SCOPE Work Package 8
Lifecycle Pharmacovigilance

Competency Recommendations

2016

SCOPE

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Contents

Acknowledgments

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1. Introduction

1.1 Purpose of the document

The purpose of this document is to provide recommendations arising from Work Package 8 (WP8) – Lifecycle pharmacovigilance (PV) Topic 5. WP8 lead is Italy (AIFA), and Topic 5 is led by Italy (AIFA) in collaboration with Ireland (HPRA), and the United Kingdom (UK).

These recommendations are based on analysis of the competency survey data. Further elaboration was performed in the context WP8 group and integrations have been made considering the global analysis of findings in different WP8 Topics. The recommendations for competency complement recommendations for the other WP8 topics, which concern PV procedure-specific competency (Risk Management Plan (RMP), Post Authorisation Safety Studies (PASS), Periodic Safety Update Report (PSUR), Single assessment of Periodic Safety Update Reports (PSUSA) and referral procedure assessment).

1.2 Definitions and abbreviations

Terminology	Description
B/R	Benefit/risk
EMA	European Medicines Agency
EU	European Union
MS	Member State
NCA	National Competent Authority
PASS	Post Authorisation Safety Studies
PSUR	Periodic Safety Update Report
PSUSA	Single assessment of Periodic Safety Update Reports
PV	Pharmacovigilance
RMP	Risk Management Plan
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SOP	Standard Operating Procedure
WHO	World Health Organisation
WP	Work Package

1.3 Background

In the context of the effective operation of the PV system in the EU, improvement of benefit/risk (B/R) assessment throughout the lifecycle of medicines, and promotion of consistency, such as high-level standards, in the context of PV procedures across Member States (MSs), is one of the most important aspects of the PV legislation that came into force in July 2012 (system implementation). In areas of healthcare, including PV, professionals are expected to have attained an appropriate level of competence, which, when combined with their past experience and knowledge base, enables them to make decisions and take valid and efficient regulatory actions. Assessors should be skilled to provide high-quality assessments, including the B/R decision-making, which is a complex and challenging task. It is not only restricted to evaluation of safety data; in the process of assessment and decision-making, other aspects must be considered as well, including handling data heterogeneity, lack of data, long-term outcomes, consistency across assessments, flexibility and ability to deal with uncertainty, ability to work in teams and to adhere to proposed timeframes, good coordination and collaboration with other participants and stakeholders in the process, and so on.

1.4 Context

In the context National Competent Authorities (NCAs) diversity, build-up of assessors' competency and its continuous maintenance assume particular importance for the improvement of the effectiveness of the whole PV network and European medicines regulatory system. Furthermore, the European Union (EU) encourages the exchange of experiences, knowledge and good practices between NCAs for the promotion of high-level standards for medicine evaluation.

Relying on the competence of other MSs also reduces duplication of efforts, shares the workload and ensures the efficient and effective regulation of medicines across the EU (see 'European regulatory system for medicines and the EMA, A consistent approach to medicines regulation across the European Union').

Other EU projects have addressed some aspects of the competency of PV assessors.

The EU Network Training Centre (www.hma.eu/otsg.html) aims to create a European central platform for the exchange of information and supply of regulatory and scientific training across the EU regulatory network.

Eu2P (www.eu2p.org) aims to improve understanding of the risks and benefits of medicines in large groups of people, by developing a European training and education platform in pharmacovigilance and pharmacoepidemiology. The Eu2P programme offers courses in pharmacovigilance and pharmacoepidemiology, with courses specialising in benefit assessment, regulatory aspects, risk quantification, public health and risk communication, as there is a clear need to explain and sensitise the public to the realities of the risks and benefits associated with medicines. EU2P courses in pharmacovigilance and pharmacoepidemiology are provided and updated by a strong partnership of seven universities, 15 pharmaceutical companies, the French Medicines Agency – L'Agence nationale de sécurité du médicament et des produits de santé (ANSM) and the European Medicines Agencies (EMA).

In addition, the recommended regulatory assessor's competencies are provided in Annex 2 of the World Health Organisation (WHO) guide 'Practical Guidance for Conducting a Review – based on the WHO Data Collection Tool for the Review of Drug Regulatory Systems for definition of assessor professional profile'.

2. Aims

The overall aim of the competency recommendations is to contribute to the development of PV assessors' competencies across the EU, in terms of both practical advice on facilitation of the assessment process (organisational matters) and defining the necessary expertise and curricula for the PV assessor professional profile.

This document aims to highlight the factors that could impact on the continuous professional development of NCAs' assessors involved in B/R assessment of medicines, in order to support the quality, consistency and efficiency of the assessments process and to promote high-quality assessment standards and decision-making on regulatory measures. Moreover, the aim of the recommendations is to create the opportunity for work-sharing, linkage and cooperation among NCAs.

This recommendation outlines some useful good practice examples concerning: processes and organisation, professional profiles requirements (Junior and Senior assessors), useful training courses and literature recommended by NCAs, such as some aspects relative to internal quality systems. Furthermore, this document provides the grounds and the basis for the future organisation of an exchange programme of EU pharmacovigilance assessors between NCAs.

3. Methodology

In the context of the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action WP8, a survey was conducted between July and November 2014, in order to collect information regarding the competency levels and organisation amongst NCAs. In total, 25 NCAs responded and all 25 completed the whole questionnaire. On the basis of the NCAs' feedback and further elaboration at the WP8 level, the final recommendations for Topic 5 have been agreed.

3.1 Development

These recommendations have been extrapolated from the survey report on this WP8 topic. NCAs' responses to the survey have been analysed in order to create a list of recommended training courses and a list of useful literature.

Considering the responses from different NCAs participating in the SCOPE Joint Action, a further elaboration and integration was performed by participants in WP8, in order to define some useful criteria that could be applied to define Junior and Senior Assessor profiles.

In addition, on the basis of the input of some NCAs, it has been agreed within the WP8 to integrate the recommendations, including a concept paper on "Exchange programme for EU Pharmacovigilance assessors". This concept paper provides the grounds for the future organisation and possible implementation of an exchange programme dedicated to EU pharmacovigilance assessors.

3.2 Challenges/limits

Among the challenges that limit these recommendations is the fact that not all European NCAs participated in the SCOPE project, and that a low response rate was registered among those who are participants. Therefore, the present recommendations don't provide a complete picture of explored competency aspects across the EU.

Due to the substantial differences in the structure and contexts of NCAs across MSs, not everything in this paper will be possible to implement, or relevant for everyone – nor it is intended to be.

4. Recommendations

4.1 Process and organisation

- Collaboration with quality, pre-clinical and clinical assessors and experts in (pharmaco)epidemiology/statistics is recommended during the assessment of the specific PV procedures.
- Establishing assessment teams in the context of the evaluation of specific PV procedures is encouraged.
- The efficient and transparent selection of external experts could be of particular importance when the specific know-how (appropriate expertise outside of NCA) is necessary for the successful management of PV procedure assessment. It is therefore recommended that the specific expert databases are established and periodically updated by NCAs to facilitate selection and engagement of external experts. This could also facilitate the declaration of conflicts of interests (DoI) evaluation process and consultation, if necessary, with different experts in one or more procedures.
- Besides specific expertise, some additional criteria are important in the selection of experts. It is recommended that they should:
  - Possess or develop a working knowledge and understanding of the national/European medicines regulatory procedures
  - Be able and prepared to speak on a range of relevant issues and not just on their own areas of specialty
  - Be able to operate effectively on a national expert scientific committee
  - Be skilled communicators
  - Be able to assimilate complex scientific information at short notice
  - Be recognised by their peers and/or be fellows of the relevant academia institutions
  - Have a track record of achievement in their specialty

4.2 Build up internal quality systems

- Enhancement of quality systems (e.g. Standard Operating Procedures (SOPs) describing the evaluation process for the main PV procedures) aimed to ensure a good level and consistency of assessment is recommended.
- Enhancement of quality systems (e.g. SOPs describing assessor professional profile, introduction and training programmes, mentoring systems) aimed to ensure a good level of expertise for newly employed assessors and for maintenance of assessors' appropriate level of knowledge is recommended. In the mentoring system and peer-reviewing a senior assessor could play a particularly important role.

- Other interventions/approaches that could increase assessors' motivation to participate in training events are the enhancement of continuing professional development programmes (programmes where attendees gain and collect training/educational credits), such as implementation of personal educational forms (records concerning training attended in period of time) etc. These could be recommended when appropriate.

4.3 Professional profile requirements

Some essential competences/abilities necessary and recommended for the professional profile of PV/clinical assessors are listed below:

- University degree in biomedical sciences
- Working experience in a specific field
- High-level knowledge of English
- Ability to work in a team – good social and cooperation skills
- Ability to manage own workload and to adhere to proposed timelines
- Ability to perform critical analysis of scientific research findings and literature
- Basic knowledge of regulatory procedures
- Adequate knowledge and use of computer applications
- Capacity to adhere to the on-the-job training

Two detailed descriptions of NCAs' approaches to the definition of skills and compulsory knowledge, experience and expertise for junior assessors have been identified in the survey and could be helpful for other NCAs, if necessary.

Few replies on the compulsory expertise and experience level for senior assessor were received. Two examples of criteria for definition of a senior assessor profile were identified in the survey that could help NCAs to address this issue if necessary. More details are available in WP8 Topic 5 report.

4.4 Training and education

On the basis of NCAs' input, a list of recommended training useful for PV assessors was created and is recommended for the continuous education of PV assessors (see Annex 1).

4.5 Useful literature

On the basis of NCAs' input, a list of recommended literature useful for PV assessors was created and is recommended for the continuous education of PV assessors (see Annex 2).

4.6 Exchange programme

The development of an exchange programme for assessors as a valuable tool for the promotion of close collaboration, exchange of information and consistency for PV procedures evaluation is recommended.

The benefits that could be obtained by implementation of an exchange programme for PV assessors are addressed in a WP8 concept paper (see Annex 3). This paper explores the grounds for competence, experience and knowledge-sharing among assessors from MSs and explores the possibilities for implementation of the secondment/exchange programme as a tool for improvement of the effectiveness of the PV network.

5. Impact assessment (anticipated)

The work in this WP8 topic s focused on building up assessors' competencies across different European NCAs. The expected impact on the EU PV system is that this will promote consistency in medicines evaluation throughout their lifecycle. It could also foster collaboration and exchange of experiences, knowledge and good practices between NCAs. These objectives could be achieved through implementation of the recommendations and the proposed exchange programme for PV assessors.

Annex 1. Table of training courses

European	Provider / link	Level	Length (days)	Main focus
EMA training for PhV assessors (12)	EMA EMA training for PhV assessors (12) http://www.ema.europa.eu/ema/	Basic	1	Templates, PSUR, RMP, Referrals, signal detection and evaluation.
TOPRA – An introduction to Pharmacovigilance (3)	TOPRA https://www.topra.org	Advanced	>15	The Organisation for Professionals in Regulatory Affairs, whose membership comprises regulatory affairs professionals working in the pharmaceutical, medical device and veterinary medicines industries, offer several courses in medicines regulation. The regulatory affairs courses range from one-day basics through intensive introductory courses to a series of continuing professional development modules. The organisation also offers degree courses in conjunction with universities.
DSRU Critical appraisal of medical and scientific papers (4)	Drug Safety Research Unit (DSRU) https://www.on-course.eu/providers/dsru-drug-safety-research-unit/	Basic	3	DSRU 1 is an introductory course providing practical foundations for those working in drug safety.
EudraVigilance/EVDAS (4)	EMA https://eudravigilance.ema.europa.eu/human/training4.asp	Basic	3	ICSR reporting training, data management in EVDAS.
IWG (Inspection Working group) Training course EMA	EMA http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000163.jsp&mid=WC0b01ac0580029753	Basic	3	The Pharmacovigilance Inspectors Working Group (PhV IWG) was established by the European Medicines Agency with the remit to focus on harmonisation and coordination of PhV-related activities at the European Union (EU) level. In particular, PhV IWG is involved in the preparation of new and revised guidance and EU procedures relating to PhV inspections.
EMA webinars: SmPC, RMP, PSUR, signals, PSUSA, referrals (4)	EMA http://www.ema.europa.eu/ema/	Basic	1	Short trainings organised by EMA regarding SmPC, RMP, PSUR, signals, PSUSA, referrals.

European	Provider / link	Level	Length (days)	Main focus
Regulatory Affairs Professional Society, (RAPS), Online University	RAPS http://www.raps.org/	Advanced	>15	The Regulatory Affairs Professional Society (RAPS) is a global society with members in North America, Europe and Asia. Its mission is to support the lifelong learning of regulatory professionals and, to achieve this mission, the society works with subject matter experts to develop courses that assist members to increase their knowledge, competencies and performance in regulatory affairs. The organisation offers online regulatory affairs certificate courses in medical devices and in pharmaceuticals, as well as a dual course covering both medical devices and pharmaceuticals. In addition, the society hosts conferences, workshops and webcasts. RAPS Online University is a self-paced continuing education for healthcare products regulatory professionals, its Regulatory Affairs Certificate Program is a unique series of 9 or 14 courses that provides knowledge and expertise. Courses are developed by industry experts and offer flexible, self-paced, independent study pertaining to the medical device and/or pharmaceutical industries, with a final exam in one of three centres in USA or UK. RAPS also runs an Executive Development Program in conjunction with the Kellogg School of Business Management at Northwestern University in Illinois, USA. Designed specifically for the experienced regulatory professional, the RAPS Executive Development Program builds key management, business and leadership skills through intense discussions with key business professors in an intimate learning environment. Topics covered are Change Management, Crisis Management, Decision-making, Negotiation, New Product Development, Operations Management and Strategy. The 4-day course costs around USD7,500. Several universities across Europe and North America also offer certificate, diploma and postgraduate degree courses in medicines regulatory science and regulatory affairs. Some examples include, but are not limited to, the University of Copenhagen (M.Sc. Pharmaceutical Regulatory Affairs), University of Southern California (MS and PhD in Regulatory Science), Johns Hopkins University (MS in Regulatory Science) and University of California Berkeley Extension (Professional Program in Regulatory Affairs). All the courses offered by the institutions, whether universities or professional societies, are aimed at individuals employed, or who want to enter, the private sector.

European	Provider / link	Level	Length (days)	Main focus
LSHTM Certificate in Pharmacoepidemiology & Pharmacovigilance	The London School of Hygiene & Tropical Medicine (LSHTM) https://www.lshtm.ac.uk/study/cpd/scpp.html	Advanced	>15 (230 h)	The aim of this programme is to equip students with a basic understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance. The course aims to provide an introduction to epidemiology, statistics, pharmacoepidemiology and health economics. It also covers the historical and legal background to pharmacovigilance and pharmacoepidemiology, and pharmacological basis of adverse drug effects, addressing adverse drug effect issues at individual and population levels, and the application of pharmacoepidemiological principles and methods to practical drug issues. This training is part-time and comprises 230 hours (approximately one day per week on average), which are spent as follows: 80 hours formal teaching and contact time, 80 hours self-directed study and 70 hours project work.
PharmaTrain MSc	PharmaTrain http://www.pharmatrain.eu/	Advanced	>15	PharmaTrain is a project formed and funded under the Innovative Medicines Initiative Joint Undertaking. The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative, established to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe. It is a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The aim of this joint project is to provide courses designed to meet the needs of professionals working in medicines development. The main objective of the PharmaTrain project is to harmonise, build and implement modular master's-level programmes in Pharmaceutical Medicine/Medicines Development. These programmes will enable graduates to lead the drug development process, aiming to give Europe a competitive advantage in developing innovative medicines. Training centres, which offer diploma courses, master's-level programmes and CPD modules under the PharmaTrain brand share the PharmaTrain standards and undergo quality assessments.

European	Provider / link	Level	Length (days)	Main focus
Nordic Pharmacovigilance Meeting	http://nordic-pharmacovigilanceday.eventify.it/	Advanced	1-2	This conference is an opportunity to meet colleagues and listen to regulatory authority representatives and key actors in the field. The main audience is pharmacovigilance personnel. Professionals who have an interest in pharmacovigilance, regulatory affairs, compliance and risk management and want an update on the planning for the implementation of the new EU PV legislation in the Nordic countries.
Use of MedDRA for Coding & Reporting of Medication Errors (2)	MedDRA https://www.meddra.org/training/schedule/european-industry-meddra-user-group-webinar	Basic	1	This one-day course is designed to provide an understanding of the scope, structure, and characteristics of MedDRA and the application of the terminology in coding clinical data. It is designed for individuals involved with coding, those affected by coding guidelines and associated standard operating procedures, and those involved with synonym lists. Participants will be given an overview of the MedDRA Term Selection: Points to Consider document and will perform hands-on coding exercises to demonstrate the principles described in the document.
Pharmacovigilance pharmacoepidemiology courses	The Division of Clinical Pharmacology, Karolinska Institute, Karolinska University Hospital, Stockholm http://ki.se/start	Advanced	3	Pharmacovigilance and pharmacoepidemiology aspects.
Practical Pharmacoepidemiology	The London School of Hygiene & Tropical Medicine (LSHTM http://www.lshtm.ac.uk/study/cpd/spp.html	Basic	4	Develop knowledge of pharmacoepidemiological concepts and methods, with a focus on database studies. Gain practical experience of testing study feasibility and performing analyses in STATA, using primary care data from the Central Practice Research Datalink. Gain insight into the application of pharmacoepidemiology in pharmaceutical risk management.

National	Provider / link	Level	Length (days)	Main focus
Post-graduate Programme in Pharmaceutical Medicine/Medicines Development Sciences: Module 2, Non-clinical testing, pharmaceutical and early clinical development	PHARMED http://www.ulb.ac.be//medecine/pharmed/	Basic	5	Non-clinical testing, pharmaceutical and early clinical development.
Post-graduate Programme in Pharmaceutical Medicine/Medicines Development Sciences: Module 3, Clinical development of medicines	PHARMED http://www.ulb.ac.be//medecine/pharmed/	Basic	5	Clinical development of medicines.
Post-graduate Programme in Pharmaceutical Medicine/Medicines Development Sciences: Module 6, Drug safety, Pharmacovigilance & Regulatory affairs	PHARMED http://www.ulb.ac.be//medecine/pharmed/	Basic	5	Drug safety, Pharmacovigilance & Regulatory affairs.
Análisis y Gestión de Riesgos en Farmacovigilancia (Analysis and Management of Pharmacovigilance risks course)		Basic	3	The course focuses on the main aspects of planning and conducting pharmacoepidemiology studies and on critical analysis of the results from published studies.

National	Provider / link	Level	Length (days)	Main focus
XXII Corso Introduttivo di Farmacoepidemiologia (Basic Course on Pharmacoepidemiology)	http://www.iss.it/esps/index.php?lang=1&anno=2013&a=corsi	Basic	5	The course focuses on the main aspects of planning and conducting pharmacoepidemiology studies and on critical analysis of the results from published studies.
Curso básico de Farmacoepidemiología (Basic course on Pharmacoepidemiology)		Basic	2	Pharmacoepidemiological methods.
Internal MPA training courses		Basic	6	Drug safety, Pharmacovigilance & Regulatory affairs.
PhD course within drug toxicology (FRM 5720), University of Oslo		Basic	5	Toxicology – specifically designed for the education of toxicologists working in academia and among regulators.
Curso avanzado de Farmacoepidemiología (Advanced course on Pharmacoepidemiology)		Advanced	2	The course focuses on the main aspects of planning and conducting pharmacoepidemiology studies and on critical analysis of the results from published studies.
Belgian Centre for Evidence-Based Medicine: Evidence-based medicine		Basic	3	Pharmacovigilance
Internal MPA introduction program		Advanced	1	Shorter courses over a few months, covering all aspects of training in assessment, including benefit/risk and all safety-related procedures.
Master Farmacoepidemiología y Farmacovigilancia (Master's degree in Pharmacovigilance and Pharmacoepidemiology)	University of Alcalá – Alcalá de Henares, Madrid, Spain	Advanced 60 ECTD	9 months	Full master's programme focused on pharmacovigilance and pharmacoepidemiological methods, to make the trainees familiar and able to understand the main epidemiological and statistical principles, concepts and tools that are used in pharmacovigilance and pharmacoepidemiology practices and research. Aimed to train on the main health indices used to describe mortality and morbidity of the population and to learn the principles used to design and appraise observational studies. Master's course also includes the basics concepts of communicating written and oral scientific results.

National	Provider / link	Level	Length (days)	Main focus
Statistical analysis Courses – Centre for Support and Training in Analysis and Research at University College Dublin	University College Dublin http://www.ucd.ie/researchcareers/ http://www.cstar.ie/courses/cstarcourses/	Advanced		A basic statistics course covering the basic methods of analysis needed for quantitative research. A mix of practice and theory. No prior knowledge of statistics is assumed although you will require a basic knowledge of using SPSS and/or other statistical software packages. This course will be mainly suited to those from the sciences or medical fields, but others may find it useful. Subjects covered include: Sampling Data analysis – an overview; types of data; scales of data measurement; coding questionnaire data Describing data using graphical and numerical methods Normal probability distributions Confidence intervals and hypothesis testing (parametric and non-parametric) Multivariable analysis – qualitative (categorical) variables; chi-squared tests Multivariable analysis – quantitative (continuous) variables – scatter plots, correlation and regression.
Master's in "Scienze Regolatorie del Farmaco" AIFA (specialization course on Regulatory Science)	Italian Medicines Agency (AIFA) and Università La Sapienza http://dff.uniroma1.it/it/didattica/offerta-formativa/master/master-scienze-regolatorie-del-farmaco	Advanced	>15 (1500h)	The master's is aimed to develop a real expertise in the field of drug regulatory disciplines, with participants acquiring skills they can use in the public or private sector in the development, evaluation and monitoring of medicinal products. The lessons are held by teachers from the University "La Sapienza", the Executives of the Italian Medicines Agency (AIFA) and International experts working in drug-regulatory.

International	Provider / link	Level	Length (days)	Main focus
Vienna School of Clinical Research, (Austria), Introduction to Clinical Epidemiology	Vienna School of Clinical Research	Basic	3	The course objective is to qualify participants for designing, conducting, analysing, and presenting clinical studies. Students will also become familiar with international legal and ethical standards in clinical research. Graduates of the programme will acquire the competence to successfully lead research projects and compete on an international level.
The UMC's international pharmacovigilance training course (3)	Uppsala Monitoring Centre http://www.who-umc.org/graphics/28281.pdf	Basic	10	The course focuses on topics essential to effective pharmacovigilance, including sessions to strengthen the overall WHO Programme, e.g. pharmacovigilance best practices, signal detection, regulatory aspects, reporting culture, benefit/harm assessment and pharmacovigilance tools. The programme also includes a management component designed to help participants improve their capacity to influence sustainable change in their countries. Issues related to health economics, communications, fundraising and risk management will be covered. Training, built around lectures, workshops and hands-on exercises, takes place in an open and interactive environment. Plenty of opportunities to interact with UMC staff, faculty experts and fellow course participants will be provided.
Introduction to Biostatistics	Vienna School of Clinical Research, (Austria) http://www.vienna-omi.at/en/	Basic	3	The programme provides students with a solid understanding of health research methodology and biostatistics, and confers practical skills, e.g. in project management.
Pharmacoepidemiology – training course in Portsmouth	University of Portsmouth http://www.port.ac.uk/ http://www.dsru.org/courses	Basic	5	This course is aimed at introducing delegates to the core concepts of this scientific discipline. Attendance at this course can be used as part of the training required for the Drug Safety Surveillance module of the Pharmaceutical Medicine Specialty Training (PMST).
Introduction to Clinical Research	Vienna School of Clinical Research, (Austria) http://www.vienna-omi.at/en/	Basic	3	Training courses (lectures, workshops) on different topics related to clinical research. ("The course modules have been designed to offer as broad a range of subjects within clinical research to as many different disciplines working within this field as possible.")
ISPE Meetings (2)	ISPE http://www.ispe.org/			Specifically designed for education of toxicologists working in academia and among regulators.

International	Provider / link	Level	Length (days)	Main focus
Drug Information Association – DIA Training (3)	DIA https://www.diahome.org/en/Meetings-and-Training.aspx	Advanced		Pharmacovigilance pre-conference courses on pharmacovigilance and general regulatory aspects. The DIA is a non-profit association which stands for a global forum for therapeutic innovation and regulatory science. The mandate includes provision of continuing education to help healthcare professionals maintain and improve their knowledge and skills. The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The Drug Information Association has been accredited as an Authorised Provider by the International Association for Continuing Education and Training (IACET). The Drug Information Association has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI).
ISOP Training Courses (3)	International Society of Pharmacovigilance http://www.isoponline.org/index.php?page=training	Advanced	3-4	Pharmacovigilance and regulatory aspects.
Erasmus summer programme: pharmacoepidemiology	Erasmus Medical Center Rotterdam http://erasmussummerprogramme.nl/	Advanced		Its objective is to qualify participants for designing, conducting, analysing, and presenting clinical studies. This course refers to established drug safety problems in order to highlight some of the complex aspects of outcome and exposure assessment in pharmacoepidemiology.
Conducting Hypothesis Testing Research in Healthcare Databases	Prof. Miriam Sturkenboom, FISPE, Erasmus University Medical Center, the Netherlands and ISPE Conducting Hypothesis Testing Research in Healthcare Databases	Advanced		Workflows in Single and Multiple Database Studies.
Lareb: International Meyler Course on pharmacovigilance	Netherlands Pharmacovigilance Centre Lareb http://www.lareb.nl/whocc?lang=en-GB	Advanced	5	LAREB as a collaborating centre we want to serve as a platform for knowledge transfer by providing training, conducting research and developing best practice for staff active in pharmacovigilance, both at national centres and in academia. These activities will hopefully help to further develop pharmacovigilance and increase the awareness of adverse drug reactions (ADRs) and ADR reporting. A three-day introduction to practical aspects of collecting information about ADRs and the organisation of pharmacovigilance worldwide.

International	Provider / link	Level	Length (days)	Main focus
UMC WHO Risk, What risk? Whose Risk?	Uppsala Monitoring Centre http://www.who-umc.org/DynPage.aspx?id=122497	Advanced	2	This symposium will showcase and debate some of the latest methods and fields of enquiry in safeguarding patients.
European Programme in Pharmacovigilance and Pharmacoepidemiology EU2P (2) – Master's, PhD, independent courses, etc.	European Programme in Pharmacovigilance and Pharmacoepidemiology: coordinated by the University of Bordeaux, with several partners (EMA, 7 universities, pharmaceutical companies, EFPIA, etc), http://www.eu2p.org/	Depending on the type of training: from Basic to Advanced	>15	PhV and pharmacoepidemiology – targeted to scientists and students from industry and academia, including online/distance learning.
EMA Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing Training Course (3)	EMA https://eudravigilance.ema.europa.eu/human/docs/13522_PGM.pdf	Advanced	5	This course is designed to provide a firm grounding in key aspects of global clinical pre- and post-marketing safety. The five-day training course, presented by the European Medicines Agency, is now also including highlights and updates on the implementation of the new pharmacovigilance legislation and the latest news on the international harmonisation and standardisation activities in pharmacovigilance.
Essentials of Clinical Study Management	DIA http://www.diahome.org/en-GB/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=3107678&EventType=Training%20Course	Basic	2	This training course provides a comprehensive overview of the essential elements of study management and the clinical study environment in the context of the overall drug development process. After successful completion of the training course, participants will be able to plan, execute and manage a clinical study from protocol to final report. Key Topics: Drug Development, Process Feasibility, Assessment Study, Planning Tools Regulatory Framework, Quality Management System, Essentials of Site Management, Resource Management, Investigational Product Handling, Risk Management, Safety Reporting, Study Evaluation and Reporting.

International	Provider / link	Level	Length (days)	Main focus
Medicademy	Medicademy (The international medical academy) http://medicademy.net/pharmacovigilance/Pages/About-Pharmacovigilance.aspx	Advanced	Eight modules, each of 2-4 days	Medicademy Pharmacovigilance is a flexible, part-time postgraduate programme with special emphasis on understanding pharmacovigilance issues based on a practical industry approach. The eight modules cover key stages of a drug's lifecycle and aim to satisfy the educational needs of practicing pharmacovigilance professionals. All eight modules can be attended individually, in random order, and according to educational or professional needs. Any individually attended module can be incorporated in the diploma. To obtain a diploma in pharmacovigilance, participants must attend and pass the exams for five modules within five years. One module from the Medicademy Regulatory Affairs Programme may be included in the Medicademy Pharmacovigilance Diploma.
International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) – pre-conference courses	ICPE https://www.pharmacoepi.org/meetings/27thconf/index.cfm	Advanced	1-2	A number of different short courses concerning: Introduction to Pharmacogenetic Epidemiologic Methods; Pharmacoepidemiology; Drug Utilization Research; Registries/Prospective Cohort Studies; Healthcare Databases; Comparative Effectiveness Research; Comparative Effectiveness Research; Therapeutic Risk Management and Evaluation; Advanced Drug Utilization/Health Services Research.
Interactive e-training programs	Pharmawebinars https://www.pharmawebinars.com/about.html	From basic to advanced	1	Pharmawebinars e-training programs are interactive, instructor-led live training solutions, which effectively provide the most recent regulatory updates, expectations and guidance from the FDA, EU, Health Canada, and ICH as well as other regulatory bodies and scientific organisations. They also provide the latest operational and technical trends to companies and professionals in the pharmaceutical arena. The courses are certified.

*The list also includes the trainings reported in other WP8 topics.

Other reported national trainings:
PhV Training Course provided by the Estonian Agency
Université Libre de Bruxelles: Evidence-based medicine
Lääkefoorumi, In House Lecture Series: Pharmaceutical Forum – Drug Forum Lectures, Finland
Lääketiedepäivät, lääkesessio, Medicine days, the drug session – Annual Medical Congress, Drug session, Finland
Lääkevalvonnan koulutus -Pharmacovigilance training – Drug surveillance education, Finland.

Annex 2. List of useful literature

The following list of textbooks and scientific papers useful for pharmacovigilance assessors' activities was recommended by NCAs in the WP8 – Competency survey.

General issues

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Annex 3. Concept paper: Exchange Programme for EU Pharmacovigilance Assessors

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1. Introduction

1.1 Purpose of the document

This concept paper provides the grounds and the basis for the future organisation of an Exchange Programme of EU Pharmacovigilance Assessors between National Competent Authorities. It is based on the work in WP8 – Lifecycle Pharmacovigilance: Competency. WP8 lead IT, Topic Lead IT in collaboration with ES, IE, PT,NO and UK

1.2 Definitions and abbreviations

Terminology	Description
AR	Assessment Report
B/R	Benefit/risk
CAP	Centrally Authorised Products
EEA	European Economic Area
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EU	European Union
EU NTC	EU Network Training Centre
HMA	Head of Medicines Agencies
MS	Member State
NAP	Nationally Authorised Products
NCA	National Competent Authority
PASS	Post Authorisation Safety Studies
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
PSUSA	Single assessment of Periodic Safety Update Reports
PV	Pharmacovigilance
RMP	Risk Management Plan
SCOPE	The Strengthening Collaboration for Operating Pharmacovigilance in Europe
UMC-WHO	Uppsala Monitoring Center - World Health Organization
WP	Work Package

1.3 Background

The new legislation on pharmacovigilance includes a number of provisions to strengthen the post authorisation follow up of medicinal products during the life cycle and to reassess the B/R balance when necessary. The continued B/R assessment of a medicinal product through its lifecycle is a cornerstone for the effective operation of the pharmacovigilance system in the EU. Improvement of assessor skills in this field and harmonisation of the assessment process among Member States (MSs) is one of the most important aspects of the new PV legislation and its implementation throughout the EU.

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) has the aim of supporting operations of PV in Europe following new requirements introduced by the European PV legislation that came into effect in June 2012. Funded by the Consumers, Health and Food Executive Agency and with contributions from the involved member states, SCOPE will run from 2013 to 2016 and will gather information and expertise on how Member States run PV activities. Using this information, SCOPE will develop and deliver guidance, training in key aspects of PV, and tools and templates to support best practice.

The development of a competency framework to support exemplary PV throughout the product lifecycle and to create a forum for interaction amongst European NCAs to strengthen regulatory collaboration is among SCOPE high level objectives. This will lead to improved understanding of the different challenges faced by member states. SCOPE will seek a collaborative approach to develop solutions to these challenges, enabling NCAs' staff to work and communicate more closely together to strengthen the European and global PV network.

1.4 Context

A consistent approach in the assessment within PV procedures (e.g. RMP, PASS, PSUR/PSUSA and Referrals) is needed to support conclusions and actions to be taken by the European network. Use of the new and existing tools and a build-up of competences in the Member States to effectively address the examination of B/R of medicines in the context of the main PV procedures are warranted.

Exchange programmes in the field of education (students and teachers) in Europe (i.e. Erasmus+ programme) and worldwide are well established strategies in order to promote exchange of expertise and experience, to create links between institutions of different EU countries and to ultimately increase the level of competence of the staff involved in all the participant institutions.

In the field of medicines regulation, the EMA has a national expert secondment programme[1]. Through this programme staff from NCAs works at the European Medicines Agency for short periods. During the year 2014, twenty eight national experts in different fields, including PV, benefited from this programme. This programme has been working successfully for many years and the aim is that the Seconded National Experts should enable the EMA to benefit from the high level of their professional knowledge and experience, in particular in areas where such expertise is not readily available[2].

It should be noted that the European medicines regulatory system is based on a network of medicines regulatory authorities from the 31 EEA MSs, the European Commission and the EMA. In a number of aspects in the regulation of medicines, and particularly in PV Member States rely on each others' assessments. Therefore, the exchange of competence, experience and knowledge among assessors from MSs seems a very relevant initiative for improving the effectiveness of the network, especially the work of the PRAC. However, the above-mentioned EMA secondment programme is limited to exchanges from MSs' staff to the EMA but a programme of exchanges between NCAs has not been considered so far.

This concept paper follows discussions during the SCOPE WP8 face to face meeting in Oslo in June 2015, based on the preliminary recommendations of the Competency Report and other WP8 Reports with further discussions in content at the SCOPE WP8 face to face meeting in Rome in November 2015.

[1] National Experts on Secondment http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/q_and_a/q_and_a_detail_000083.jsp&mid=WC0b01ac0580029403

[2] EMA/754455/2014 Executive Director Decision laying down rules on the secondment of national experts to the Agency. 1 December 2014 ()

2. Issue statement and justification

The Work Package 8 of SCOPE (Lifecycle Pharmacovigilance) aims to explore existing standards for PV assessments and deliver a report on good practices useful to ensure that NCAs are able to support the PRAC with high-quality assessments. Surveys performed within SCOPE WP8 have gathered information on how NCAs support exemplary PV throughout the product lifecycle, how NCAs explore existing good practices for PV assessments on RMPs, PASS, PSURs and referral procedures, and explore good practices concerning assessor competency. In this context, the information gathered and the derived recommendations support the current exchange programme proposal.

The WP8 Topic 2 Survey Report deals with RMP assessment. In general, the objective of WP8 Topic 2 is to improve the tools and skills of assessors for the successful evaluation of RMPs. In particular, exchanging and sharing national experiences and guidance material developed on RMP assessment at national level is considered essential.

Methods for facilitation of specific assessor training were sought in the survey. When asked for actual practice used for training of assessors (Q42), on the job training expressed as reading other assessment reports (92%), and mentoring by senior assessors (75%) were the most common forms of training in NCAs. When questioned on any other challenges concerning assessment of RMPs (Q44), sharing information and knowledge with more experienced colleagues from other NCAs is explicitly mentioned. The report concludes that a key issue for efficient and consistent assessment is the availability of sufficient competent assessors. The need to help NCAs to identify and set up standardised training programmes for assessors has been highlighted.

WP8 Topic 3 Survey Report deals with PASS protocol and report assessments. In response to this survey (and also survey on Topic 2), it is clear that several member states have no or little experience with the assessment of synopsis of PASS protocols or PASS protocols per se. With regards to current practice by NCAs to assist with PASS assessments, comparison with other study protocols/reports was the most frequently (70%) reported method. Regarding training, responses to Questions 23-29 show that on-the-job training was the most common (60%) reported. Using examples (55%) and mentoring/coaching (55%) are the two second most commonly mentioned methods. In conclusion, the mainstay in training is “on the job training”, with senior PV colleagues acting as mentors. A future collaboration is foreseen between NCAs who have come far in the journey of PASS assessment and NCAs who are just starting their journey, perhaps in terms of alliances between both.

WP8 Topic 4 Survey Report deals with post-authorisation B/R assessment in the context of PSUR/PSUSA and Referral procedures. The overall goal of the work includes promoting the exchange of experiences, successful methods and good operating PV. The final deliverable is a recommendation to be used in a training package for assessors to promote consistency in the evaluation of B/R of medicines post-authorisation. The complexity of some PSUSA procedures has been highlighted as a particular challenge. Gaining experience in a number of these procedures is highlighted as the most important way of solving the issue. The recommendation for topic 4complements those for WP8 topic 5, as assessors should be competent in providing high-quality assessments including complex and challenging B/R decision making.

WP8 Topic 5 Survey Report deals with assessors' competency in particular. Identification of the experienced assessors' skills and useful methods aimed to ensure and maintain a good level of knowledge could be of particular interest in promoting high-quality and consistent assessments. Different factors have been explored in the survey. Responses to Questions 6-8 concerning assessors' education and experience show in general there is a need to address the gap in competency between junior and senior assessor. The gap in competency is mainly based in education and practical experience.

A specific question on the NCAs´ opinion on an Exchange Programme intended as a voluntary organisational exchange activity between organizations (e.g. NCAs, EMA, UMC etc.)showed that all 25 responding NCAs recognised this would be a valuable tool for promoting close collaboration, exchange of information and harmonization of high standards for assessment in PV procedures.

Almost all (23/25, 92%) NCAs described the most important reasons for considering an assessors' exchange programme to be useful. These reasons are summarised below:

- Related to the quality of the assessments:
  - Improvement of assessors' qualification, enhancement and harmonisation of the assessment quality: exchange/learning of useful information concerning best/good practices
  - The need for practical experience on different approaches for organisation of activities, work flow and evaluation process and the quality assurance leading to comparable assessments' quality
  - The need for keeping assessors up to date
- Related to sharing experience and knowledge:
  - Direct communication and sharing expertise between experts of different MSs leading to understanding better other colleagues' opinions, decision-making and prioritisation methods
  - Opportunity for involvement in "every-day" practice including other activities beyond the preparation of reports (e.g. management of databases, interface with other colleagues)

- Related to proposals for getting more value from the organisation of the exchange programme:
  - The most useful exchange programme would be among assessors of NCAs "on-site training". Trainer facilitation is recognised as more cost effective in specific situations (trainer coming over to the recipient NCA)
  - Very targeted short term exchanges may be preferable when the host agency has some specific skill or knowledge to offer.
  - Mutual exchange programmes allow for development of strengthened relationships between NCAs and in this way encourage collaboration across organisations.
  - Exchange programmes between NCAs and EMA have been recognised as useful.

Furthermore, in response to the question on methods that NCAs apply to ensure that assessors' technical/scientific and regulatory knowledge is kept up to date, "On-the-job training" was mentioned as the most frequent method for both scientific (23 NCAs) and regulatory (22 NCAs) knowledge.

The WP8 Report finally recommends that an exchange programme for assessors should be endorsed and encouraged at the European Union level.

In conclusion, there is a need to foster the exchange of professional experience and expertise in PV by temporarily assigning PV assessors from one NCA to another.

3. Aims

The main goal is to establish the grounds for a sustainable programme of secondment for European PV assessors enabling the exchange of experience and knowledge and facilitate an on-the-job training framework. The ultimate goal is to improve the consistency in PV assessments in all MSs facilitating at the same time a more active contribution of MSs in the PV tasks foreseen in the legislation.

The main focus is increasing scientific and regulatory knowledge and experience, but the organisation of PV activities should also be considered.

4. Exchange programme description

4.1 Candidate profile(s)

Candidates for secondment will be staff with responsibility for performing PV assessments in a NCA(PV assessors). In this regard the following options/requirements may be considered:

- The concept “pharmacovigilance assessor” may differ among MSs. For the purpose of this document a pharmacovigilance assessor is an assessor in NCAs involved in any of the main pharmacovigilance procedures considered in SCOPE WP8 (i.e.: assessment of RMPs, PASS, PSUR and PV Referrals). In this sense a PV assessors depending on the internal organisation at NCAs may be also involved in other PV procedures that can eventually be part of the exchange programme.
- In any case, a minimum period of time (at least 1 year) of experience in pharmacovigilance tasks would be required before applying for secondment in other NCA.
- The candidate should be employed by and working at the NCA. In principle external assessors should not be included.
- The involvement of less experienced assessors and more experienced assessors in the exchange programme will be different. The distinction is based on the following roles:
  - Less experienced assessors are those with less experience in one or more PV type of assessments. A person can have a limited experience in general or in a specific field. Thus, a senior assessor in most fields of PV may be considered a less experienced assessor in a specific field. The objective in general of any exchange should be to provide on-the-job training for less experienced assessors.
  - Experienced assessors are those with longer time expertise in one or several PV type of assessments. Their role in the exchange is to act as mentors/tutors for the less experienced assessors. Thus, they should also have additional skills and experience at NCAs as coordinators and supervisors of the NCA pharmacovigilance teams in the relevant PV procedures. For senior assessors visiting other NCA, one approach would be acting as a mentor of a group of junior assessors in this NCA. A second approach for a senior assessor would be to get very specific experience in a field that the other NCA has greater experience in and to then take that back to their own NCA as a trainer.

- The exchanges can be organised in both directions, depending on the availability of the interested persons and characteristics of the involved NCAs. Thus, normally less experienced assessors will visit other NCA in secondment to get on-the-job training from experienced assessors able to tutor them. Also, an experienced assessor may be visiting other NCA in secondment and act as a supervisor and trainer of a group of less experienced assessors in this NCA. A second approach for an experienced assessor would be to get very specific experience in a field that the other NCA has greater experience in and to then take that back to their own NCA as a trainer.
- For all, gaining experience and participation in procedures that are not routinely addressed in their own NCAs will be of value.

4.2 Hosting NCAs/organisations and selection criteria

In principle NCAs responsible for the regulation of human medicines in the EEA will be enabled as hosting organisations for the exchange programme. NCAs willing to host Pharmacovigilance assessors from other NCAs should announce the number and characteristics of positions that they would be able to have in a time period. In the end, a bidding and appointment process for the assessors in secondment will have to be established.

In addition, ad hoc exchanges in the format of two way, simultaneous, exchanges between two NCAs would be more efficient and in particular for agencies that might have limited staff exchange could be a way forward to overcome significant loss of work force (see also section 4.5). The initial impact on human resources in both sender and host NCAs should be considered.

4.3 Period of secondment

The duration of the secondment can be adapted to specific objectives. The fulfilment of specific tasks as a minimum may be established if this is consistent with the objective of a secondment. In general a period between 2 and 6 months is envisaged.

It is acknowledged that an exchange of experiences often will benefit from physical presence, however prolongation of the stay may be challenging in different aspects. A general principle for a minimum duration of the secondment is to allow for the full participation of the secondee in the drafting of the preliminary assessment report of at least one specific procedure. However, not only the writing of the assessment report, but also the outcome of PRAC discussion, requested supplementary information, assessment of response, updating AR and final PRAC outcome, are relevant elements in order to increase the experiences. Therefore, where the period in secondment is not enough to cover the full assessment process some provisions should ensure involvement of the assessor in the later steps when he/she has come back to the original agency in writing and with the use of teleconferences..

4.4 Job description: objectives and areas to be covered during the exchange programme

The tasks of the assessor in secondment should be previously defined and tailored to the needs of the NCA of the candidate. On the side of the hosting NCA, the secondee will normally be assigned as one of the assessors for specific pharmacovigilance procedures for which the hosting NCA is Rapporteur/Lead MS. The secondee will be part of team but is not meant to be the main assessor for the procedure. In addition, the time to be spent at the hosting NCA should be optimised so, the secondee will be involved in other tasks according to the needs of the NCA of the candidate, the on-going procedures at the hosting NCA at that time and the availability of resources in the hosting NCA pharmacovigilance team.

The grounds for the exchange programme are derived from feedback obtained within SCOPE WP8, which is focused on specific PV activities/procedures (RMP, PASS, PSUR, Referrals). However it is sensible to include also other activities under the responsibility of PV assessors in most MSs. Particularly, capture and assessment of individual case reports, signal detection and assessment, risk communications, evaluation of educational materials derived from RMPs, safety variations, and renewals, could be considered to be included among the tasks for assessors in secondment

Additionally, the seconded assessor will participate and learn from the hosting NCA in organisational aspects: management of databases, standard operating procedures and local guidelines, functioning of local committees, etc. and can be included as specific objective of the exchange period.

The tasks to be performed during the secondment will be different according to the objectives:

- For less experienced assessors, one or various types of procedures would be defined as the tasks for the assessor in secondment, depending on the agreed needs and the duration of the secondment. The assessor should be fully involved in the key phase the assessment assigned to him/her as one of the assessors in the team. Follow up of the procedures until final adoption and implementation will be of interest if possible within the timeframe of the stay. When this is not possible follow up should be ensured in writing and by teleconferences. When this is within the objectives of the secondment, a minimum number of reports should be pre-defined. The assessor in secondment will have a mentor in the recipient NCA that will oversee the works performed.
- In addition to on-the-job-training, the assessor should be given the opportunity to participate in training activities (courses, seminars, etc.) recommended by his/her mentor during the stay. The recipient NCA should facilitate and/or promote these complementary activities. Furthermore, optimally the hosting NCA may wish to adapt training programmes intended for its own staff to the needs of the assessors in secondment.

- After the exchange period the assessor is expected to return to his/her NCA (upon completion of the programme)and share with his/her assessor colleagues the exchange experience and knowledge/skills acquired.
- A generally considered experienced assessor in a NCA could also be seconded in other NCA to get experience in a specific field. In this case the job will be analogous to the tasks will be focused to the type of procedure for which the hosting NCA is covering the need of the visiting assessor.
- For experienced assessors with the objective of giving their experience to a number of assessors in the hosting NCA, a reference person in the recipient NCA should be designed to guide the visitor. The visiting assessor will act as a consultant for the assessments under the responsibility of the local assessors and will provide oversight in general for the procedures within his/her expertise. In addition, seminar or conferences for the local assessors should be previously defined and agreed with the visiting assessor, according to his/her area of expertise and also the needs of the hosting NCA's assessors. This option is efficient when several PV assessors in the hosting NCA are good candidates as receivers of practical on-the-job training.

4.5 Organisation

General scheme and responsible organisations

The organisation of the programme should take advantage of the experience of other secondment programmes (e.g. the EMA national expert secondment programme).

A central, EU level organisation should implement the Programme. The European Commission and/or Head of Medicines Agencies would be involved. The SCOPE WP8 team has also considered an alternative option, this is one NCA to be in charge of the practicalities on behalf of the network. Depending on the way the programme is financed a different approach would be taken. The different options would have to be agreed in the corresponding fora and it is beyond the scope of this paper to present a specific proposal.

In particular, the recently launched Joint HMA/EMA initiative of an EU Network Training Centre may have a key role in the organisation of the exchange programme.

The EU Network Training Centre (EU NTC) is a new initiative on training endorsed by the HMA (the HMA meeting in Athens in February 2014) and during the EMA Management Board meeting in March 2014. The EU NTC aims:

- To improve the quality, consistency and efficiency of the work of the European Medicines Regulatory Network (EMRN)To promote harmonised operation of the regulatory framework and guidelines throughout the EMRN

- To foster science based, pragmatic and consistent assessment, inspection, PV, decision making and carrying out of regulatory measures
- To provide continuous professional development for staff of national regulatory agencies and EMA and, possibly, others involved in development of medicines regulation.

The objectives of the EU NTC are fully aligned with the exposed objectives of the proposed exchange programme and therefore it is in an excellent position to consider taking on board this initiative. It also has the relevant institutional support that needs to endorse a project like this.

Economic aspects and funding options

Pending discussions at the appropriate level for further development of the project, it can be foreseen that the following needs will have to be covered:

- Daily allowance for the staff during secondment. This should allow for the additional expenses related to the stay in the town of destination and should not serve as an extra income for the assessor in secondment.
- Travel expenses to the hosting country at the beginning and at the end of the secondment. Also some additional return home weekend trips particularly in case of prolonged exchanges should be considered.
- Organisational costs for the central body and for management aspects at the level of participating NCAs would have to be considered.

The seconded staff would continue to receive their salaries from their own NCA during their stay. So, the scheme followed by the EMA's national expert on secondment programme would be followed.

A general principle is that financing the exchange shouldn't be up to the individual NCAs since there is a risk of not covering the real needs of the less experienced assessors and teams in MSs. So, a central basic EU support is warranted. This doesn't precludes that Member States may additionally support the exchange of their assessors with different types of incentives from other funding sources (e.g. scholarships and training support programmes from other national or EU funds)

Handling conflicts of interests

The assessor in secondment should be included in the list of EU experts maintained by the EMA before the initiation of the secondment as scientific assessment expert from his/her NCA. This can be required as a condition of the secondment. Updated Public Declaration of Interests and Confidentiality Undertaking are already public in the EMA website for the list of European experts. Therefore, this information will be checked before deciding whether or not to include him or her as assessor for specific procedures and activities.

In case NCA policy on conflicts of interests or confidentiality undertaking covers additional aspects compared to the EMA rules, the hosting NCA may require further declaration.

Development of specific organisational aspects:

In terms of specific organisational aspects that need to be established, some areas will have to be developed following the experience of existing exchange programmes:

1. NCAs willing to host Pharmacovigilance assessors from other NCAs should announce the number and characteristics of positions that they would be able to have in a time period (e.g. yearly). This will be made public in a dedicated web portal maintained by the central organisation in charge of the programme. Characteristics will include the following:
   - General job description, including specific area or areas of work (i.e. PASS, RMP preauthorisation, PSUR, referrals, etc.). The list of areas of work/expertise would have to be defined (normalised) for the whole project and should be aligned with the recognised areas of expertise of the hosting NCA. Availability of experienced assessors able to act as supervisors/tutors will be included. However, the specific scope of the assessments would be worked up together with the seconded assessor following the appointment.
   - Optimal (minimum and maximum) duration of the secondment.
   - Additional training activities that may be offered to assessors in secondment by the NCA or academic institutions in the hosting country.
   - Other particularities can be also presented at this stage, like the possibility of the NCA to send some experienced assessors able to act as supervisors/tutors in secondment in case this is the most efficient option for some NCAs with a number of less experienced assessors good candidates for the exchange programme. Also whether the hosting NCA needs the secondment to be mutual, i.e. other assessor from this NCA will go for secondment to the other NCA at the same time.
2. After the list of available positions in all participant MSs is announced/made public, a bidding process will have to be established. PV assessors willing to be secondees would select the NCA that they consider to be most appropriate in agreement with the overall needs of their NCAs. Two-way mutual, simultaneous exchanges between assessors of two NCAs may be arranged at this stage by bilateral contacts of NCAs.
3. The appointment process will follow. As there could be more potential secondees than hosts, rules around appointments would have to be developed:
   - Rules should be adopted in order to have balanced appointments according to priorities previously established by the European network.
   - Probably an ad hoc board should be convened in order to recommend on the appointments with the agreement of the hosting NCA.

4. Once the assessor has been appointed to a secondment, a specific programme would have to be organised together with the hosting NCA. The secondee will propose his/her specific objectives for the exchange. An adaptation programme would be organised if considered necessary for overcoming differences in work culture among countries, as a "pre-departure training". The specific scope of the assessments would be worked up together with the seconded assessor following the appointment.

4.6 Evaluation

For each exchange, the visiting assessor and the host organisation will have to prepare an assessment of the secondment. This assessment should be shared with the NCA of the assessor. Clear learning objectives should be agreed beforehand and these learning objectives evaluated at given periods throughout the secondment as well as at the end. A template for this could be developed.

Annual reports on the exchange programme from the central organisation will be expected with a summary of the performance and the main achievements.

5. Challenges/limits

The implementation of this programme may imply different challenges and difficulties that will have to be overcome:

Language issues

Pharmacovigilance assessors write the Reports and interact with other NCA and EMA colleagues in English but most NCAs daily work is performed in the official language of that country. So, for the exchange to be efficient this difficulty should be addressed. Some knowledge of the recipient language by the seconded assessor would be the optimal option but also an adaptation of the host team to the need of the exchange programme, i.e. ensuring an English speaking environment for most or all the activities in which the seconded assessor will be involved. In this regard, one-by-one interactions of the seconded assessor with the PV staff (i.e. the mentor) are easier to be developed in English while other activities (working meetings, local committees, training courses, etc.) should be adapted if considered essential for the objectives of each exchange.

Establishing selection and prioritisation criteria for the exchange

These criteria would be related to the type and need of the involved NCAs. Some objective criteria would have to be developed related to the size of the staff working in PV, demonstrable limited expertise (lack of involvement in EU procedures as Rapporteur/Lead MS), etc. Also if specific areas would be favoured (for instance, PASS protocol assessment, referrals, PSUSA for NAPs or RMPs). The elaboration would rely on a specific Board with involvement of HMA and PRAC.

Immediate effect of loss of the work force of the seconded staff during the exchange

Some provisions can be anticipated to minimise this possible drawback. For instance, a careful plan establishing flexible dates for starting and finishing the secondment period could be useful. This should probably be synchronised with the timelines for specific procedures. Specific solutions should be explored for small NCAs with a number of less experienced assessors who are good candidates for exchange and where the impact of having some of them in simultaneous or consecutive secondment would be greater. For instance, in these situations an experienced visiting assessor from other NCA may be the one who goes on secondment providing training and oversight of the assessment reports for several assessors in the hosting country. Also simultaneous, mutual exchange of assessors among to NCAs may be considered.

Existing workforce may feel uncomfortable with a new person being brought in

Good communication to the hosting workforce should be carried out beforehand informing them that the seconded assessor will be there only for a specific period of time and to expand his/her knowledge and benefit from the experience and good practices of the hosting team. It should be highlighted that the hosting team will also benefit from the exchange experience. Providing a mentor for the seconded assessor is good way of overcoming some obstacles they would probably face. Good support and good interpersonal relationships throughout the exchange period is also essential.

Discouragement in returning

During the exchange period the seconded assessors may experience such a rewarding time that when returning to their original NCA it is possible they may want to leave their job. To overcome this issue should be agreed that returning assessors would be immediately encouraged to put their new skills and experience into practice and share all the learning with their assessor colleagues. Also, timelines for returning to the origin NCA will be established in advance and a compromise from the seconded assessor to stay during the limited period will be obtained.

Legal issues

National legislations and organisational characteristics among NCAs might collide (e.g. labour legislation, insurance issues). All these issues will need to be previously provided in a fully detailed secondment agreement.

Extent of participation

Not all the assessors/NCAs that in principle may benefit from the programme are likely to participate in a timely manner. Optimisation of the processes involved and implementation of different actions to overcome the challenges and limitations may minimise this issue. For those assessors/NCAs who are not covered other options should be considered so they may also have the opportunity to improve their knowledge/skills and benefit from the expertise of assessors from other NCAs. Therefore other options to complement this programme should be considered. In particular, a common on-line forum for exchange of views and experiences could be developed. This would include a web tool where advisory groups composed of experiences assessors in the different areas of PV may provide responses to questions, initiate forum discussions, host training tools, etc.

6. Recommendations

This document constitutes the starting point of a future European programme and reflects the needs and views initially expressed by PV experts in NCAs who responded to the specific question in the SCOPE WP8 Survey, with further reflections an elaboration from WP8 active contributors. Therefore, this document constitutes a recommendation for further discussions at the appropriate level.

Thus, the main recommendation is that an EU programme for exchange of PV assessors should be organised within the European Medicines Regulatory Network. For this purpose different aspects are presented in this document including some of the next steps.

In addition, it is also recommended that other activities aimed to those who are not covered by the present proposal should be considered so they may also have the opportunity to improve their knowledge/skills and benefit from the expertise of assessors from other NCAs: exchange of assessment reports, programme of exchanging ideas or questions between assessors, improvement of reports' templates, among others. Additional details will be included in the Recommendations Report for SCOPE WP8.

7. Impact assessment (anticipated)

It is foreseen that a continued programme of exchange of PV assessors in Europe will help to:

- Increase the level of competence of PV assessors in Europe
- Ensure the overall quality of the PV assessments
- Promote pragmatic and consistent approach in the assessment, use of the new and existing tools and a build-up of competences in the MSs' NCAs
- Improve the ability to refine the results, conclusions and actions taken by competent authorities to guarantee the safety of patients and public health
- Enhance the level of involvement of Rapporteurs/Lead MS representative of different MSs at PRAC by enhancing the level of expertise of their teams of assessors
- Enhance collaboration and communication among NCAs across EU.

8. Next steps

Additional work can be identified in the following areas.

Organisational structure

- Set goals and plans for results following appropriate external consultation and endorsement of involved organisations.
- Organisations involved should be defined with roles and responsibilities.
- A name and an acronym will be relevant elements for branding purposes.
- A web portal should be developed which is dedicated to the exchange programme and allows sharing and dissemination of information and electronic application.
- For this purpose a formal presentation to HMA meeting and to the team responsible for EU Network Training Centre is envisaged.

Funding

- An estimation of the cost of the project with an initial budget calculation should be performed. This would be a relevant element in order to study the feasibility of the programme.

Legal issues

- National legislations and organisational characteristics among NCAs might collide with regard to labour legislation, worker insurance issues, etc. Experience with other actual exchange schemes should also be sought. In particular a contact with the EMA team in charge for the current EMA national expert secondment programme would help to clarify some of these issues.

Subsequent to this analysis, a **pilot programme** could be proposed. This can be organised first with a limited number of MSs (e.g. MSs already involved in SCOPE WP8) and objectives. The pilot may serve to assess the feasibility and sustainability of the programme as well as the relevance for the final objective, which is to create a permanent forum for interaction amongst European National Competent Authorities to strengthen regulatory collaboration to strengthen the European and global PV network.