DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

09th September 2024

Ref: 1983G/DR/NDA-09/2024

To: Marketing Authorization Holders
Local Technical Representatives

**CIRCULAR NO. 003/DPAR/2024**

**FAST-TRACK ASSESSMENT OF VARIATIONS (AMMENDMENTS) AND CTD DOSSIER APPLICATIONS.**

National Drug Authority wishes to inform you that it commenced receipt of variations (amendments) and CTD dossier applications for fast-track assessment.

As per the National Drug Policy and Authority (Fees) Regulations 2022, under S I No. 5 part one "Fees for Registration of drugs, retention, notification, and amendment," the National Drug Authority (NDA) allows for the fast tracking of: -

## 1. Variations (Amendments) Applications

***Please note that:***

i. Fee per application.
   a. Major amendment -**USD 2,100**.
   b. Minor amendment -**USD 1,200.**

ii. The timeline for feedback on:
   a. Major amendment - **12** working days.
   b. Minor amendment - **10** working days.

iii. The applicant should compile the variations (amendments) application as per the NDA guidelines available on the NDA website. www.nda.or.ug.
   a. Guidelines on variations to registered pharmaceutical products.
   b. Guidelines on variation of registered Biotherapeutic products.
   c. Guidelines for Variation of Registered Vaccines.

## 2. Common Technical Document (CTD) dossier applications

***Please note that:***

i. Fee is **USD 10,000** per application.
ii. The timeline for feedback on a CTD fast track application is 3 months. This period does not include additional information if requested. The timeline for feedback on additional information is 1 month.
iii. The Finished Pharmaceutical Product (FPP) manufacturing site(s) must possess a valid NDA Good Manufacturing Practices (GMP) certificate or should have applied for an NDA GMP inspection at the time of submission of the application.
iv. The applicant should compile the CTD dossier application as per the NDA guidelines on Submission of Documentation for Registration of a Pharmaceutical Product for Human Use (PAR GDL 004) available on the NDA website. www.nda.or.ug.

Yours faithfully,

David Nahamya
**SECRETARY TO THE AUTHORITY**