Learning from the East

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Secondment at Badan POM

During 2013 the UMC put special focus on Asia and specifically the ASEAN region by supporting harmonization efforts around safety reporting requirements and systems. The goal was to ensure stakeholders in the region can collect, share, analyze, and act upon suspected medicines-related safety problems.

A VigiFlow training session in Jakarta

To better understand working processes, daily routines and challenges of pharmacovigilance centres in the region I had a two-week secondment in August at the Indonesian national centre (Badan POM). The objective was to learn about Indonesia's pharmacovigilance processes and interaction with other organizations in the ASEAN region.

Indonesia was part of the WHO Programme in 1975 – the only developing country of the 18 Programme members at the time. Initially a pilot project in six public hospitals, it progressed over the years, but a specific pharmacovigilance unit was not established until 2004, within the National Agency of Drug and Food Control (Badan POM). In 2012 mandatory reporting by pharmaceutical industry came in and Badam POM staff have trained industry in how/what to report.

The collaboration and interactions between the pharmacovigilance unit and other directorates within Badan POM (as well as global organizations) are successful, and there is a political mandate and support from higher management.

I attended the AEFI national committee and national launch of a pentavalent vaccine (for five major childhood diseases: diphtheria, tetanus, pertussis, hepatitis B and Haemophilius influenza type B) produced in Indonesia (Bio Farma) which demonstrated just how important collaborations are in pushing forward pharmacovigilance in a country.

Indonesia is large geographically, with over 250 million people, and to succeed in all provinces is a major task. With its own systems, including an electronic ADR reporting for HCPs 'e-MESO' UMC is supporting them in implementing VigiFlow as part of the handling of case reports from both industry and HCPs. With 31 regional offices VigiFlow could enhance the PV unit's collection of case reports from as many provinces as possible.

My time with Head of Pharmacovigilance Ms Siti Asfijah Abdoellah and her dedicated team was truly awarding. I had the great pleasure to spend time with everyone in the team and gained a clear picture how they work and useful insights into how UMC services and tools are implemented (or not) and why.

On to Viet Nam

Vietnam joined the WHO Programme in 1999, but the first pharmacovigilance centre in Hanoi was established in 1994. Since 2009 the National DI & ADR Centre has undertaken all PV activities on behalf of the Regulatory Authority (DAV) and is now located at Hanoi's University of Pharmacy (HUP). The NC's dedication and target-oriented work has led to great progress. An independent centre that combines expertise from both academia and hospitals, it also has a close collaboration with DAV. 15 staff, mainly pharmacists, support the NC's core job to ensure rational use and effective drugs by:

Dr. Nguyen Hoang Anh (Technical Vice Director DI & ADR Centre), Dr. Vo Thu Thuy (Administrative Vice Director DI & ADR Centre), Helena Wilmar (UMC), Comfort Suku (Global Fund)

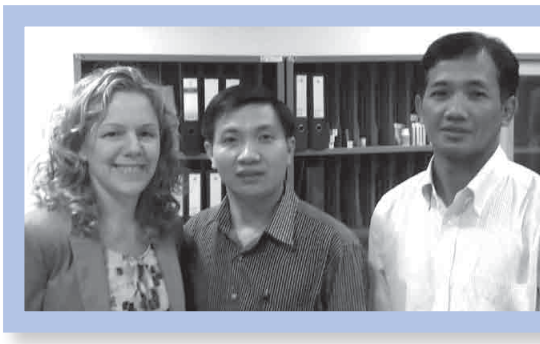
- Data collection, analysis and evaluation
- Feedback on ADRs, substandard drugs and irrational drug use
- Information to HCPs and the public
- Under/post-graduate training
- Research projects
- Consultation services
- International cooperation (WHO, UMC, MSH, ISoP, other NCs).

Close collaboration with public health programmes is ongoing and projects involving CEM on ARVs and second-line anti-tuberculosis drugs as well as targeted spontaneous reporting (TSR) of ARVs are part of the centre's scope.

The Vietnamese DI & ADR Centre is in many ways already functioning effectively. However, as well as creating a national system based on local requirements, there is also a need for global harmonization of ICSRs data. National Centre–UMC discussions on how to share data from the newly-launched Vietnamese database on a regular basis with VigiBase are on-going.

Potential in Cambodia

The Pharmacovigilance Center in Cambodia is part of the Essential Drug Bureau, Department of Drugs and Food (DDF). DDF consists of 75 staff in five Bureaus; Drug Regulation, Pharmaceutical Trade, Drug Registration, Food Safety and Essential Drug. Cambodia joined the WHO Programme in 2012 and since then has received around 400 ADR reports. They use VigiFlow to send reports to the UMC, but the complete version of VigiFlow is desired, to both collect and manage all Cambodian case reports.



UMC's Helena Wilmar, PV Head Mr. Sea Thol and Dr. Cheap Thon Vuthy

Mr. Sea Thol, Deputy Chief of the Essential Drug Bureau and the Head of CPVC, has a tough mission (with his tiny staff team) trying to make medicines safer for more than 15 million people in Cambodia. Guidelines and SOPs are already in place; funding and a political mandate are yet to be fully realized.