

REPORT OF THE WORKSHOP ON
DISSEMINATION OF INFORMATION ON
REGULATORY AFFAIRS, (39TH
MEETING OF DRUGS CONSULTATIVE
COMMITTEE)

HELD ON 10TH DECEMBER, 2008
AT FDA BHAWAN,
KOTLA ROAD, NEW DELHI.

CDSO

CENTRAL DRUGS STANDARD
CONTROL ORGANISATION
DIRECTORATE GENERAL OF HEALTH
SERVICES
MINISTRY OF HEALTH AND FAMILY
WELFARE

AGENDA NO. (2)**PHASING OUT OF ORAL SINGLE DRUG FORMULATIONS OF ARTEMISININ AND ITS DERIVATIVES FROM THE MARKET ON THE RECOMMENDATIONS OF WHO**

The office of DCG (I) had earlier approved various anti malarial formulations of Artemisinin derivatives like artesunate, artemether, arteether for marketing in the country. As the drug is no longer considered as a new drug, permission for manufacture for sale of these drugs is at present being granted by the State Licensing Authorities. Artesunate and artemether have been approved both in injectable form as well as oral tablet/capsule form while arteether is approved in injectable form only. Currently many firms are manufacturing various formulations of artemisinin derivative in the country.

Various artemisinin based combination (ACT) products like artesunate + sulphadoxine – puiithamine, artemether + lumefantrine , artesunate + mefloquin have also been approved by this Directorate for marketing in the country.

WHO has recommended withdrawal of oral artemisinin based monotherapies from the market to ensure that malaria parasite does not become resistant to the drug. It recommends the use of artemisinin in combination with other effective anti-malarial as artemisinin based combination therapy (ACTs) for the treatment of uncomplicated falciparum malaria. In a high level meeting held on 13-14 October, 2008 at WHO regional office for South East Asia Region, New Delhi on anti-malarial treatment it has been recommended that the State Licensing Authorities should withdraw the manufacturing licences and export licenses for marketing oral artemisinin monotherapies in a period of 6 months i.e. by July, 2009, as finished formulations.

In view of the above recommendations and to ensure that artemisinin derivatives remain effective in the treatment of resistant malaria, the State Licensing Authorities should not grant any new manufacturing license or renew any licence for marketing oral artemisinin monotherapies and withdraw the permissions granted to manufacturers under their jurisdictions for marketing artemisinin monotherapies within a period of six months.

DCC may kindly deliberate and formulate roadmap for the implementations of the recommendation.

RECOMMENDATIONS

Shri A.K. Pradhan, ADC (I) briefed the members that artemisinin derivatives, artesunate and artemether were approved for manufacture and marketing both in injectable form as well as tablets/capsule form and are being marketed in the country by various manufacturers. In order to ensure that malaria parasite does not become resistant to the drug, WHO has recommended for the withdrawal of oral artemisinin based mono therapies from the market. It has further recommended the use of artemisinin in combination with other effective anti-malarial as artemisinin based combination therapies (ACTs) for the treatment of uncomplicated falciparum malaria.

The members after deliberations agreed that oral single drug formulations of artemisinin derivatives like artesunate and artemether should be withdrawn from the market in a phased manner and the following steps may be taken for the purpose.

- (v) No new licence should be granted for the said formulations.
- (vi) Manufacturing licences granted earlier should be withdrawn by March 2009.
- (vii) The formulations should be phased out from the market by July 2009.
- (viii) DCG (I) office should issue directive to all State Drug Controllers in the matter for uniform compliance in the country.

Speed Post



Dr. Surinder Singh
DRUGS CONTROLLER GENERAL (INDIA)

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F.No. X-19013/1/2009 -D
Dated, the 19th June, 2009.

To,

All State Drugs Controllers

Sub: Phasing out of oral single drug formulations of artemisinin and its derivatives from the market by July 2009 – regarding.

Sir,

The formulations of artemisinin derivatives, artesunate and artemether have been permitted for manufacture in the country as anti-malarial formulations both as injectable and capsule/tablet form. In order to ensure that malaria parasite does not become resistant to the drug, WHO recommended for the withdrawal of oral artemisinin based mono therapies from the market. It however, recommended the use of artemisinin in combination with other effective anti-malarials as artemisinin based combination therapies (ACTs) for the treatment of uncomplicated falciparum malaria.

The question of phasing out of oral single drug formulations of artemisinin and its derivatives from the market was considered in the 39th meeting of the Drugs Consultative Committee held on 10th December 2008 at FDA Bhawan, Kotla Road, New Delhi. The committee after deliberations agreed that oral single drug formulations of artemisinin derivatives like artesunate and artemether should be withdrawn from the market in a phased manner by July 2009, and the following steps may be taken for the purpose.

1. No new licence should be granted for the said formulations.
2. Manufacturing licences granted earlier should be withdrawn by March 2009.
3. **The formulations should be phased out from the market by July 2009.**

The Minutes of the meeting were forwarded to all State Drugs Controllers in March, 2009.

It is therefore, requested that in compliance to the above decision, you may kindly ensure that oral single drug formulations of artemisinin derivatives like artesunate and artemether are not permitted to be manufactured or sold under your jurisdiction after 31st July 2009.

Action taken in the matter may kindly be intimated to this office.

Yours faithfully,

(Dr. Surinder Singh)
Drugs Controller General (India)