MEETING OF THE TECHNICAL COMMITTEE FOR THE FINALISATION OF SPECIFICATIONS OF ARTEETHER INJECTIONS AND RAPID DIAGNOSTIC KITS HELD ON 8TH AUGUST 2003.

A meeting of the Technical Committee was held under the Chairmanship of Addl.DGHS (RKS) on 8th August 2003 to finalise the specifications of Arteether injections and Rapid Diagnostic Kits. The meeting was attended by all the members of the technical committee except Drug Controller General (India) or his representative. Dr. Satyawan Singh, Deputy Director & Head Pharmaceutics Division, CDRI Lucknow, attended the meeting as a special invitee.

ARTEETHER INJECTION

Dr. Satyawan Singh of CDRI mentioned that sulphated ash related to specifications for Arteether bulk drug and therefore need not be included in the technical specifications for Arteether injections. He also clarified that the limit of components of α:30 $\pm$ 5% was range of 25 to 35. Similarly, the limit component of β was 70 $\pm$ 5% was range of 65 to 75. He also said that near neutral pH was acceptable.

The technical committee agreed that the specifications as given by the DCG(I) may be used for the procurement under NAMP. Specifications related to Arteether bulk drug such as sulfated ash contained should not be included in the above technical specifications.

The technical committee approved the specifications of Arteether injections, as specified by DCG(I), given below:

- pH neutral
- Colourless Solution
- Contain not less than 70 mg and not more than 80 mg per ml of Arteether.
- Limit of components:
  α = 25 to 35%
  β = 75 to 65%

Assay Arteether: 95 to 105%

RAPID DIAGNOSTIC KITS

Director NAMP explained that the proposed revision of specifications of Rapid Diagnostic Kits was due to the fact that in the last bid evaluation it was noted that one of the two bidders had given specifications which deferred slightly as given in the bid document and that the price of this bidder was substantially lower than the other bidder. Moreover, NAMP had received representations from manufacturers of Rapid Diagnostic Kits which detected both *P.falciparum* and *P.vivax*. She clarified that although priority for the programme was to detect *P.falciparum* there was no reason to exclude Rapid Diagnostic Kits which tested both *P.falciparum* and *P.vivax* malaria and were available at the same or lower price. The procurement would follow the international competitive bidding (ICB) guidelines of the World Bank. The specifications, circulated to the technical committee, had been drafted by an expert group which included Dr. Sarala K. Subbarao, Director, MRC; Dr. Veena Mittal, Joint Director, NICD, Dr. Neena Valecha, Deputy Director, MRC, Dr. Jotna Sokhey, Director NAMP and Dr. GPS Dhillon, Joint Director NAMPduly approved by Director NAMP.

The minutes of the meeting of this expert group held on 4.4.2003 had been circulated to all the members of the technical committee.

The technical committee approved the following revised specifications of Rapid Diagnostic Kits as given below:

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The rapid diagnostic kit for malaria should comprise of test card/strips and reagents including buffer solution in a dropper bottle. The test kit should be able to conduct the rapid diagnosis for *P.falciparum* alone or both *P.falciparum* + non-falciparum malaria (*Plasmodium* specific). The test should be based on the principle of capture of parasite antigen from blood using monoclonal antibodies specific for antigen target. Tracer antibodies (specific for Pf or Pf+Pan specific for *Plasmodium*) should be present as immobile phase. Each test kit should contain all the material required for conducting the test including individually packed sterile lancets for pricking, heparinised capillary tubes (diameter – 1 mm) with relevant markings and reaction tubes with stand/wells if required. The required packing standards and labeling should meet the Good Manufacturing Practices (GMP) standards. One should be able to perform the test with the blood taken by finger prick of the patient. Overall sensitivity and specificity (using microscopy as the "gold standard") should be 90% or above as evidenced by test reports from a standard recognized laboratory.

Dr. V.K. Saxena,
Joint Director, NICD

Dr. P.K. Phukan.
Addl. Director, NAMP.

Dr. Ashok Kumar
DDG (Leprosy)

Mr. I.S. Garg
Director(Proc.)

Dr. Ashwini Kumar
DCGI,

Dr. G.K. Biswas
Addl.DGHS

Dr. Jotna Sokhey
Director (NAMP)

Dr. R.K. Srivastava
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