SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

CLINICAL VARIATIONS FEE SCHEDULE AND EXPLANATORY NOTES

May 2021

1. Clinical Variations Fee Schedule

1.1 Product rescheduling fees

South African Rand (ZAR) 15,000 basic fee for evaluation of an application for the rescheduling of a registered product.

1.2 Type IAin notification-only Professional Information (PI)/Patient Information Leaflet (PIL) updates

ZAR 2,600 basic fee for evaluation of an application for a notification-only safety update where clinical data are not required to support the application. The fee above applies to both generic and innovator products.

1.3 Type IB minor safety PI/PIL updates

ZAR 2,600 basic fee for evaluation of an application for a notification-only safety update where clinical data are not required to support the application. The fee above applies to both generic and innovator products.

1.4 Type II major safety PI/PIL updates

ZAR 15,600 basic fee for evaluation of an application for a major safety update where clinical safety data are required to support the application.

1.5 Type II major efficacy and safety PI/PIL updates

ZAR 15,600 basic fee for evaluation of an application for a major efficacy and safety update where clinical efficacy and safety data are required to support the application.

1.6 Masters and duplicates

Masters, duplicates, and clones (as defined) will be charged separately and according to the type of variation applied for. Please refer to the guideline on “Multiple Submissions of the Same Application for Registration with Different Proprietary Names” (May 2019) for additional information.

2. Explanatory Notes

2.1 Rescheduling applications include those applications that request an amendment of the current product schedule and are product-specific. These applications require clinical safety and efficacy data to support the request to amend the scheduling status of the product. Such applications undergo assessment of the risk/benefit of the requested scheduling status in relation to patient safety for the requested change in the level of access.

2.2 Type IAin notification-only PI/PIL updates include those applications that essentially contribute to safer use of the product by implementing minor updates to the safety sections of the PI/PIL and do not involve deletion of any part of the PI/PIL. Such applications are verified for compliance with Type IAin variations requirements, in line with the current Clinical Variations Guideline. These applications also include minor editorial changes and format update of the PI and PIL

2.3 Type IB minor PI/PIL safety updates include those applications that also contribute to enhanced safe use of the product and are assessed for compliance with Type IB variations requirements in line with the current Clinical Variations Guideline. Such applications are also reviewed for any shifts in the current benefit/risk balance that may obtain from the update.

Although clinical safety and efficacy data is not required for clinical Type IB variation applications, an EU SmPC/a PI from a Recognised Regulatory Authority (RRA) is an acceptable supporting reference, *in lieu* of a South African innovator, where the latter is not available or is outdated.

2.4 Type II major PI/PIL safety updates include those applications that involve major safety issues that invariably affect the current benefit/risk balance of the product and may result in restrictions of use of the product to certain patient populations. Such applications should be supported by clinical safety data to allow assessment of any new benefit/risk issues that may obtain from new clinical safety data.

For Type II major PI/PIL safety updates, in addition to the required clinical safety data, an EU SmPC/a PI from an RRA, un-redacted rapporteur assessment reports from RRAs or a Letter of Access are also acceptable to facilitate an abridged review process (see the current Clinical Variation Guideline). It should be noted that “abridged” does not equate to “abbreviated” by default. The reviewer retains the option to access the clinical safety data submitted in support of the application to clarify any questions during the abridged review.

2.5 Type II major PI/PIL safety and efficacy updates include those applications requesting new indications, and may also include new clinical safety data. Such applications should be supported by clinical efficacy and safety data for a consolidated clinical review of the

benefit/risk balance that may obtain from addition of the new indication and its related risks in new patient populations.

For Type II major PI/PIL safety and efficacy updates, in addition to the required clinical safety and efficacy data, an EU SmPC/a PI from an RRA, un-redacted rapporteur assessment reports from RRAs or a Letter of Access are also acceptable to facilitate an abridged review process (see the current Clinical Variation Guideline). It should be noted that “abridged” does not equate to “abbreviated” by default. The reviewer retains the option to access the clinical safety and efficacy data submitted in support of the application to clarify any questions during the abridged review.

DocuSigned by:
Boitumelo Semete-Makokotlela
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Dr Boitumelo Semete-Makokotlela: SAHPRA CEO