



Centre of Regulatory Excellence In-Country Training on Pharmacovigilance

10 – 11 August 2017
Phnom Penh, Cambodia



Introduction

The Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School, with the support of the Asian Development Bank (ADB), was pleased to conduct a training workshop on pharmacovigilance (PV) in Cambodia from 10 - 11 August 2017.

The training programme was designed to address key needs of the national regulatory authority (NRA) in Cambodia with respect to PV, by helping to increase support for PV activities, improve stakeholder engagement and increase adverse drug reaction (ADR) reporting.

Participants & Faculty

The workshop was attended by 73 participants. Overall, 12 participants were from the NRA or government (i.e. Ministry of Health (MoH) or Cambodian Pharmacovigilance Centre); 13 participants from hospitals or public health programmes, such as the National Center for Parasitology, Entomology and Malaria Control; and the remaining 48 participants were regulatory professionals from the provinces. The workshop served as a valuable platform for interaction and exchange between participants from Phnom Penh and the provinces.

The workshop faculty consisted of three subject matter experts including Ms. Adena Lim from the Health Sciences Authority (HSA) of Singapore, Ms. Deliana Aboka from the Uppsala Monitoring Centre (UMC), and Dr. Jean-Christophe Delumeau from Bayer Southeast Asia and the International Society of Pharmacovigilance (ISoP).

Opening Address by Her Excellency Dr. Or Vandine

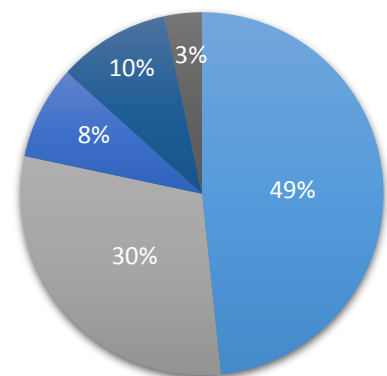


Her Excellency Dr. Or Vandine, Director General of Health, MoH, was the Guest of Honour at the opening of the PV workshop. Sharing her insights and experience in her opening address, she encouraged participants to stay vigilant, and emphasised the important contribution of PV to improving healthcare. She urged participants to apply their knowledge, follow up on reports with the MoH, and share their knowledge with others.

The workshop objectives were to:

1. Equip participants with messaging and a general stakeholder engagement strategy to enable them to seek more support for PV activities.
2. Clarify the process of ADR report collection and identify opportunities for its optimisation.
3. Increase awareness of risk management plans and their significance for patient safety and stakeholder engagement.

Breakdown of Participants by Workplace



- Hospital
- Regulatory Authority - Provincial Office
- Regulatory Authority - Central Office
- Ministry of Health
- Others

Workshop Sessions

The workshop was divided into three, half-day sessions, each addressing one of the workshop objectives.

Session 1: Protecting Public Health through PV

To address the need for increased support for PV activities and better communication among stakeholders, the aim of the first workshop session was to equip participants with relevant messaging and a general stakeholder engagement plan. The participants were provided with pre-reading materials that included real-life examples to illustrate how PV contributes to patient safety. The inclusion of malaria-related examples in the pre-reading material helped demonstrate the importance of PV while increasing awareness of the challenges posed by drug-resistant malaria.

Session 2: Improving ADR Reporting

The second workshop session aimed to discuss two complementary approaches to increase ADR reporting: by reviewing and identifying opportunities to optimise the ADR reporting workflow and related processes, and by motivating stakeholders to submit ADRs. The pre-reading material for this session reviewed concepts fundamental to ADR reporting, including definitions and basic workflow as well as tools and resources for ADR report collection.

Session 3: Risk Management Planning: Requirements and Considerations

The third workshop session applied risk management planning to illustrate the link between signal identification and policy decisions, highlighting the importance and impact of PV activities while describing another means of stakeholder engagement. More specifically, this session aimed to increase awareness of risk management plans and the role they play in providing feedback and updated safety information to PV stakeholders.

Feedback

The post-workshop survey yielded very positive feedback.

Participants agreed that the workshop had met its stated objectives and 94% found the topics relevant. Further, 96% felt that the training material supported their learning and that they had indeed gained new knowledge and skills. 86% believed that they could apply learnings from the workshop to their own work, such as the ideas shared on communication and stakeholder engagement, managing ADR data, and clarifying roles and responsibilities.

96%

**Gained New Knowledge
and Skills**

94%

**Found the Topics
Relevant**

86%

**Can Apply Learnings
To Work**

As a follow-up to this PV workshop, the faculty recommended collaborating with the Uppsala Monitoring Centre and the World Health Organisation to take a sustained, strategic approach to training.