NAMIBIA MEDICINES CONTROL ACT

SAPRAA meeting
18 March 2011

Presented by:
Johannes Gaeseb
Registrar of Medicines
NAMIBIA

LABELLING REQUIREMENTS

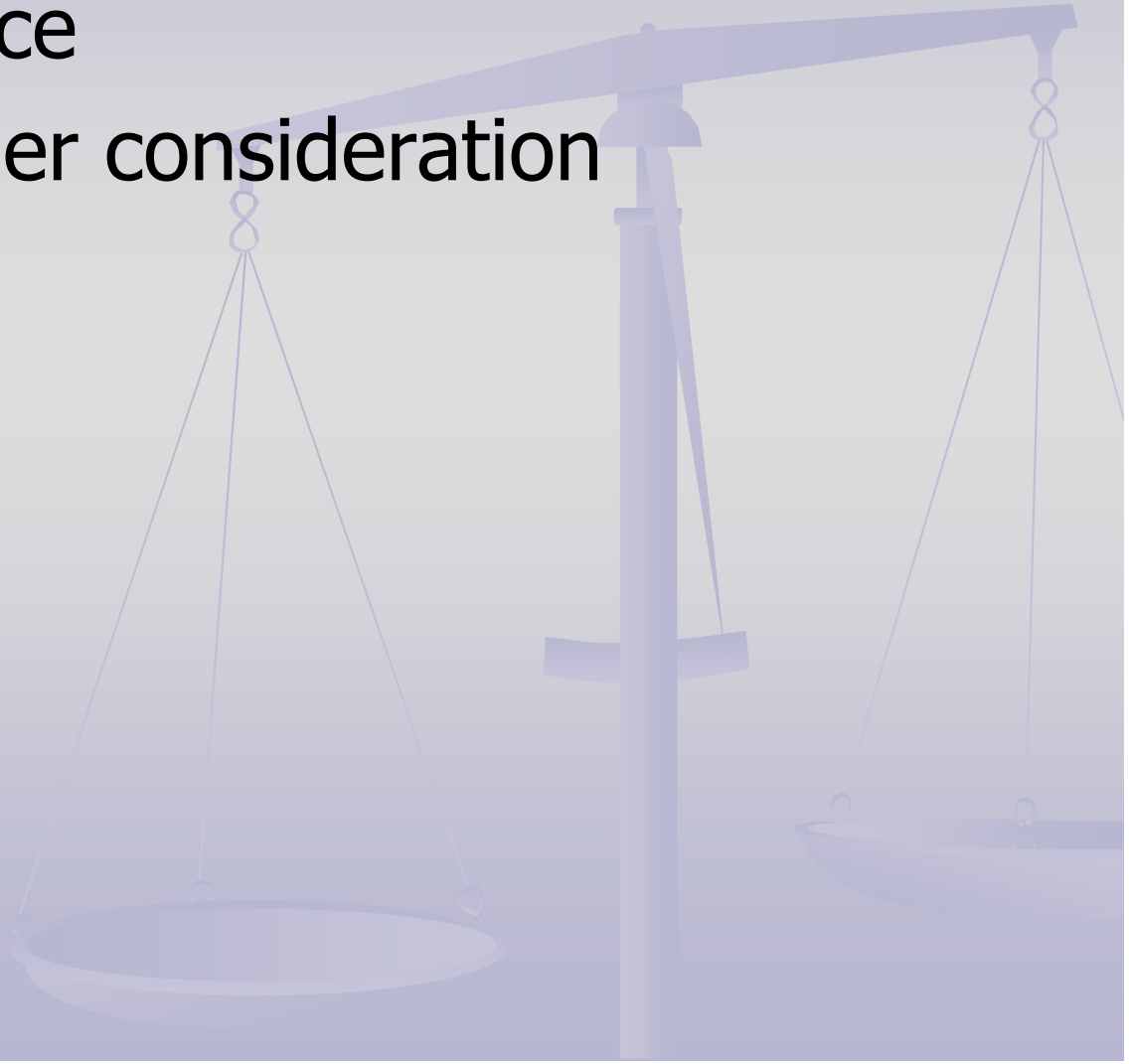
- The following are to be on label:
  - Registration number given by NMRC
  - Namibian scheduling status
  - Both manufacturing and expiry dates must be on label
- COUNCIL RESOLUTION:
  - Exempt the manufacturing site information and manufacturing date
  - Require the submission of site master file

GUIDELINES

- The following guidelines are being drafted:
  - Post registration amendments
  - Medicines recall/withdrawal
  - Supply of unregistered medicines to a patient (Compassionate clearance)
  - Marketing of Medicinal products
  - Import/export licencing
  - Section 31 licences
  - Medical representatives
  - Complementary medicines
  - Pharmacovigilance

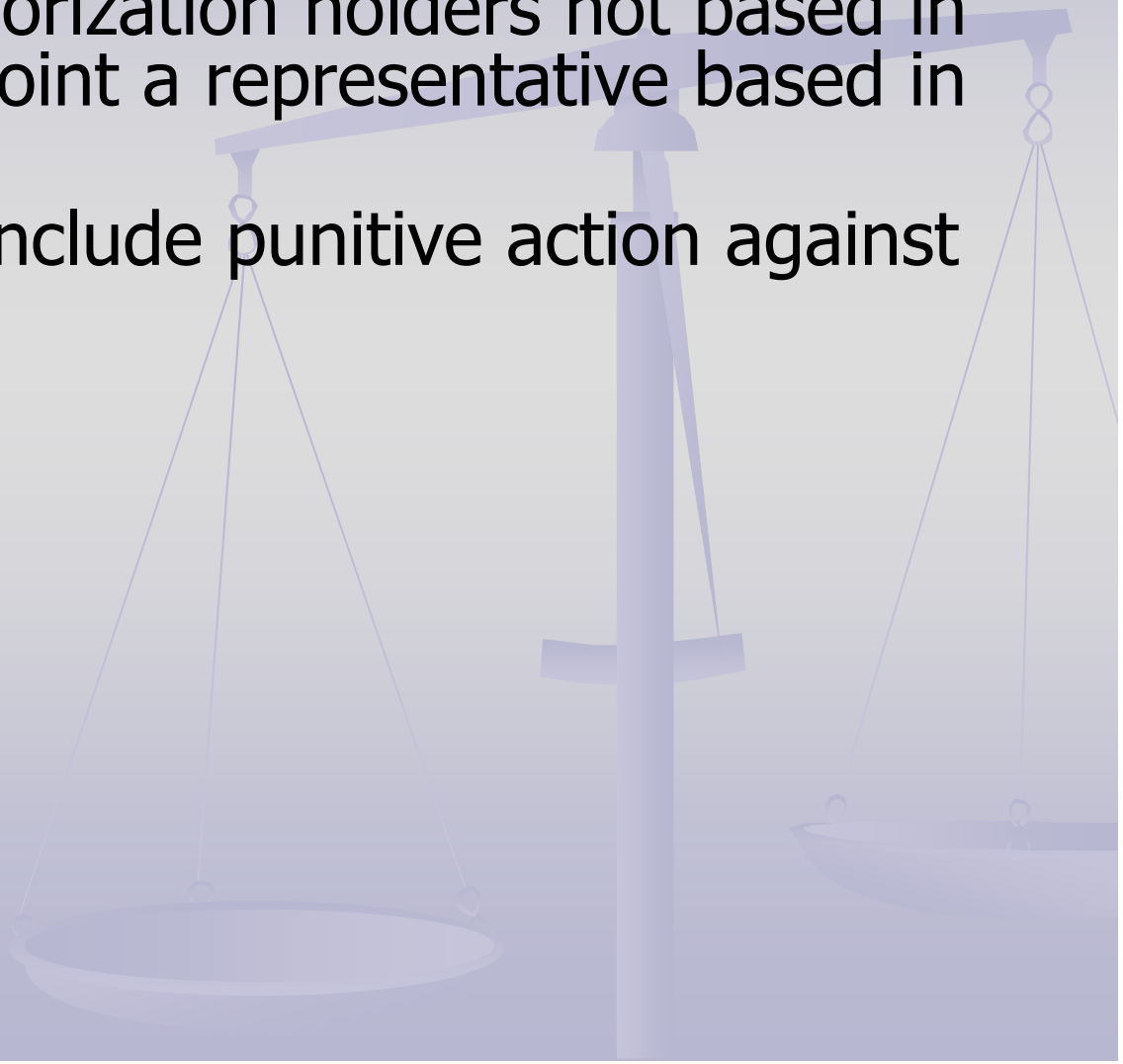
MEDICINES APPLICATION FORM

- MRF1 still in place
- CTD format under consideration



LOCAL REPRESENTATIVE

- All marketing authorization holders not based in Namibia must appoint a representative based in Namibia.
- Reviewing Act to include punitive action against non-compliance



IMPORT OF MEDICINES

- Any company wishing to import any medicines (including schedule 0) require a license
- Importation of medicines restricted to Pharmaceutical Wholesalers for products of schedules higher than 0
- Schedule 0 medicines maybe be imported by non- pharmaceutical wholesalers

CONTACT DETAILS

- WEBSITE: www.nmrc.com.na
- E-mail: regmeds@nmrc.com.na
- Tel: +264 61 203 2400/03
- Fax: +264 61 225 048
- Postal Address: Private Bag 13366,
  Windhoek
  Namibia

I THANK YOU