

MEMORANDUM OF UNDERSTANDING

BETWEEN

INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

AND

THE UPPSALA MONITORING CENTRE

1 Parties

- (i) The International Society of Pharmacovigilance (ISoP) is a global professional, independent, non-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.

- (ii) The 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 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

ISoP and 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.

In addition to this Memorandum of Understanding, the parties will for each year of the term of this agreement make an Appendix with certain specifics governing the cooperation hereunder.

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 Uses of Funding

The UMC will provide funding per annual agreement as specified in the Appendix for each calendar year.

The funding may be used to cover:

- Sponsorship for travel of participants (to be determined by ISoP)
- Logistical support (ISoP Secretariat)
- Use as "float" to cover local organizer expenses and reduce financial risk to ISoP
- Graphic design services
- Speakers will not be charged a fee for their participation. Travel (economy class, and premium economy for flights over 6 hours) and accommodation will be covered.

Registration fees for speakers would be waived. Per diem will not be paid.

Disbursement of agreed funding from UMC can be requested from ISoP as soon as an agreement has been reached between the parties regarding the venue, time and local organizer of each course specified in the annual appendix.

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 upon 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". The PV Curriculum would focus on the topics based on the published 'WHO-ISoP core elements of a comprehensive modular curriculum'.

5.1 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.

5.2 Target Audience

The prime audience would be pharmacovigilance and health care professionals and when relevant also other stakeholders.

6 Logistics

6.1 Location

Training location as agreed upon annually and specified in the Appendix for each calendar year.

6.2 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.

6.3 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.

6.4 Responsibilities of UMC

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

6.5 Responsibilities of the LOCs

Venue consideration, room facilities, catering/hotel, translation services.

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 2019, upon which point this Memorandum of Understanding will expire without prior notice.

An Appendix of the annual plan and budget shall be produced by 31st of December 2017 and 2018 for each respective following year.

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 for the calendar year during which such termination is done.

Modifications of and Appendices to 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 into 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.

UPPSALA MONITORING CENTRE

INTERNATIONAL SOCIETY OF
PHARMACOVIGILANCE

X

By: Marie Lindquist
Director

X

By: Sten Olsson
President

X

Date & Place:

X

Date & Place