



SAPRAA MEETING
BAU Variation Update
22 April 2022

Highlights (What went well)

- Reduction in the number of rejections
- ITG variations working group
- Dedicated query email
postregqualityvariations@sahpra.org.za

PEM Quality Variations

- **Type I s DVP & FTP**

Implementable after 37 working days if the application was not reviewed however SAHPRA may request additional information if data provided is not sufficient as per the EMA and SAHPRA Q & BE guidelines.

Backlog (older than 37 working days, 15 Feb 2022): **FTP – 29 & DVP 47**

- **Type II – FTP**

Changes that could have major effects on the overall safety, efficacy and quality of the FPP therefore Prior approval by SAHPRA is required before changes can be implemented.

120 working days timelines

No backlog (no applications older than 06 months, 15 October)

- **Responses**

Evaluated immediately when received in the unit.

Challenges/Interventions

Post reg unit receives large number of application that are not fully compliant with requirements = queries raised more responses which results in delay

EMA guideline + Quality & Bioequivalence guidelines should be used together

Common deficiencies during evaluations

1. Additional API source using the CEP

- EMA Requirement

Release & shelf life remains unchanged, unchanged additional specs for impurities, not a sterile, updated CEP.

- SAHPRA Q&BE guideline Requirements:

3.2.S.4 & 3.2.S.5 (FPP manufacturer)

Challenges/Interventions

2. Additional Manufacturer of the finished product

EMA requirements:

- Batch no's corresponding to batch size used in the validation study, approved release & shelf-life specifications, conditions of transport & bulk storage should be specified & validated if the manufacturing + packaging site different

Q&BE guideline requirements:

- FPP master production documents for each manufacturing site, proposed strength & commercial batch should be provided

Challenges/Interventions

3. API Source change using DMF

No communication between the applicant & APIMF holder

APIMF holders send the link which expires within few days which delays the evaluation process of the DMF

Uploading zipped folders also contribute to the delay in accessing the DMF as they are blocked by the system

Screenshot of the successful upload of the DMF should be requested to address this issue

Applicants requests the login credentials on behalf of the APIMF holder – not acceptable because the information is confidential

It is the responsibility of the APIMF holder to notify the applicants & SAHPRA about any changes to the open or closed part of the dossier.

General

- All queries related to PEM quality variation applications should be submitted via the dedicated email address:
postregqualityvariations@sahpra.org.za
- All queries related to the APIMF should be submitted at the following email address APIMF@sahpra.org.za

THANK YOU