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Post-Registration  
Amendments – Quality fees.

# Fees Overview

## Relevant guidelines:

- Government Gazette 11214 – **Vol 666 22 December 2020** – Available on SAHPRA website
- Explanatory note on fees payable for technical amendments related to quality – **Version 2 – Implemented April 2021** – Available on SAHPRA website

- **Type IA/IAin variations**

R3300 per variation/**group of 3 variations in a single application**

- e.g. 2 x Type IA variations applied for = 1 x R3300 = R3300
- e.g. 4 x Type IA variations applied for = 2 X R3300 = R6600

- **Type IB variations**

R5400 per variation/**group of 2 variations in a single application**

- e.g. 2 x Type IB variations applied for = 1 x R5400 = R5400
- e.g. 5 x Type IB variations applied for = 3 X R5400 = R16200

- **Type II variations**

- Type II level 1 variation = R28500 **per variation in a single application**
- Type II level 2 variation = R13300 **per variation for the first 2 variations in a single application** thereafter Type II level 3 fee applies for each subsequent variation (see below)
- Type II Level 3 variation = R4400 **per variation for the third and subsequent type II variations that are included in a single application**

# Some common issues to take note of:

- **Submission date:**
  - What fee guideline is applicable at the time of submission?
  - Latest fee guideline may not be relevant to re-submissions – applicant will have to include proof that this was a resubmission.
- **How much is due?**
  - Fees are charged per individual product/registration number.
  - How many variations? What type of variations?
  - Group appropriately.
  - No payment required for response submissions.
- **Joint applications i.e. applications involving variations from multiple units**
  - Differentiate between amount due for PEM variations vs amount due for other variations
  - **Inspectorate variations:**
    - Currently the only variation (s) affecting both inspectorate and quality is “Replacement or addition of a manufacturing site for part or all of the manufacturing process of the **finished product**” – B.II.b.1.c, B.II.b.1.e, B.II.b.1.f. Therefore a fee is charged by both inspectorate and PEM.
    - Changes to primary and/secondary packers, FPRC, HCR of **final product** are not currently evaluated by PEM. Therefore no fee is charged by Quality unit.

# Some common issues to take note of:

- **Underpayments**
  - Miscalculation of fees -It is **essential** that applicant provide payment breakdown.
  - Incorrect grouping of variations: What is considered a single variation?
  - Payment not made per individual product
  - Duplicated/Re-used proof of payment
- **Overpayments**
  - Applicant paying quality variation fees for inspectorate amendments
  - Applicant paying per individual variation rather than grouping.

## Action to be taken:

- Underpayment:
  - **Screening:** Application not to proceed past screening phase until full payment is made. Flag application on database. Email applicant requesting balance due. Application is only available for allocation once payment is received.
  - **Evaluation:** If evaluator notices discrepancy in payment, inform unit manager and pause evaluation until matter is resolved.
    - Amount due for an application is determined by variations listed on the cover letter. Therefore only variations listed on the cover letter will be evaluated. Additional variations found on the amendment schedule will not be evaluated as they have not been paid for.
- Overpayment: Make note of overpayment on report/database – matter to be resolved by finance.