

MEMORANDUM OF UNDERSTANDING

BETWEEN

JSS COLLEGE OF PHARMACY

AND

UPPSALA MONITORING CENTRE

1 Parties

- (i) The JSS College of Pharmacy (JSSCP) is a constituent college of Jagadguru Sri Shivarathreeshwara University, in Mysore, India. JSS University is recognized by the Ministry of Human Resource Development, Government of India as an accredited university. The vision of JSSCP is to be a leader in pharmaceutical sciences & pharmacy practice education, research and continuous professional development for pharmacists with the aim of providing competent patient care and drug development to national and international communities.
- (ii) 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

JSSCP and UMC have a common interest to promote pharmacovigilance training and best practice. This Memorandum of Understanding establishes a strategic framework for collaboration between JSSCP and UMC to conduct pharmacovigilance training in Asia, carrying out their common goal of pharmacovigilance capacity building for the Asia region. In addition to this Memorandum of Understanding, the parties will for each year of the term of this agreement compile an Appendix with certain specifics governing the cooperation hereunder.

3 Expected Benefits

Building sustainable pharmacovigilance systems, particularly in low-and middle-income countries, is one of UMC's strategic goals. Between 2015 and 2017 UMC and JSSCP have organized 3 successful joint Pharmacovigilance courses.

The Indian National Pharmacovigilance Programme (PvPI), started in 2010 has rapidly developed and the responsibility for overall coordination of PV training in India resides with the National PV Centre.

The formal collaboration between UMC and JSS Colleges of Pharmacy, JSS University, Mysore, India (JSSCP) has proved to offer high quality teaching and capacity building in pharmacovigilance practices in support of the development of national pharmacovigilance systems in South Asian countries and beyond.

4 Objectives

Through the collaboration, a yearly training course will be offered including education on the scientific principles of pharmacovigilance and training on best practices in pharmacovigilance based on global experiences, adapted to local needs. The capacity building will focus on training needs of the national pharmacovigilance systems in the region and will emphasize the importance of compliance with global standards.

5 Expected deliverables

JSSCP will consult with PvPI about the dates of conduct of training program and consider to include any particular topic as recommended by PvPI within this framework prior to the initiation of a new course. JSSCP will organize and provide pharmacovigilance education and training per a curriculum that has been developed jointly with UMC. Theoretical elements, discussions and practical exercises will be included. The curriculum will be aligned with that used at the annual UMC pharmacovigilance training course, and training provided will be of the same standard as provided by UMC. Pharmacovigilance tools and methods that are established as best practice within the WHO Programme for International Drug Monitoring (WHOPIDM) will be employed.

The main faculty would be JSS speaker(s) and preferably local speaker(s). Faculty members from the UMC will take part in the execution of the training in person and/or remotely - choice, number and presence of UMC staff is decided by UMC. Which speakers are required will depend on the agenda topics, once agreed.

A maximum of 30-35 students will be admitted at the time to attain high quality of training. Preferably students from several countries in the region will be admitted.

Selection of students lies within the responsibility of JSSCP, with preference given to students working for National Centres within the WHO Programme for International Drug Monitoring. UMC will be provided regular updates on applicants prior to the course and a final list of all students completing the course with their contact details.

The training activities will be marketed by both parties with the names and logos of both

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organizations prominently displayed on marketing material, in compliance with established rules for use of names and logos established by the two organizations. Students who have completed the full course will receive course certificates signed by representatives of both organizations.

Course evaluations, adapted from a standard provided by UMC, will be made after each course and results will be shared with UMC.

The Role of JSS Colleges of Pharmacy

Faculty members will, as far as possible, be recruited by JSSCP, without compromising the quality of the training.

JSSCP will provide suitable premises to host courses, including facilities for lectures, seminars and computerized sessions. Broad-band internet facilities (minimum 10Mb/s) need to be available for video conferencing, distance learning, data management and data retrieval exercises.

JSSCP will arrange for administrative support to manage course preparations, including design and distribution of course announcements, management of applications, acknowledgements and course fees. The administrative service also must include arrangements for accommodation of course participants and their convenient transportation to and from the course venue. Facilities for meals and refreshments for course participants need to be organized by JSSCP.

The Role of UMC

UMC will actively participate in the development of training curricula to be used for the pharmacovigilance courses offered jointly by JSSCP and UMC. The training programme, including its faculty, will be agreed by both parties for it to be presented as a joint training. UMC will be responsible for ensuring that the scientific standard and key messages are in line with what is normally taught at UMC courses. Teaching on pharmacovigilance tools and methods that are specific to the WHOPIDM, e.g. VigiFlow, VigiLyze, WHO dictionaries and UMC signal analysis methods have initially been given by UMC staff but JSSCP and/or PvPI staff can take responsibility also for training on specific WHOPIDM related modules. A representative from UMC will be present during the course, the two weeks can be split between different UMC staff members. Course administration and production of course material will as far as possible be done in India.

UMC will promote the joint training through its normal communication channels.

Principles of cost sharing

To keep course fees at an accessible level for participants from the Asian region, such fees should be based only on direct costs and overheads borne by JSSCP. JSSCP will have the right to charge participants a course fee in advance of commencing the training. Costs for accommodation and student subsistence during the course will not be included in the course fee. Information about alternatives for accommodation and meals will be provided in the course announcement.

UMC will cover its own costs for involvement in the joint training.

6 Term, Termination and Modification

This Memorandum of Understanding shall become effective upon signature by both parties and will remain in force until 31st of January 2019, upon which point this Memorandum of Understanding will expire without prior notice.

7 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.

UPPSALA MONITORING CENTRE

JSS University



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Director/CEO

Dean, Global Engagement

Uppsala June 26, 2017

Mysuru, July 12, 2017

Date and place

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