FEEDBACK FROM SAPRAA WORKSHOP WITH MCAZ

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Delegates:

- MCAZ: Luther Gwaza
- IPASA: Linda Forsyth
- SMASA: Rhoda Kruger
- SAPRAA: Salma Ismail, Lindiwe Ngcanga, Yolanda Peens, Corinne Pillai, Charlene Roopnarain
- OTHER: Salima Mahomed,Collen Dikobo, Fiona Smith, Varsha Mistry, Tammy Pillay

Questions:

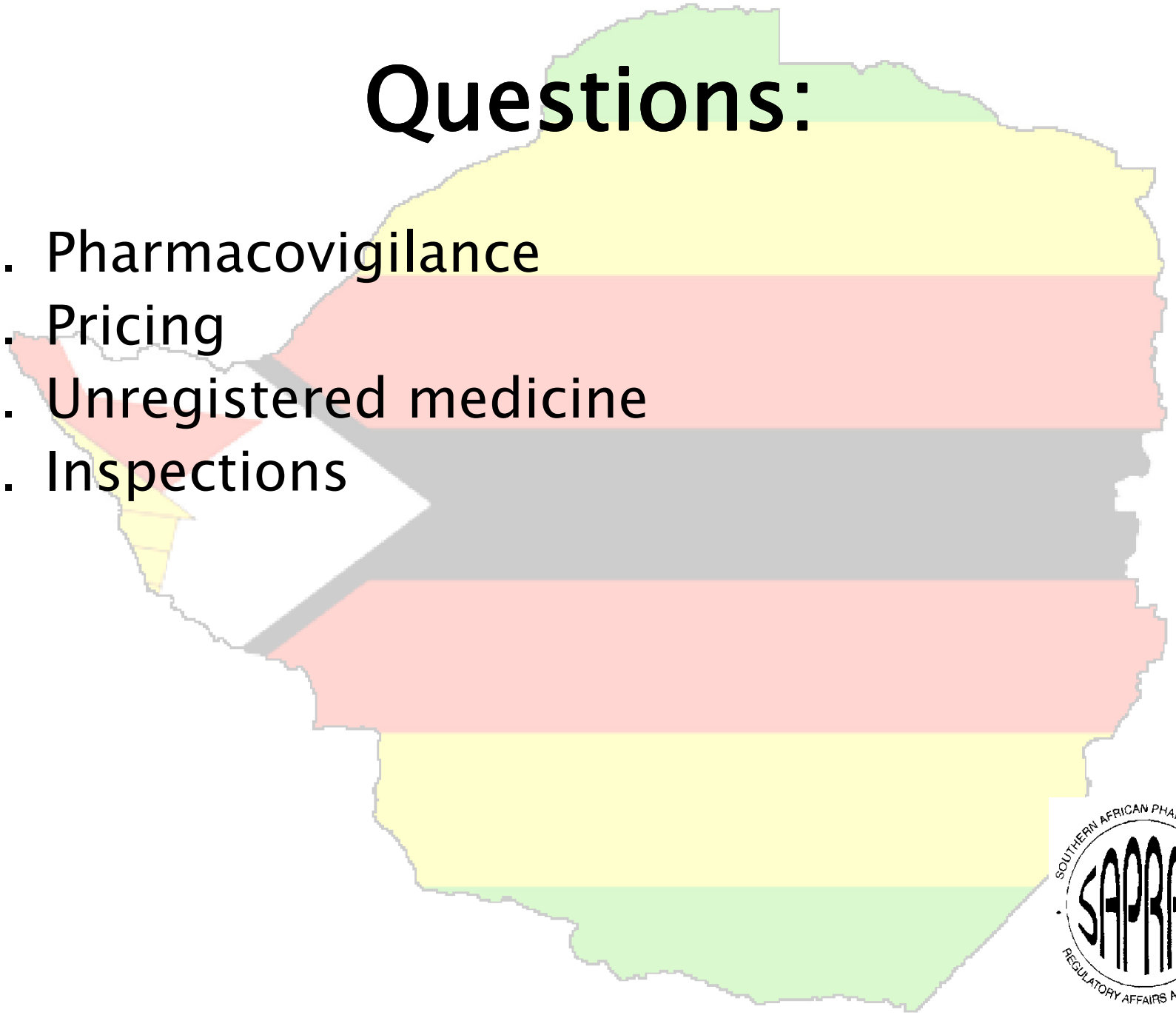
1. New submissions

i. NCEs
ii. Line Extensions
iii. Vet Medicines
iv. Complementary medicines
v. Other: Medical Devices; Vaccines; Vitamins; Biologicals
vi. Expedited Review Process

2. Amendments / Variations
3. Labelling
4. Administration/General
5. Harmonisation

Questions:

6. Pharmacovigilance
7. Pricing
8. Unregistered medicine
9. Inspections



New Submissions:

Question1.

Currently the Zim authority requires that hard copies of all modules be submitted including 2,4 & 5 (NCE's). These are often extremely large volumes documents and can extend to even hundreds of hard copy volumes for modules 4 & 5. Will the Zim authority consider accepting CD's / DVD's of these sections?

MCAZ response: The current requirement is 1 hard copy and one electronic copy in CD. Electronic copies alone can be acceptable where volume is an issue.

New Submissions:

Question 2a.

For the Quality Information Summary and the Quality Overall summary is it possible to cross refer to the CTD modules?

MCAZ response: No

- The QOS should include sufficient information from each section to provide the Quality assessor with an overview of Module 3.
- The QOS should also emphasize critical key parameters of the product and provide, for instance, justification in cases where guidelines were not followed.

New Submissions:

- The QOS should include a discussion of key issues that integrates information from sections in the Quality module and supporting information from other Modules (e.g. qualification of impurities via toxicological studies), including cross-referencing to volume and page number in other Modules
- The QIS template should be completed to provide a condensed summary of the key quality information for the PD and constitutes part of the submission package.
- The QIS provides an accurate record of technical data in the PD at the **time of registration.**

New Submissions:

Question 2b.

The QIS and the QOS-PD that need to be completed as requested by the Authority are essentially similar to the ICH QOS but have differences. What is the purpose of each document. There is information that is repeated for both documents. Resulting in duplication of work?

MCAZ response:

- The QIS is a condensed version of the QOS-PD and represents the final agreed-upon key information on the API and FPP from the PD assessment (including, but not limited to, identification of the manufacturer(s), site addresses, API/FPP specs, stability conclusions and relevant commitments).

New Submissions:

Question 3.

If the QOS is in the ICH format, can we submit only first 2 pages of QOS-PD document & not re-work

MCAZ response:

Should be acceptable

New Submissions:

Question 4a.

What is the rationale for Zim authority requesting different strength, same molecule CTD formatted dossiers to be submitted as two completely separate sets of dossiers?

MCAZ response:

Each strength is considered a separate application.

New Submissions:

Question 4b.

Would the Zim authority be willing to consider the current application process for different strength same molecule/formulation dossiers as ZA has adopted? (i.e. separate application forms, stability and other data as applicable in a consolidated dossier)

MCAZ response:

Each strength is considered a separate application.

Mr Gwaza considered to take back to MCAZ for discussion and would feedback to ZA

New Submissions:

Question 5.

CoPP – is it from country of manufacturer/ supplying country

MCAZ response:

Consider where the product is manufactured, could require one or two CoPPs.

Mr Gwaza to FB to ZA after discussion at MCAZ

Line Extensions:

Question 6.

What is the approval timeline?

MCAZ response:

Follow definition of LE in MCAZ guideline and timelines for amendment or for New Submission will apply.

Timelines:

Question 7.

Please provide the estimated timelines for approvals i.e. for variations and new products

MCAZ response:

Estimated timelines for variation approval are 3 to 6 months depending on the number of amendments per application submitted

NS: Mr Gwaza to elaborate more on the process of registration and the timelines

Veterinary medicine:

Question 8.

Clarity on packaging components:

PI and labeling (Primary packaging)

Name and physical address of the manufacturer must it appear on both?

Manufacturing date and expiry date and batch number to appear on both?

On labeling, carton, etc. can understand

PI: PIs do not include manufacturing and expiry date and batch numbers. This seems impractical and costly since the expiry date, batch numbers already appear on labels, cartons etc. PIs are not printed per batch.

Veterinary medicine:

MCAZ response:

Requirements are the same as for Human Medicines, the MCAZ does not consider cost implications

Discussion: Who is considered the manufacturer

Manufacturer/packer/site of release; if all three are different, which must be stated on the pack?

MCAZ response:

Manufacturer must appear on the pack, will also FB after discussion at MCAZ

Veterinary medicine:

Question 9.

GMP was requested:

Company response: GMPs are not always available

E.g. Ectoparasiticide APIs are not produced as per GMP requirements. This is not a requirement in most countries for ectoparasiticides.

Although the active substances that enter in the composition of the FP do not need to be manufactured in accordance with the detailed guidelines on GMP for starting materials, these active substances are of appropriate quality to ensure that the finished product meet its registered quality.

Veterinary medicine:

MCAZ response:

Currently requirements and assessments are the same as for Human Medicines.

Development of Vet guidelines in in progress and such cases will be taken into account.

Complementary medicine:

Question 10.

Is there a separate complementary unit already set up at MCAZ. Would MCAZ consider having the guidance document for submission of complementary medicines (in terms of what is allowed or not allowed) while still in process of finalising the Act/Regulations.

-Is there a submission process for CAMs and Devices. If not how are these products being handled in Zimbabwe (i.e. do they have to pass through a different department within the health sector)

MCAZ response:

No separate unit but specific people are dedicated to CAMs.

Use M.C.8 Form for now

Complementary medicine:

Question 11.

Complementary guideline Draft review. A lot of detail is required in the form, however a lot of information is not available

MCAZ response:

If data is not available/applicable, state and wait for reviewer's assessment.

Discussed possibility of sending draft guidelines to ZA via SAPRAA for comment.

Complementary medicine:

Question 12.

What guidance document, if any is available for claims made for complementary medicines where an exemption was granted.

MCAZ response:

Mr Gwaza to comment later.

Complementary medicine:

Question 13.

What guidance document, if any is available for claims made for complementary medicines where an exemption was granted.

MCAZ response:

Mr Gwaza to comment later.

Other:

Question 14.

- Is there a separate biological evaluation process?
- How do Vaccines get registered by MCAZ?
- Complementary medicines: Vitamins – is registration required?

MCAZ response:

- No, all within the same process and within ICH (default) guidelines
- M.C.8 also for devices
- Yes

Expedited Review:

Question 15.

- Is there a fast track process for products that treat conditions with a high need e.g. HIV, tuberculosis or malaria.

MCAZ response:

- Yes, Submit a cover letter motivating why the product must be considered as essential drug for national health. Additional fee is required for expedited review process
- Not limited to HIV, malaria and TB

Expedited Review:

Question 16.

- How does it work e.g. does one apply before submitting the dossier?
- Does MCAZ have a fast track process for products listed in EDLIZ
- What is the current EDL version?

MCAZ response:

- Yes
- Yes, case by case
- EDL 2011

Amendments:

Question 17.

There are no variation guidelines available on the MCAZ website. If we are to submit a variation to the MCAZ what guidance document do we follow e.g. WHO guideline for variation or EMEA guideline variations? Is the MCAZ working on a variation guideline?

MCAZ response:

Variation guidelines are available on MCAZ website under Pharmacovigilance and Clinical trials downloads titled MCAZ Amendment guidelines. MCAZ is in the process of reviewing these Guidelines

Amendments:

Question 18.

Is it imperative that the compendia year is provided – it is not acceptable to merely state the latest edition.

MCAZ response:

Yes

Stating 'Latest Edition' is acceptable

Amendments:

Question 19.

How do we conduct a MAH transfer, what sections are required.

MCAZ response:

Refer to guideline

Amendments:

Question 20.

Who conducts the Transfer, proposed new MAH or current.

MCAZ response:

Does not matter so long as the correct legal documents are submitted

Amendments:

Question 21.

Is there a grace period for product phase out of the old MAH.

MCAZ response:

None specified or submit request on a case by case basis, may not apply to everyone

Amendments:

Question 22.

Can an amendment be submitted in parallel or with an application for MAH transfer.

MCAZ response:

Have TOA approved and have amendment submitted therafter

Amendments:

Question 23.

What documents must be notarized/legalized.

MCAZ response:

Guidelines are specific as to what documents are required.

CoPPs must be notarised.

Amendments:

Question 24.

If a manufacturing site changes plus process change, how many months stability is required on initial submission of the variation, Is long term and accelerated data required.

MCAZ response:

Variations Guidelines (Mar 2010).

Amendments:

Question 25.

Does MCAZ require separate API/FPP manufacturer site registrations, if yes what documents are required?

MCAZ response:

Not yet, however internally at MCAZ processes are being updated to accommodate this process

Amendments:

Question 26.

Long term in ZA = 25 degrees /60% RH but Zim indicates 30 degrees /65% RH, will 25 degrees /60% RH data be ok?

MCAZ response:

Stability studies CZ II and CZ IV are acceptable. Motivate the use of specific stability

Amendments:

Question 27.

Amendment process:

Is there a process for conversion to CTD format.

MCAZ response:

No deadline has been set, can convert as you do variations

Submission of amendment: which format should be used if dossier was not submitted in CTD format.

Same as for ZA as for hybrid CTD

LABELLING:

Question 28.

- Market size in Zimbabwe does not warrant a dedicated pack size.
- I know of some companies that have been granted exemption but some not – unfortunately we are one of them and we were asked to make the following changes:
  1. generic name must be larger than trade name
  2. add manufacturer details

  we are happy to add Zim details, reg status and reg no. but feel above is not warranted.
- What other options are available and why do some companies get exemption and some not?

LABELLING:

MCAZ response:

- Current legal requirement on labeling and packaging requirements (MASCA)
- Policy for exemptions apply to innovator products (only).
- No Exemption from reg number/mnf details- the concerns will be raised at MCAZ regarding multiple mnfs/packers etc & overlabelling may not be authorised and SAPRAA to have letter sent to MCAZ requesting blanket exemption with strong motivation

LABELLING:

Question 29.

What is the rationale for Zim authority requesting 20 colour copies of proposed Zim labeling documents and reference label documents?

MCAZ response:

Based on the current legislation – under review. Authority has been flexible on this. One copy is fine.

LABELLING:

Question 30.

What is the rationale for Zim authority requesting 20 colour copies of proposed Zim labeling documents and reference label documents?

MCAZ response:

Based on the current legislation – under review. Authority has been flexible on this. One copy is fine.

ADMIN/GENERAL:

Question 31.

Is it acceptable for dossier submission to be provided as double sided copies?

MCAZ response:

Yes, no problem

ADMIN/GENERAL:

Question 32.

What is the best method for contacting the MCAZ i.e. phone, email etc.

MCAZ response:

Both should be fine – email better

Encouraged to send complaints/reviews to DG

ADMIN/GENERAL:

Question 33.

Do you need a local office or is a common Agent utilized for registration & distribution?

MCAZ response:

At the moment, No. Under discussion as Authority prefers to deal with professional people.

ADMIN/GENERAL:

Question 34.

Would MCAZ consider having list of products registered in Zimbabwe available from the website?

MCAZ response:

Yes, will put it as a pdf copy for now, as this is public info.

PHARMACOVIGILANCE:

Question 35.

What is the current requirement for the reporting of Adverse Drug Reactions by MAH? Are there published guidelines / regulations which can be referenced.

MCAZ response:

Currently for reporting ADRs MCAZ uses the ICH guidelines

PHARMACOVIGILANCE:

Question 36.

Are there requirements for the submission of periodic safety reports (PSURs) for registered products?

MCAZ response:

Periodic safety updates reports are not a requirement currently but may be requested on a product by product basis at the evaluator at the time of registration or for a post registration variation or when safety issues arise.

PRICING:

Question 37.

Does MCAZ regulate price?, if yes, please provide detail of process.

MCAZ response:

No, MCAZ has no legal mandate to regulate pricing.

HARMONISATION:

Question 38.

What role is Zimbabwe playing in the SADC harmonisation process. Is SADC following the rapid roll out of the regulatory harmonisation that is happening in the other Economic communities (for example the East African Community).

MCAZ response:

Zimbabwe is an active and keen participant in the SADC Harmonisation initiative.

HARMONISATION:

Question 39.

Does MCAZ recognize approvals within Africa especially within SADC?

MCAZ response:

No. Regulations not stringent enough and challenge within region is that Regulators do not readily share information.

UNREGISTERED MEDICINES:

Question 39.

Is there a separate process of getting unregistered medicine into Zimbabwe for specific patient use

MCAZ response:

Yes. Unregistered medicines can be allowed into Zimbabwe through Section 75.

INSPECTIONS:

Question 40.

Does MCAZ conduct API and manufacturing facility inspections for GMP (overseas facilities)?

MCAZ response:

No.

No inspections in ICH associated/PIC countries OR

If you have been inspected by WHO


THANK YOU