

Communication to Industry

Friday, March 25, 2022

**Submission of Post-Importation Testing Exemption requests for
Biological and Biosimilar Medicines**

Attention All Stakeholders

Currently, Section 2.0 Scope of Guideline 2.04 Post Importation Guidelines, version 4 states:

This guideline applies to the following pharmaceutical products: It is important to note the Exclusions.*

*... e) * Combined Category A and B that are Biological and Biosimilar Medicines*

As of the 1st of April 2022, the post-importation testing exemption requests for Biological and Biosimilar medicines should be submitted as per the requirements of Guideline 2.04. For submission process, please refer to section 3.0 Post-Importation Testing Exemptions (PITE).

Please note that the review of PITE for Biological and Biosimilar Medicines will be conducted by the Inspectorate Unit for applications submitted from 01 April 2022 onwards. Applications received prior to 01 April 2022 will be reviewed to completion by the Biological Medicines Unit in the Pharmaceutical Evaluation Management Programme.

For PITE Applications for Biological and Biosimilar Medicines prior to 01 April 2022, applicants are advised to send the notification of applications with their proof of payments to the Biological Medicines Unit PITE email address as follows: BiologicalPITE@sahpra.org.za cc Unit Manager.

Guideline 2.04 Post Importation Guidelines will be updated accordingly.



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