



RESOLUTION
RBM/BOM/2010/RES.1 29
APR 2010

General distribution
English, French

RBM Board Meeting – Geneva 12 - 14 May 2010

18th RBM Board Resolution on ACT Manufacturing in Malaria Endemic Countries

Context

The increased funding available to malaria-endemic countries for scaling up treatment will create a significant increase of the demand for artemisinin combination therapies (ACTs). Many pharmaceutical manufacturers, particularly in Sub-Saharan Africa (SSA), have deployed significant efforts to meet the standards of Good Manufacturing Practices (GMP) and ensure that their products achieve WHO prequalification status. To date, none of the ACTs produced in SSA have obtained WHO Prequalification and therefore do not meet Global Fund quality assurance (QA) requirements and to date, only one SSA company has received a WHO pre-qualification; a Ugandan manufacturer of ARVs.

The Board applauds and encourages the efforts of manufacturers from malaria endemic countries to reach WHO prequalification standards as this will ensure greater availability of high quality ACTs. The RBM Partnership therefore wishes to advocate for approaches / activities which would lead to an increase in the number of ACT manufacturers meeting the WHO prequalification standard, including manufacturers in SSA where possible, of course, without any compromise in the quality.



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The RBM Board therefore:

- 1) **Encourages** ALMA's continued leadership at national and regional level, together with partners, to explore opportunities for local manufacturing of essential malaria commodities;
- 2) **Advocates** for the continued strengthening of the technical capacity of National Drug Regulatory Authorities in malaria endemic countries thus strengthening their ability to ensure the quality of medicines including ACTs circulating in the countries;
- 3) **Advocates** for continued strengthening of the capacity of manufacturers in endemic countries in order to meet GMP standards and WHO pre-qualification;
- 4) **Encourages** WHO to disseminate widely and pro-actively, all relevant information with regard to the required global standards and prequalification process;
- 5) **Encourages** relevant technical partners to identify obstacles impeding ACT manufacturers in malaria endemic countries from achieving prequalification. In line with this, the RBM Board calls on:
 - a) **Relevant partners** to support ACT manufacturers to access technical information and guidance to upgrading manufacturing facilities and processes to achieve WHO prequalification;
 - b) **ACT manufacturers in malaria endemic countries**, to pursue joint ventures, as appropriate, with partners who can provide investment, technology transfer - including technical assistance - and access to markets;
 - c) **WHO, UNICEF and/or donor agencies** to continue the practice, as appropriate, to have manufacturers who have submitted a dossier for, and are near to obtaining WHO Prequalification, to be informed of all relevant quality assurance meetings, for a better understanding of the environment in which tenders take place and accelerating access;



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- 5) **Calls upon the donor constituency** to further support the strengthening and expansion of the WHO Prequalification Program's capacity to process prequalification dossiers and provide technical assistance;
- 6) **Urges governments** to provide the required enabling environment to support the manufacturing quality ACTs and/or enact laws to ensure only quality medicines are manufactured and or distributed in the country;
- 7) **Requests the Secretariat**, with the support of relevant technical partners, to provide the Board with an annual update on the number of manufacturers that have been pre-qualified by WHO.

Adopted by RBM Board on 14 May 2010

Thomas Teuscher for RBM Secretariat