Pharmacovigilance Workstream

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PV Workstream coordinators and co-chairs

PSM Working Group

History…

- Created in 2009 to guide:
  - *Responsible drug use*
  - *Rational procurement*
  - *Rational use*

Terms of Reference of PV Workstream

- To facilitate and guide the various international and in-country efforts in pharmacovigilance of antimalarials on behalf of RBM's PSM-WG
- To create a central repository of all independent ***malaria-focused*** pharmacovigilance activities
- To work with all partners including the WHO on resource mobilization for PV
- To assist countries in the implementation of PV programmes
- To contribute to the advocacy process for PV in malaria-endemic countries

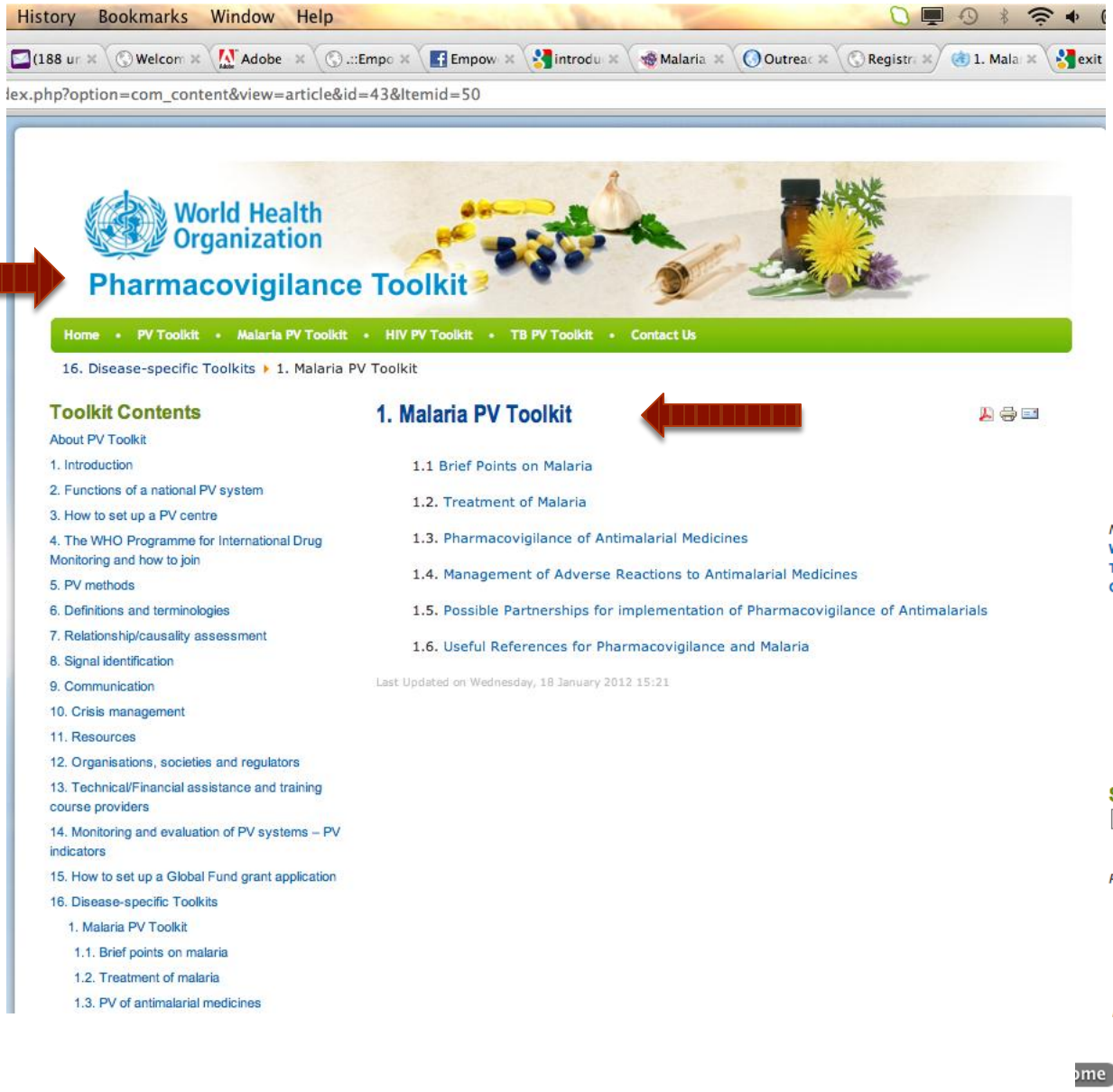
Activities / Achievements

Provided support to countries (PRs) for completing GF proposals

- Developed template to support PRs in completing proposals for malaria-focused PV activities
- Template included a mix of key activities and corresponding budgets
- Approach applied by several malaria-focused grants

Development of malaria-specific PV toolkit

- www.pvtoolkit.org
- http://www.pvtoolkit.org/index.php?option=com_content&view=article&id=43&Itemid=50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World Health Organization
Pharmacovigilance Toolkit
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16. Disease-specific Toolkits ▸ 1. Malaria PV Toolkit
Toolkit Contents
About PV Toolkit
1. Introduction
2. Functions of a national PV system
3. How to set up a PV centre
4. The WHO Programme for International Drug Monitoring and how to join
5. PV methods
6. Definitions and terminologies
7. Relationship/causality assessment
8. Signal identification
9. Communication
10. Crisis management
11. Resources
12. Organisations, societies and regulators
13. Technical/Financial assistance and training course providers
14. Monitoring and evaluation of PV systems – PV indicators
15. How to set up a Global Fund grant application
16. Disease-specific Toolkits
1. Malaria PV Toolkit
1.1. Brief points on malaria
1.2. Treatment of malaria
1.3. PV of antimalarial medicines
1. Malaria PV Toolkit
1.1 Brief Points on Malaria
1.2. Treatment of Malaria
1.3. Pharmacovigilance of Antimalarial Medicines
1.4. Management of Adverse Reactions to Antimalarial Medicines
1.5. Possible Partnerships for implementation of Pharmacovigilance of Antimalarials
1.6. Useful References for Pharmacovigilance and Malaria
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Partners:
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ROLL BACK MALARIA

Published article on malaria ADRs published in malaria journal

- Assessment of ADRs caused by ACTs and AMTs
- http://www.malariajournal.com/content/10/1/57/abstract

Research

Highly accessed Open access

Assessment of global reporting of adverse drug reactions for anti-malarials, including artemisinin-based combination therapy, to the WHO Programme for International Drug Monitoring

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Abstract

Background

In spite of enhanced control efforts, malaria remains a major public health problem causing close to a million deaths annually. With support from several donors, large amounts of artemisinin-based combination therapy (ACT) are being deployed in endemic countries raising safety concerns as little is known about the use of ACT in several of the settings where they are deployed. This project was undertaken to profile the provenance of the pharmacovigilance reporting of all anti-malarials, including ACT to the WHO adverse drug reaction (ADR) database (Vigibase™) over the past 40 years.

Methods

The WHO Programme for International Drug Monitoring, the Uppsala Monitoring Centre (UMC) provided anonymized extracts of 2008. All countries in the programme were clustered according to their malaria control

Mapped malaria focused pharmacovigilance capacities and activities in countries served by the AMFm

- Key points
  - Mapping of ten AMFm phase 1 countries-- Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Tanzania, Zanzibar and Uganda
  - Data collection through a structured questionnaire sent to PV centres of the corresponding countries, and follow-up phone interviews
  - Report published in January 2011

Promoted pro-pharmacovigilance policies with major donors and countries

- Hosted an RBM session and promoted the need for PV during the International Society of Pharmacovigilance meeting in Accra, Ghana 03-06 November 2010
- Participated at the PV stakeholders meeting, Accra, Ghana, 2010

2012 and beyond

- Market has evolved: from single ACT– Coartem– to a plurality of ACTs (not just suppliers, but drugs)
- Large number of 'unapproved' suppliers of mono-combo therapy
- Issues of…
  - Therapeutic ineffectiveness (quality issues)
  - Potential resistance
  - OTC status
  - Irrational use
- The example of AS-AQ and dystonia: allegations of cover-up
  - Reports analysed
  - Signal Published (May 2011)
    - First ever signal based exclusively on data from Africa
  - SPC being updated

- Pharmacovigilance:
  - watchdog that
    - Provides evidence
    - Informs policies
    - Improves use
    - Ensures public confidence on access programmes
- PV workstream in CMWG….
- PV needs to continue, regardless of where it is hosted…