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# NAMIBIA MEDICINES REGULATORY COUNCIL

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OFFICE OF THE REGISTRAR OF MEDICINES

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Inq: Bertha Alpo

04 October 2021

Ref no: 13/3/1/1

To: All Healthcare Providers

Dear Sir/Madam

## **REF - ACECLOFENAC AND DICLOFENAC SCHEDULING PROPOSAL**

### **Background**

It has come to the attention of the Namibia Medicines Regulatory Council (NMRC) that there was a message circulated amongst pharmacists stating that pharmacists can now dispense Refpain® tablets without a prescription. The NMRC has only approved Refpain® plain (aceclofenac) to be dispensed without a prescription i.e. schedule 1 (NS1), but not the Refpain (aceclofenac and paracetamol) which is a combination medicine. What has been currently gazetted (Gazette No. 7509) is not how it is intended to be stated.

In light of the above, NMRC intends to schedule medicines containing aceclofenac or diclofenac in combination with other medicines as schedule 2 (NS2) medicines as proposed below:

#### ***Schedule 1 (NS1)***

##### ***Aceclofenac -***

- a) when intended for application to the skin; and*
- b) for the emergency treatment of post traumatic conditions such as pain and inflammation such as that in osteoarthritis, rheumatoid arthritis*

*and ankylosing spondylitis in adults, for a maximum period of 5 days, where the recommended daily dose of aceclofenac does not exceed 200 milligrams.*

*c) except in combination with other scheduled substances (NS2).*

*Diclofenac,*

*a) if intended for application to the skin, for emergency treatment of acute gout attacks and for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days.*

*b) except in combination with other scheduled substances (NS2).*

**Schedule 2 (NS2)**

*Aceclofenac*

*a) When in combination with other scheduled substances*

*b) except for the emergency treatment of post traumatic conditions such as pain and inflammation such as that in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in adults for a maximum period of more than 5 days (NS1).*

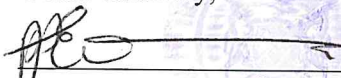
*Diclofenac*

*a) In combination with other products scheduled substances*

*b) Except when intended for application to the skin, when intended for emergency treatment of acute gout attacks and intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of more than 5 days (NS1).*

If any party has an objection to the proposed scheduling, please make your submission to the Registrar of Medicines on or before 30 October 2021.

Yours sincerely,

  
**MR JOHANNES GAESEB**  
**REGISTRAR OF MEDICINES**

**CC: PHARMACEUTICAL SOCIETY OF NAMIBIA**  
**NAMIBIA MEDICAL SOCIETY**  
**MEDICAL ASSOCIATION OF NAMIBIA**  
**NURSING SOCIETY OF NAMIBIA**  
**ALL ALLIED HEALTH PROFESSIONS SOCIETIES**