

REGULATORY DIRECTIVE ON MANDATORY SUBMISSION OF DRUG MASTER FILE (DMF) IN PRODUCT DOSSIERS

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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

REGULATORY DIRECTIVE ON MANDATORY SUBMISSION OF DRUG MASTER FILE (DMF) IN PRODUCT DOSSIERS

1. Purpose

The quality, safety and efficacy of a finished pharmaceutical product (FPP) depend substantially on the identity, synthesis, control and safety of the drug substance or active pharmaceutical ingredient (API) used in its production. In a bid to assure the quality and safety of finished pharmaceutical products marketed and used in Nigeria, a directive making it mandatory to provide comprehensive drug substance master file(s) (DMF) in every product dossier is issued, and the acceptable mechanisms for protecting an API manufacturer's confidential information.

2. Scope

This Directive applies to all new applications for registration or marketing authorization of human medicinal products, whether locally manufactured or imported.

3. Directive

With effect from the date stated in this Directive, every product dossier submitted for the purpose of registration of human drugs shall be accompanied by a complete and current Drug Master File (DMF) from the API manufacturer. The DMF, which should be prepared in Common Technical Document (CTD) format, shall be in English or translated into English and attached as a folder in the S-Part of the product dossier. It should be noted that provision of a DMF in the dossier does not absolve the Finished Product manufacturer of the requirement to provide the FPP manufacturer's API information such as the FPP manufacturer's specifications in the relevant sections of the dossier.

Following this directive, a product dossier without relevant Drug Master File (DMF), or Active Substance Master File (ASMF) or Active Pharmaceutical Ingredient Master File (APIMF) shall not be regarded as complete.

4. Closed/Restricted part of the DMF

Depending on the API information submission option selected in the dossier by the applicant, the restricted/closed part of the DMF may also be required.

4.1 Submission of the restricted/closed part of the DMF is not required when the following API options are used.

- i. Confirmation of API Prequalification document (CPQ)
- ii. Certificate of suitability to the European Pharmacopeia (CEP)

4.2 Submission of the restricted/closed part of the DMF along with a letter of Access is required when the API option is via:

- i. Active pharmaceutical ingredient master file (APIMF) or Drug Master File (DMF) procedure.

4.3 Where the option of API submission is full details, all the information in both the open and closed part of the DMF shall be provided in the dossier.

4.4 Submission of confidential submission

Where applicable, the restricted/closed part of the DMF/APIMF shall be submitted directly by the API manufacturer or authorized master-file holder to NAFDAC via the submission channels prescribed by NAFDAC and shall be cross-referenced to the relevant product application.

5. Responsibilities

5.1 Applicant/Marketing Authorization Holder

Ensure that the open/applicant part of the DMF and all product-specific information are complete, consistent and current.

Ensure that the restricted part and valid Letter of Access/Authorization reach NAFDAC within the prescribed application timeline.

Maintain an effective quality agreement with the API manufacturer and notify NAFDAC of reportable changes in accordance with applicable variation requirements.

5.2 API Manufacturer/Master-File Holder

Submit the complete restricted/closed part directly to NAFDAC and respond promptly to regulatory queries.

Maintain the master file throughout its lifecycle, with clear version control and a consolidated current version where required.

Inform NAFDAC and the applicant/marketing authorization holder of any changes that may affect the quality of the API or FPP, subject to applicable regulatory requirements.

6. Confidentiality

NAFDAC shall handle proprietary information submitted directly by a master-file holder as confidential regulatory information in accordance with applicable law and Agency procedures. The use of a master-file procedure does not diminish the applicant's responsibility for the quality of the API and the finished product.

7. Non-compliance

An application that omits the required drug-substance information, contains an incomplete or inaccessible master file, lacks a valid Letter of Access/Authorization, or does not permit identification of the API manufacturer and manufacturing site shall be considered deficient and would be rejected at the screening stage.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature



Date: August 18, 2026