

Strengthening Collaborations for Operating Pharmacovigilance in Europe Joint Action

**11th Stakeholder forum on the
pharmacovigilance legislation**

21 September 2017, London

Louise Loughlin, MHRA



- **Aims and objectives of the Joint Action**
- **SCOPE achievements and highlights**
- **SCOPE outreach and sustainability**



SCOPE Joint Action



To maximise effective implementation of EU Pharmacovigilance legislation

To enable coordinated pharmacovigilance operations in the EU Network making best use of work-sharing and resources

To help ensure a consistent approach across the Member States in identifying and managing risks relating to medicines...

SCOPE Joint Action



Collaboration of Member States

70% funding from European Commission

30% funding from NCAs

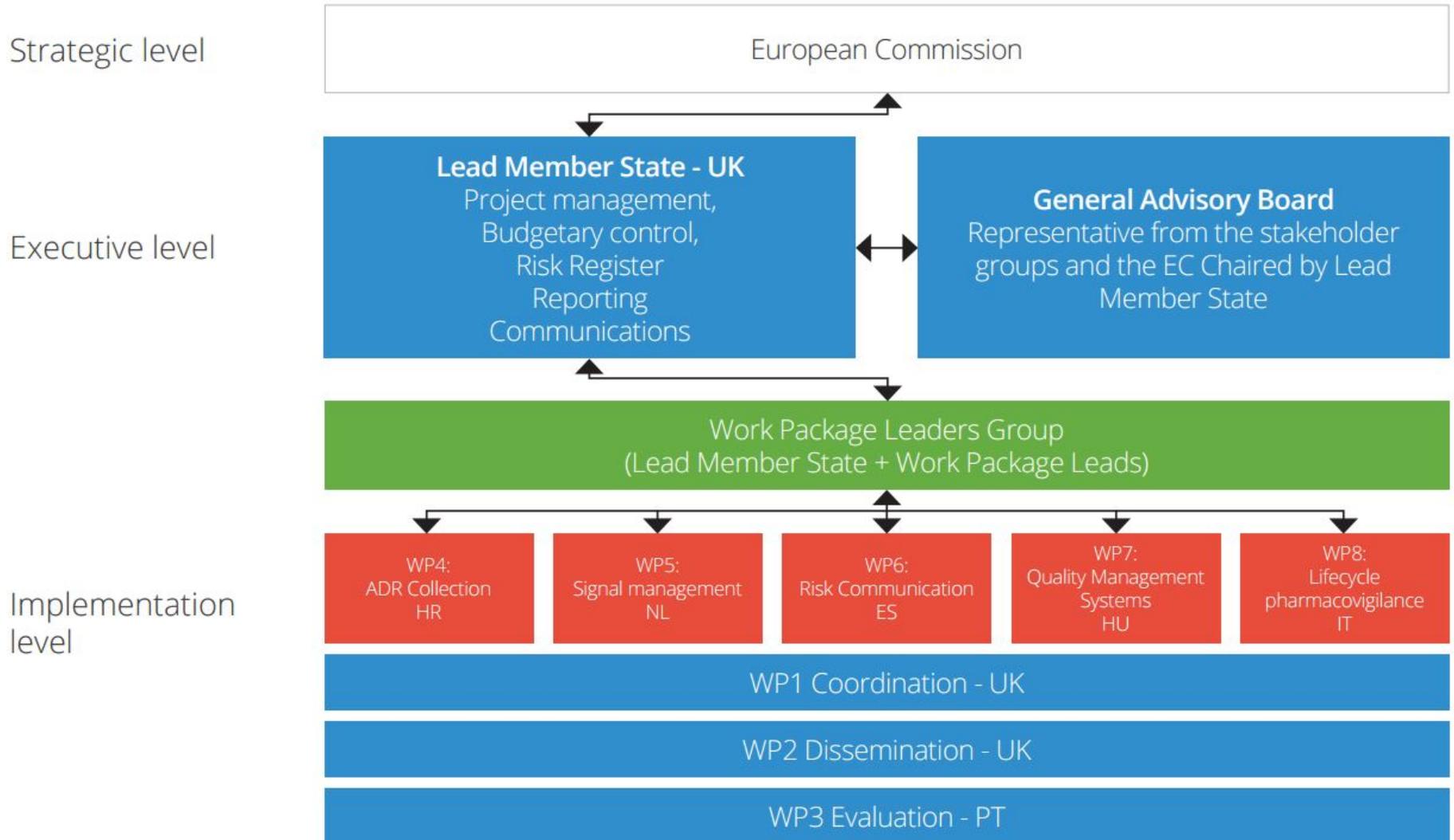
Share expertise and best practice

Deliver practical tools and guidance

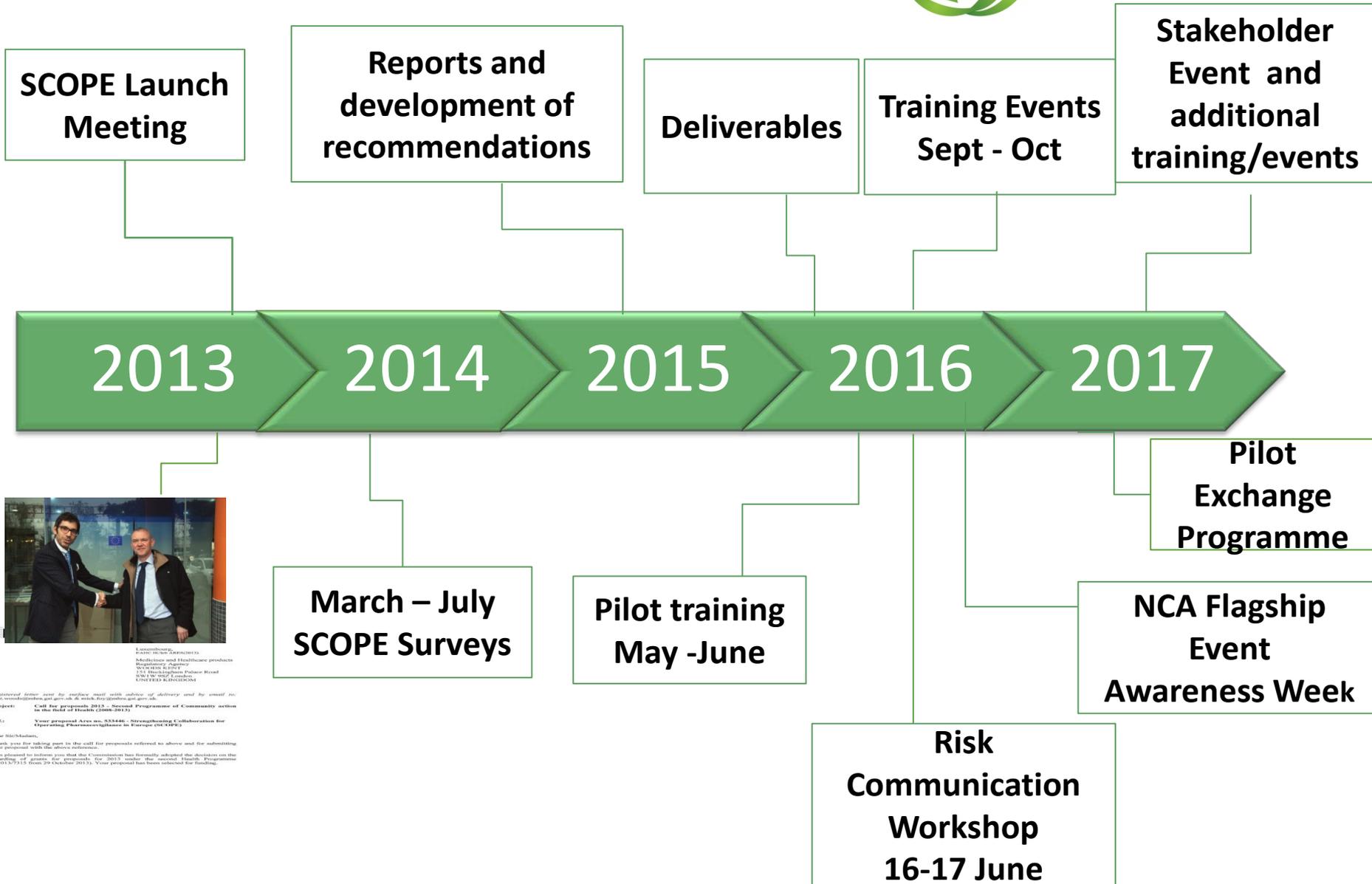
Operate pharmacovigilance in Europe



Governance structure



SCOPE Timeline



© 2013 European Commission
 Health Policy Department
 Medicines and Healthcare products
 Regulatory Agency
 Unit 11, The College Park Road
 Welwyn Garden City, UK
 AL9 7TA
 T: +44 (0)1438 743000
 E: info@ema.europa.eu

Registered letter sent by surface mail with advice of delivery and by email to: ema.communications@ema.europa.eu or ema.communications@ema.europa.eu
 Subject: Call for proposals 2013 – Second Programme of Community action in the field of Health (2008-2013)

Ref: Your proposal Acc no. 2013-0000 – Strengthening Collaboration for Operating Pharmacies in Europe (SCOPE)

Dear Sir/Madam,
 Thank you for taking part in the call for proposals referred to above and for submitting your proposal with the above reference.
 It was pleased to inform you that your submission has formally adopted the deadline on the second call of grants for proposals for 2013 under the second Health Programme (2013-13-13) from 24 October 2013. Your proposal has been selected for funding.

Work on SCOPE



60 face-to-face meetings

75 deliverables

>9300 days work by partners

SCOPE Outputs



Survey Reports



Pilot Training



Guidance documents and recommendations



E-learning modules



ADR Web-form



Publications



Risk Communication Workshop



Training WPs 4, 5, 7 and 8



ADR Awareness Campaign



SCOPE Flagship Event



Stakeholder meetings

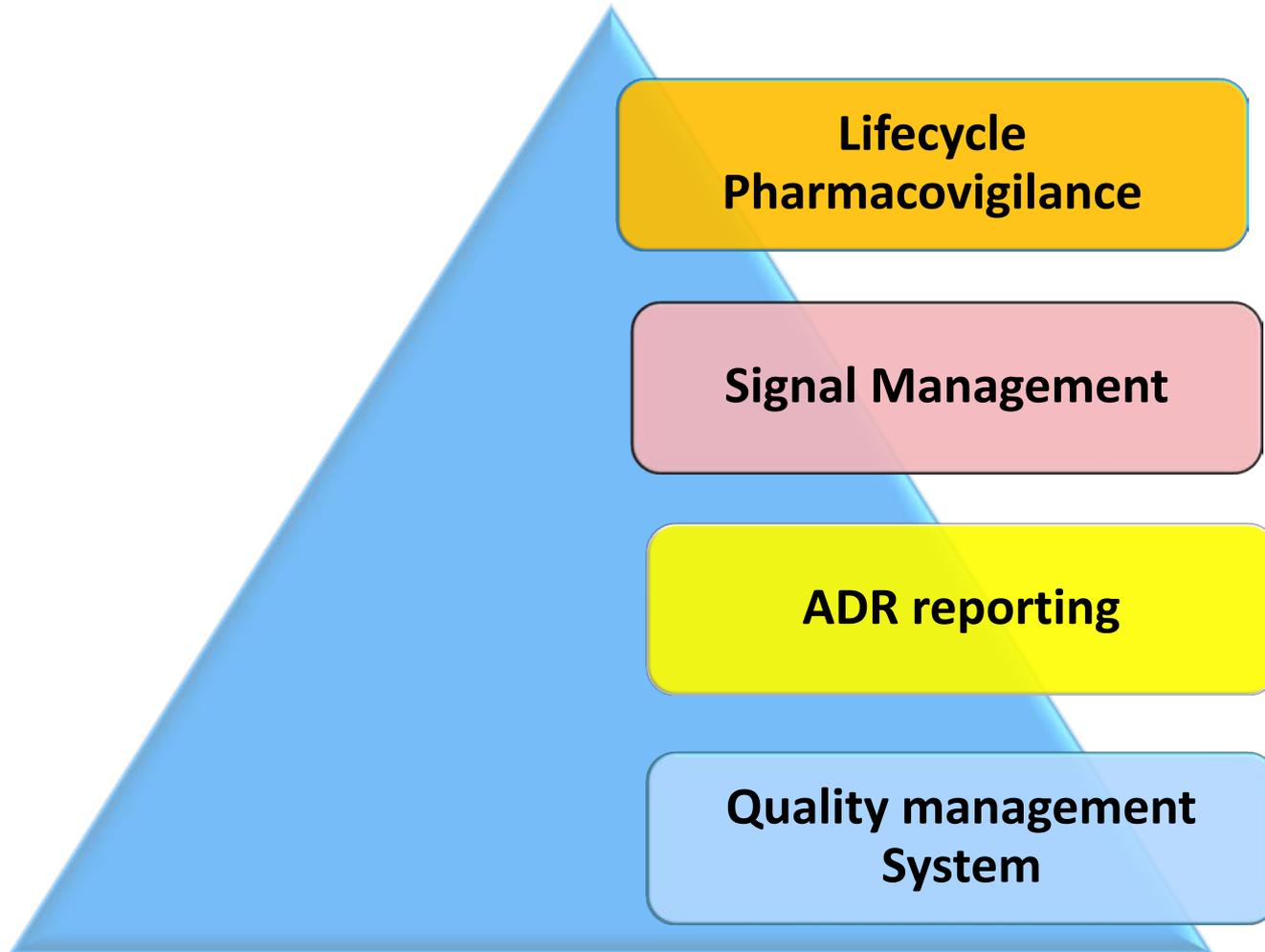


Pilot PV Exchange Programme

SCOPE “pyramid” of deliverables



SCOPE



Quality Management Systems SCOPE

Deliverables:

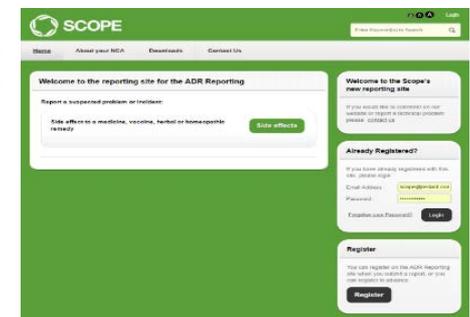
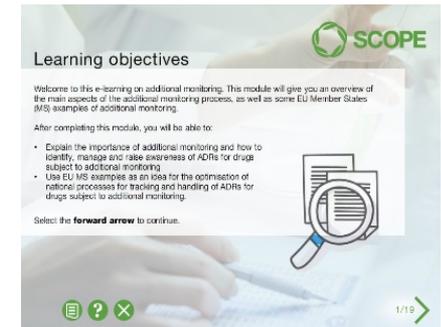
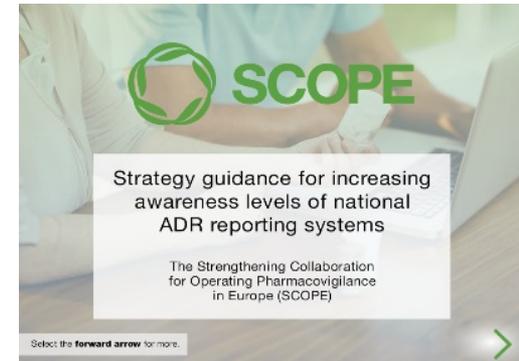
- Based on surveys, site visits and EU network experience
- Toolkit for further development of a QMS –documents, reports and **4 e-learning modules**
- WP7 training 4 October 2016 in Budapest
- Co-training with WP8 and WP4



ADR Collection

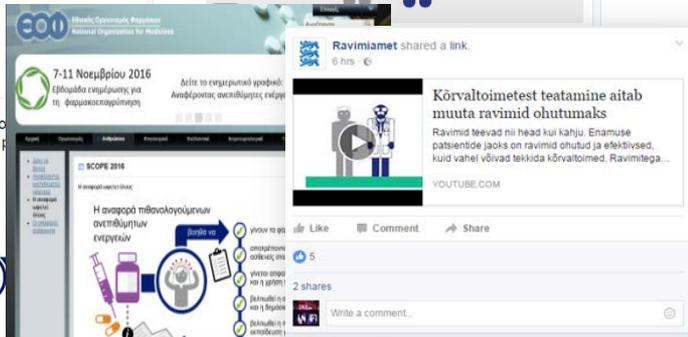


- Surveys in European NCAs – information was gathered to understand national PV reporting systems
- Outputs: toolkit for raising awareness of ADR reporting systems, best practice guidelines, e-learning modules, a training course for NCAs, social media campaign, webform for ADR reporting



EU ADR social media campaign SCOPE

- **21 NCAs**
- **13%** increase in reporting (1,056 reports) in EU over campaign week
- **2,562,071** people were reached
- **337,781** people viewed the animation
- **22,584** likes, clicks, retweets and shares on Twitter, Facebook, LinkedIn and YouTube
- All participants indicated it was worthwhile running
- **88%** would support another campaign



Uppsala Reports Issue 75

April 17



- Read about the ADR campaign in the April 2017 issue of WHO's UR



Communications

ADR reporting awareness on social media



21 National Competent Authorities came together in the first-of-its-kind EU-wide social media campaign during an adverse drug reaction awareness week in 2016.

COMMUNITARIANISM is a business model that brings together a group of people who share a common goal or interest. They share their knowledge and expertise, and work together to achieve their common goal. In the pharmaceutical industry, this model is used to bring together experts from different countries to share their knowledge and expertise in the field of adverse drug reactions (ADRs). This is done through various means, such as conferences, workshops, and online forums. The goal is to improve the quality of ADR reporting and to ensure that patients receive the best possible care.

"SCOPE has provided an invaluable opportunity allowing the development of a new ADR web form and the launch of an ADR campaign, which were both a great success."

Communications

Interestingly, their study results also showed that 16% of patients did not know how to report ADRs. This is a significant finding, as it highlights the need for better patient education and support. The study also found that 14% of patients did not know where to report ADRs, and 14% did not know how to report ADRs. These findings are important for healthcare providers and regulators, as they indicate areas where patient education and support are needed. The study also found that 14% of patients did not know how to report ADRs, and 14% did not know where to report ADRs. These findings are important for healthcare providers and regulators, as they indicate areas where patient education and support are needed.



One of SCOPE's patient reporting campaigns. Image: SCOPE

Communications

"A cultural shift is needed, and continuous commitment to patients and consumers such as the Awareness Week, repeated each year, together with other media, is the cornerstone of that change."

It was encouraging to see some NCA reporting rates improved, indicating only five had not met media reporting targets. The overall ADR reporting rate increased by 13% (1,575 reports) during the campaign week, and the number of ADRs reported through Twitter, Facebook, LinkedIn and YouTube. A range of initiatives were also reported which the NCA's demonstrate necessary, including patient or provider, health or professional bodies, academic health systems, academia, government, student societies, general and trade press, and media organisations. In the webinar, all NCA representatives indicated that they had a range of initiatives in place to support ADR reporting and that they would not report on their website during the campaign week.

Dr Nicola Piria, President of National Agency for Medicines and Medical Devices (ANMAD) of Romania, said: "SCOPE has provided an invaluable opportunity to identify the development of a new ADR web form, and to launch an ADR campaign, which was both a great success. It is the

Campaign highlights

21

13%

2,562,071

337,781

NCAs participated with awareness messages to promote reporting of suspected ADRs.

increase in suspected ADR reporting (1,575 reports)

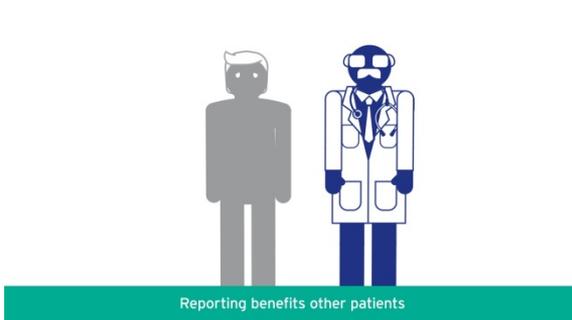
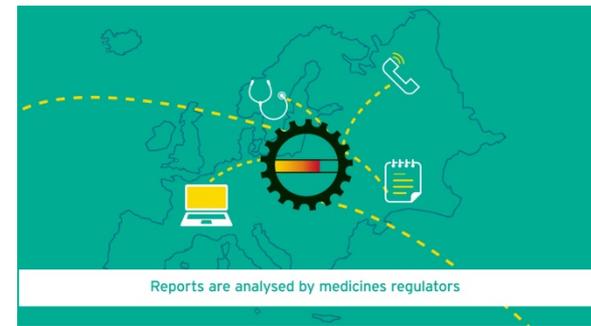
people were reached through social media.

people visited the awareness

Key feature: animation



- Tailored and translated into 24 versions
- Simple but key messages for the ADR lifecycle which were broken down into small clips over the week supported by infographics



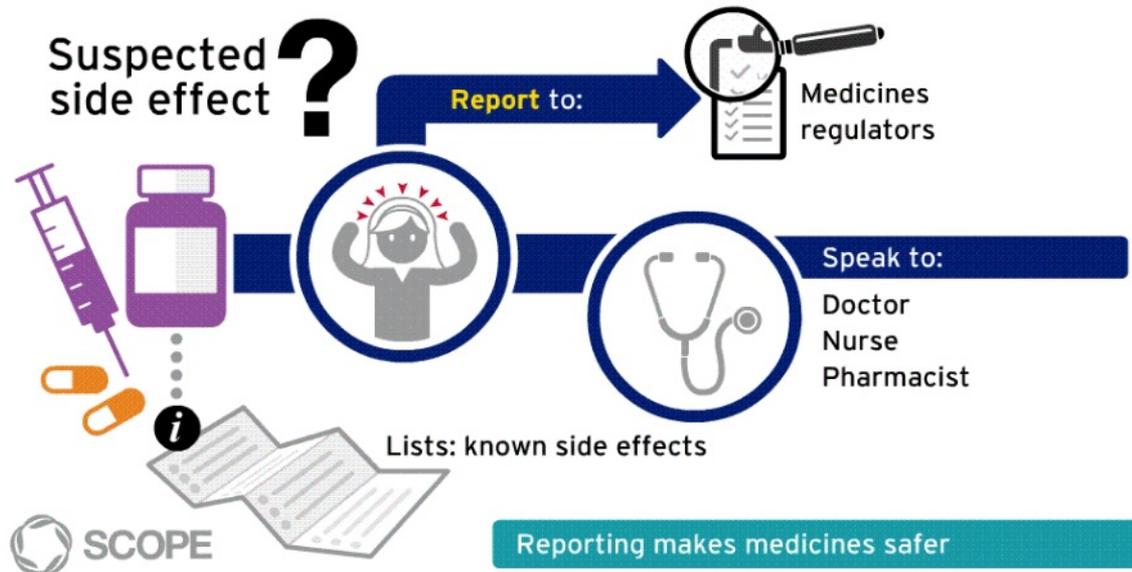
Example infographics



Reporting suspected side effects



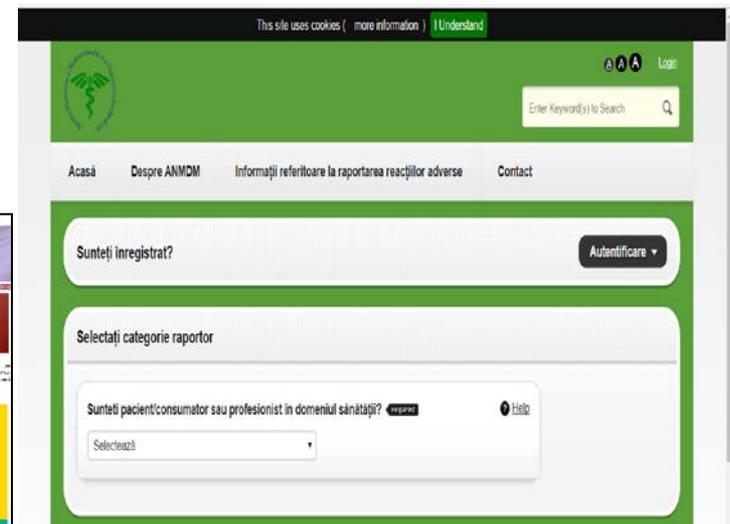
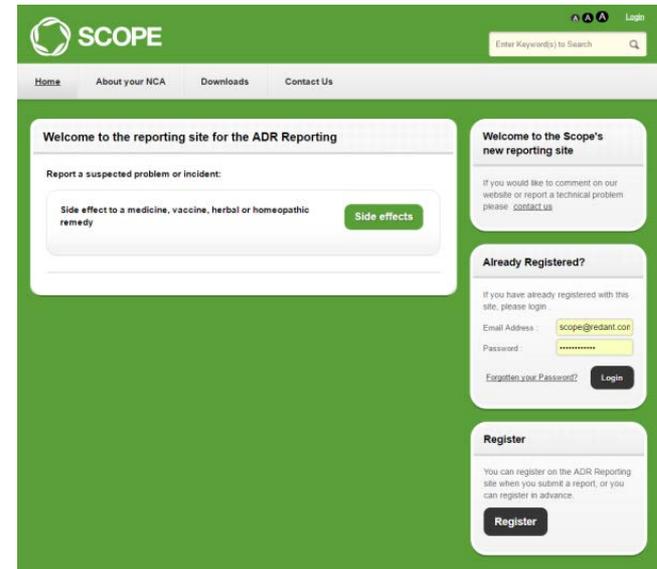
Suspected side effect ?



ADR Reporting Web Form



- Reporting from patients & healthcare professionals
- Transmits ICSRs direct to NCA database and EMA
- Can act as NCA database if required
- Adopted by Romania



ADR e-learning for HCPs



Introduction



E-learning and CPD/CME accreditation

This e-learning is designed for all healthcare professionals at any stage of their careers and it may be used as part of curriculum for students. It is accredited for Continuing Professional Development (CPD) or Continuing Medical Education (CME) purposes as outlined below.

The European Accreditation Council for Continuing Medical Education (EACCME) accredits this e-learning across EU and beyond as CME activity for doctors and medical specialists. Upon completion through certification, the EACCME awards 1 European CME credit (ECMEC)* for this e-learning.

EACCME is an institution of the **European Union of Medical Specialists (UEMS)**.



* Such CPD/CME is recognised by National Accreditation Authorities across EU. Doctors should claim only those credits for time spent in the educational activity. American physicians can convert EACCME credits to American Medical Association PRA Category 1 Credits.

Select the **forward arrow** to continue.



HPRA An tUdárás Riálaíola Tairgí Sláinte Health Products Regulatory Authority

ABOUT US MEDICINES VETERINARY MEDICAL DEVICES BLOOD, TISSUES, ORGANS COSMETICS CONTROLLED SUBSTANCES

Medicines - News & Events

- Our Role
- Medicines information
- Safety information
- Safety Notices
- Regulatory information
- News & Events
- Special Topics
- Emergency Medicines

New SCOPE ADR e-learning module receives European-wide CME/CPD accreditation

News Category: Regulatory news
Date: 02/05/2017

Tuesday 2 May 2017: Doctors across Europe can now learn more about the importance of reporting suspected adverse drug reactions (ADRs) via a free e-learning module. Prompt reporting helps to make medicines safer and is part of a doctor's responsibility. This includes informing patients and carers on how they can help by reporting suspected side effects themselves.

Regulators like the Health Products Regulatory Authority (HPRA) rely on the reporting of suspected ADRs to make sure medicines on the market are acceptably safe. However, all reporting systems suffer from underreporting, and training healthcare professionals to report suspected ADRs is important to both raise awareness and to help to strengthen the system.

The e-learning module has now received the highest order of accreditation from the European Accreditation Council for CME (EACCME)*. This means doctors are awarded 1 EACCME credit upon completion of the 45-minute ADR e-learning module. The ADR e-learning module was created by the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action project. A survey conducted by SCOPE found that many European countries lacked sustainable educational materials about ADR reporting. This e-learning aims to support healthcare professionals and medicines regulators by providing clear guidance which is rewarded with CME/CPD points.

Dr. Joan Gilvary, Director of Human Products Monitoring at the HPRA, said: "The key aim of our work is to make sure medicines are effective and acceptably safe. The reporting of suspected ADRs is vital in helping us achieve this aim. Doctors are critical to this as their position on the front line of care means they are often the first to recognise an adverse drug reaction. We've created this e-learning module to help doctors so they can have confidence that their reports are indeed a difference."

*All healthcare professionals, and indeed patients themselves, can help to make medicines safer by reporting any suspected side effects easily and quickly through our online report form which is available on our website www.hpra.ie. Other countries collect reports in similar methods."

News

- Archive 2017
- Archive 2016
- Archive 2015
- Archive 2014
- Archive 2013
- Archive 2012th
- Archive 2011
- Archive 2010
- Archive 2009
- Archive 2008
- Archive 2007
- Archive 2006
- Archive 2005
- Press Releases
- Professional and Scientific Events
- Public education campaigns
- Publications and reports
- Frequently Asked Questions



This certificate confirms that

completed the 45 - 60 minute e-learning module
Adverse Drug Reactions: reporting makes medicines safer

Keep this certificate as a record for your Continuing Professional Development (CPD) or Continuing Medical Education (CME)

The European Accreditation Council for Continuing Medical Education (EACCME) accredits this e-learning across EU and beyond as CME activity for doctors and medical specialists.
EACCME awards 1 European CME credit (ECMEC)* for this e-learning.
EACCME is an institution of the European Union of Medical Specialists (UEMS)



Mr Mihai Jidejda, Special Projects Manager
Dr Raife Savarna, Expert Medical Assessor
Authors, working for the Medicines and Healthcare products Regulatory Agency (MHRA), UK

*Doctors should claim only those credits for time spent in the educational activity. Only those e-learning materials that are displayed on the UEMS EACCME website have been accredited. Through an agreement between the UEMS and the American Medical Association (AMA), physicians may convert EACCME credits to an equivalent number of AMA PRA Category 1 Credits. Information on the process to convert EACCME credit to AMA credit can be found at www.ama-assn.org/credentialing

Developed for the Strengthening Collaboration for Operating Pharmacovigilance SCOPE Joint Action project
www.actionpharmacovigilance.eu

Zāļu valsts aģentūra

TWEETS 1,158 FOLLOWING 308 FOLLOWERS 741 LINES 137

Tweets Tweets & replies Media

@ZVALatvija
Zāļu valsts aģentūras oficiālās Twitter konts. Oficiāla un neatkarīga informācija par aktuālītātēm farmācijas nozarē.

Jerikas iela 15, Rīga, Latvija
zva.gov.lv
Joined July 2013

AIFA - Attivita - Pagine dal Mondo - Concorsi - Bandi - Modificazioni e Linee Guide - Open Data - News - Banca Dati Farmaci - Farmaci line - Intramnet

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Nuovo modulo di e-learning europeo sulla segnalazione di sospette reazioni avverse ai medicinali

Il progetto europeo SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe) si è avvia. L'AIFA ha partecipato attivamente insieme ad altre agenzie dei medicinali dell'UE. Le notizie sul modulo di formazione on line destinato agli operatori sanitari per rafforzare l'efficacia della segnalazione delle sospette reazioni avverse ai medicinali.

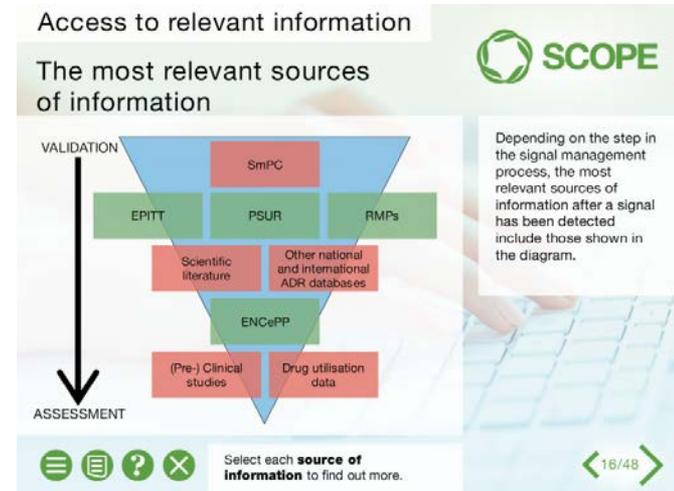
Il modulo di formazione on line ha l'obiettivo di sensibilizzare medici e cittadini sull'importanza di segnalare eventuali avverse avverse osservati a seguito dell'assunzione di medicinali e contribuire così a rendere l'impiego più sicuro.

Il modulo di formazione on line ha una durata di circa 45 minuti e consentirà di partecipare al credito EACCME (European Accreditation Council) per l'educazione continua in medicina riconosciuta dal GME.

Signal management

Deliverables:

- Comprehensive guide to all aspects of signal management
- Survey, e-learning module, literature review
- Training: 5 October 2016, Budapest, 24-25 April 2017



SCOPE Work Package 5 Signal Management

Best Practice Guide

June 2016



Validation

Important considerations for signal validation

During the validation of a signal, the evaluation of the data should be aimed at deciding if further analysis is necessary. The focus should be on determining if the signal reflects new information, and if it is at least a reasonable possibility in terms of causality.

For signals originating from spontaneous reports, important considerations should include, as a minimum, ensuring that the signal is not based on duplicate reports and that there is a plausible time to onset.

In order to validate a signal, it is important to check if the event is already reflected in the SmPC of the product(s) in question. A signal can relate to an already known safety issue (e.g. not reflect new information) and therefore not fulfil the definition of a signal.

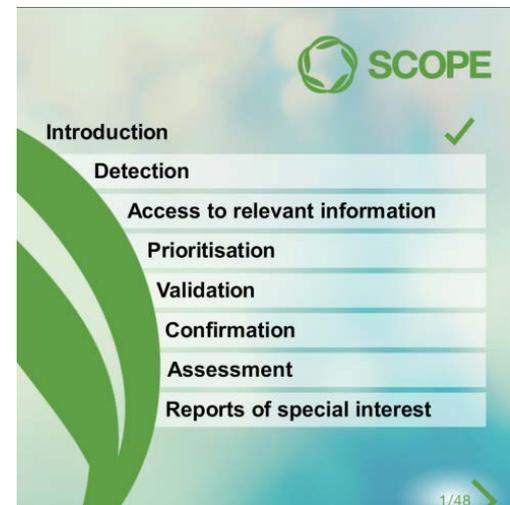
Other data sources can also be checked for any previous awareness of the issue.

Depending on the organisation and the resources at national level, the validation of a signal might differ between MSs. Some MSs may have an additional decision-making loop at national level. A more extensive evaluation of data might take place before next steps are taken.



Select the **forward arrow** to continue.

26/48



Risk Communication



Deliverables:

- Surveys Reports – NCAs and HCPs
- Web-portals Good Practice Guide, literature review
- Workshop 16-17 June 2016, Madrid, 103 delegates: PV and communication experts, WHO, EMA, academia, patients, consumers, and HCPs
- Videos and presentations from the workshops;

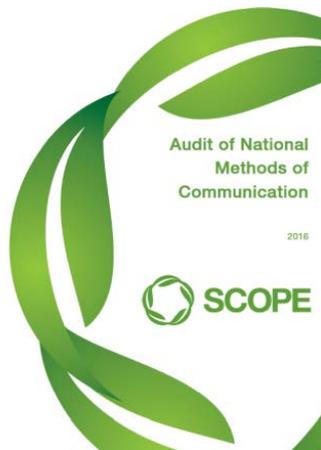
SCOPE Work Package 6
Risk Communication



SCOPE Work Package 6
Good Practice Guide



SCOPE Work Package 6
Survey Report



SCOPE Work Package 6
Healthcare Professional Survey



SCOPE Work Package 6
Survey Report





Publication on risk communications



SCOPE

Drug Saf

DOI 10.1007/s40264-017-0535-0



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ORIGINAL RESEARCH ARTICLE

Communication on Safety of Medicines in Europe: Current Practices and General Practitioners' Awareness and Preferences

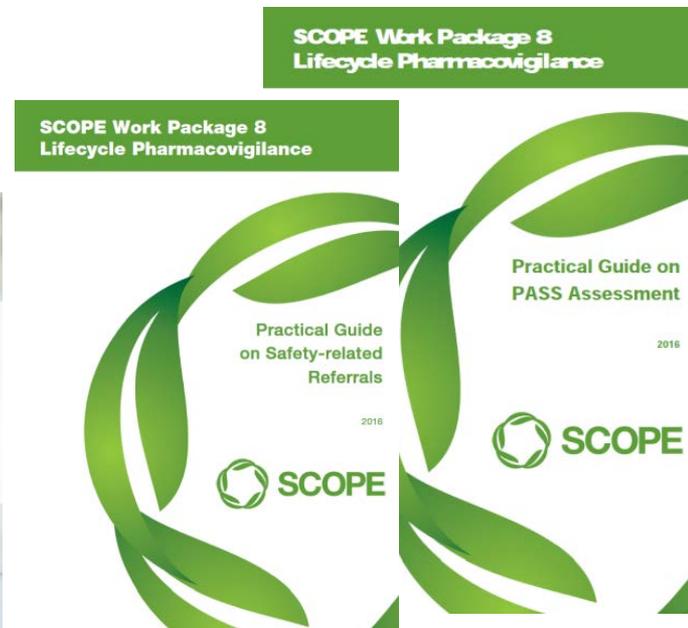
Sieta T. de Vries¹  · Maartje J. M. van der Sar^{1,2} · Amelia Cupelli³ ·
Ilaria Baldelli³ · Anna Marie Coleman⁴ · Dolores Montero⁵ · Ivana Šipić⁶ ·
Adriana Andrić⁶ · Annika Wennberg⁷ · Jane Ahlqvist-Rastad⁷ · Petra Denig¹ ·
Peter G. M. Mol^{1,2} · On behalf of SCOPE Work Package 6

Lifecycle Pharmacovigilance



Deliverables:

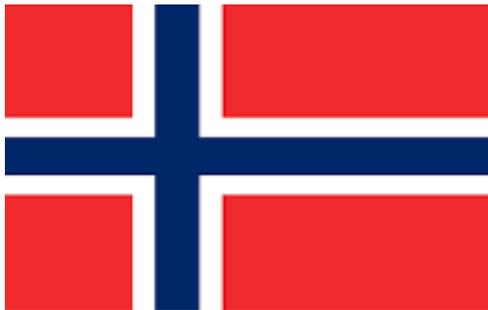
- Recommendations, practical guides
- 4 e-learning on Additional Data Sources, Risk Management Plans, Post Authorisation Safety Studies, Periodic Safety Update Report, Safety related referrals
- Training 20 - 21 September 2016



Pilot of EU programme for exchange of PV Assessors



- Grounds for a sustainable programme for European PV assessors
- Exchange of experience, knowledge and an on-the-job training
- Working group established: UK, PT, NO, ES
- Ran from Jan - Feb 2017; completed March 17
- Very positive comments: 'excellent' collaborative working



SCOPE training & stakeholder engagement



- Workshop on Risk Communication (June 16)
- 5 training sessions for NCAs (Sept-Oct 2016, Signal management repeat training April 17)
- SCOPE flagship event (Nov 16)
- SCOPE stakeholder event (March 17)
- Local stakeholder events in Croatia & Hungary (Mar- Apr 17)
- Further signal management training in the Netherlands (April 17)



Joint training opportunity



EURORDIS-SCOPE PHARMACOVIGILANCE TRAINING

22nd March 2017, 8.30 to 13.30

Holiday Inn London Regents Park, Carburton Street, W1W 5EE: Trinity room

François Houyez

22nd March, London

EURORDIS.ORG

SCOPE Website

www.scopejointaction.eu



SCOPE Partner Login | ShareFile | High Contrast Version

About **Outputs & Results** Work Packages Partners News Events Documents Links Glossary Contact

SCOPE Joint Action

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action was aimed to help medicine regulators operate pharmacovigilance systems to the EU legislative requirements. Regulators have worked together to improve the skills and capability in the pharmacovigilance network to help safeguard public health in both national territories and the EU as a whole.

[Find out more](#)

Latest news: SCOPE Stakeholder Event 20-21 March 2017 London

[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 delivering 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 deliverables available in **EU Network Training Centre** learning platform
- **PV Training Curriculum** for NCAs



The screenshot shows the website for the EU Network Training Centre. At the top, it features the logos for HMA (Heads of Medicines Agencies) and the European Medicines Agency (EMA), along with the text 'An agency of the European Union' and the European Union flag. A navigation menu includes links for Home, News, Categories, Calendar, Contact Us, Feedback, Useful Information, FAQs, and EudraPortal. The main heading is 'EU Network Training Centre'. Below this is a large image of a doctor's hands with a stethoscope, overlaid with a hexagonal grid of medical icons. To the right of this image is the mission statement: 'Our mission is to ensure that good practice is spread throughout the network by making training material available and by further harmonising and establishing training standards'. At the bottom, there are three call-to-action buttons: 'Register to the LMS!' with a 'Click to learn more' link and a molecular structure image; 'Find out more' with 'Access documents and forms' and a European Union flag image; and 'Questions?' with 'View our FAQ's' and an image of a blue and white capsule.

SCOPE Further Outreach



- SCOPE publications & posters
- Presence at conferences & meetings – eg DIA, ISOP
- ?ISoP Pharmacovigilance training curriculum



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[Training](#)



- Materials available to use within your organisations

- Sharing SCOPE materials through the International Coalition of Medicines Regulatory Authorities



- Supporting launch of ADR app in Zambia and Burkina Faso (IMI WEB-RADR)



Working together



REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

CHAFEA



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



Thank you

Contact:

scope@mhra.gov.uk