Supporting Global Pharmacovigilance Efforts to Ensure Rapid and Responsible Adoption of Artemisinin Combination Therapies

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The Terms of Reference (TOR) of the Procurement and Supply Chain Management Working Group (PSMWG), which were updated by the RBM Board in May 2010, indicate that the PSMWG is mandated by the RBM partnership Board to coordinate RBM partners in their efforts to support the implementation of PSM activities in country operational plans.

Therefore, in principle, the PSMWG Pharmacovigilance workstream's mandate is to coordinate RBM partners in their efforts to support the implementation of pharmacovigilance activities in country operational plans for malaria control.

**Background:**

The last few years have seen an increased and concerted effort by several global players including the World Health Organisation, the Roll Back Malaria Partnership and the Bill & Melinda Gates Foundation to provide the tools, interventions and resources needed to control malaria with a view to elimination and eradication as soon as feasible. One of the cornerstones of these campaigns is increased availability of good quality affordable artemisinin-based combination treatment (ACT) for the management of uncomplicated malaria. The aim is to ensure that ACTs are available to everyone who needs them in all settings. Such widespread deployment of ACTs needs to be accompanied by robust pharmacovigilance (PV) systems to assure patient safety. The WHO has, since 2003, carried out several training programmes on PV of antimalarials and has also trained a group of African health professionals to act as consultants on PV of antimalarials. In addition, the WHO’s Collaboration Centre for International Drug Monitoring, the Uppsala Monitoring Centre (UMC), has been providing the tools and technical support necessary for effective PV of antimalarials to all countries participating in the global PV programme. These efforts need to be complemented by those of other partners including the PSMWG in order to raise the needed funds and provide the expected advocacy and technical assistance to ensure optimum development and deployment of PV systems in countries where ACTs are being rolled out on a large scale.

This concept paper describes the activities required for effective deployment of comprehensive and robust pharmacovigilance systems and solutions for countries deploying ACTs.

**The objectives and activities of the PV Workstream are:**

1. To coordinate and guide the various international and in-country efforts in pharmacovigilance of antimalarials on behalf of RBM’s PSMWG:
   Activities:
   a. Map out and create (and/or update) a central repository of all independent malaria-focused pharmacovigilance activities (by country and by type of activity)
b. Inform pharmacovigilance organizations regarding on-going activities (perhaps via a regular newsletter or a dedicated website or list-serve)

2. To participate in policy development on PV for antimalarials in collaboration with WHO
Activities:
   a. With WHO as a lead, to provide support to countries that do not have a policy for pharmacovigilance
   b. Provide technical support in conducting the assessment of ACT adverse drug reactions (ADRs) received to date [this is a follow on activity from the one that was recently completed and published in the malaria journal]

3. To work with all partners including the WHO on resource mobilization for pharmacovigilance.
Activities:
   a. Develop proposals to request funding for pharmacovigilance from various donors, including bilateral agencies as well as charitable foundations and non-governmental organizations.
   b. Provide support in obtaining funding from donors (support in completing proposals, etc)
   c. Coordinate with GF Round 8-9-10 countries to provide them technical assistance in developing and implementing pharmacovigilance plans.

4. To assist countries in the implementation of PV programmes
Activities:
   a. Disseminate and adopt technical and implementation tools for conducting pharmacovigilance which can be used by all countries that are interested in implementing pharmacovigilance [expand on pharmacovigilance tool kit, which has already been launched]
   b. Provide support to 5-10 malaria-endemic countries using ACTs
      i. Provide support in building local capacity (HR, IT, and systems) and in implementing pharmacovigilance programs
         1. For implementing CEM studies
         2. For establishing pregnancy registers
         3. For establishing systems for spontaneous reporting
         4. For conducting Phase IV studies
      ii. Catalyze more countries to become full member of the WHO’s Pharmacovigilance Program
      iii. Provide training in the conduct and implementation of pharmacovigilance to these countries.

5. To contribute to the advocacy process for PV in malaria-endemic countries
Activities:
a. Provide evidence of the work carried out to policy makers, governments and global multi-lateral agencies including funding organisations
b. Publish papers
c. Present papers and findings in international symposia

**Deliverables:**

1. A central repository of all independent malaria-focused pharmacovigilance activities (by country and by type of activity).
2. Regular updates to pharmacovigilance organizations.
3. Technical support for the ACT ADR assessment.
4. Support to countries that do not have a PV policy.
5. Technical assistance to GF Round 8,9, 10 recipient countries on the development and implementation of PV plans.
6. Support to countries in obtaining funding for PV.
7. Dissemination of technical and implementation PV tools.
8. Assistance to 5-10 malaria endemic countries in the implementation of pharmacovigilance programs.
9. Publications and presentations on ACT pharmacovigilance.

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