



National Agency for Food & Drug Administration & Control (NAFDAC)

Drug Registration and Regulatory Affairs (DR & R) Directorate

DOSSIER SUBMISSION GUIDE

INTRODUCTION OF SUBMISSION WINDOWS

1. There will be four (4) window periods per year (i.e every quarter) available to applicants for submission of product dossier(s).
2. The duration of each window period will be the first two (2) weeks in the first month of each submission cycle or quarter.
3. Submission will be via an upload link which will be made available on the NAFDAC website (see section for industry) at the start of each submission cycle.

INVITED PRODUCTS

1. Drug products for use in public health emergencies, oncology and other emergency/lifesaving as may be determined by the Agency are eligible for priority screening.
2. A maximum of two (2) products (dossiers) can be submitted by each applicant during each submission window.

NOTE: The Agency may use its discretion to specify which product(s) will be invited for submission during any submission cycle.

WHAT YOU SHOULD NOTE BEFORE UPLOADING YOUR DOSSIER

- The dossier should be placed in a folder and properly labelled with the name of the applicant along with the product name as a suffix (e.g., XYZ Limited – Ibuprofen 500mg Tablets).
- You need to have a stable and fast internet connection for a successful upload. A slow and unstable internet connection may lead to a fragmented and unsuccessful upload.

UPLOADING STEPS

- | | |
|--------|--|
| Step 1 | Click on the link provided on the website |
| Step 2 | A dialogue box with instruction to ‘Add file’ will pop-up |
| Step 3 | Click on “Add Files” |
| Step 4 | A dialogue box will pop-up with three options to add files |

- Step 5 Click on “folders from computer” and select the folder you wish to upload from your computer.
- Step 6 Click “upload” to begin uploading your folder
- Step 7 When uploading is completed, a display showing “Finished uploading” will appear on the screen to indicate that the upload was successful
- Step 8 Click on “upload more files” if you want to upload additional files or close the window if you are done uploading your dossiers.

ALTERNATIVELY,

- Step 1 After step 2 above, you can drag the dossier folder into dialogue box to begin the upload.
- Step 2 Follow steps 7 & 8 above to complete the upload or to add more files as applicable.

WHAT COULD LEAD TO REJECTION OF YOUR UPLOADED DOSSIER

- Non-use of Common Technical Document
- Exceeding the number of products allowed for each applicant during each submission cycle.
- Inappropriate labelling of the dossier folder.
- Incomplete upload of dossier(s).
- Uploading dossiers as zipped files.

Note: All applicants will get a confirmation of submission at the end of each window, kindly ensure that you have provided a valid email address in your cover letter from the local applicant (Market Authorization Holder) in Module 1 for communication.

Click [here](#) to start your upload