

## **Key Points to Note when Preparing Documents for Therapeutic Product Application Dossier Submission via EasiShare**

Submission of application dossier and DMF via EasiShare must strictly adhere to requirements outlined in points 2 and 3 of this guidance to ensure that HSA can receive, identify, and retrieve your submitted documents to match with your PRISM application/DMF Submission Form.

The date of successful download of the application dossier will be considered as the submission date and the start of the screening timeline. Any download failure will result in the inability to proceed with the screening of your application.

### **1) One *File Upload Request* URL per company**

- Companies can request for a *File Upload Request* URL from HSA using the Request form (<https://go.gov.sg/tpb-file-upld-req-form>)
- Each company, specific to the company's client code, should only submit ONE request for a *File Upload Request* URL.
- Upon receipt of your request, each company will receive one *File Upload Request* URL via email. Company users with access to the URL can share it with additional users within the company.
- Anyone with access to the URL will be able to upload documents to the same folder.

### **2) Use of zipped file format**

- Each product application must be submitted in zipped file format to preserve the folder organization of the dossier. Please note that EasiShare does not support folder structures.
- For application dossier submissions:
  - Each zipped file should be named with the **product name** and at least one relevant **PRISM application number** to facilitate easy identification.
  - E.g. *TRADENAME\_2412345P\_zip1*
- For DMF submission:

- Each zipped file should be named with the **active ingredient name**. If available, please include the **DMF number** in the file name.
- E.g. *APINAME\_015999\_zip1*
- E.g. *APINAME\_newDMF\_zip1*

### 3) Max file size of 450MB

- Each zipped file should not exceed 450 MB in size.
- If the total file size of the submission exceeds 450 MB, please reorganize and submit the files as multiple zipped files, with each zipped file not exceeding 450 MB.

### 4) Check before refreshing

- Users can see the files they have uploaded before the view is refreshed and can add or remove uploaded files.
- Once the view is refreshed, the files become inaccessible and cannot be retrieved, removed, deleted, or viewed by any of the company users.
- The file submission process is one-way, allowing users to upload files but not access them after the view is refreshed. The file transmission is irreversible.