Guideline for Preparation and Publication of Public Assessment Reports

ETHIOPIAN FOOD AND DRUG AUTHORITY

Medicine Evaluation and Marketing Authorization Lead Executive Office

Guideline for Preparation and Publication of Public Assessment Reports

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Document History

Version No.	Reason for Amendment	Effective Date
001	New Prepared	**01/11/2022**
002	Inclusion of periodic review for SmPC and PIL	**15/11/2023**
	Inclusion of withdrawal assessment reports to the public	
	Inclusion of public assessment reports to deferred and rejected products	
	Updating of EtPAR during variation	
	General formatting including document numbering and document history	

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1) Introduction

As part of the commitment to transparency, the Ethiopian Food and Drug Authority (EFDA) should prepare and publishes information relating to the evaluation of applications via public assessment reports to provide a summary of the grounds for the opinion in favor of a marketing authorization or for deferred and rejected products ‘Here in after ‘Ethiopian Food and Drug Authority Public Assessment Report (EtPAR)'.

According to Article 5 (25) of Regulation number 531/2023, the authority is mandated to establish and implement modern regulatory system by serving as a regulatory information center. One of the regulatory information is publication of positive and negative opinion on an application for a marketing authorization for human medicines. The Ethiopian Public Assessment Report (EtPAR) shall include a summary written in a manner that is understandable to the public.

2) Purpose

The purpose of this guideline is to provide guidance on the procedure for the preparation of Ethiopian Public Assessment Report (EtPAR) following initial marketing authorization applications with a positive or refusal of marketing authorization. It is also intended to provide the pathway for publishing Ethiopian Public Assessment Report.

3) Transparency

The Ethiopian Public Assessment Report (EtPAR) shall include a summary written in a manner that is understandable to the public. EFDA publishes the public assessment report for medicinal products for human use within not more than 60 working days of authorization of the medicinal product, the public assessment report shall include a summary of information that has a certain value for health care providers, pharmaceuticals manufacturers, researchers and public.

EtPAR may include information about any conditional approval requests for authorizing medicinal

products with details of their respective post-approval submission deadline.

4) Responsibility

The Medicine Evaluation and Market Authorization Lead Executive Office is responsible for preparing the EtPAR based on the outcomes of the evaluation process, after removing the Commercial Confidential Information and personal data from all reports prior to publication. i.e. Information that comes into the public domain after the publication of EtPAR is not considered as commercially confidential upon the confidential intellectual property and trade secrets.

5) List of product categories require publication of EtPAR

Not all prescription medicine applications require an EtPAR. EtPARs are published for applications where the significance to the public is considered high EtPAR. Table 1 describes application which require publication of EtPAR.

Table 1: Application categories require EtPAR publication.

Application categories and types		EtPAR required?
1.	New chemical or biological entity	Yes
2.	New salt/ester of previously approved active ingredients	Yes
3.	New Biological Medicines	Yes
4.	Bio similar medicine	Yes
5.	New combination of previously approved active ingredients	Yes
6.	Vaccines	Yes
7.	Generic medicines	EFDA decision case bycase

6) Commercially confidential information and personal information

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The EtPAR is derived from the assessment of the documentation submitted by the applicant and the discussions undertaken during the evaluation process. As the authority makes the EtPAR available to the public, it is essential that any commercially confidential information (CCI) and personal information be identified and where appropriate removed prior to publication. Information on how we identify and treat CCI and personal information when drafting an EtPARis available at Guidance for the deletion of commercially confidential and personal information in an EtPAR

7) Language versions

The components of the EtPAR should be published in English.

8) Content and structure of report

The reports summarize assessments of the data provided on the quality, safety, and efficacy of applications. Each report outlines the outcomes of the evaluation process and provides scientific reasoning on decisions made to approve an application for marketing authorization. The published report is composed of administrative information, complete quality data, nonclinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or studies unless those data protected with a copy right.

9) Review by Market Authorization holder

Market authorization holders (MAH) have 10 wording days to undertake a review of the draft EtPAR and identify anyinformation considered CCI or personal information.

If the review identifies significant issues that require resolution, the EFDA will provide the MAH with an additional 3 to 7 calendar days to review the EFDA response.

Sponsors must justify any claims that information is CCI or personal information which they seek to be excluded from an EFDA-PAR. Sponsors are required to carefully consider the definitions of CCI and personal information in crafting their justification.

10) Outcome of MAH review of a draft EtPAR

a. Following a MAH's review of a draft EtPAR, the EFDA would review any proposed changes relating to the removal of CCI by a MAH.

b. Where there are significant disagreements about the proposed removal of CCI content, the Authority will apply an internal review process. The MAH will be asked to provide a request/ justification in writing for the removal of the content which will be referred internally for advice (as needed) prior to a final decision being made.
c. The internal review process is undertaken with the aim of publishing the completed EtPAR within 12 weeks from the date the product is included on the EFDA-eRIS list (approved).
d. If there is no response from a MAH to EFDA request to review a draft EtPAR, the EFDA reserves the right to publish the finalized EtPAR without further reference to theMHA.

11) Deferred and rejected products

a. To ensure transparency and build public confidence; deferred and rejected application should be published. A clear and transparent standard operating procedure should be followed for publication of refused marketing authorization applications and withdrawnapplications.
b. If the Medicine Evaluation and Market Authorization Lead Executive Office refuse marketing authorization, an applicant may request in writing a re- examination of the opinion within 30 days after the receipt of the opinion.(as per EFDA compliant handling Directive).
c. The refusal assessment report of the initial opinion should be updated to clearly reflect the re-examination and should be published within four weeks of the EFDA decision.

12) Withdrawal assessment reports

When an applicant seeks to withdraw an application for a marketing authorisation or extension of indication, it shall communicate the reasons for doing so to EFDA. Within 1 months of receipt of the withdrawal letter, EFDA will publish assessment report for all withdrawn applications for new marketing authorization applications and extensions of indication.

13) Timing of publication

The EtPAR for selected medicine should be published or updated after the Authority has issued a decision regarding the application. In addition, whenever the product information is updated, themedicine's EtPAR is updated accordingly to reflect the latest version. The EtPAR shall be published within 60 working days

of authorization on the website.

14) Publically available information

EtPARs published on the EFDA website are searchable by active ingredient, product name or **MAH.**

15) Product Information (SmPC, PIL and label)

Product information (PI)'s of all approved medicine should be published on the authority's website. Approved product information (PI) should be published together with the EtPARdocument for those product categories require EtPAR publications.

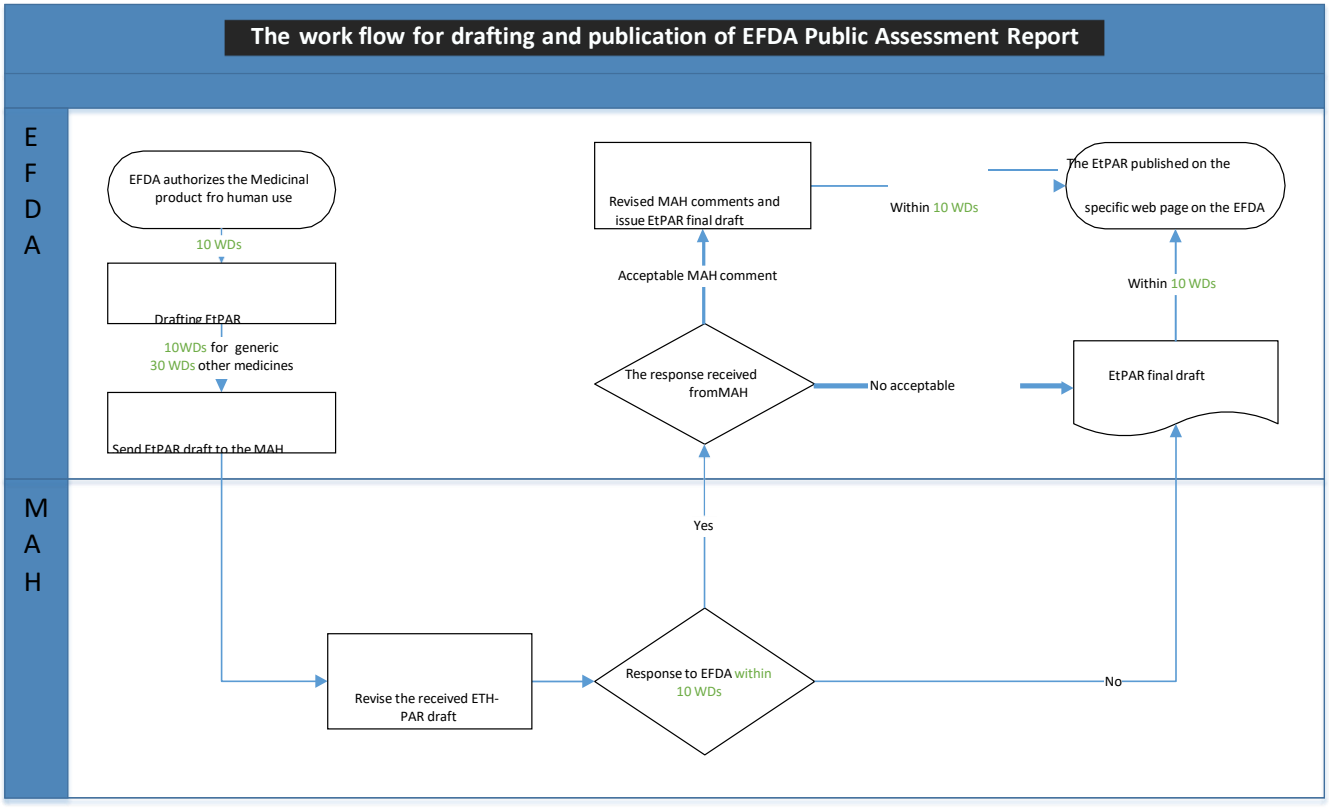
16) Periodic review of Product Information (SmPC, PIL and label)

Periodic review of PI (SmPC, PIL and label) should be conducted every two years. The applicants and/or manufacture are expected to update their SmPC and PIL. The applicants and/or manufactures can perform update of the SmPC and PIL at any time. Besides periodic review, the authority shall notify all applicant and/or manufacture to update their SmPCs and PIL if there are important change/updates on safety, indication and posology information.

17) Variation on EtPAR

The EPARs are updated throughout the life cycle of the product to reflect changes to the original terms and conditions of the marketing authorization. The EtPAR is amended or updated whenever variations that affect the contents of the variation application are approved.

18) Publication process flow chart



19) References

1. Reflection paper_ EPAR SUMMARY FOR THE PUBLIC_ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/reflection-paper-european-public-assessment-report-summary-public_en.pdf
2. Procedural advice on publication of information on negative opinions and refusals of marketing authorization applications for human medicinal products https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-publication-information-negative-opinions-refusals-marketing-authorisation_en.pdf
3. A council of ministers regulation to provide organization , powers and duties of the Ethiopian food and drug authority http://www.efda.gov.et/wp-content/uploads/2023/03/Definition-of-Organization-Powers-and-Duties-of-the-Ethiopian-Food-and-Drug-Authority-Council-of-Ministers-Regulation-No-531-2023.pdf