Guidelines on the Rules and Procedures of Listing Active Pharmaceutical Ingredients (APIs) for Medicinal Products

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1. Introduction

-This guide is concerned with regulating the rules and procedures of the voluntary listing of the active pharmaceutical ingredients of the submitted medicinal products, in order to establish a public database including quality files of the active pharmaceutical ingredients approved by Egyptian Drug Authority.

-The quality file of the active pharmaceutical ingredient (Drug Master File/ Quality Module 3 "S-part") shall refer to the file that contains the chemical description of an active pharmaceutical ingredient, the site and method of its manufacturing, its specifications, limits of impurities therein, methods of analysis and validation thereof, storage data and validity period of use.

2. Scope

Entities permitted to submit a listing application are:

-Active pharmaceutical ingredient factories inside or outside the Arab Republic of Egypt, their agents or their legal representatives.

-Licensed medicinal products' factories or companies recorded in toll manufacturing register.

3. Definitions

3.1 **Active pharmaceutical ingredient (API).** Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form, and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.

3.2 **API Master file (APIMF):** other global terms include DMF (drug master file) and ASMF (active substance master file) is a document containing complete information on an Active Pharmaceutical Ingredient (API) containing factual and complete information on a drug product's chemistry, manufacture, stability, purity, impurity profile, packaging, and the cGMP status of any human drug product. A drug master file comprises two parts: the Applicant's Part (Open Part), which contains all the information that the license-holder needs to assess the quality and submit a license or amendment application; and the Restricted Part (Closed Part), which contains confidential information about the manufacturing procedure only disclosed to the authorities.

3.3 **Applicant:** The person or company who submits an application for marketing authorization of a new

pharmaceutical product, an update to an existing marketing authorization or a variation to an existing market authorization.

3.4 Finished pharmaceutical product (FPP): A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.

4. Procedures

4.1 Submitting a listing application for an active pharmaceutical ingredient:

4.1.1 In the event of submitting an application for listing active pharmaceutical ingredients that have quality files for these active pharmaceutical ingredients and that have been assessed and approved by Egyptian Drug Authority; The listing applicant shall submit an application to the General Administration of Human Pharmaceuticals Registration at the Central Administration for Pharmaceutical Products, indicating the data and version number of the quality file of the active pharmaceutical ingredient, which file was assessed and approved by the Administration of Technical Affairs for Human Pharmaceuticals, in order to list this active ingredient in Egyptian Drug Authority's approved list of the active pharmaceutical ingredients.

4.1.2 In the event of submitting an application for listing active pharmaceutical ingredients that have quality files for these active pharmaceutical ingredients but they have not been previously assessed by Egyptian Drug

Authority; The listing applicant shall submit an application to the General Administration of Human Pharmaceuticals Registration at the Central Administration for Pharmaceutical Products, indicating the data of the quality file of the active pharmaceutical ingredient. The applicant shall pay the service fees of applying for listing an active pharmaceutical ingredient. The request shall be accompanied with the quality file of the same active pharmaceutical ingredient, which has the same data and version number submitted in the application.

4.2 The receipt and initial screening of the quality file of the active pharmaceutical ingredient

4.2.1 The listing applicant shall submit the quality file of the active pharmaceutical ingredient, accompanied with the listing application, to the General Administration of Human Pharmaceuticals Registration to carry out receipt reviewing process, file reception and file initial screening to verify that all of the file parts and contents are complete, within 15 days from the date of submitting the file by the listing applicant. After these procedures, the listing applicant shall be notified of the status of the file.

4.2.2 The submitted listing applications shall be arranged in accordance with the day and hour of their submission. When applying for the same active ingredient that belongs to the same source, completed applications shall take priority over other applications. When applications are equally complete, priority shall be given on a first-come, first-served basis, and the order of precedence shall be in accordance the date of submission of the application.

4.3 Technical assessment of the quality file of the active pharmaceutical ingredient

4.3.1 After receiving the quality file of the active pharmaceutical ingredient, the Administration of Technical Affairs for Human Pharmaceuticals shall assess and examine the file in accordance with the most recent pharmacopoeia and international guidelines.

4.3.2 The report of the technical requirements and documents to be fulfilled by the active pharmaceutical ingredient manufacturer shall be finalized within a period not exceeding 45 days from the date of receiving the completed file. If required, the file can be presented to the Quality Module Evaluation Committee.

4.4 Accepting the quality file of the active pharmaceutical ingredient and issuing an approval for listing the active pharmaceutical ingredient

4.4.1 When the company completes the file and fulfills the requirements of examining and assessing the file, which file shall be then approved by the Administration of Technical Affairs for Human Pharmaceuticals, an approval of listing the active pharmaceutical ingredient shall be issued in the name of the listing applicant. The said approval shall include the data and version number of the quality file for the active pharmaceutical ingredient from the General Administration of Human Pharmaceuticals Registration at the Central Administration for Pharmaceutical Products.

4.4.2 In the case of quality files for active pharmaceutical ingredients that have been previously assessed and approved by Egyptian Drug Authority, an approval shall be issued for listing the active pharmaceutical ingredient in the name of the listing applicant. The said approval shall include the data and version number of the quality file for the active pharmaceutical ingredient from the General Administration of Human Pharmaceuticals Registration at the Central Administration for Pharmaceutical Products, based on the application submitted by the listing applicant.

4.4.3 The active pharmaceutical ingredient, its data and the version number of this pharmaceutical ingredient file, which has been approved, shall be listed in the list of active pharmaceutical ingredients approved by Egyptian Drug Authority. Such listed pharmaceutical ingredient shall be announced on the Authority's website to be utilized in registering other medicinal products.

4.4.4 The company owning the active pharmaceutical ingredient shall be obligated vis-a-vis Egyptian Drug Authority to notify the Authority in the event of any change in the version number or content of the active pharmaceutical ingredient file. The said company shall be obligated also to notify the finished product manufacturers of any related change in the active pharmaceutical ingredient file. Upon technical re-assessment, the database of the active pharmaceutical ingredient quality files shall be updated and then a new approval for listing shall be issued after paying the prescribed service fees.

4.4.5 The validity of the listing approval shall expire after a lapse of five Gregorian years from the date of the first issuance. In the event that the listing applicant is desirous to re-list the active pharmaceutical ingredient, he must submit an application for re-listing within the last six months of the validity period of the listing approval.

4.5 Using the active pharmaceutical ingredient listed by Egyptian Drug Authority

4.5.1 In the event that any of the holders of marketing licenses for medicinal products make use of listed active pharmaceutical ingredients that were manufactured in one of the active pharmaceutical ingredients' factories inside or outside the Arab Republic of Egypt, which materials were listed through active Pharmaceutical ingredients' factories inside the Arab Republic of Egypt, active Pharmaceutical ingredients' factories outside the Arab Republic of Egypt, their agents or their legal representatives, or through other marketing license holders, they shall be entitled to enjoy benefits indicated in the appendix of the Regulatory Guide for the Rules and Procedures for Listing Active pharmaceutical ingredients for Human Medicinal Products after obtaining the approval of Egyptian Drug Authority to use the listing active pharmaceutical ingredients published on the Authority website.

4.5.2 The validity of approval for the use of the listed active pharmaceutical ingredients shall be connected with the listing approval.

5. References:

5.1 Decree of the President of Egyptian Drug Authority No. (213) of 2023 Concerning Regulating the Rules and Procedures of Listing the Active Pharmaceutical Ingredients of the Medicinal Products

6. Annexes

Annex I: Benefits enjoyed by the holder of the listing application or the user of the listed file

1. The holder of the listing application or the user of the listed file shall enjoy a price advantage in accordance with the requirements of the case and the technical study.
2. **The holder of the listing application is one of active pharmaceutical ingredients' factories inside the Arab Republic of Egypt, their agents or their legal representatives:**

In the event that any of the holders of marketing licenses for human medicinal products make use of listed active pharmaceutical ingredients that were manufactured in one of the active pharmaceutical ingredients' factories inside the Arab Republic of Egypt**, they are entitled to enjoy the following benefits:**

2.1 Applying for "Line Extension" registration for the same active ingredient without adhering to the pharmaceutical dosage form specified in the Simitar Box.
2.2 Applying for "Fast Track" system to submit the product dossier for registration or re-registration.
2.3 Additional grace period of 3 months to be added to the original deadline to complete the registration / re-registration procedures.
2.4 Modifying the batches release system in case of adding/changing the API supplier, where submission of Stability Study is the condition for FPP release instead of approving the stability study.

3. **The holder of the listing application is one of active pharmaceutical ingredients' factories outside the Arab Republic of Egypt, their agents or their legal representatives:**

- In the event that any of the holders of marketing licenses for pharmaceutical products, make use of active pharmaceutical ingredients that were listed by active pharmaceutical ingredients'

factories outside the Arab Republic of Egypt, their agent, or their legal representatives**, they are entitled to enjoy TWO of the following benefits:**

3.1 Applying for the "Fast Track" system to submit the product dossier for registration or re-registration.
3.2 Additional grace period of 3 months to be added to the original deadline to complete the registration / re-registration procedures.
3.3 Modifying the batches release system in case of adding/changing the API supplier, where submission of Stability Study is the condition for FPP release instead of approving the stability study.

4. **The holder of the listing application is the one who owns the marketing license for the human medicinal product or his legal representative:**

The holder of marketing license has the right to **choose TWO of the following benefits:**

4.1 Applying for "Line Extension" registering for the same active ingredient without adhering to the pharmaceutical dosage form specified in the Similar Box.
4.2 Appling for "Fast Track" system to submit the product dossier for registration or re-registration.
4.3 Additional grace period of 3 months to be added to the original deadline to complete the registration / re-registration procedures.
4.4 Modifying the batches release system in case of adding/changing the API supplier, where submission of Stability Study is the condition for FPP release instead of approving the stability study.

5. **The user of listed file which was listed by a third party who is one of the holders of marketing license:**

In the event that any of the holders of marketing licenses for pharmaceutical products make use of listed pharmaceutical ingredients that were manufactured in one of the active pharmaceutical ingredients' factories outside the Arab Republic of Egypt and that were listed by other holders of marketing license**, they are entitled to enjoy ONE of the following benefits:**

5.1 Modifying the batches release system in case of adding/changing the API supplier, where submission of Stability Study is the condition for FPP release instead of approving the stability study.
5.2 Appling for "Fast Track" system to submit the product dossier for registration or re-registration.

5.3 Additional grace period of 3 months to be added to the original deadline to complete the registration / re-registration procedures.

Version number	Issue Date	Summary of Change
1	10/04/2023	New Issue
2	01/09/2025	Addition of Definitions to the Guidelines on the Rules and Procedures of Listing Active Pharmaceutical Ingredients (APIs) for Medicinal Products