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Explanatory note on general fees payable to the Quality variations (Type 1A, 1B & II) for medicinal products for human use.

UPDATE HISTORY

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Note: This section on fees for quality variations of medicinal products for human use should be read in conjunction with the SAHPRA new fees published on the Government Gazette dated 22 December 2020 (http://www.gpwonline.co.za/Gazettes/Gazettes/44026_22-12_Health.pdf) and Guidance on the payment of fees, version 5 dated November 2020 (https://www.sahpra.org.za/wp-content/uploads/2020/11/SAHPRA-Payment-Guideline-Nov-2020.pdf)

Introduction

The SAHPRA fees gazetted is implementable from 23 December 2021. The fees outlined in most cases are self explanatory, however in the case of fees payable for quality variations there are several options listed which requires clarification and hence this explanatory note is provided for this purpose

It is also important to note that some of the quality variations involve review from different units although it shares the same code. In such instances clarification is provided on how to calculate the fees. Some examples have been inserted for purposes of illustrating how the fees are to be calculated. Please note that when payments are made the respective references made should be aligned with that of the SAHPRA guidance on payments of fees.

1.1 Definitions

Type IA variation (inclusive of Type IA_{IN})

'Minor variation of type IA' means a variation which has only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product concerned;

Type IB variation

'Minor variation of type IB' means a variation which is neither a minor variation of type IA nor a major variation of type II nor an extension;

Type II variation

'Major variation of type II' means a variation which is not an extension, and which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned;

1.2 Fees

1.2.1 Type IA variation (inclusive of Type IA_{IN})

R3 300.00 (Basic fee)

For a minor variation to a marketing authorisation, as defined in the current Variations Addendum for Human and Veterinary Medicines and Biological medicines Amendment guideline

1.2.2 Type IB variation

R5 400.00 (Basic fee)

For a minor variation to a marketing authorisation, as defined in current Variations Addendum for Human and Veterinary Medicines and Biological medicines Amendment guideline

1.2.3 Inspectorate Type IA and IB Variation

Fees applicable to Inspectorate variation codes is for amendment of entries in register:

Basic fee: R800

1.2.4 Type II variations

R28 500.00 Level I (Basic fee)
For a major variation with new quality or pre-clinical or clinical data to a marketing authorisation, as defined in current Variations Addendum for Human and Veterinary Medicines and Biological medicines Amendment guideline (Note that Bioequivalence data qualify as clinical data)

R13 300.00 Level II (Basic fee)
For a quality variation for which no clinical or non-clinical data are submitted or no cross-references to previously submitted clinical or non-clinical data are made by the applicant (HCR). (Note: Bioequivalence data qualify as clinical data. Biowaiver dossiers are not considered as clinical data.)

R4 400.00 Level III (Basic fee)
For each of the third and subsequent type II variations that are grouped in a single application. For example, if 2 Type II variations are included in one application/submission, and the next each subsequent type II variation on the same application/submission will be charged as level III.

1.3 Grouping procedures for variations

- The applicable fee specified in section 1.2 shall be payable for each individual variation to a marketing authorisation that is grouped in a single notification or a single application.
- The applicable level I and level II basic fees specified in sub-section 1.2.4 above are payable for the first and second type II variation respectively when both levels of fees are applicable to variations in the same grouping.
- Consequential variations in a grouping shall be similarly charged the applicable fees as specified above.
- In the case of grouping of the same Type IA variations to the terms of several products owned by the same applicant, the applicable fee shall be payable for each individual Type IA variation and for each marketing authorisation in the grouping.
- For inspectorate variation codes fees are payable per application.

1.4 Examples of the determination of fees for variations to a marketing authorization

- It should be noted that the calculation of the total fee is determined by the number and type of variations (IA, IB, II).

Scenario 1
The submission of addition of the FP manufacturer (B.II.b.1.e or B.II.b.1.f, Type IB), Change in FP batch size (B.I.a.3.a, Type IA), Change to in-process test (B.I.a.4.a, Type IA) and change in immediate container (B.I.c.1.c, Type IB)

- The fee payable for quality will be: 2 Type IA fees + 2 Type IB fees, i.e 2 x R3 300.00 + 2 x R5 400.00 = R17 400.00
- Fees with Quality and Inspectorate review will be: R800.00 (amendment of entries in register B.II.b.1. e or B.II.b.1.f: Inspectorate) + R17 400.00 (Quality) = Total R18 200.00

Scenario 2

The submission of addition of the FP manufacturer (B.II.b.1.e or B.II.b.1.f, Type IB), Change in FP batch size (B.I.a.3.a, Type IA), Change to in process test (B.I.a.4.a, IA) and change in immediate container (B.I.c.1.b, Type II)

- The fee payable for quality will be: 2 Type IA fees + 1 Type IB fees + 1 Type II, level 2 fees, i.e 2 x R3 300.00 + 1 x R5 400.00 + 1 x R13 300.00 = R25 300.00
- The fee payable of quality and inspectorate will be: R800.00 (amendment of entries in register B.II.b.1. e or B.II.b.1.f: Inspectorate) + 25 300,00 (Quality)

Total R26 100.00

Scenario 3

The submission of changes in the composition (excipients) of the finished product (B.II.a.3.b.5, Type II) (Change that is supported by a bioequivalence study)

- The fee payable will be: R28 500.00 (Type II, level 1)

Scenario 4

The submission of a change in the specification parameters (B.I.b.1.e, Type II) and change in immediate container (B.I.c.1.b, Type II)

- The fee payable will: 2 Type II, level 2 fees, i.e 2 x R13 300.00 = R26 600.00

Scenario 5

The submission of a change in the specification parameters (B.I.b.1.e, Type II), Change in coating weight of oral dosage forms or change in weight of capsule shells (B.II.a.4.b, Type II) and change in immediate container (B.I.c.1.b, Type II)

- The fee payable will: 2 Type II, level 2 fees + 1 Type II, level 3, i.e 2 x R13 300.00 + 1 x R4 400.00 = R31 000.00

Scenario 6

The submission of a change in the specification parameters (B.I.b.1.e, Type II), Change in coating weight of oral dosage forms or change in weight of capsule shells (B.II.a.4.b, Type II), Change in concentration of a single-dose, total use parenteral product, where the amount of active substance per unit dose (i.e. the strength) remains the (B.II.a.5, Type II) same and change in immediate container (B.I.c.1.b, Type II)

- The fee payable will: 2 Type II, level 2 fees + 2 Type II, level 3, i.e 2 x R13 300.00 + 2 x R4 400.00 Total = R35 400.00

Scenario 7

The submission of a Transfer of Applicancy (A.1-Type II) and replacement or addition of a manufacturing site B.II.b.1.e

- Fee payable: R800.00 (amendment of entries in register: Inspectorate) + R3 300.00 (Type 1B: Quality) + R1050 (transfer of certificate of registration) = Total R5060