health
Department:
Health
REPUBLIC OF SOUTH AFRICA

MEDICINES CONTROL COUNCIL
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COMMUNICATION TO INDUSTRY

To All Applicants

SCHEDULING MATTERS

ACCESSIBILITY OF MALARIA PROPHYLAXIS MEDICINES

The Medicines Control Council is considering a risk assessment of anti-Malaria medicines with consideration given to rescheduling of some anti-Malaria medicines. Risk management is a systematic process for the assessment, control, communication and review of risks to the safety of the patient.

It has come to the Council's attention that the lack of easy accessibility to anti-Malaria medicines for prophylaxis results in many people entering a malaria area without the necessary protection - a problem commonly encountered with international tourists, the latter not being in public interest.

1. In light of the concerns regarding the increasing threat of malarial disease claiming many lives, an effort is hereby made to strengthen control of the disease by increasing access to these medicines.
2. In accordance with the Department of Health guidelines (2008) for the prevention of malaria in South Africa, the use of the following substances are proposed:
   - Mefloquine
   - Doxycycline
   - Atovaquone and Proguanil
3. Currently these substances are all listed in the Schedules to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as Schedule 4.
4. It is the intention of the Medicines Control Council to encourage access to malaria prophylaxis medicines.
5. To facilitate this process and inform the risk assessment of these medicines, all stakeholders and applicants are requested to submit fully substantiated motivations for the rescheduling of one or more of these anti malaria medicines containing the said substances.
6. The aforementioned substances will only be considered for rescheduling for malaria prophylaxis, in line with the existing National Department of Health guidelines on the prevention of malaria. Each motivation should be based on available data on safety and be in compliance with the existing guidelines on scheduling, as published by the Medicines Control Council.
7. All supporting interventions, such as communication and education campaigns directed at the public and / or pharmacists should be outlined in detail.
8. Inputs, proposals and clinical safety data must be submitted to the Registrar of Medicines using the Inspectorate and Law Enforcement code "BSR" .

Yours faithfully

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MS M HELA
REGISTRAR OF MEDICINES
5 March 2009