APMEN TechTalks Webinar Report
Hosted by the APMEN VxWG

"Pharmacovigilance of Antimalarial Drugs"

Monday, 7 November 2022. 1 PM Singapore time

Introduction

The Asia Pacific Malaria Elimination Network (APMEN) is a sustainable, collaborative network for the delivery of technical malaria expertise and uses a brokering approach to connect national malaria control programs (NMCPs) with relevant technical information. APMEN comprises of National Malaria Programmes from 21 countries and 52 Partner Institutions. The APMEN Secretariat works closely with partners to facilitate regional and multi-sectoral collaboration around evidence-based practices and research to reach the goal of malaria elimination in the region. APMEN facilitates technical exchange through its three Working Groups on Surveillance & Response, Vector Control and Vivax.

The APMEN Vivax Working Group (VxWG) is significantly shifting the focus from research & development to policy & optimized implementation. The VxWG has been working on the implementation challenges faced by countries and supporting them with decision making tools while considering the introduction of new tools for radical cure. The goal of the VxWG (2021-2022) is to contribute towards accelerating the uptake and implementation of optimized radical cure for vivax malaria.

The 'APMEN TechTalks' series focuses on the specific thematic areas of the APMEN Working Groups, namely Vivax, Vector Control and Surveillance & Response. It aims to highlight key technical areas of interest and facilitate knowledge exchange around research and implementation, latest guidelines as well as lessons learned from the field.

Webinar description

Pharmacovigilance system strengthening has been identified by the Asia Pacific National Malaria Programs as a key priority to support vivax malaria elimination, through an extensive prioritization exercise conducted by the APMEN Vivax Working Group. In this webinar, a panel of experts from WHO, Thai FDA, and Drug Regulatory Authority of Pakistan (DRAP) will discuss how pharmacovigilance of antimalarial drugs can be strengthened and integrated into research and routine public health systems.

Facilitator

- **Dr. Caroline A. Lynch**, Co-chair, APMEN VxWG and Regional Advisor, MMV, Chiang Mai, Thailand

Speakers/ Panellists

- **Dr. Shanthi Pal,** Team Lead, Pharmacovigilance, World Health Organization, Geneva, Switzerland
- **Dr. Watcharee Rungapiromnan,** Pharmacist, Health Product Vigilance Center, Thai Food and Drug Administration, Nonthaburi, Thailand
- **Dr. Obaidullah,** Director, Drug Regulatory Authority of Pakistan, Islamabad, Pakistan

Webinar Q&A

Q&A Box

Muhammad Farooq Sabawoon	Thanks for the presentation, and these are very informative. I was wondering if there is any line of demarcation between adverse effect and idiosyncrasy? How this will be interpreted if someone is showing some reactions to primaquine/tafenoquine? Is it adverse event or an idiosyncrasy? Any guidance that will help out?
Dr. Shanthi Pal	Idiosyncratic drug reactions are Type B reactions defined as adverse reactions that cannot be explained by the known mechanisms of action of the offending agent, do not occur at any dose in most patients, and develop mostly unpredictably in susceptible individuals. It is considered a reaction (and not an event) in the sense that it is caused by the drug, PV helps capture this but may not help identify the mechanism. Hope this clarifies

Fe Espino	Great presentation, Dr. Pal. What are the minimum PV requirements for low resource NRAs and how are capacity and competency assessed? Many thanks!
Dr. Shanthi Pal	Minimum Requirements for a Functional National Pharmacovigilance System The following are the minimum requirements that the WHO and partners agree should be present in any national pharmacovigilance system. 1. A national pharmacovigilance centre with designated staff (at least one full time), stable basic funding, clear mandates, well defined structures and roles and collaborating with the WHO Programme for International Drug Monitoring. 2. The existence of a national spontaneous reporting system with a national individual case safety report (ICSR) form i.e. an ADR reporting form. 3. A national database or system for collating and managing ADR reports. 4. A national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication. 5. A clear communication strategy for routine communication and crises communication

Sanjaya Acharya	What kind of studies will suffice for post market approval for PV of antimalarial drugs?
	Generally, the Thai FDA does not require marketing authorization holders (MAHs) of conditional drugs (e.g. tafenoquine) to conduct studies. However, Medicines Regulation Division will make a decision how to monitor the safety profile of drugs based on existing evidence at the time of drug approvals and the drug risk. MAHs of drugs without conditional drug status (e.g. primaquine) are not required to conduct studies during post market approval.

	For tafenoquine, the Thai FDA does not mandate the Department of Disease Control (DDC) to conduct the feasibility study of tafenoquine. The DDC decided to conduct the study by itself.

Sanjaya Acharya	What should be reported as an AE? How to prevent over-burdening of the system? Should every side effect be reported or should health workers decide themselves what is and is not an AE?
	The Thai FDA mandates MAHs of conditional drugs to send all adverse events since this kind of drug status tends to be new drugs. The safety profile of drugs is limited. As you can see in the presentation of Shanti, thousands of people involving in studies of medicine during phases 1-3 before drug approval, it is difficult to find all or most adverse events during these periods, the Thai FDA requires MAHs to report all adverse events during drug conditional drug status which takes about two years which is not long period. Healthcare professionals in hospitals voluntarily report adverse events to the Thai FDA. If they have burden of their work, we encourage them to report serious adverse events. The Thai FDA encourages the study sites of the feasibility study of tafenoquine report all adverse events due to small number of patients receiving tafenoquine. Moreover, its safety profile is limited.

Bipin Adhikari	Why are pharmacovigilance system/activities heterogenous between different countries? is the PV system poor in LMICs in general?
	The main goal of pharmacovigilance is to promote the safe and effective use of health products. Since different countries have different resources (e.g. human resources, facilities) and healthcare systems, these countries develop or use a pharmacovigilance system/activities which suit their circumstances.

Chat Box

Binyam Kassa	kindly elaborate on reliance of countries with low resources on other capable countries -collaboration
Dr. Shanthi Pal	Dr Kassa - Reliance can be applied in various activities such as adopting/adapting assessment reports of risk management plans from other authorities. In other words, a country could use the core RMP assessment report on tafenoquine and only add additional activities such as feasibility studies for their own settings