सत्यमेव जयते

Dr. Surinder Singh
Drugs Controller General (India)

F. No. 4-1/2011-DC (Pt. FDC Misc-17)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi-02
Dated 25 APR 2011

To,
All State Drugs Controllers

Subject: **Artemisinin-based Combination Therapy.**

Sir,

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agreed that oral single drug formulations of Artemisinin derivatives like Artesunate and Artemether should be withdrawn from the market in a phased manner by July 2009.

WHO wrote again in November 2010 that there is increasing evidence that the continued use of the Artemisinin derivatives as monotherapy is one of the main factors which contributes to the development and spread of resistance. Resistance to Artesunate was first reported in 2009 in limited geographical area at the Thai-Cambodian border, where Artemisinin have been used alone as monotherapies for many years, especially in the private sector.

Artemisinin based combination therapy is the first line of treatment for all P. Falciparum malaria cases around the world. Monotherapy with the Artemisinin has been withdrawn in India also. However, it has been brought to the notice of this office that some of the manufacturers are exporting the monotherapies of Artemisinin to other countries. Monotherapy with Artemisinin poses a great threat to global malaria control as resistance in any part of the world can be detrimental to the use of Artemisinin-based Combination Therapy in other parts of the world.

In view of above, it is requested that the manufacturing licence granted to the manufacturers to manufacture the same should be cancelled with immediate effect. Further, manufacturing of the monotherapy of Artemisinin for export to other countries should also be stopped with immediate effect.

A list of the manufacturers/ exporters provided by the Ministry of Health & Family Welfare is enclosed herewith for necessary investigation and taking necessary action in the matter.

It is also requested that immediate measures may be taken in this regard and the action taken intimated to this office immediately.

Yours faithfully,

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

Copy to:-
1. All Zonal/subzonal/port offices of CDSCO for infomation and follow up.

Copy forwarded for information to:-
PS to Joint Secratary, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.
(Kind Attention :- Sh. R.S. Shukla, J.S.)

F. No. 4-1/2011-DC (Pt. FDC Misc-17)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services

FDA Bhawan, Kotla Road,
New Delhi-02

Dated 26 APR 2011

Office Memorandum

Subject: **Artemisinin-based Combination Therapy.**

This is in continuation to this letter no. 4-01/2011-DC (Pt. FDC Misc-17) dated: 25.04.2011 on the subject cited above.

In this regard, you are directed to ensure that no consignment of oral single drugs formulations of Artemisinin and its derivatives is exported from India with immediate effect.

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

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

To

All the port offices of CDSCO

Copy forwarded for information to:-

PS to Joint Secratary, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.
(Kind Attention: Sh. R.S. Shukla, J.S.)