MEMORANDUM OF UNDERSTANDING

INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE AND THE UPPSALA MONITORING CENTRE

1 Parties

1.1 ISoP is a global professional, independent, not-for-profit society, open to anyone with an interest in the safe and effective use of medicinal products. ISoP aims to foster science, learning and research in pharmacovigilance in all countries.

1.2 Uppsala Monitoring Centre (UMC) is an independent non-profit foundation and centre for international service and scientific research. UMC's vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Its mission is to support and promote patient safety through effective global pharmacovigilance practice.

UMC also serves as a Collaborating Centre to the World Health Organization (WHO) where UMC provides scientific leadership and operational support to the WHO Programme for International Drug Monitoring.

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 the use of medicinal products. This Memorandum of Understanding establishes a strategic framework for collaboration between ISoP and UMC to conduct training, which will carry 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 globally, following in-country visits and interaction with local national centres and an anticipated demand from countries becoming more active members 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 engaged at Annual Meetings, training courses and regional chapters.

4 Cost Sharing

UMC will provide ISoP funding of 5 000 EURO and graphic design services of up to 2 500 EURO per training course. 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 (ISoP Secretariat)
- Support travel of 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 (economy class, and premium economy for flights over 6 hours), accommodation will be provided. Registration fees for speakers would be waived. Per diem will not be paid.

5 Core Requirements

All joint training efforts would be planned and coordinated jointly by ISoP and UMC 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 and should incorporate the needs of local or regional institutions. The training would provide opportunity for members of the PV community to receive increased overall knowledge covering everything within the scope pharmacovigilance from "start to finish".

5.1 The PV Curriculum would focus on the following topics (based on the published 'WHO-ISoP core elements of a comprehensive modular curriculum'):

- What is and why do we need pharmacovigilance (PV)?
- Fundamental clinical aspects of ADRs
- Important ADRs and "Risk driving" ADRs of important medicines
- "Individual Case Safety Reports" (ICSRs)
- Pharmacovigilance in clinical trials
- Counterfeiting, quality defects and medication errors
- Spontaneous ICSR Reporting Systems (SRS)
- Signal detection and management
- Post-authorisation observational studies and clinical trials in PV
- Benefit-risk-assessment
- Pharmacovigilance- and Risk Management Systems, Risk Management Plans, inspections
- Industry and regulatory authorities, mandatory procedures from legislation
- PV organisation and public health
- Communication
- Sources of information

5.2 Faculty and Support

The main faculty would be UMC staff, ISoP speaker(s) and preferably 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 Logistics

6.1 Time frame

This Memorandum of Understanding is valid until the end of the calendar year when it was signed.

6.2 Location

UMC suggests that trainings take place in locations as specified in the Appendix.

6.3 Course length

Both parties agree on a course length 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 Responsibilities of ISoP

ISoP will be responsible for: the liaison with UMC for scientific programme, invitation of speakers, liaison with LOC for logistics, managing registrations, budget, advertising and evaluation of trainings

6.5 Responsibilities of UMC

UMC will be responsible for: liaison with ISoP for scientific programme, financial support, advertising and evaluation of trainings

6.6 Responsibilities of the LOCs

Venue consideration, room facilities, catering/hotel

7 Term, Termination and Modification

This Memorandum of Understanding shall become effective upon signature by both parties and will remain in force until 31st of December 2016, upon which point this Memorandum of Understanding will expire without prior notice.

Should the UMC or ISoP at any time find that no further collaboration is necessary, the parties shall have the right to terminate this Memorandum of Understanding with a two month notice. The Notification of termination shall be made in writing. Such termination shall not affect ISoP's right to financial support of 5 000 euro (according to section 4) and not either for financial support regarding graphic design services related to training courses (also according to section 4) that are agreed to the day of termination. However, the UMC shall not be liable to financially support the ISoP for graphic design services related to training courses after the termination date.

Modifications of this Memorandum of Understanding should be agreed and signed by both parties.

8 Other terms

If the parties wish to continue to collaborate and enter a new Memorandum of Understanding, to meet the purpose as stated above in clause 2, such negotiations for a new Memorandum of Understanding shall be initiated not later than three months prior to the expiration of this Memorandum of Understanding.

This Memorandum of Understanding has been drawn up in two originals, of which each party has taken one.

APPROVED AND ACCEPTED FOR UPPSALA MONITORING CENTRE

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By: Marie Lindquist, Director

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, Education and Training Programme Committee

Date & Place: _____