Monitoring Medicines –

Project Periodic Report

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Final Report	
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Name of the scientific representative of the project's coordinator and organization	
Project Coordinator:	Sten Olsson (UMC)
Project Manager:	Ennita Nilsson (UMC)
Project lead Partner:	Shanthi Pal (WHO)
Project coordinator organization name:	Stiftelsen WHO Collaborating Centre for International Drug Monitoring

Project Website address: www.monitoringmedicines.org

4.1 Final publishable summary report

4.1.1 Executive summary

Pharmacovigilance actively, detect, assess, understand, and prevent adverse effects or any other medicine-related problem for safer patients. Monitoring Medicines project with the full title "Optimising drug safety monitoring to enhance patient safety and achieve better health outcomes" was set up in 2009, **to learn more about the underlying reasons why adverse reactions to medicines occur and what more can be done to reduce patient deaths and negative health impact from undetected medicine safety problems globally.** The consortium of 11 partners from Africa, Europe, and Asia carried out the project for nearly four years, September 2009 to July 2013.

The objective was to coordinate and encourage greater involvement of all stakeholders in a coherent effort to reduce medicine related patient harm and by influencing decision-making policies. Upon its completion in July 2013 this Coordination and Support Action project had achieved its anticipated results and beyond. Piloted activities and studies now develop into bigger research projects and best practice technology to enhance patient safety.

The project stimulated the participation of Small Medium Enterprise (SMEs), established relationships with European and global research schemes and is now disseminating best practices and knowledge across Europe and beyond. By bringing together partners from different parts of the world, coming with different skill sets from different backgrounds, opportunities for innovative solutions have emerged that might not otherwise have been explored.

The work was organised in four main layers:

- Supporting and empowering patients in reporting medicine-related problems
- Pharmacovigilance centres collecting problems related to medication errors
- Better use of existing global pharmacovigilance data
- Strengthening pharmacovigilance systems be developing additional methods

The project has made huge progress over the four years. Although the official end date of the project has passed, new developments and further research opportunities are still emerging from the project.

Key achievements:

- A WHO handbook for reporting of medicine-related problems from the general public was published.
- Practical tools for web-based reporting were developed with patient groups and regulatory authorities and implemented in countries
- Guiding principles for detection, analysis and prevention of medication errors for pharmacovigilance and patient safety centres were developed.
- Methods for identification of products of sub-standard quality from pharmacovigilance databases were developed

- Novel indicators for early identification of potential dependence liability from pharmacovigilance databases were developed and tested
- Comprehensive tools for assessment of patient risks related to HIV/AIDS medicines were developed and made available to the public
- New methods for safety monitoring of medicines introduced in Public Health Programmes were developed and field tested. Handbooks and data management tools were made available to investigators.
- Online tools for assessment of patient risks related to HIV medicines was developed