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REMOVAL OF ORAL ARTEMISIN MONOTHERAPIES

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Issue: The parasite that causes the most dangerous form of malaria - **Plasmodium falciparum** has developed resistance to all previous first-line treatment therapies, but new combination medicines containing artemisinin derivatives show an over 95% cure rate. Artemisinin derivatives need to be used in combination with other effective antimalarial medicines for the treatment of uncomplicated falciparum malaria. However, the widespread practice of using oral artemisinin-based monotherapies, which are easier and cheaper to produce and buy, poses an enormous risk and could result in the loss of artemisinins to parasite resistance. Removal of artemisinin-based monotherapy depends on effective drug regulation at country level. Only the removal of marketing authorizations for oral artemisinin-based monotherapies will make them unavailable in the public and formal private sectors. Persistence of artemisinin monotherapy in the informal private sector, which is common in many malaria-endemic countries, can be overcome by the provision of good access to quality medicines through a national drug supply management system.

In 2007, the World Health Assembly adopted a resolution to progressively remove oral artemisinin-based monotherapy from the market and replace it with artemisinin-based combination therapies (ACTs) for the treatment of uncomplicated falciparum malaria. Globally, 34 countries have withdrawn marketing authorization for oral artemisinin-based monotherapy, but 28 countries have not yet taken regulatory action, including 18 in Africa. Out of 76 companies involved in the production and marketing of these medicines, a total of 36 companies have de-listed oral artemisinin-based monotherapy from their product catalogues but 40 companies, mainly those targeting the private sector markets of malaria-endemic countries, are still actively providing monotherapy.

ALMA action on removal of oral artemisinin monotherapies: In partnership with WHO, and RBM, ALMA is urging all ALMA countries to ensure that regulatory measures to stop marketing of oral artemisinin-based monotherapies and to promote access to artemisinin-based combination therapies (ACTs) are in place by end 2010.