

# Minutes of the Technical Committee Meeting

held under chairmanship of Additional Director General & Director, NICD, to review technical specifications of DEC tablets and antimalarials held on 28.8.06 at 9.45 A.M. at Nirman Bhawan, New Delhi.

1. A meeting of the Technical Committee was held under chairmanship of Additional Director General & Director, NICD, on 28.8.06 at 9.45 A.M., at Nirman Bhawan, New Delhi, to review technical specifications of DEC, Chloroquine and Primaquine tablets, with respect to their shelf life. Following were present:

Dr. D. Kanungo, Additional DG (Stores), Dte. GHS

Dr. Ashok Kumar, Director, CBHI

Dr. S.D. Seth, Ex-Professor, AIIMS, New Delhi

Dr. A.B. Ramteke, Joint DCG(I), Dte. GHS

Dr. R.C. Dhiman, NIMR

Dr. P.L. Joshi, Director, NVBDCP

Dr. A.B. Ramteke, Deputy DCG(I) and Dr. R.C. Dhiman, NIMR attended the meeting in place of Dr. Ashwani Kumar, DCG(I) and Dr. A.P. Dash, Director, NIMR. Shri I.S. Garg, Director, Procurement Dte.GHS had been transferred to DGS&D and as the post of Director (Procurement) was vacant.

2. The Committee deliberated on para 11 of the minutes of the last meeting of the Technical Committee held on 18.8.06.
3. As per para 11 of the minutes of the last meeting, information was sought by DCG(I) representative from major manufacturing companies located in Gujarat, Maharashtra, Andhra Pradesh, Madhya Pradesh and Tamil Nadu regarding the approved shelf life of DEC, Chloroquine and Primaquine tablets.
4. DCG(I) representative informed the Committee that information had been telephonically received from nine companies regarding DEC tablet manufactured by them, wherein five companies have informed that they have assigned a shelf life of two years, three companies have informed that they have assigned a shelf life of three years and that one company has informed that they have assigned shelf life of up to five years. The details are annexed.

As regards Chloroquine and Primaquine tablets, the DCG(I) representative informed that shelf life of Chloroquine and Primaquine tablets is not specifically prescribed under Drugs & Cosmetics Rules. However, as per Rule 96 1 (vii) of Drugs & Cosmetics Rules 1945, stable products like Chloroquine phosphate and Primaquine tablets shall bear on their labels the date of manufacture and also the date of their expiry, which shall not exceed 60 months from the date of manufacture. Usually, the manufacturers of such finished formulations tend to mention 2 to 3 years of shelf life for their products. Therefore, there may not be any objection in this regard.

The Committee observed the following:

- 6.1. The shelf life of DEC tablets manufactured by different companies varies from two years to five years. However, two years has been given by majority manufacturers.
- 6.2. As per the written communication received from DCG(I), as further substantiated by his representative in the meeting, the shelf life of Chloroquine phosphate is not specifically prescribed under Drugs & Cosmetics Rules. However, as per Rule 96 1 (vii) of Drugs & Cosmetics Rules 1945, stable products like Chloroquine phosphate tablets shall bear on their labels the date of manufacture and also the date of their expiry, which shall not exceed 60 months from the date of manufacture. Usually, the manufacturers of such finished formulations tend to mention 2 to 3 years of shelf life for their products.
- 6.3. Similarly regarding shelf life of Primaquine tablets, a written communication from DCG(I) which was further substantiated by his representative in the meeting, shelf life of Primaquine tablets is not specifically prescribed under Drugs & Cosmetics Rules. However, as per Rule 96 1 (vii) of Drugs & Cosmetics Rules 1945, stable products like Primaquine tablets shall bear on their labels the date of manufacture and also the date of their expiry, which shall not exceed 60 months from the date of manufacture. Usually, the manufacturers of such finished formulations tend to mention 2 to 3 years of shelf life for their products.
- 6.4. In view of need of NVBDCP, drugs have to be administered within the validity period.
- 6.5. As per information given by NVBDCP, the drugs are procured annually as per technically assessed requirement and are consumed within a period of maximum two years.
- 6.6. Thus, if a drug is procured with a shelf life of three years or more, it will help NVBDCP in getting competitive price by getting more number of

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bidder. At the same time the NVBDCP would have adequate time period to utilize spillover drugs from the balances of previous years without any risk of wastage on account of expiry of the drugs.

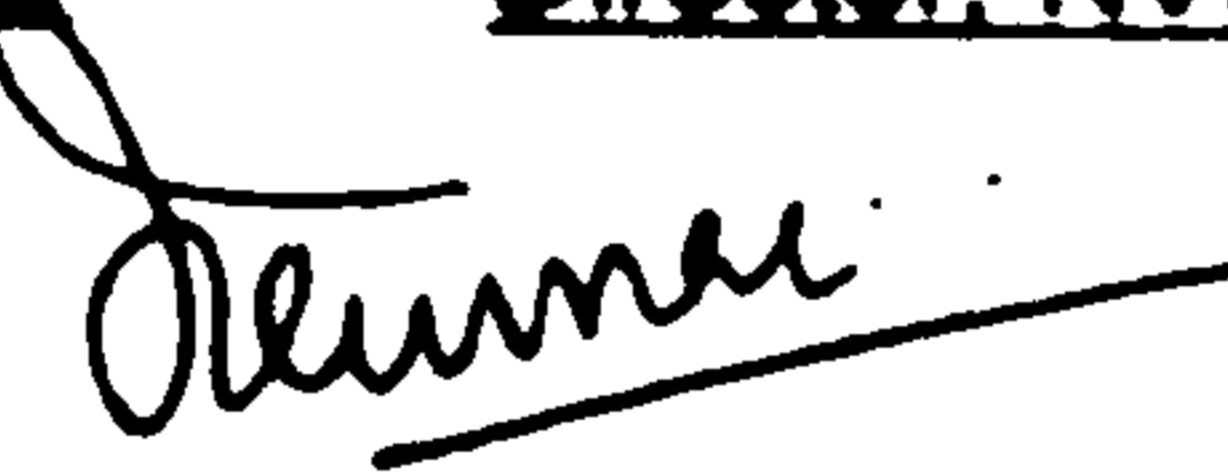
- 7. After detailed deliberations, the Committee decided as under:
  - 7.1. The shelf life of DEC tablets should be accepted as three years or more. (Not to exceed 60 months)
  - 7.2. The shelf life of Chloroquine phosphate tablets should be accepted as three years or more. (Not to exceed 60 months)
  - 7.3. The shelf life of Primaquine tablets should be accepted as three years or more. (Not to exceed 60 months)

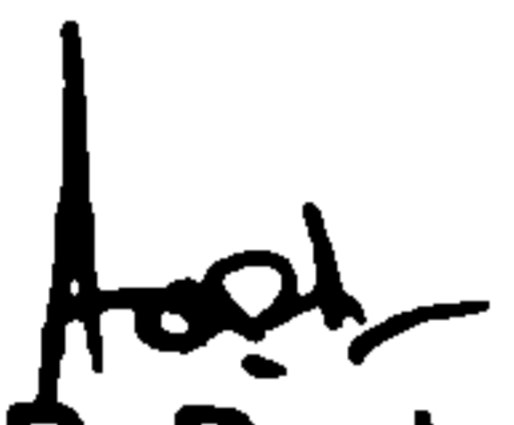
  
Dr. Ashwani Kumar,  
DCG(I), Dte. GHS

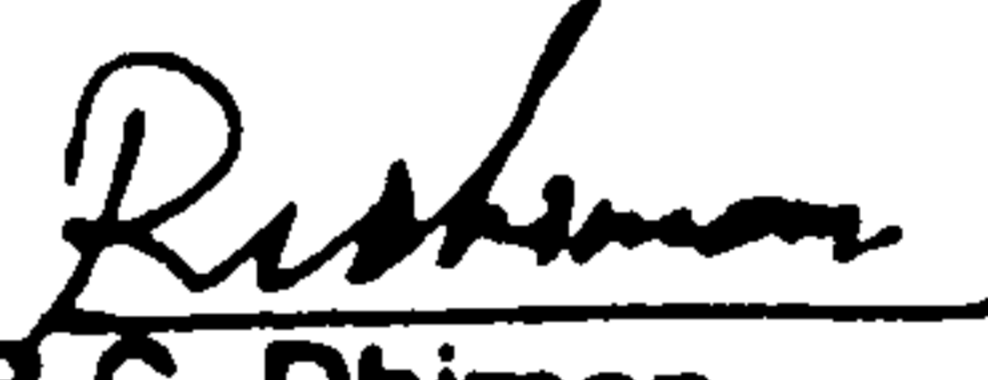
  
Dr. Anil Samteke,  
Deputy DCG(I), Dte. GHS

  
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Dr. R.C. Dhiman,  
NIMR

  
Dr. D. Kanungo,  
Additional DG (Store)

  
Dr. Shiv Lal,  
Additional DG & Director, NICD