



Medicines & Healthcare products  
Regulatory Agency

# Update on SCOPE - Strengthening Collaborations to Operate Pharmacovigilance in Europe



# Background – Review Of The EU System



Fraunhofer  
Institute  
Systems and  
Innovation Research

## **Assessment of the European Community System of Pharmacovigilance**

**Final Report – Final version**

25 January 2006

European Commission  
Enterprise and Industry Directorate-General, Unit F2, Pharmaceuticals

Reference: Service Contract N°: FIF.20040739

Submitted by the  
**Fraunhofer Institute for Systems and Innovation Research, Karlsruhe,  
Germany**

# Pharmacovigilance Legislation

## **2012: EU Pharmacovigilance legislation**

Directive 2010/84/EU (amending Dir 2001/83/EC)

Regulation (EU) No 1235/2010 (amending Reg (EC) No 1394/2007)

Extensive changes to the way PhV conducted

Supported by guidance: Good Vigilance Practice modules (replacing Vol. 9a)

In UK: transposed into: Human Medicines Regulation 2012 (consolidates most of Medicines Act 1968 & >200 statutory instruments)

# GUIDANCE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)

MODULE I	Pharmacovigilance Systems and their Quality Systems
MODULE II	Pharmacovigilance System Master File
MODULE III	Pharmacovigilance Inspections
MODULE IV	Pharmacovigilance Audits
MODULE V	Risk Management Systems
MODULE VI	Management & Reporting of Adverse Drug Reactions
MODULE VII	Periodic Safety Update Reports
MODULE VIII	Post-Authorisation Safety Studies
MODULE IX	Signal Management
MODULE X	Additional Monitoring
MODULE XV	Safety Communications
MODULE XVI	Risk Minimisation Measures & Education Materials

# SCOPE Context in EU



Progress to implement legislation

Establishment of:

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

Member States now need to operate pharmacovigilance to legislative requirements

EC recognise varying level of maturity in the system

# SCOPE Joint Action



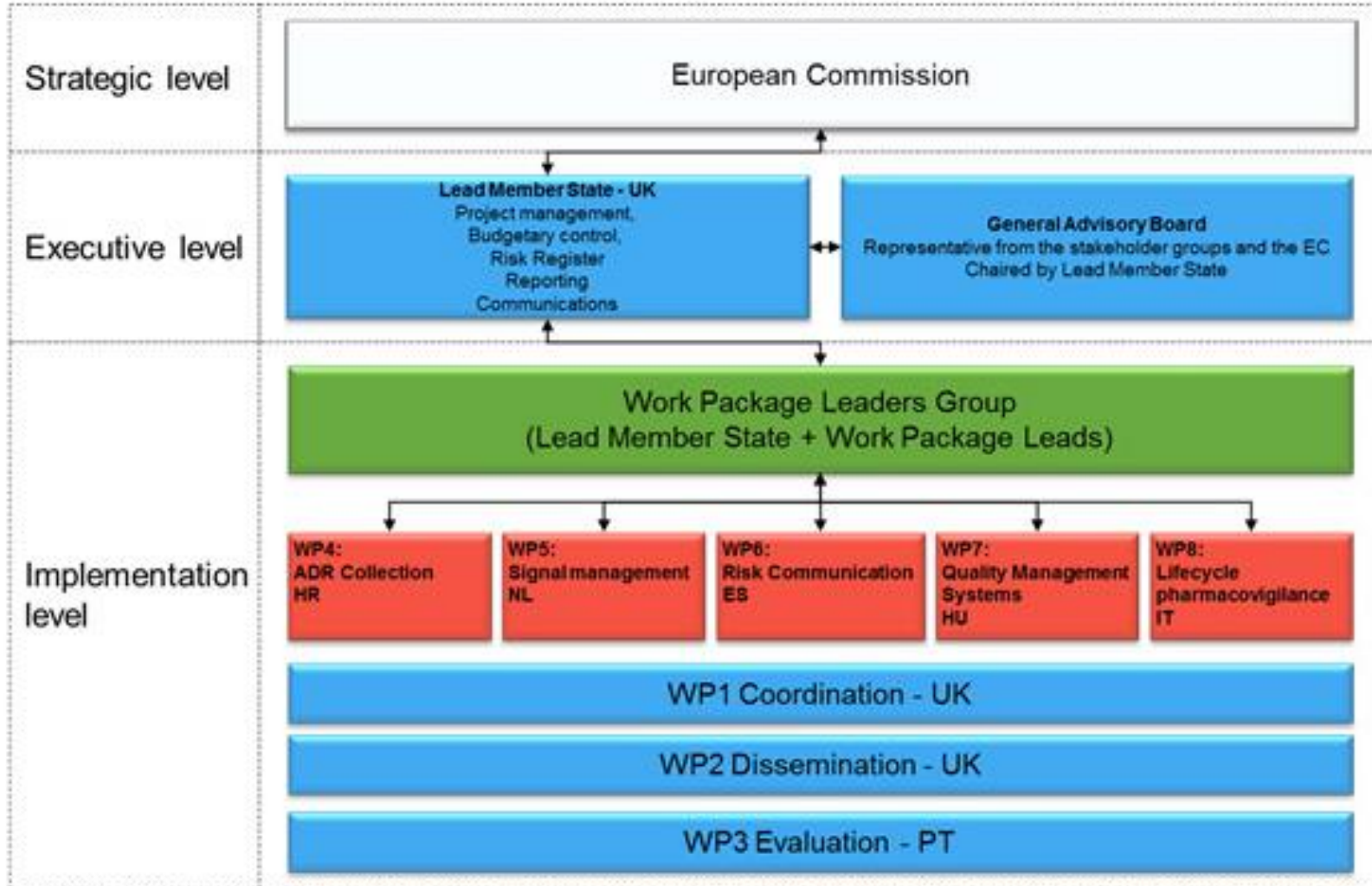
Formal award decision adopted by Commission  
SCOPE 36 month project launched in November  
2013

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

“Exceptional utility”



# Governance Structure



# Working together



[www.scopeiointaction.eu](http://www.scopeiointaction.eu)



REPUBLIC OF ESTONIA  
AGENCY OF MEDICINES

CHAFEA

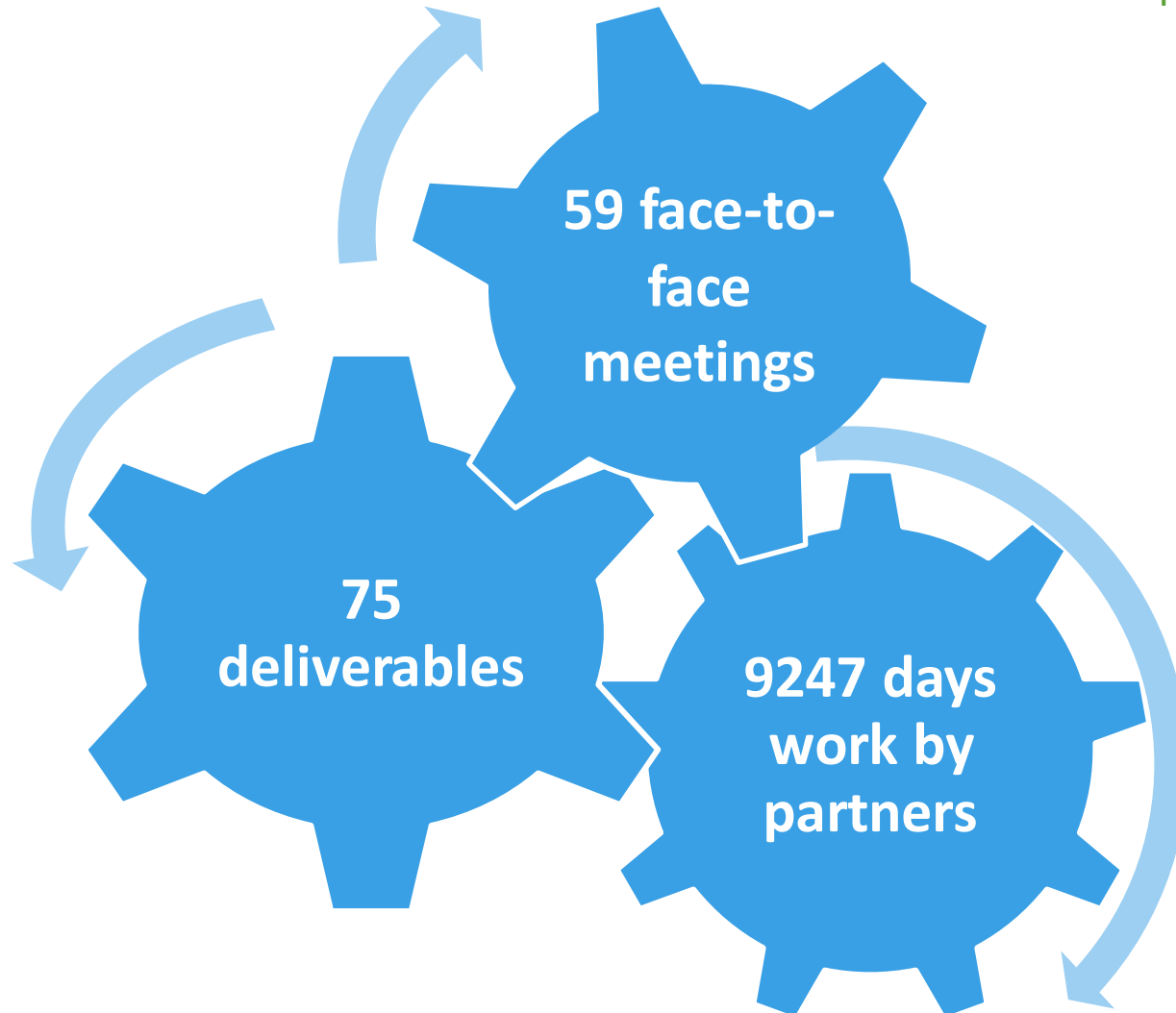


Agency for Medicinal Products  
and Medical Devices  
of the Republic of Slovenia





# Work on SCOPE



# What SCOPE has delivered



- Survey findings/reports from each work package
- 34 “Best Practice” guidance documents
- 14 e-learning modules
- Web reporting form for free uptake
- Supported by
  - Interactive pdfs
  - Digital posters/infographics
  - Recordings of workshops and training
- Publications in scientific journals
- Training and stakeholder events

# SCOPE Training Events



ADR Lifecycle

Signal Management

Quality Management Systems

Lifecycle Pharmacovigilance



# SCOPE Workshops

## Risk Communication on Medicines

*16-17 June 2016*



**KUPP –**  
kunnskapsbaserte oppdateringsvisninger

**ST. OLAVS HOSPITAL**  
UNIVERSITETSSYKEHUSET I TRONDHEIM  
Avd. for Klinisk Farmakologi

**RELIS**

### Riktigere bruk av NSAIDs

**HØVEDBUDSKAP:**

- ▶ Hvis mulig; unngå selektive COX-2-hemmere

forenkelt, bruk naproksen i kortest mulig  
eventuelt under dekke av en proton-  
pumpehemmer.

og de med hjerte/kar risiko, nedsatt nyrefunksjon  
som bruker ACE-hemmere, All-blokkere og  
diuretika er spesielt utsatt.

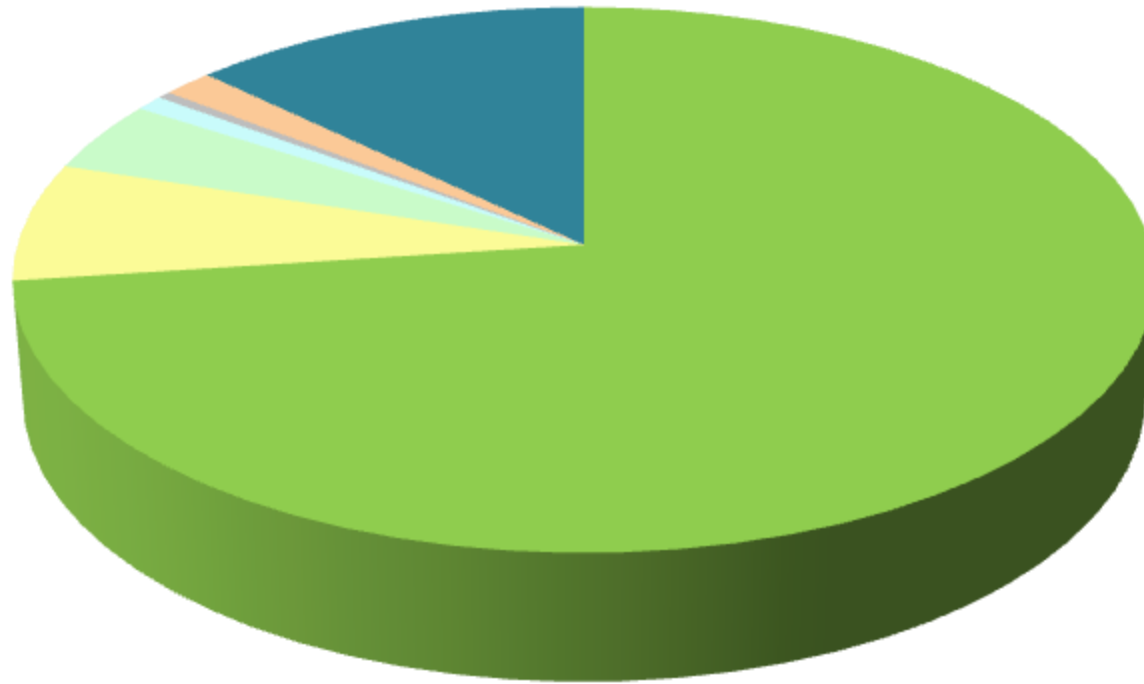
overflattiske bløddelskader eller smerter i hudnære ledd som hender,  
og anklær vil NSAID-gel være et godt alternativ.

de vil alene eller i tillegg ha god nytte av paracetamol.

risikobehovet ved bruk av NSAIDs er større for mage/tarm-bivirkninger enn for  
bivirkninger, men fordi alvorlige hjerte/kar-hendelser er vanligere enn alvorlige  
bivirkninger er den absolutte risikobehovet størst for hjerte/kar-bivirkninger;  
også hjerte/kar-bivirkningene av mer alvorlig karakter og mer irreversible enn  
bivirkningene.

**Key:** Riktigere bruk av NSAIDs  
**Duration:** 25 minutters oppdatering om bruk av NSAIDs

# Spend on SCOPE



■ Staff

■ Travel

■ Hotel & Subsistence

■ Consumables

■ Equipment

■ Other

■ Subcontractors

# WP4 – ADR collection



## Deliverables:

- Best Practice Guides:
  - Additional Monitoring
  - Duplicate detection
  - Approaches to comparing reports (HCP & Patient)
  - Medication errors
  - Collaboration with patient organisations
  - Feedback to patients
  - ADR IT systems (at differing levels of maturity)
  - Tools for measuring and improving quality of ADR reports

# WP4 – ADR collection



## Deliverables:

- Online E-learning:
  - Additional Monitoring
  - Duplicate detection
  - CPD accredited e-learning for health professionals

# E-learning module: Additional monitoring



## Learning objectives

Welcome to this e-learning on additional monitoring. This module will give you an overview of the main aspects of the additional monitoring process, as well as some EU MS examples of additional monitoring.

After completing this module, you will be able to:

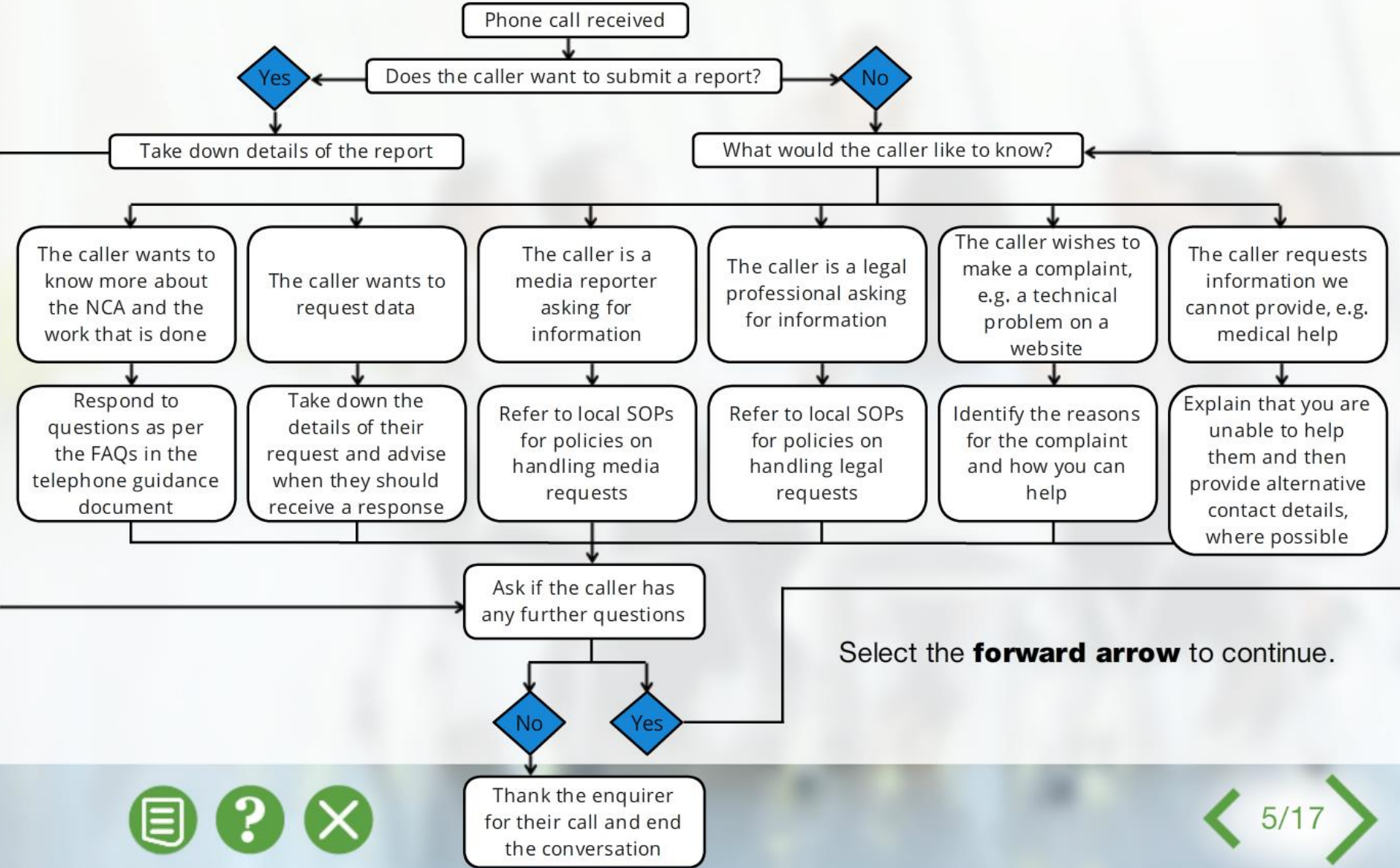
- Understand why and how to identify, manage and raise awareness of ADRs for drugs subject to additional monitoring
- Use EU MS examples as an idea for the optimisation of national processes for tracking and handling of ADRs for drugs subject to additional monitoring.

Select the **forward arrow** to continue.





# Flowchart for responding to callers



# Raising awareness levels of national ADR systems in EU



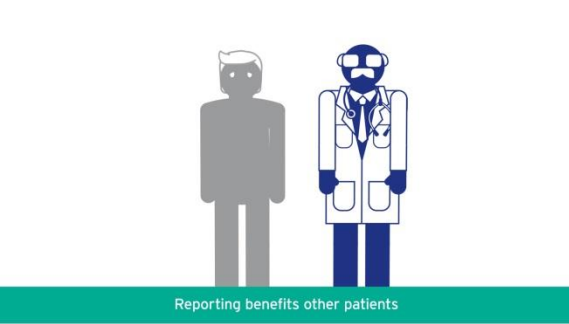
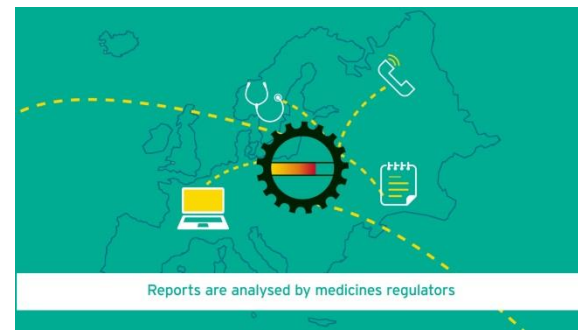
- SCOPE developed a media toolkit to raise awareness levels
- Social media campaign ADR week: 7-11 November 2016
- A first of its kind in Europe
  - Use of animations, polls, infographics, articles, press release etc
  - Twitter, LinkedIn, Facebook, websites
- **22 countries took part**
  - Support from Heads of Medicines Agency Working Group for Communications Professionals



# Key feature: animation



- Tailored and translated into 22 versions
- Simple but key messages for the ADR lifecycle which were broken down into small clips over the week supported by infographics



# Initial results & example animated infographics



- UK example :



During our **SCOPE campaign** last week:

**Each day** more than **72,000 people** saw our key messages

Our animation has been seen more than **136,000 times**

Our infographics were **retweeted 650 times**



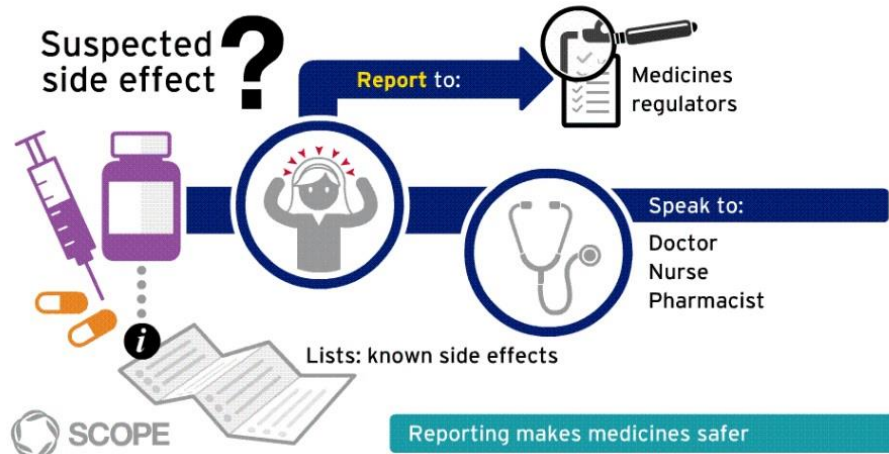
Medicines & Healthcare products Regulatory Agency

**Yellow Card**

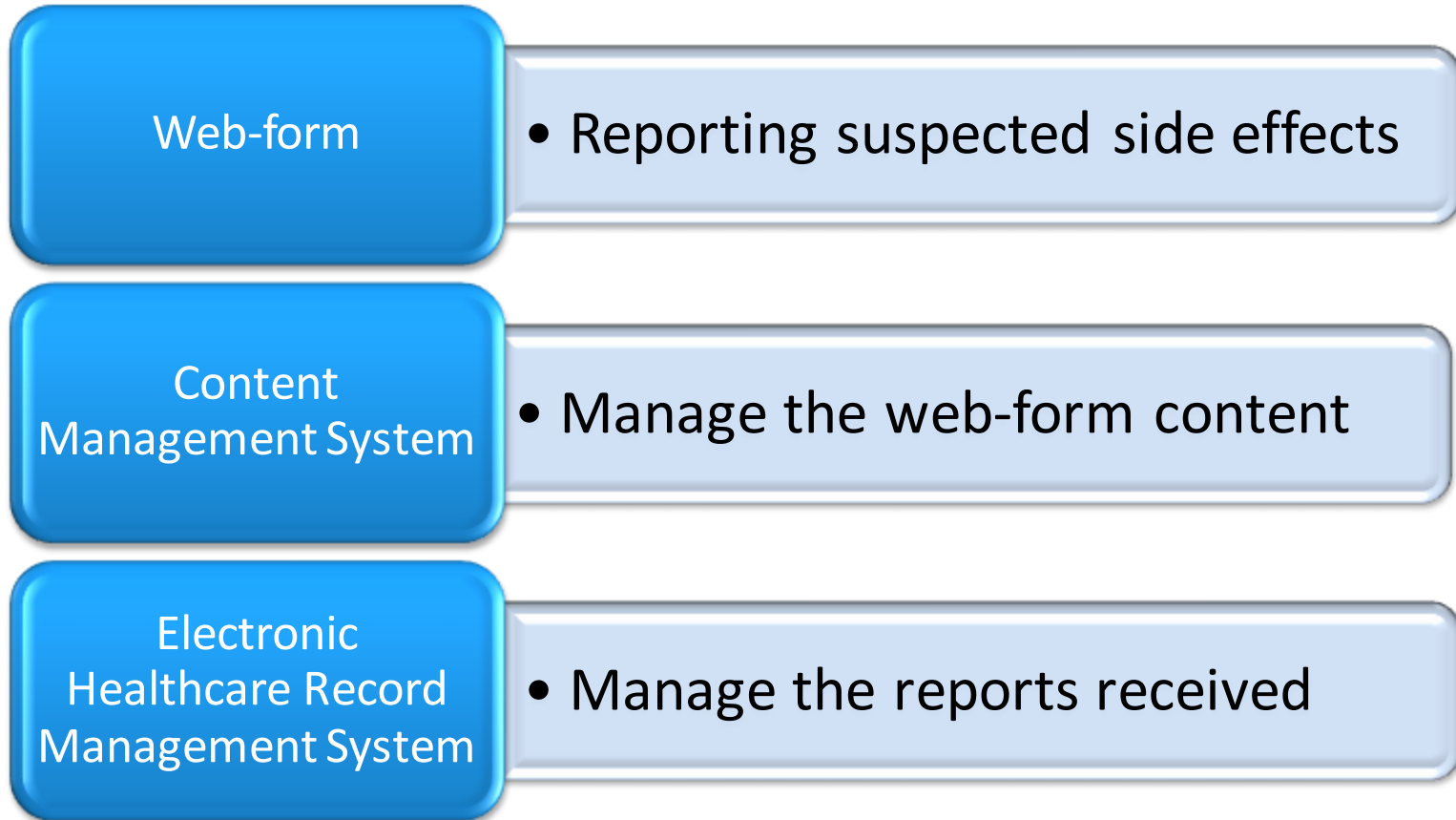
## You can report:

- Suspected side effects from medicines
- Adverse incidents with medical devices
- Defective medicines
- Counterfeit medicines
- Side effects or safety concerns for e-cigarettes

Through our **Yellow Card Scheme**



# SCOPE WEBFORM



Detailed guidance document accompanies the web-form for local management after deployment

# New ADR reporting site for Romania



<https://adr.anm.ro/>

The screenshot shows the homepage of the Romanian Agency for Medicines and Medical Devices (ANM) ADR reporting site. The header includes the ANM logo and the text "Agenția Națională a Medicamentului și a Dispozitivelor Medicale". A search bar is located in the top right corner. The main navigation menu contains links for "Acasă", "Despre raportarea reacțiilor adverse", "Formulare pentru raportarea reacțiilor adverse", and "Contactați-ne".

The main content area is divided into two columns. The left column features a welcome message: "Bun venit pe pagina de raportare a reacțiilor adverse la medicamentele de uz uman!" and a button labeled "Reacții adverse" for reporting. The right column contains a registration section titled "Sunteți înregistrat?" with a login form and an "Intră" button. Below this is an "Înregistrare" (Registration) section with a description of the optional service and an "Înregistrare" button.

At the bottom right, there is a logo for the European Union and the text: "SCOPE is funded by the Health Programme of the European Union".

The screenshot shows the homepage of the ANM website. The header features the ANM logo and the text "Ministerul Sănătății" and "Agenția Națională a Medicamentului și a Dispozitivelor Medicale". The main navigation menu includes "DESPRE INSTITUȚIE", "INFORMAȚII DE INTERES PUBLIC", and "CONTACT".

The main content area is divided into two columns. The left column features a list of links: "Prima pagină", "Medicamente de uz uman", "Dispozitive medicale", "Programa și strategiile", "Raportare de activitate", "Buletinul informativ", "Informații utile", "Comunicate de presă", and "Legături utile". Below this is a "facebook" logo and the text "Agenția Națională a Medicamentului și a Dispozitivelor Medicale".

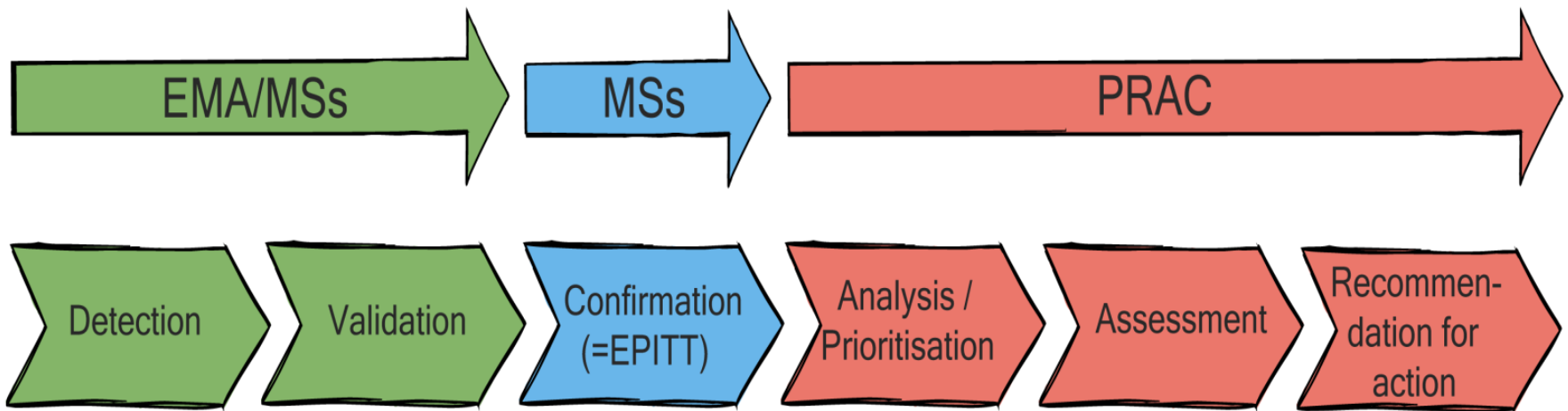
The right column features a banner for "Medicamente de uz uman" and "Dispozitive Medicale". Below this is a text block: "In perioada 7-11 noiembrie 2016, Agenția Națională a Medicamentului și a Dispozitivelor Medicale (ANM) desfășoară o campanie media pentru promovarea raportării reacțiilor adverse suspectate la medicamente, în cadrul unei campanii europene de conștientizare a publicului larg. Urmăriti mesajele video pe pagina de Facebook a ANM!"

At the bottom, there is a large image of a blister pack containing 18 x 10mg tablets, with the text "Prospectul conține reacțiile adverse cunoscute" below it.



- WP 5 – Best practice in signal management within the network of National Competent Authorities (NCAs)
  - *Focus on the NCAs and the work at national level in SM*
    - *Make the best use of the currently available tools*
      - *Identify best practices in MSs*
  - *Focus on practical aspects and opportunities to improve at NCA level*

# Signal Management From Implementation to Operation

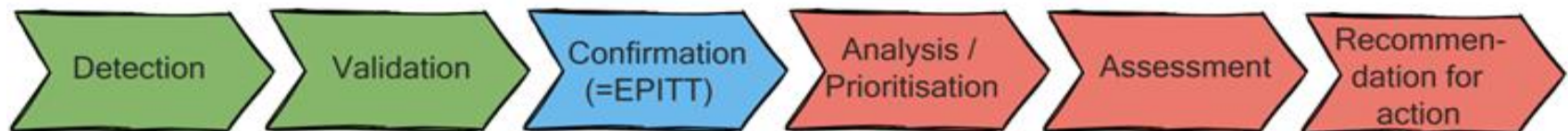




# What we hope to have achieved



- More clarity on the concepts and the flow of the SM process in the EU
- Understand the concepts of **prioritisation, validation, confirmation, assessment** in the EU SM process
- Increase awareness regarding additional data sources and how to use them in signal management
- Gain some further insights in signal detection
- Awareness of existing supportive tools
- Awareness of possible approaches for reports of special interest to be used at national level
- Put into practice the knowledge acquired : real case scenarios workshop

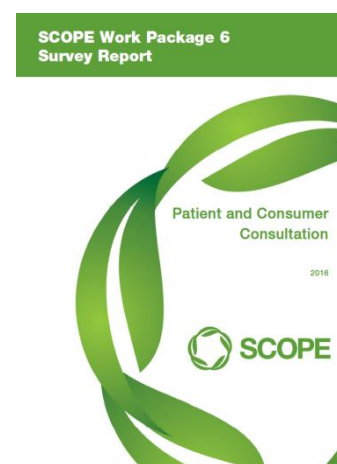
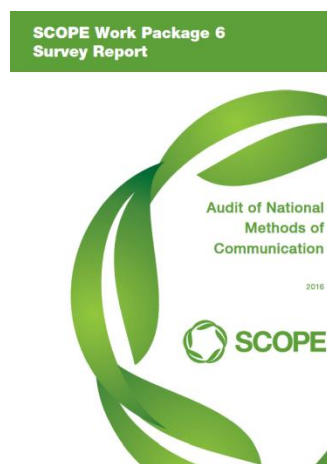


# WP6 – Risk Communication



## Deliverables:

- Surveys Reports – NCAs and HCPs
- Web-portals Good Practice Guide
- Proposals for Improvement Document
- 3 publications in preparation



# WP6 HCPs survey- Medicines Safety Communications and their effectiveness



3625 respondents

**Aim:** explore the attitudes, knowledge, preferences and behaviours of HCPs in Europe, regarding methods to communicate safety issues of medicines.

## Target population

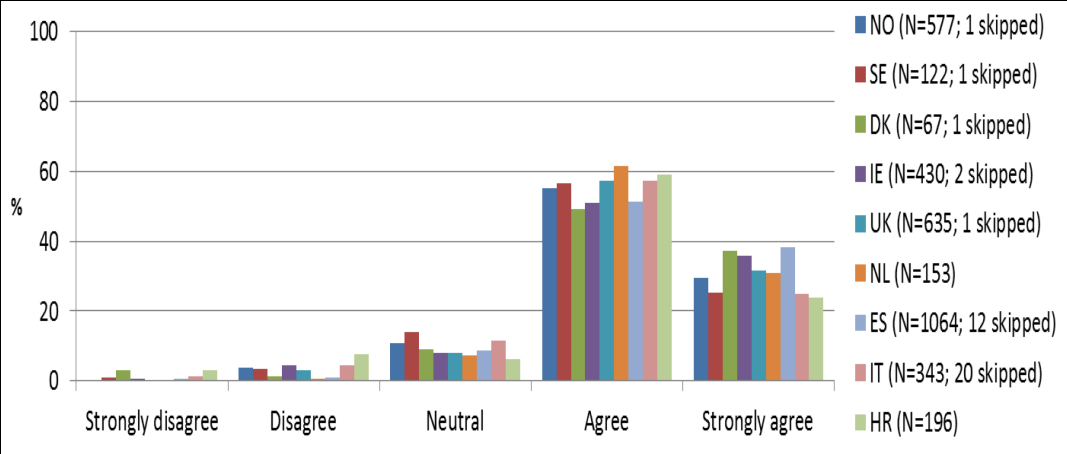
- General practitioners (GPs)
- Cardiologists
- Pharmacists (except ES, SE)
- *Other responders (HCPs active in clinical practice)*

	N (%)
Female	2215 (61)
Primary employment setting	
Community-based	2570 (70)
Hospital-based	857 (24)
Other	244 (6)
Age	
<35 year	625 (17)
35 – 45 year	964 (27)
46 – 55 year	1071 (30)
>55 year	964 (27)
Accreditation	
<5 years	370 (10)
5 – 20 years	1394 (38)
>20 years	1859 (51)

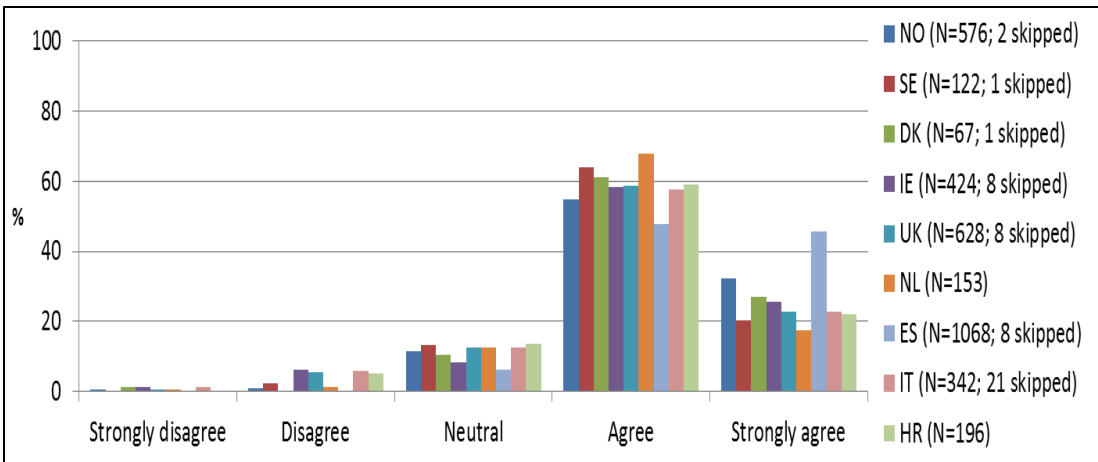
# Sender



- I only read the safety information if, I trust the sender of the safety message



- I only take action in response to a safety warning if, I trust the sender of the safety message



## MOST POSITELY EVALUATED SENDERS

NCA

Professional bodies

## MOST NEGATIVELY EVALUATED SENDERS

Lay press

Pharmaceutical companies

# WP6 – Risk Communication workshop



- Hosted by AEMPS 16<sup>th</sup>- 17<sup>th</sup> June 2016, Madrid
- PV and communication experts, WHO, EMA, academia, patients, consumers, and healthcare professionals – 103 delegates
- Designed to share the results of WP6, and discuss how EU national agencies can improve their communication on the risk associated to medicines
- Videos and presentations from the workshop:  
<http://www.scopejointaction.eu/events/wp6-workshop/>

# Some recommendations



- Promote role of trusted sender (eg. NCA, professional body)
- Increase awareness of educational material, clear distinction from promotional materials
- GPs considered useful reminders of messages
- Format and alternative channels for distribution to be based on national preferences
- Integrate communication in electronic prescribing tools (point of care alerts)

# WP7 (QMS) Objective and topics



Objective: enabling Member States to understand and develop their Quality Management System for pharmacovigilance

- Topic 1: to understand the functioning of national quality systems at various degrees of maturity across the EU
- Topic 2: resource management
- Topic 3: pharmacovigilance inspection

## WP 7: Deliverables



1. Practical guidances (tool-kit) on how to improve quality management systems furthermore on interface of PV inspectors and assessors
2. 25-min e-learning course (Introduction of quality management systems)
3. Training(s)



# Work Package 8: Lifecycle PV



# SCOPE

**Topic 1: Identification of available data sources outside spontaneous reports**

**Topic 2**

NO lead

AC: ES, IE, IT, SE, PT, UK

**Topic 3**

SE lead

AC: ES, IE, IT, NO, PT, UK

**Topic 4**

IT lead

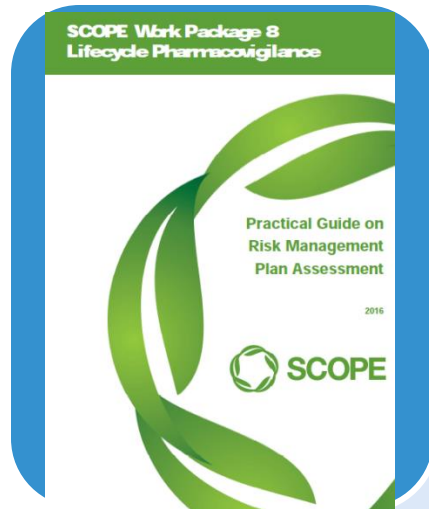
AC: ES, IE, NO, PT, SE, UK

**Risk  
Management  
Plan  
assessment**

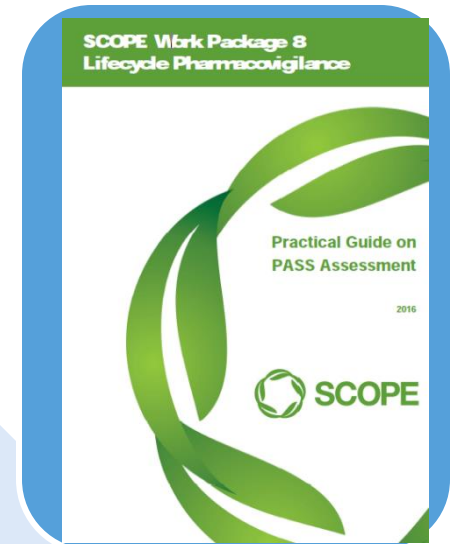
**PASS  
assessment**

**Benefit/risk  
assessment  
PSURs and Referrals**

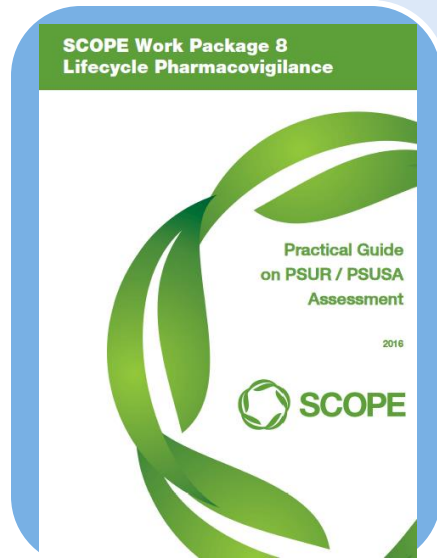
**Topic 5:  
Competency**



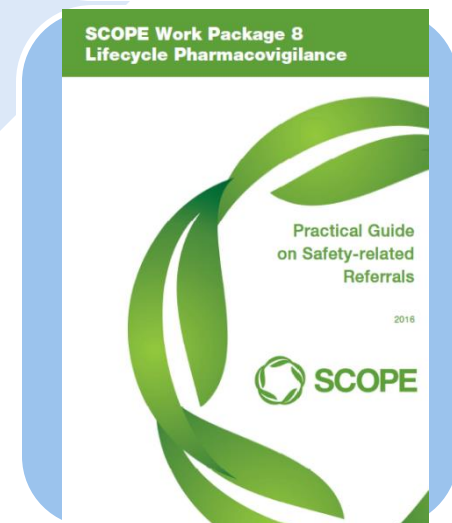
➤ **Key challenges and learnings from PRAC on handling PV procedures assessment**




➤ **Practical advice on some aspects**



➤ **“From assessors for assessors”**



00\_02



**Introduction** ✓

**What is a safety referral procedure?**

**Key stages in a referral**

**Other considerations**

**When you're not (co)-rapporteur**


**Summary** ✓

**Quiz**

This course contains seven sections. Select each heading to go to that section.

1/52 >

03\_01




## Key stages in the referral procedure

### Key stages and other important considerations

This interactive timeline illustrates key stages and other important considerations during a referral from an assessor's perspective. Click on the stages to jump to the relevant section.

Select each of the **stages** to find out more.



1/52 >

**Menu:**  
Select here to return to the main menu for this e-learning

**Resources:**  
Select here to access your bank of resources for this e-learning

**Help:**  
Select here for help on how to use the screens


**Exit button:**  
Select here to exit the course at any time

1/52

**Page counter example:**  
This will tell you what page you are on, and how many you have left

**Forward and back arrows:**  
Use these arrows to navigate backwards and forwards through the course

07\_01



## Quiz

### Question 1: The purpose of a safety referral

What is the purpose of a safety referral (article 20, article 107I, article 31)?

That's still not quite right, the correct answers are highlighted.

A more appropriate way of harmonising the SmPC and PIL between nationally-authorised products in all member states would through an article 30 referral procedure.

Requesting additional data is a possible outcome of a referral but is not generally the reason for triggering one.

Resolving differences of opinion between MS raised during a safety variation assessment should be done via an article 13 referral arbitration procedure.

- To harmonise the SmPC and PIL between nationally-authorised products in all member states
- To establish if additional data would be useful to support the positive B/R balance of the product
- To resolve issues over the safety or balance of benefits and risks of a medicine or class of medicines
- To establish whether measures to minimise harm to patients are required throughout Europe
- To resolve differences in opinion between MS raised during a safety variation assessment
- To establish whether the MA for a product or group of products should to be varied, maintained, suspended or revoked in the light of concerns about safety or the balance of benefits and risks

39/52 >

[https://www.walkgroveonline.com/MHRA/WP8/wp8sr\\_gold\\_2/story.html](https://www.walkgroveonline.com/MHRA/WP8/wp8sr_gold_2/story.html)



# Deliverables: e-learning modules

- RMP
- PASS
- PSUR/PSUSA
- referral

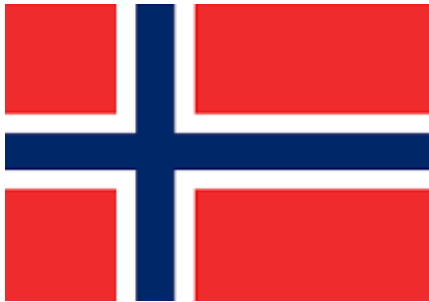
.....to maximise training opportunities for PV assessors



# Pilot exchange programme



- Launch Nov '16 - Apr '17
- Focus on WP8 areas:  
RMPs, PASS, PSURS,  
referral procedures
- Norway, Portugal & Spain  
supporting pilot exchange
- Working group looking at  
practicalities - UK, PT, NO, ES



# Sustaining SCOPE Deliverables

The background of the slide features a blurred image of various pills and capsules on a wooden surface. The SCOPE logo is overlaid on the top left of this background.

Adverse Drug Reactions:  
Reporting makes medicines  
safer

The Strengthening Collaboration  
for Operating Pharmacovigilance  
in Europe (SCOPE)

Select the **forward arrow** for more.

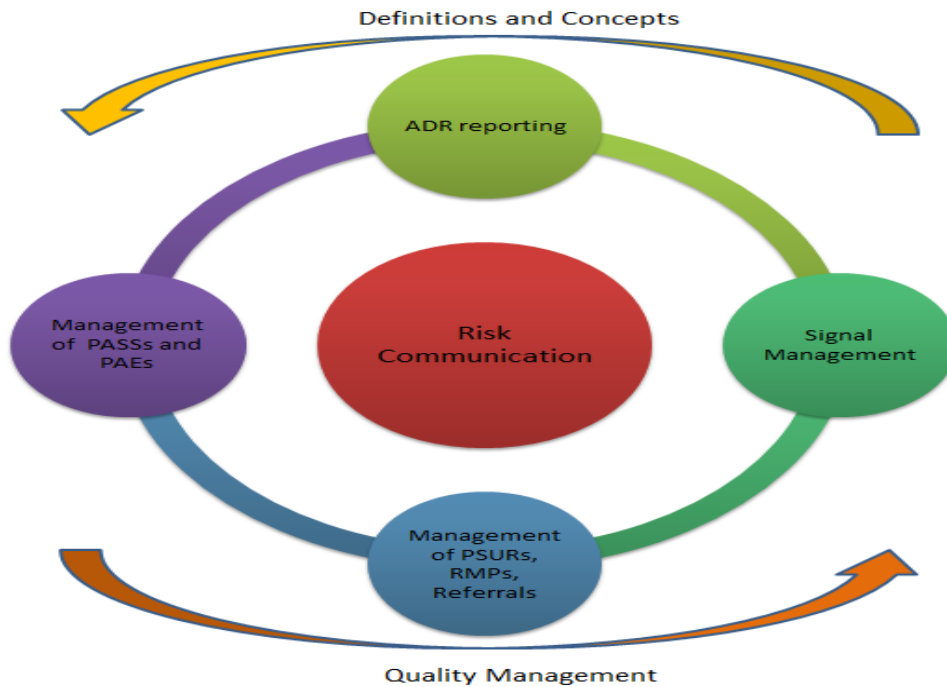
A green arrow pointing to the right, located in the bottom right corner of the slide.

# Sustaining SCOPE Deliverables



## Pharmacovigilance Life Cycle Management

### Pharmacovigilance staff role in the different areas



The screenshot shows the user interface of the SCOPE learning management system. At the top, there is a navigation bar with tabs for 'Home', 'My Employees', 'Organisation', 'My Classes', and 'Admin'. Below this, the main content area is titled 'My Learning Assignments'. It features a search bar with the placeholder 'Keyword' and a dropdown menu for 'All Assignment Types'. A section titled 'DUE ANYTIME' lists several assignments:

Assignment Title	Priority	Recommendation	Action
How to organise a webinar with the EU NTC	PRIORITY 3	RECOMMENDED	REGISTER NOW
SF Supervisor	PRIORITY 3	RECOMMENDED	CONTINUE COURSE
SF User	PRIORITY 3	RECOMMENDED	START COURSE
The case-population strategy in pharmacovigilance	PRIORITY 3	RECOMMENDED	REGISTER NOW

On the right side of the interface, there are three panels: 'Find Learning' with a search bar and a 'Go' button; 'My Curricula' with a message 'You currently have no required curricula' and a 'Go to Curriculum Status' link; and 'Learning History' with a 'View All' button and a list of recently added items: 'CT Overview' and 'Youtube Self-Development EMA', both marked with green checkmarks.

# Summary



- SCOPE has been an exemplar of collaboration across the EU network
- SCOPE has helped provide the learning and tools to improve national pharmacovigilance systems
- The transition of materials to support the PV curriculum via the EU NTC will ensure sustainability
- MHRA have been proud to lead on this important Joint Action



Ask

