MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Deficiencies noted in Re-Registration/MA Renewal applications

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BACKGROUND

- **WHO-GBT** Requirement for **NRA** to have documented procedure to **Renew** and or **Periodically Review** MA applications
- Registration of a medicinal product is valid for a period of **five (5) years** unless the product is cancelled or suspended.
- The registration should therefore be renewed before the expiry of the validity period.
- A guideline on the renewal of product registration **(EVR-GL-06)** is available on the MCAZ website to assist applicants to prepare applications for renewal of product registrations .
- **A product cannot be renewed if it has been cancelled or suspended.**

Common deficiencies noted during assessment of re-registration applications

- MC8 forms
- Labelling
- Pharmacovigilance plan
- Adverse drug reactions
- Consolidated list of variations
- Stability studies data
- Quality information summary

MC8 FORM

- **Not submitted** in some cases
- Submitted but not **signed and dated**
- Submitted, signed and dated but not completed correctly for example the **Proprietary name** filled in on the **Approved name** slot.
- Incomplete **names and addresses** of applicants, manufacturers, and principal.

Labelling (inner and outer)

- Submission of proposed pre-registration label of product.
- Omission of submission of labelling
- Submission of outer labelling only or inner labelling only
- Some applicants are only submitting labelling for some pack sizes and omitting the labelling for the other pack sizes from the applications

Applicants should submit the labels that are currently in use

If any change is being proposed to the currently approved labelling the changes should be specified and provided as a separate document.

Pharmacovigilance plan and Adverse drug reactions reports

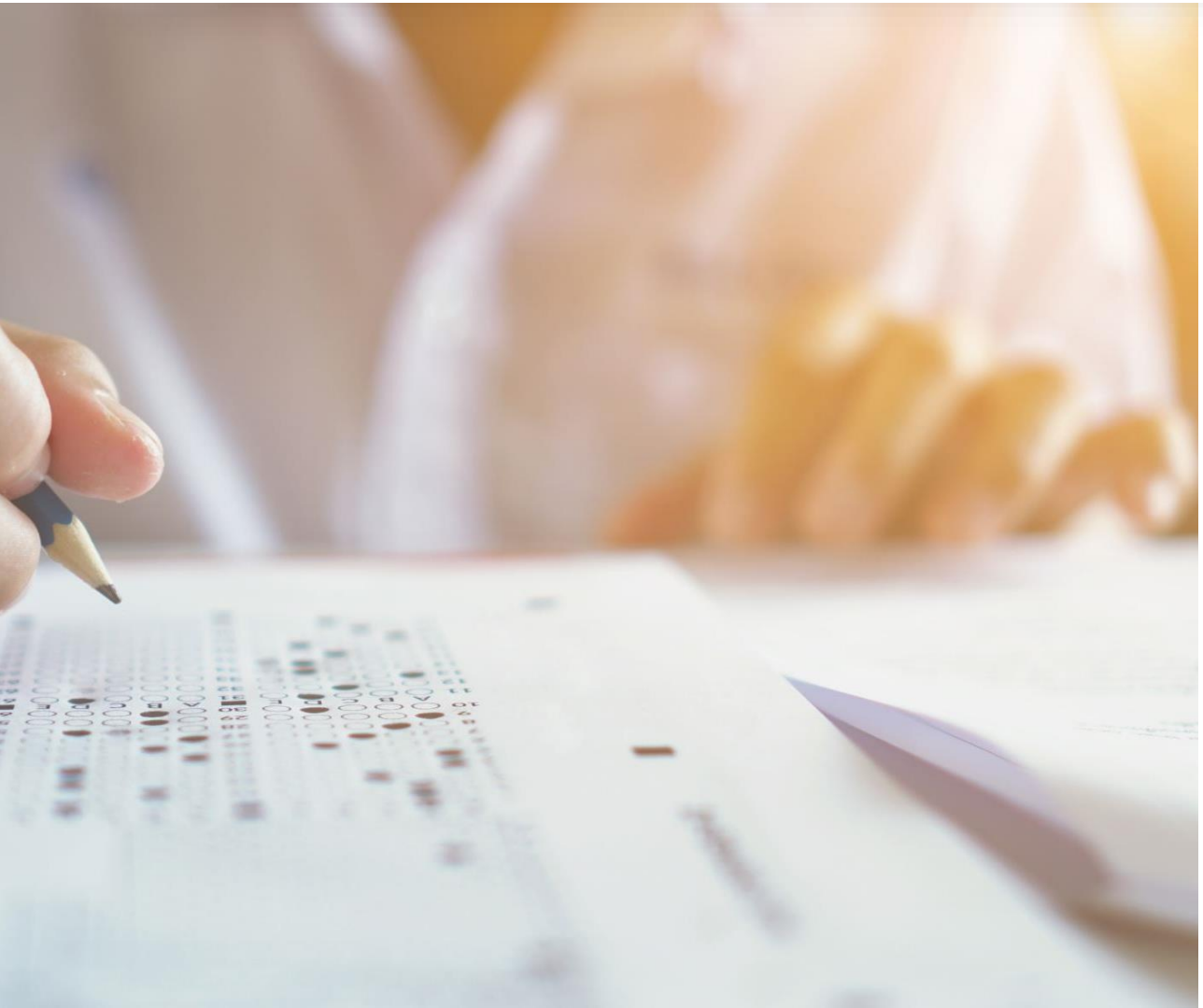
- The PV plans are **not** being submitted
- The summary of the safety reports are **not** being submitted.
- A consolidated report on the adverse drug reaction reports should be submitted
- The applicant needs to provide this information so that the benefit-risk balance of the product staying on the market is assessed.

Consolidated list of variations

- Some applicants are **not** submitting the list at all.
- Some are submitting the list but leaving out **some variations**
- No new variation submissions in applications are permitted and variation approval letters should accompany the applications.

Applicants are being urged to refrain from sneaking in variations in the renewal applications.

Quality information summary



- **QIS** is **not** being submitted in MS Word format
- **QIS** is **not** being completed correctly
- **QIS** is not being submitted by some applicants

Stability studies data

- Changes in shelf-life, without submission of a variation application/approval.
- Post-approval stability data omitted from the submission

It is necessary that applicants provide current stability data showing the performance of the products manufactured post approval of the product registration.

Other deficiencies

- Submission of **expired** GMP certificates
- Submission of **outdated** API specifications as well as FPP specifications
- Submission of the summary of product characteristics (SmPC) in **PDF** format only
- For applications submitted before the CTD format was implemented a copy of the complete dossier in CTD format should be submitted.
- Application forms for re-registrations (EVRF 74) should be duly completed and ensure that you attach all documents stated and as required by the form.

Other deficiencies

- **Grossly deficient** submissions which are not in line with the Guideline on the renewal of product registration (EVR-GL-06) are being **rejected** and should be resubmitted in accordance with the guidelines.
- Applicants are **required to respond to queries** and additional data requests at the stipulated time in the letters or emails or the application will be **rejected**.
- Starting from the 1st of May 2024 all the renewal application will now be accompanied by a renewal fee. The fees will be communicated to applicants in due course.

Thank you!