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

# Contents

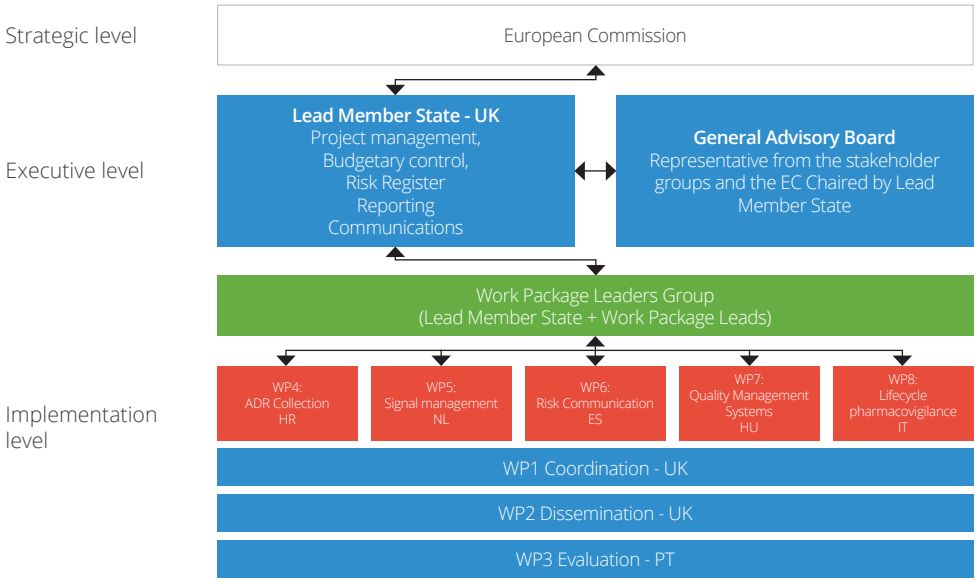


# Overall Aims of SCOPE

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action has been established to maximise the effective implementation of the European Pharmacovigilance legislation 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 contributions from the member state partners, SCOPE aims to provide practical tools and guidance for NCAs 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 the EU network, 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 work that spans 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 assessment of quality management systems. SCOPE will use the benefits of a central cross-EU governance structure to bring noticeable improvements to the pharmacovigilance systems of individual 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.

## SCOPE Management Structure



# Work Package Overviews

## WP 1 – Coordination

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

This WP has overall responsibility for the coordination and project management of SCOPE. It will ensure that the Joint Action will be accomplished on time, within budget, and with high-quality deliverables. The work package lead will coordinate and organise meetings for Work Package Leaders and the independent advisors who form the General Advisory Board. This WP includes the responsibility for establishing and running appropriate administrative, financial and project processes, as well as reporting on progress of the Joint Action.

## WP 2 – Communication and Dissemination

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

The purpose of this WP is to effectively maintain internal communications between SCOPE partners as well as disseminating information to all relevant stakeholders outside the Joint Action. The main deliverables that will be achieved are the SCOPE website, an informative leaflet, and Stakeholder Engagement workshops. Through these channels of communication, WP2 will provide a means for disseminating the best practice guidance and tools delivered by the other work packages.

**Objectives:**

- To make the SCOPE known to relevant target groups and stakeholders through the website
- To ensure that the results and deliverables of SCOPE are communicated to partners and stakeholders

## WP 3 – Evaluation

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

WP3 focuses on the evaluation of SCOPE. A plan will be put in place by this WP to establish the guidelines for evaluation in order to verify that the project is being implemented as planned. It also will provide a mechanism for feedback from the on-going evaluation processes to ensure it prospectively supports the achievement of the SCOPE objectives. Active monitoring and vigilance during the project will occur through regular audits of SCOPE WPs and the compilation of reports. One crucial aspect of this WP is ensuring consistency and value of the training provided by SCOPE Work Packages. WP3 will culminate in a report giving a final evaluation, impact on secondary users and future recommendations for the evaluation function for a sustainable pharmacovigilance network following SCOPE.

**Objectives:**

- To evaluate SCOPE to verify it is implemented as planned and achieves the objectives
- To have oversight of training delivered within SCOPE to ensure consistency

## WP 4 – ADR Reporting

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

WP4 focuses on national schemes for the spontaneous reporting of ADRs and aims to provide National Competent Authorities with a full understanding of and best practice in systems for collecting adverse drug reactions. Information will be gathered from European NCAs to understand their national pharmacovigilance IT system capabilities as well as implementation of patient reporting, types and reporting forms developed, and electronic reporting developments including those from clinical healthcare systems. This information will be used to create a media toolkit for raising awareness of ADR reporting systems, best practice guidelines, and performance indicators which will be supported through delivery of a training course for NCAs.

**Objectives:**

- Provide an overview of national ADR reporting systems and identify best practice
- Develop media toolkit for raising awareness of national ADR reporting systems

## WP 5 – Signal Management

### Lead: Medicines Evaluation Board (MEB), Netherlands

This WP seeks to develop an improved understanding of best practice in signal management within the network of National Competent Authorities. Questionnaires will be used to gather information on capabilities for all aspects of signal management including signal detection, signal validation, signal assessment, and dealing with reports of special interest. It will also build on work done to improve signal detection from medication error and misuse/ abuse of medicines. Using this intelligence, best practice guidelines will then be created and shared with the European Network through the training sessions with the aim of improving signal management amongst EU NCAs.

**Objective:**

- Implementing shared understanding of best practice in signal management across the EU network

## WP 6 – Risk Communications

### Lead: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Spain

WP6 focuses on risk communications about medicines. Information will be collected on the risk communications practice in the EU network to understand the communication channels and tools used, along with frequency, strategy, and engagement approaches. This will be used to develop a series of recommendations in the form of a communications toolbox including guide for the media on scientific risk communication. There will be a particular focus on web portals and the development of guidance (informed by the above activities) on the preparation of information for web portals, and the successful presentation and coordination of information on these platforms in the EU network.

**Objective:**

- To define best practice in Risk Communications through the creation of standardised recommendations and a toolkit

## WP 7 – Quality Management Systems

### Lead: National Institute for Quality - and Organizational Development in Healthcare and Medicines (GYEMSZI), Hungary

The focus of WP7 is to develop common quality standards in pharmacovigilance systems, based on an understanding of EU national systems. Starting from information already collected by the Benchmarking of European Medicines Agencies (BEMA) audits, and informed by visits to a cross section of NCAs representing a range of system maturities and capabilities, a questionnaire will be developed to perform an audit of national pharmacovigilance systems. Building on this, the WP will develop a checklist of performance indicators for continual self-assessment of quality systems to support development and capacity to grow assessment capability. Best Practice guidelines and a core list of SOPs will be produced for Member States accompanied by a training session.

**Objectives:**

- Enabling Member States to understand and assess their quality management systems for pharmacovigilance through delivery of a checklist for self-assessment and identification of aspects of the systems which require further development
- To define best practice guidelines and a core list of SOPs to support NCAs work to improve quality management systems
- To provide a report on the impact of new pharmacovigilance legislation on quality management systems for pharmacovigilance in NCAs

## WP 8 – Lifecycle Pharmacovigilance

### Lead: Agenzia Italiana Del Farmaco (AIFA), Italy

WP8 aims to explore existing standards for pharmacovigilance assessments and deliver a report on best practices useful to ensure that NCAs are able to support the Pharmacovigilance Risk Assessment Committee with high-quality assessment and advice on: risk management plans; post authorisation studies, periodic safety update reports and referral procedures. It will also examine the availability and use of alternative (epidemiological) data sources for assessment of these procedures in different European NCAs settings. Through focusing on key risk-management tools to establish current assessment practices, best practice in use of these tools will be defined alongside development of an assessor competency framework.

**Objective:**

- Developing a competency framework to support exemplary pharmacovigilance throughout the product lifecycle

# Expected Outcomes

1. SCOPE will enable Member States to develop a fuller understanding of, and develop best practice in, reporting mechanisms for adverse drug reactions.
2. The implementation of shared understanding of best practice in signal management across the EU network.
3. To define best practice in Risk Communications through the creation of a standardised toolkit.
4. To enable Member States to develop, understand and assess their quality management systems for pharmacovigilance.
5. The development of a competency framework to support exemplary pharmacovigilance throughout the product lifecycle.
6. To create a platform for interaction amongst European National Competent Authorities to strengthen regulatory collaboration.

# 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 (GYEMSZI), HU – leading WP7 and topic 7.1

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

## Other Topic Leads

Sundhedsstyrelsen
Danish Health and Medicines Authority

Danish Health and Medicines Authority (DHMA), DK – leading topic 5.3

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority (HPRA), IE – leading topic 6.2

Statens legemiddelverk
Norwegian Medicines Agency

Norwegian Medicines Agency (NOMA), NO – leading topic 8.2

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency (MPA), SE – leading topic 6.1 & 8.3

## Active Partners

Bulgarian Drug Agency (BDA), BG

State Institute for Drug Control (SUKL), CZ

National Organisation for Medicines (EOF), GR

State Medicines Control Agency (SMCA), LT

## Other Partners

Federal Agency for Medicines and Health Products (AFMPS), BE

Pharmaceutical Services, Ministry of Health (PHS), CY

State Agency of Medicines (SAM), EE

Finnish Medicines Agency (FIMEA), FI

Agence Nationale de Sécurité des Médicaments et des Produits de Santé (ANSM), FR

Icelandic Medicines Agency (IMI), IS

State Agency of Medicines of Latvia (ZVA), LV

Medicines Authority (MA), MT

Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL), PL

The National Agency for Medicines and Medical Devices (NAMMD), RO

Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), SI

State Institute for Drug Control (SIDC), SK

## Collaborating Partners


University Medical Center Groningen


University of Maastricht


University of Nottingham


LAREB


World Health Organisation – Uppsala Monitoring Centre


The UK Medicines and Healthcare Products Regulatory Agency is coordinating the SCOPE Joint Action which received funding from the European Union.

The project will run for 36 months, 1 November 2013 –31 October 2016.

SCOPE

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