations for Operating Pharmacovigilance in Europe (SCOPE)

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SCOPE context in EU



Two years of operation

Establishment of:

- Pharmacovigilance Risk Assessment Committee
- Good Vigilance Practice modules
- Additional Monitoring

Member States need to operate pharmacovigilance to legislative requirements

EC recognise varying level of maturity in the system

From implementation to operation

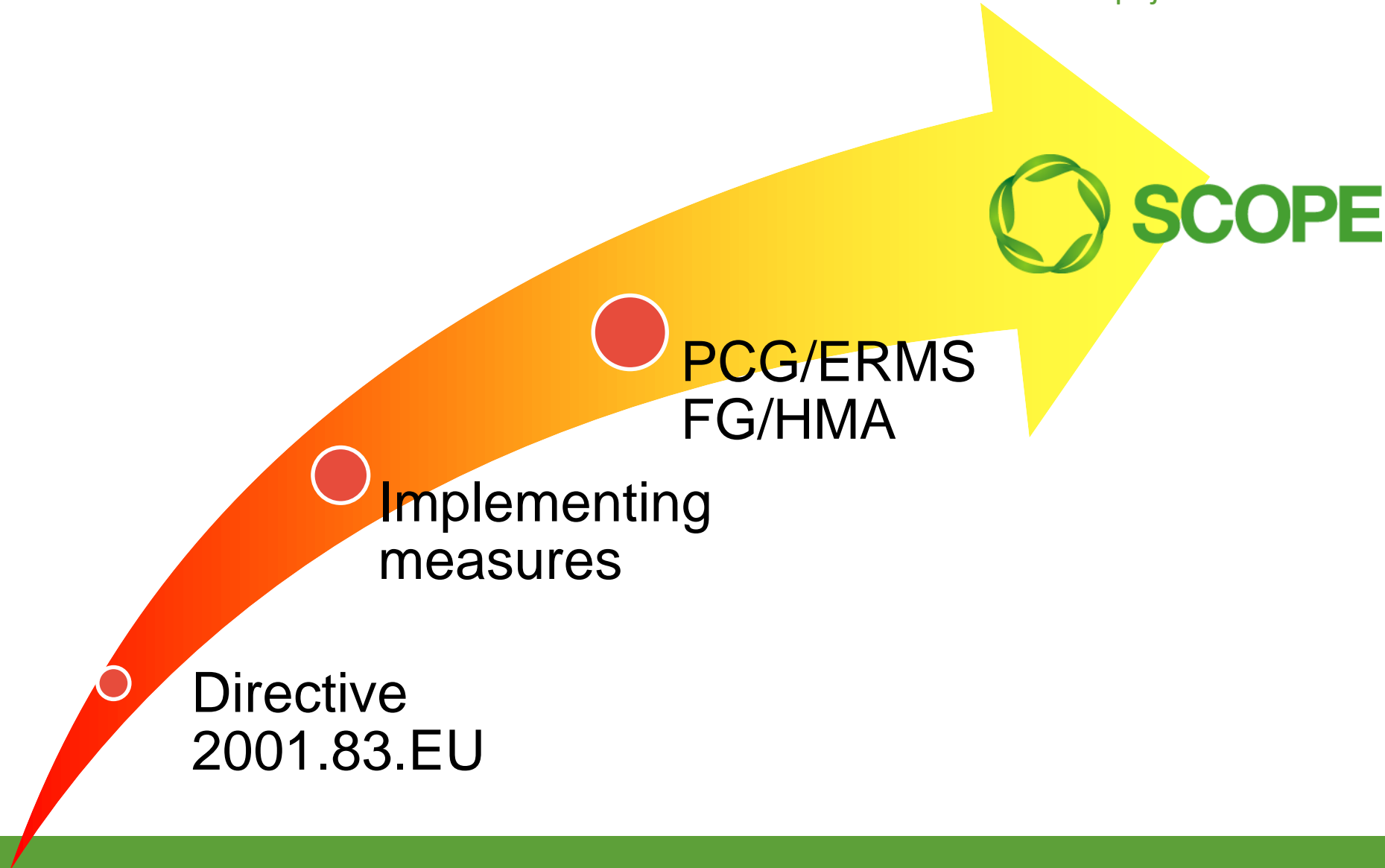


SCOPE

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SCOPE



Directive
2001.83.EU

Implementing
measures

PCG/ERMS
FG/HMA

SCOPE Joint Action



Share expertise and best practice

Deliver practical tools and guidance

Operate pharmacovigilance in Europe

By Member States

For Member States

With Member States



Delivery

- Focus is on enabling and supporting capabilities of EU regulators
- Delivering tools for regulators
 - ‘best practice’ – i.e. recommendations/guidance based on successful systems/implementations
 - Training – such as for assessment
 - Practical tools – such as toolset for national promotion of reporting systems
- Deliverables may be relevant to other organisations/outside EU
- Deliver towards end of Joint Action i.e. in 2 years
- Complementary to existing EU system – supporting use of templates and procedures developed by Project teams/Project Co-ordination Group/ERMS FG/HMA

SCOPE Joint Action



Formal award decision adopted by Commission
SCOPE 36 month project launched in November
2013

Maximum level & largest possible contribution of
70% funding from Commission: *Consumers, Health
and Food Executive Agency (CHAFEA)*

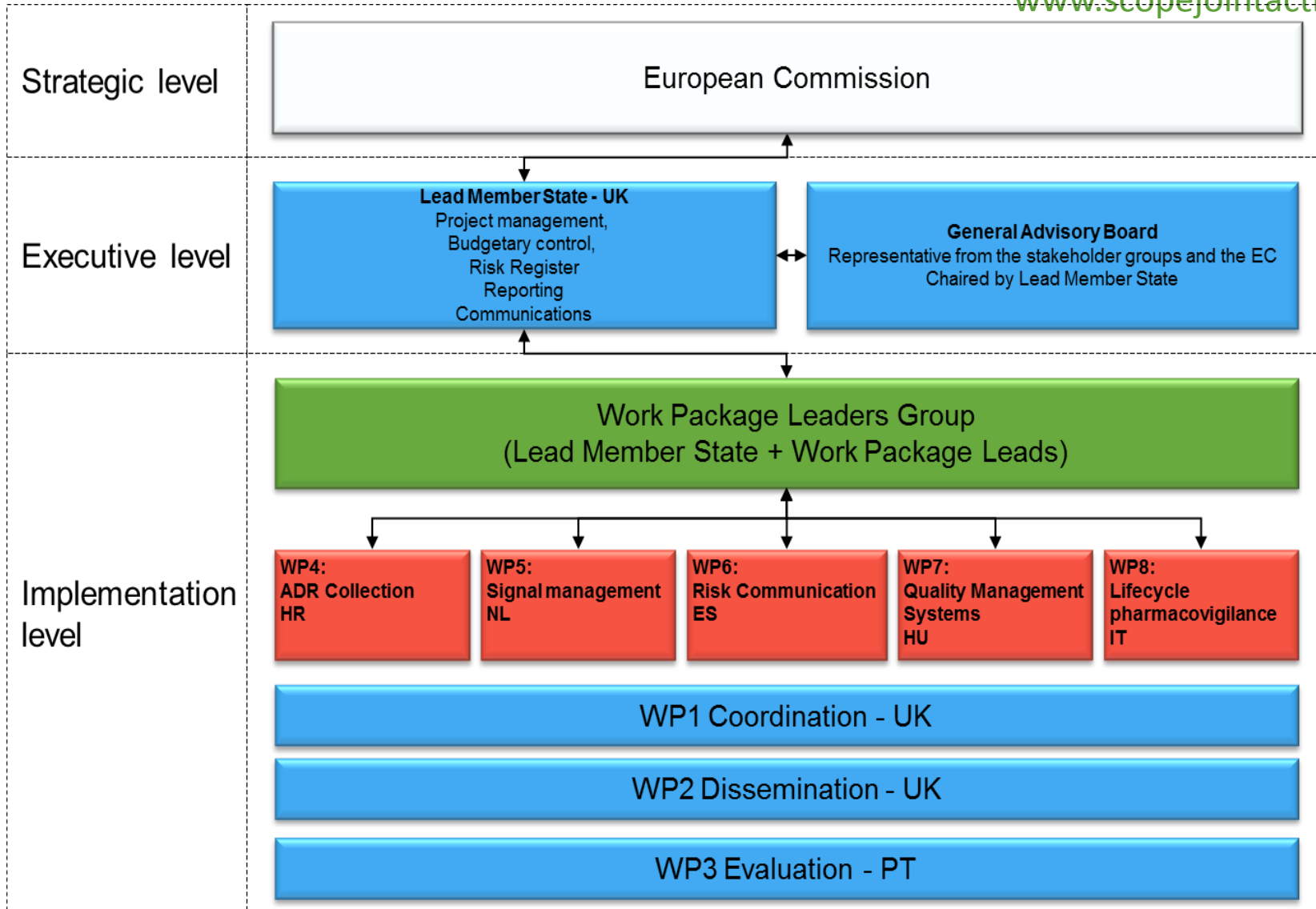
“Exceptional utility”



SCOPE structure



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Industry stakeholder forum



- Originally intention to include industry representative on SCOPE General Advisory Board
- Later considered to be preferable to have separate forum for industry
- Enables all industry stakeholders to participate
- Plans under way to organise
- Expected Q1 2015
- Invitations via EU trade associations

WP1 – Coordination

Lead: **UK**  **MHRA**
Regulating Medicines and Medical Devices

Active Partners: **ES, HR, HU, IT, NL, PT**

- Delivery of project plan, manual
- Budget (time recording, expenses)
- Project Tools; Governance; reporting



Work Package Leaders/General Advisory Board AB meetings held

Project management/planning/finance systems

WP2 - Dissemination

Lead: **UK**  **MHRA**
Regulating Medicines and Medical Devices

Active Partners: **ES, HR, HU, IT, NL, PT**

- Delivery of dissemination and communications plan, including **links with other projects**
- Stakeholder analysis & engagement
- Branding; Promotional activity work packages; Quarterly updates; stakeholder meetings; lay report

Website and promotional leaflet in place/updates



SCOPE Joint Action

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action aims to help medicines regulators operate pharmacovigilance systems to the EU legislative requirements. Regulators are collaborating to improve skills and capability in the network which will help safeguard public health in both national territories and the EU as a whole.

Find out more

Latest news: New SCOPE Website Launched Read more

Work Packages

Work Package 1 – Governance

Lead: Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Work package 1 delivers the coordination and project management functions for SCOPE

Package details

Work Package 2 - Dissemination

Lead: Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

This work package aims to effectively disseminate information about SCOPE and its deliverables

Package details

Work Package 3 – Evaluation

Lead: National Authority of Medicines and Health Products, I.P. (INFARMED), Portugal

This work package focusses on the evaluation of SCOPE to verify that the project is delivers what was planned to achieve the objectives

Package details

Work Package 4 – ADR collection

Lead: Agency for Medicinal Products and Medical Devices (HALMED), Croatia

This work package focuses on national adverse drug reaction reporting schemes, including patient reporting and efforts to improve awareness of national systems

Package details

SCOPE leaflet



SCOPE

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Strengthening Collaborations for Operating Pharmacovigilance in Europe (SCOPE) Joint Action

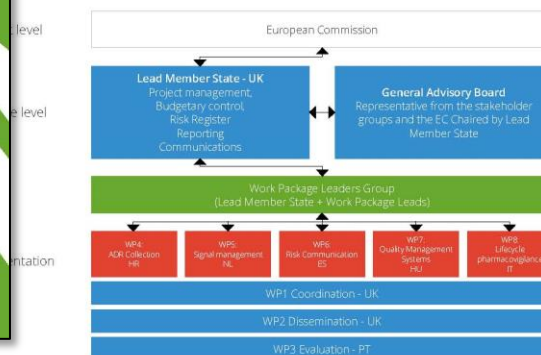
The SCOPE Joint Action has received funding from the European Union

Overall Aims of SCOPE

Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action was established to maximise the effective implementation of the European Pharmacovigilance Regulation that came into effect in June 2012 by the National Competent Authorities (NCAs) in EU member states. Funded by The Consumers, Health and Food Executive Agency (CHAFEA), with support from the member state partners, SCOPE aims to provide practical tools and guidance to develop their pharmacovigilance systems and also ensure that those developments are sustainable into the future. This Joint Action will enable coordinated pharmacovigilance operations in Europe, which will lead to a consistent approach across all member states.

The Joint Action is made up of eight work packages, three of which are 'horizontal', and carry out tasks that span all areas of the project. The other five work packages are 'vertical'; these will deliver specific and measurable objectives, ranging from improvements in Adverse Drug Reaction reporting to the development of quality management systems. SCOPE will use the benefits of a central cross-network structure to bring noticeable improvements to the pharmacovigilance systems of all member states. A key aim is to help lesser resourced NCAs develop skills and capacity in pharmacovigilance to benefit citizens in their territory and the whole network.

Management Structure



SCOPE Partners

Work Package Leads (and Topic Leads)



Medicines and Healthcare Products Regulatory Agency (MHRA), UK – leading WPs 1 and 2 and topics 4.3, 4.4, 5.4, 6.4, 7.2, 7.3 & 7.4



National Authority of Medicines and Health Products (INFARMED), PT – leading WP3 and topic 7.5



Agency for Medicinal Products and Medical Devices (HALMED), HR – leading WP4, and topics 4.1, 4.2 & 4.5



Medicines Evaluation Board (MEB), NL – leading WP5 and topic 5.1



Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), ES – leading WP6 and topic 5.2



National Institute for Quality and Organisational Development in Healthcare and Medicine (GYEMSI), HU – leading WP7 and topic 7.1



Agenzia Italiana del Farmaco (AIFA), IT – leading WP8 and topics 6.3, 8.1 & 8.4

EU context/deliverables

SCOPE Joint Action Deliverables

14/05/2014

ID	Project Team	Deliverable	Consultation	Target Date	Endorsement	Approval (PCG)	Agreement (ERMS-FG)	Adoption	Status/Comments	Interim
1.	SCOPE WP1	Three year work plan	SCOPE	March 2014	May 2014	WP leaders	General Advisory Board		Complete	N/A
2.	SCOPE WP1	First interim report to the CHAFEA about progress of SCOPE	SCOPE	Dec 2014		WP leaders	General Advisory Board			
3.	SCOPE WP1	Second interim report to the CHAFEA about progress of SCOPE	SCOPE	Oct 2015		WP leaders	General Advisory Board			
4.	SCOPE WP1	Final report to the CHAFEA about progress of SCOPE	SCOPE	Oct 2016		WP leaders	General Advisory Board			

WP3 - Evaluation

Lead: **PT**  **infarmed**
Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

Active Partners: UK, WP leads (ES, HR, HU, IT, NL)

- Establishment of baselines, success criteria, metrics
- Status reports; Audit reports;
- Audit report on training
- Ongoing Evaluation processes
- Final report & recommendations

Evaluation plan in place and collection of indicator data

SCOPE methods overview

Audit

- Review current practice and experience of NCAs
 - Literature/Survey/Visits

Assess

- Collate and assess data
 - Examples of performing systems/practice, areas for clarification
 - Identify best practice features

Report

- Recommendations/ Good/Best practice
 - Anonymised examples/case studies

Train

- Develop training packages
 - Deliver for NCA

WP4 – ADR collection

Lead: **HR**

Active Partners: **CZ, HU, IT, LT, NO, PT, UK**

- Audit of national reporting systems
- Delivering reports on operating best practice
- Toolset of materials for media campaigns
- Design of standard forms
- Review mobile reporting feasibility
- Case study of exemplar IT systems

WP4 – ADR collection

Surveys complete and analysis to start

Types of questions included:

- Reporting forms & methods used

- Fields collected

- National promotion/marketing

- Integration with clinical IT systems

WP5 – Signal Management

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Lead: **NL**

Active Partners: **DK, ES, SE, UK**

Delivering best practice for:

- Signal detection
- Signal validation/prioritisation
- Signal assessment
- Reports of special interest

WP5 – Signal Management

Surveys completed end August, analysis to start

Questions cover:

- Expert advice on signal management

- national system for tracking signals

- How signals are validated

- Structure of teams

- Data sources used

- Database/IT systems in place

WP6 – Risk Communications



Lead: **ES**



Active Partners: **DK, HR, IE, IT, NL, NO, SE, UK,**

- Audit of national methods of communications
- Impact of risk communications
- Launch of communications toolbox with workshop
- Web portal best practice guide

Surveys just closed, developing plans for study on impact of risk communications

WP6 – Risk Communications



Questions cover:

Risk communications team setup

Management of safety comms processes

Use of EU coordinated comms materials

What is provided on national web-portals

Who manages web-portals / expertise

Studies – impact of risk comms/DHPCs etc/case studies

WP7 – Quality Management Systems



Lead: **HU**

Active Partners: **BG, ES, IT, PT, UK**

- Understanding national PV quality systems
- Understand how resources are managed
- Interfaces with pharmacovigilance inspections
- Establish Best Practice; SOPs

First round of informal visits to sample of NCAs complete

WP7 - Site visits

Discussions covered:

- PV setup and organisation structure
- Interaction with PV inspectors
- Monitoring effectiveness
- Training and development
- Quality management
- Communications and websites
- Assessment
- Areas considered to work well



WP8 – Lifecycle PV

Lead: **IT**



Active Partners: **ES, GR, IE, NL, NO, SE, UK**

- Data sources used other than spontaneous reports
- RMP, PSUR and referral assessments
- Assessment of PASS/PAES
- Training workshops and Best Practice framework
- Establish Competency levels across network

Surveys close end September

WP8 – Lifecycle PV

Questions include:

RMP/PASS/PAES/PSUR assessment

Team/advisory structures

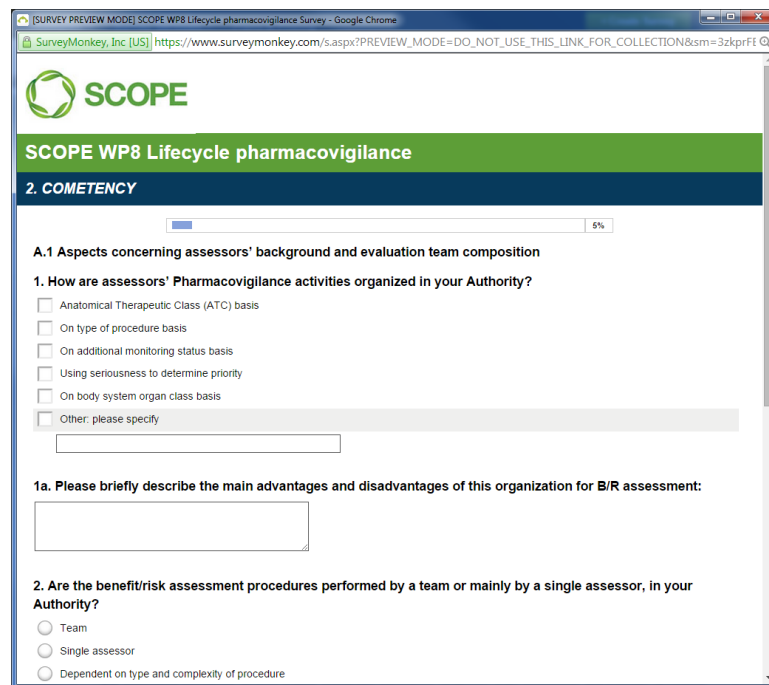
Key challenges

Training and staff competency

Management and prioritisation of work

Data sources used at assessment

Practical tools and methods used nationally



The screenshot shows a web browser window displaying a survey titled "SCOPE WP8 Lifecycle pharmacovigilance". The survey is in "SURVEY PREVIEW MODE" and is hosted on SurveyMonkey. The page header includes the SCOPE logo and the text "SCOPE WP8 Lifecycle pharmacovigilance". The survey content is divided into sections, with the current section being "2. COMPETENCY". A progress bar indicates that 5% of the survey has been completed. The first question, "A.1 Aspects concerning assessors' background and evaluation team composition", includes a sub-question "1. How are assessors' Pharmacovigilance activities organized in your Authority?". This question has five radio button options: "Anatomical Therapeutic Class (ATC) basis", "On type of procedure basis", "On additional monitoring status basis", "Using seriousness to determine priority", and "On body system organ class basis". There is also an "Other: please specify" option with a text input field. Below this, question "1a. Please briefly describe the main advantages and disadvantages of this organization for B/R assessment:" has a text input field. The second question, "2. Are the benefit/risk assessment procedures performed by a team or mainly by a single assessor, in your Authority?", has three radio button options: "Team", "Single assessor", and "Dependent on type and complexity of procedure".

Summary

- Enthusiasm and support from partners
- Wide collaboration across EU
- Significant thought and discussion on the topics

Keep up to date with progress on the website

www.scopejointaction.eu

Thank you

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Keep up to date at
www.scopejointaction.eu