

National Agency for Food and Drug Administration and Control Registration & Regulatory Affairs Directorate Plot 1, Isolo Industrial Estate, Apapa - Oshodi Expressway, Isolo – Lagos

DOSSIER SUBMISSION WINDOW OPENS

This is to inform all stakeholders that submission of product dossiers for new applications and for responses to queries raised for dossiers submitted in the previous window will open on 08 May 2023.

Please note that submissions for the new window will be made on the new NAFDAC Dossier Management portal and not on "*Dropbox*".

All applicants who intend to submit dossiers during this window should note the following.

- 1. A maximum of two (2) dossiers will be allowed for each applicant.
- 2. Applicants will need to create their company profiles on the dossier management application before they can upload dossiers on the portal.

INVITED PRODUCTS

There is currently no restriction on the type of products that can be submitted during each window. However, the following products will be given priority.

- A. Fast track applications (WHO collaborative procedure, SwissMedic MAGHP procedure, SRA approved reliance registration).
- B. Oncology products
- C. Products manufactured in Nigeria.

UPLOADING DOSSIERS ON THE PORTAL

Dossiers will be submitted through the dossier management portal during the submission window. Applicants will need to create their company profiles and thereafter create an application and upload their dossier(s).

For more information, please use the link below to learn how to:

- A. <u>Use the dossier management application.</u>
- B. <u>Create company profile.</u>
- C. Initiate/create an application on the portal.