Feedback from: Workshop held to discuss Namibia Medicine Regulatory Council Requirements

Mr. Pascal Rite-Senior Pharmacist NMRC

SALMA ISMAIL 18/11/2009

GUIDELINES

Ministry of Health & Social Services

- The following guidelines are being drafted:
- Awaiting council approval
- Still opportunity for US to make comments.
  - Post registration amendments
  - Medicines recall/withdrawal
  - Supply of unregistered medicines to a patient (Compassionate clearance)
  - Marketing of Medicinal products
  - Import/export licensing
  - Section 31 licenses
  - Medical representatives
  - Complementary medicines
  - Pharmacovigilance

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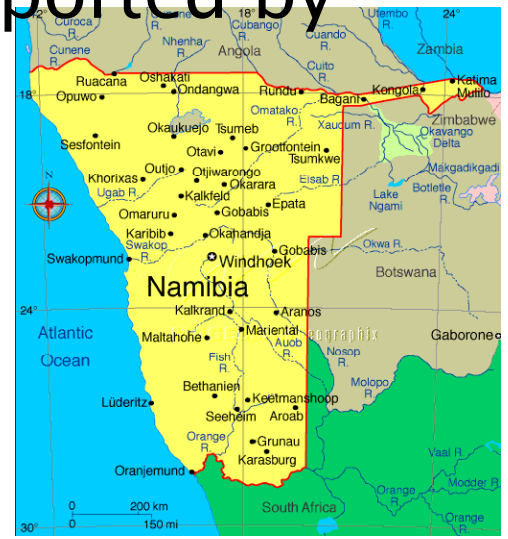
IMPORT OF MEDICINES

Ministry of Health & Social Services

- 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



NMRC MEETING DATES 2011

Ministry of Health & Social Services

- RITE\NMRC CALENDER 2011.doc
- The meeting dates are as proposed, however depend on quorum.

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MEDICINES APPLICATION FORM

Ministry of Health & Social Services

- MRF1 still in place
- CTD format under consideration however highly recommended by WHO.
- CTD format requires publication in Gazette in Namibia before implementation
- SAPRAA to ensure that latest ZA CTD guidelines are provided to NMRC as guidance

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Clarify who exactly can be the Local Representative?

Ministry of Health & Social Services

- All marketing authorization holders not based in Namibia must appoint a representative/agent based in Namibia.
- This rep, can be a pharmacist, medical practitioner or non pharmacist
- Reviewing Act to include punitive action against non-compliance

- Where should we name the Local Rep/agent in the dossier?
- There is no place for this in the dossier.
- Only a notification letter to NMRC is required

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LABELLING REQUIREMENTS

Ministry of Health & Social Services

- 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-UNTIL April 2012
  - Require the submission of site master file

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NAMIBIA MEDICINES REGULATORY COUNCIL

OFFICE OF THE REGISTRAR OF MEDICINES

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RE: REQUEST FOR EXEMPTION FROM CERTAIN NAMIBIAN LABELLING REQUIREMENTS AND EXTENSION OF THE IMPLEMENTATION NAMIBIAN LABELLING REQUIREMENTS

Your letter dated 6 December 2010 refers.

Your request was tabled at the Namibia Medicines Regulatory Council (NMRC) meeting of the 10th February 2011.

NMRC accepted your requests and agreed to the following:

1) Exemption from the inclusion of the following information on the packaging material of medicines registered in Namibia:
   a. Manufacturing site details
   b. Manufacturing date
2) Extend the exemption from complying with some of the Namibian labeling requirements for a further twelve (12) months starting from the 1st May 2011 until 30th April 2012. A notice to this effect will be placed in the government gazette before the expiry of the current exemption period.

"Health for All"

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LABELLING REQUIREMENTS ctd

Ministry of Health & Social Services

- Reg 11: Labelling-No PHRC details required ? Concern Regarding Consumer Complaints/queries
- A Multi-market label may be approved based on prior approval from the NMRC-Canada/Emea/MHRA/JAPAN/SWISS
- No overlabelling/over-sticking of any required information allowed
- English Only OR English + any other language acceptable

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SMFS

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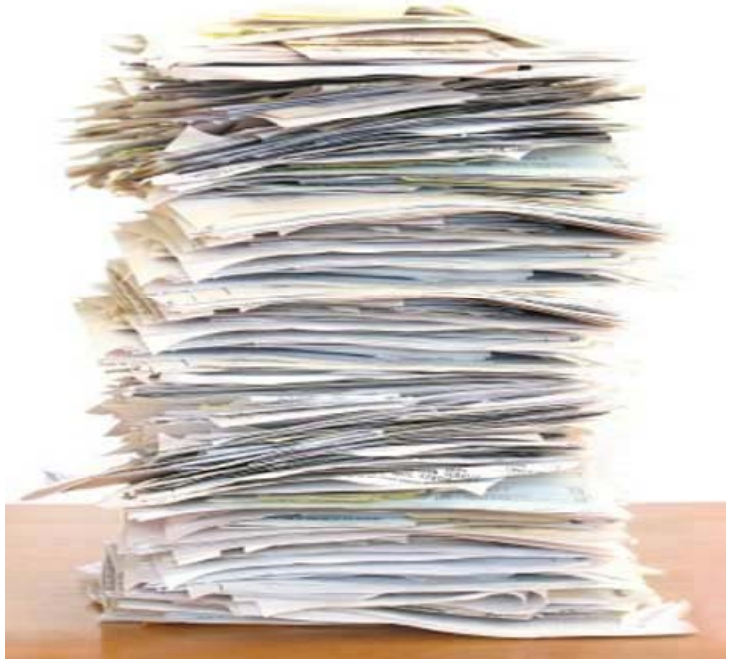
- The NMRC require SMF submitted as per ZA requirements i.e. Manufacturer sites only
- Industry Suggestion:
  - Open a register detailing sites with SMF numbers
  - Display on NMRC website to avoid duplication of submissions



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Post-registration amendments

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- Suggestion: Submit updated files that contain all variations.
- to negate filing volume capacity issues
- NMRC to consider

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Post registration amendments fees

Ministry of Health & Social Services

- 2.1 According fees payable, the amendment fee is N$1050 for product compounded outside Namibia. In absence of a guidance documents on which amendments will qualify to be accompanied by a fee, does that mean this fee is applicable for any type of amendment application or for those amendment that affect the certificate of registration or will require changes in the register only.
- Consult with the fees guideline that stipulates those that affect a registration certificate.

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2.2 According to the draft post-registration guideline, will the fee/rate be for a variation package with different changes or per change aspect

- Per variation package submitted

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Process & document requirements for "Transfer of applicancy" for a product / product range

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- MRF1 PART 1–FOR APPLICAT TRANSFER (IMPACT REG CERTIFICATE)
- ONLY REQUIRE LETTER + FRONT PAGE MRF1 + FEE

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Registration timelines e.g. we have a product that was submitted in June 2007, still not registered.

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- Perhaps the 6 months NMRC response time was not adhered to, hence product dossier to be re-submitted.
- The backlog is only 233 new registration applications in 2010.
- Anything prior to 2010 will require follow-up in writing to the NMRC

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How is the local rep details notified to the NMRC?

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- Just send a letter of appointment with what that rep/agent can or cannot do.
- Must be a person and Not a company

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Pharmacovigilance

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- A pharmacovigilance unit does exist.

- Regulation 17 (Adverse events): What is the acceptable time to inform council of an adverse event?

  NMRC are reviewing guidelines and timelines to be finalised in the guideline.

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Pharmacovigilance ctd

Ministry of Health & Social Services

Does the NMRC want to receive adverse event reports of events experienced in ZA, or only those experienced in Namibia

There is a unit and any communicate these to the NMRC P'covigilance unit.

- What about PSURs? Does NMRC have capacity to store it.

  To review this matter & follow-South Africa

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Pharmacovigilance ctd

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- What do you do with Urgent Safety Restrictions

  No system as yet/No implementation of “Dear Doctor” letter

- The new ZA CTD asks for a Pharmcovigilance officer details & CV. What is the stance for NMRC?

  This if & when required will be from the Applicant company.

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Who holds the FPRR?

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The Applicant company. This must not be the local representative.

Will NMRC require re-assay & ID of imported products?

No.

- There is no laboratory capacity at present to conduct these for all imported batches.
- only when a registration sample is suspicious

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Who will conduct the release testing of Vaccines/Biologicals?

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- Currently, no system in place.
- Acknowledge:
  - WHO pre-qualified vaccines
  - ZA NCL release

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Advertising

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- Reg 16 (4): Advertising of medicines
- The name of manufacturer must be included but not that of the PHCR/APPLICANT?

  This will be reviewed by the NMRC

- MARKETING CODE?

  To provide NMRC guidance in line with ZA developments.

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SAMPLES

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- Samples with reg dossiers, quantity can be negotiated with NMRC directly with motivation

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GMP INSPECTION

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- NMRC does accept mutual recognition –

EMEA, US FDA, HEALTHCANADA, TGA, SWISS, MHRA

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FAST TRACK/EXPEDITED REVIEW

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- FAST TRACKING OF DOSSIERS- that are registered : EMEA, US FDA, HEALTHCANADA, TGA, SWISS, MHRA

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STAFF COMPLEMENT? NAMIBIA EVALUATORS

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- 7 evaluators currently and aim is to meet the recommendations as per MSH report.

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VETERINARY PRODUCTS

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- GREY AREA PRODUCTS= DEPARTMENT OF AGRICULTURE AND FORESTRY
- MUTUAL RECOGNITION PRINCIPLE WILL BE ACCEPTED –THEN IT WILL GET REGISTERED.
- THERE WILL BE A VETERINARY REGISTER

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MEDICAL DEVICES

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- "GREY" AREA
- ZA industry to provide NMRC with latest ZA guidelines when published.

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General

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- There are some products in the old South West Africa days?
- There may be a call-up for these products, however they are usually registration numbers that start with “90”
- There are old products in Namibia with “W” in teh reg number?
- It is acknowledged that these products are unregistered but they will remain as such and marketed freely.

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NAMIBIA SCHEDULES

Ministry of Health & Social Services

- DISCREPANCY BETWEEN INTERPRETATION OF SCHEDULES IN NAMIBIA AND THE LASTEST 2009, GOV GAZETTE IN SOUTH AFRICA SCHEDULES.

- NMRC TO REVIEW LATEST MCC SCHEDULES

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FEES

Ministry of Health & Social Services

- WEBSITE: www.nmrc.com.na

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THANK YOU

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"It is the long history of humankind (and animal kind, too)
those who learned to collaborate and improvise most effectively have prevailed."
– Charles Darwin

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