MEMORANDUM OF UNDERSTANDING

INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE AND THE UPPSALA MONITORING CENTRE

1 Parties

1.1 The International Society of Pharmacovigilance, "ISoP" is an international non-profit scientific organisation, which aims to foster Pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines, in all countries.

1.2 Uppsala Monitoring Centre, "UMC", is an independent, non-profit foundation and a centre for international service and scientific research. Its priorities are the safety of patients and the safe and effective use of medicines in every part of the world.

UMC also serves as a Collaborating Centre to the World Health Organization (WHO) where UMC manages the technical and scientific operations of the global pharmacovigilance network, the WHO Programme for International Drug Monitoring.

UMC meet these priorities by innovative research and development, and by providing data, reference, consultative and training resources to medicines regulatory agencies, health professionals, researchers and the pharmaceutical industry all over the world.

2 Purpose

The International Society of Pharmacovigilance (ISoP) and the Uppsala Monitoring Centre (UMC) have a common interest to promote scientific research and practice through the mutual exchange of information on adverse events and risks related to medicinal products. This Memorandum of Understanding establishes a strategic framework for collaboration between ISoP and UMC with a primary focus on Asia and outlines **a pilot project in 2014/2015** to conduct up to two trainings in Asia between the ISOP and the UMC, which will carrying out their common goal to improve global safety and effective use of medicinal products.

3 Expected Benefits

UMC has identified a need to increase education and training efforts in Asia, following in-country visits and interaction with local national centres and an anticipated demand from China as that country becomes a more active member of the WHO Programme for International Drug Monitoring. The UMC can only address some of the identified training requirements. In order to fully reach the target audience and to cover the full scope of pharmacovigilance education and training, UMC foresees an added benefit in joining forces with ISoP's education and training expertise.

4 Cost Sharing

UMC will provide ISoP funding of 10 000 EURO and graphic design services of up to 5 000 EURO to be used for two joint training sessions in Asia during 2014. This financial support would not be intended to fully finance all ISoP operations, but ease the core financial burden on ISoP and increase ISoP financial flexibility to engage in training activities.

4.1 Uses of funding

- Sponsorship for travel of participants (to be determined by ISoP)
- Logistical support (Sophie Spence)
- Support travel of ISoP executive committee members and speakers
- Use as "float" to cover local organizer expenses and reduce financial risk to ISoP
- Speakers will not receive fee for their participation but travel (economic class, and premium economy for flights over 6 hours), accommodation will be provided. While registration fees would be waived. Per diem would not ordinarily be paid but considered on an ad hoc basis

5 Core Requirements

All joint training efforts would be planned and coordinated by ISoP with UMC support in terms of speakers and curriculum. The objective and contents of the curriculum for any specific training programme would be agreed-to in advance by both parties. The training would provide opportunity for members of the Asian PV community to receive increased overall knowledge covering everything within the scope pharmacovigilance from "start to finish".

5.1 All training planned would in general look to focus on some or all of the following topics:

- Harmonization and adherence to international standards for Adverse Drug Reaction reporting systems
- Benefits of structured data within Individual Case Safety Reports (ICSRs)
- The need for high quality data and entry for effective Pharmacovigilance systems
- PV Methodologies
- Industry reporting
- Efficient data management
- ICSR management software tools (home built, vendor provided or WHO standard tools (i.e. - VigiFlow™ and VigiLyze) with emphasis on these UMC preferred tools, while good practice (e.g. – submitting ICSRs to VigiBase using E2B) is promoted when discussing other commercial alternatives.
- Effective data analysis and causality assessment
- Detection of possible risks related to the use of medicines
- Risk minimization strategies
- Regulatory decision making
- Communication and dissemination of pharmacovigilance information towards the public and other stakeholders.
- Clinical and pharmacological assessment of adverse drug reactions

6 Logistics

6.1 Time frame

UMC suggests that one training event takes place in 1st half 2014 or 2nd half 2015. While another training event is scheduled adjacent to the ISoP annual meeting in October 2014.

6.2 Location

Beijing, China, Manila, Philippines, and Jakarta, Indonesia are the designated locations for training. Availability of dates for the National Centres' Meeting in China during Oct 2014 is the determining factor for which location will be selected.

Tianjin **or decided location of ISoP Annual Meeting** is a preferred location for China.

Dr. Ken Hartigan-Go, ISoP executive member and Philippine FDA Director, is ready and able to support training in Manila, **Philippines**.

Indonesia was identified by UMC as a key country due to mandatory reporting for industry was implemented in 2012, the NC has carried out extensive training programs for industry and Indonesia has the highest number of local pharmaceutical companies in ASEAN. They are already informed about a possible interregional course next year and have volunteered as host country.

6.3 Course length

UMC suggests a 3 day course depending on scope, resources etc. The aim is to cover as many topics as possible to make travel to the host country worthwhile both for participants and speakers.

6.4 Curriculum

The aim would be to provide an overall training covering everything from "start to finish" as exemplified in the previous section on Core Requirements.

UMC would cover topics linked to the WHO Programme, data structure and NC specific issues and ISoP would do the same for regulatory aspects and industry perspective. Certainly, some topics (e.g. signal detection, PV methodologies) can be the responsibility of either UMC or ISoP trainers, in which case an agreement can be made on which specific experts would provide that training.

6.5 Faculty and Support

The main faculty would be UMC staff, ISoP speaker(s) and local speaker(s). Which speakers are required will depend on the agenda topics, once agreed. ISoP would be expected to provide logistical support to set up meetings and manage them on-site. UMC assistance will be provided, but ISoP would be expected to take the lead.

6.6 Responsibilities of ISoP

Liaison with UMC for scientific programme, invitation speakers, liaison with LOC for logistics, managing registrations, budget and advertising

6.7 Responsibilities of the LOC

Venue consideration, room facilities, catering/hotel

7 Term, Termination, and Modification

This Understanding will take effect when signed by both ISoP and UMC. This Understanding may be modified or terminated by mutual written consent and may be terminated by either ISoP or UMC upon a 60-day advance written notice to the other.

APPROVED AND ACCEPTED FOR UPPSALA MONITORING CENTRE

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By: Antonio Mastroianni

Chief Operations Officer

Date & Place:

APPROVED AND ACCEPTED FOR INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

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By: Hervé Le Louet

President

Date & Place:

By: Andrew Bate

Chair, Training & Education