FEEDBACK FROM SAPRAA DISCUSSION WITH DRU HELD ON THE 20 MARCH 2014

Drugs Regulatory Unit
Ministry of Health

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FEEDBACK FROM SAPRAA DISCUSSION WITH DRU

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QUESTIONS

1. Amendments/Variations
i. Transfer of applicancy (TOA)
ii. Changes affecting register
iii. CTD format
2. Renewals
3. New Submissions
i. Expedited Review Process
ii. Complementary medicines
iii. Samples etc
4. Promotional Material
5. Administration/General

Amendments: Please provide conditions and documents that are required for a transfer of applicancy/MAH

DRU Response

Provided all the info remains the same, formal docs (letter of cession, letter of acceptance) from the current and proposed MAH will be required to do the Transfer of applicancy (TOA).

Amendments: Variations and TOA submission timing

DRU Response

Variations and TOA can be reviewed at the same time, e.g. Proprietary name can be reviewed in parallel to TOA.

Amendments: In case TOA is in progress, and there are variations to submit?

DRU Response

In case TOA is in progress and the need arises to submit variations: Please refer/highlight pending TOA to DRU who will prioritise/finalise, before they can continue with the review of the variation.

Once MAH approved, how long before new MAH needs to be implemented within the market, i.e. what is the implementation period/are there any phase out restrictions?

DRU Response

Amendment of the blue book can be immediate, can be done within 30 minutes.

It is up to the applicant to communicate transition period to the DRU.

Once source transfer is approved for a final product manufacturer how long before the new site needs to be implemented, i.e. what is the implementation period/are there any phase out restrictions?

DRU Response

Change of final product manufacturer is a major change that requires prior approval. Once approved, there are no restrictions:

Amendments to the blue book can be immediate.

Is it necessary to submit mock-ups of local packaging for the MAH transfer?

DRU Response

It is not necessary to submit mock ups for MAH transfer.

Comment: Only when submitting a change in the secondary packaging, are mock ups required.

Amendments:
What is the approval timeline.
Is there an expedited review process for amendments for products that are registered in non-SRA countries.

DRU Response

Approval times vary from product to product, it depends on the quality of the submission.

What is the minimum length of stability data required for submission as part of a source (manufacturer) transfer for a biological?

DRU Response

A minimum of 12 months stability is required.

Comment: Refer to stability guideline.

Is there a risk of a shelf life reduction if full term stability data is not part of the submission for a biological for a change in manufacturer?

DRU Response

A minimum of 12 months stability is required.

Comment: Refer to stability guideline.

What documents are required for change of a national batch release site?

DRU Response

Currently, there is no national batch release site in BW.

Comment: Could be planned for future.

Amendment process: • Is there a process for conversion to CTD format.• Submission of amendment: which format should be used if dossier was not submitted in CTD format.

DRU Response

DRU accepts dossiers in CTD format, this can either be the replacement of the entire dossier (old format) with CTD.

Or

Parts of the dossier can be converted to CTD e.g. can convert only the API part of the dossier.

Is the DRU considering implementing the CTD format in the future, and if yes, will guidelines on the requirements be published?

DRU Response

DRU accepts dossiers in CTD format, companies have been submitting dossiers in CTD format.

What is the status regarding the pilot study that was done in 2011 for renewal of registration.

DRU Response

The DRU has not been calling for renewals, but applicants must submit when due.

Expedited review/Fast Track process? How does it work e.g. does one apply before submitting the dossier?

- Is there are list of drugs that would follow a fast track process
- How long does it take for a medicine to be registered through the fast track review process

DRU Response

Yes, the Fast Track process does exist in BW.

Medicines registered in countries with SRA will be fast tracked and evaluated within 4 months of submission.

Does DRU consider South Africa to be a stringent regulatory authority?

DRU Response

No. As South Africa is not listed in the 2009 WHO list, DRU does not consider ZA a stringent regulatory authority.

Adobe Acrobat Document

World Health Organization

SOUTHERN AFRICAN PHARMACEUTICAL REGULATORY AFFAIRS ASSOCIATION
SAPRAA

Please elaborate on the review process when a product has been approved by a stringent regulatory authority. How does it influence review timelines etc;?

DRU Response

DRU can request extra documents, but evaluation can be done within 4 months.

What is the stance for submission and evaluation of complementary/alternative medicines. Is the DRU intending to go the South African MCC route?

Please clarify Complementary medicines requirements in BW and current status?

DRU Response

The CAM guideline is available on the Ministry of Health website.

Although in draft, applicants are using this guideline and applications in line with guideline are accepted.

A lot of the current complementary medicines in South Africa do not have stability data and detailed manufacturing processes and container closure system information, will this be acceptable?

DRU Response

No. Applicants must submit stability etc. Please adhere to the minimum requirements. If required data is not available, product will be deferred and not make it through the review process.

Requirements regarding approval of promotional material/advertising in Botswana:

Does the DRU require all promotional material intended for the public to be submitted for approval, this includes complementaries, S4 and S3 and includes displays at retail pharmacy

Are there any guidelines for Advertising of Medicines in Botswana? If not, may we use the South African guidelines?

DRU Response

Yes. All promotional material needs to be approved by the DRU.

There is no specific guideline, but promotional material must be submitted to the DRU for approval.

There is no need to include the registration number on the promotional piece.

Double sided copies: (Comment)
Saves greatly on weight of parcels hence costs to courier, space to store the dossier and is kinder to the environment.
Is it possible that the use of double sided copies can be reconsidered?

DRU Response

For the moment, no double sided copies. The DRU has already made a concession by reducing the number of copies required from 3 to 1.

Plans to move to electronic submissions.

Submissions:
Is it possible for DAB to waive submission of the hard copy of module 5 i.e. only be provided in a disk.

DRU Response

No. Submit in hard copy.

Wait for electronic submissions to be approved in BW.

Legislation/Act:
Advice on the latest development with regard the legislation/regulations e.g. fees, new regulation, etc.

DRU Response

Envisaged changes are coming soon, current Act has been amended.

These are not a lot of changes: inclusion of definitions, separation of guidelines i.e. Biologicals from orthodox medicine.

DRU can communicate changes via SAPRAA and is willing to workshop the guidelines with ZA.

Samples:

Will DAB consider/accept an application for new submission with non-English samples if the following are included:

- **Justification with English artwork(s)**
- **As condition of registration to provide the final artworks which includes the Botswana registration details (registration number and scheduling status)**

DRU Response

No. Not possible. Non-English Samples are not acceptable. Commercial samples are required.

How many samples are we required to submit. Should they be submitted together with the dossier or do we wait for the DRU to request samples?

DRU Response

Refer to the guidelines, clearly stated how many samples are required per dosage form.

Samples must form part of the application for registration.

BMR/Master formula:

The cost of translation of non-English BMR/Master are most often too steep. Is there any alternative to waiver this requirements especially in cases where:

- **the manufacturing sites has already being inspected by SRA/WHO and**
- **more than one strength is planned to be registered.**

DRU Response

All documentation must be in English, DRU cannot read any other language. If not in English, might as well not submit.

There are documents which cannot be converted into the word format for the summary of the dossier, like the executed BMR, certificates, signatures, etc. What options does the DRU allow in these cases.

DRU Response

Documents described are attachments. Summary of the dossier is supposed to be summaries of the information in the dossier e.g. brief description of BMR.

Does the DRU accept registration certificates written in foreign languages.

DRU Response

No. Have the documents translated and notarised.
Sworn translation.

Issuing of registration certificates:
Has the problem with issuing of registration certificates been resolved (i.e. printer/heavy grain paper)?
If it is foreseen that issuing of certificates will resume, will it be done for products for which we have received a "registration letter" rather than a registration certificate?

DRU Response

Logistics challenges have been overcome.

Registration letter then certificate to follow.

DRU will communicate on issuing if product license is near expiry, but in general Registration certificates will be issued on Renewal.

Labelling requirements:
Is it possible to phase in implementation of the Botswana registration details on the pre-existing labeling artwork for products registered prior 2011 e.g. within 1-2 years

DRU Response

For products registered before 2011. Botswana registration details must be implemented immediately on labelling.