ETHIOPIAN FOOD AND DRUG AUTHORITY

GUIDELINE FOR PREPARATION AND PUBLICATION OF PUBLIC ASSESSMENT REPORTS FOR APPROVED MEDICINES

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Addis Ababa-Ethiopia

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1) Introduction

As part of the commitment to transparency, the Ethiopian Food and Drug Authority (EFDA) publishes information relating to the evaluation of applications via public assessment reports, hereinafter 'Ethiopian Food and Drug Authority Public Assessment Report (ETH-PAR)'

2) Purpose

This guideline is intended to provide the pathway for publishing Ethiopian Public Assessment Report (ETH-PAR) with clarification of EFDA's Proclamation and regulation for adopting ETH-PAR from the Original Assessment Reports generated during the quality, safety and efficacy evaluation for the medicinal products together with the rationale, approach and procedure for drafting for human medicinal products recently approved by EFDA and clarifying commercially confidential data and personal data that will be deleted from the report in accordance with the Ethiopian food and drug regulatory system and relevant international agreements.

3) Transparency

EFDA publishes the public assessment report for medicinal products for human use within not more than 60 working days of authorization on the website, the public assessment report shall include a summary of information that has a certain value for health care providers, pharmaceuticals manufacturers and public.

ETH- PAR 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 registration and Licensing Directorate is responsible for preparing the ETH-PAR 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 ETH-PAR is not considered as commercially confidential upon the confidential intellectual property and trade secrets.

5) Requirements for publication of ETH-PAR

Not all prescription medicine applications require an ETH-PAR. ETH-PARs are published for applications where the significance to the public is considered high.

Summary of ETH-PAR requirements by the application category and types

Application categories and types		ETH-PAR required?
1.	New chemical or biological entity	Yes
2.	New salt/ester of previously approved active ingredients	Yes
3.	New Biological Medicines	Yes
4.	Biosimilar medicine	Yes
5.	New combination of previously approved active ingredients	Yes
6.	Extension of indications	EFDA decision case by case
7.	Generic medicines	
8.	Major Variation - Additional trade name	No
9.	Major Variation - New medicinal product strength	EFDA decision case by case
10.	Major Variation - New dosage form	
11.	Major Variation - New route of administration	
12.	Major Variation - Change/increase in patient group	
13.	Major Variation -Change in dosage	
14.	Minor Variation - Change of formulation (excipients)	No
15.	Minor Variation -Change in trade name	No
16.	Minor Variation -change of container	No

6) Commercially confidential information and personal information

As the ETH-PAR is a publicly available document, 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 ETH-PAR is available at Guidance for the deletion of commercially confidential and personal information in an ETH- PAR

7) Language versions

The components of the ETH-PAR should be published in English or Amharic. This includes:

Public-friendly overview;

Labeling;

Package leaflet and summary of product characteristics;

List of all Authorized presentations

Public assessment report(s);

The insert labeling of medicine that is included in the national essential medicine list or widely circulated in the market shall be in Amharic and in English. If the intended distribution of the medicine is limited to one region, its insert labeling shall be, at least, in English and the region's working language.

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) Market Authorization holder opportunity to identify CCI and personal information

MAH have 10 wording days to undertake a review of the draft ETH-PAR and identify any information 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 ETH-PAR

a. Following a MAH's review of a draft ETH-PAR, 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 ETH-PAR within 12 weeks from the date the product is included on the EFDA-eRIS (approved).
d. If there is no response from a sponsor to EFDA request to review a draft ETH-PAR, the EFDA reserves the right to publish the finalized ETH-PAR without further reference to the MHA.

11) Negative opinions and withdrawn applications

a. To ensure transparency and build public confidence; negative opinions and withdrawn application should be published. A clear and transparent standard operating procedure should be followed for publication of refused marketing authorization applications and withdrawn applications.
b. If the Medicine registration and Licensing directorate issues a negative opinion on a new marketing authorization application, 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 if a decision is expected or no later than three months after compliant handling committee opinion on the re-examination when no decision is expected.

12) Quality assurance

Following MAH review, and prior to publication, the ETH-PAR is further reviewed by EFDA Quality Assurance (QA) to ensure a consistent standard and level of quality of ETH-PARs.

13) Timing of publication

The ETH-PAR 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, the medicine's ETH-PAR is updated accordingly to reflect the latest version.

The ETH-PAR shall be published within 2 months on the specific web page on the EFDA website from the data of approval of a medicine.

14) Publically available information

Searching ETH-PARs

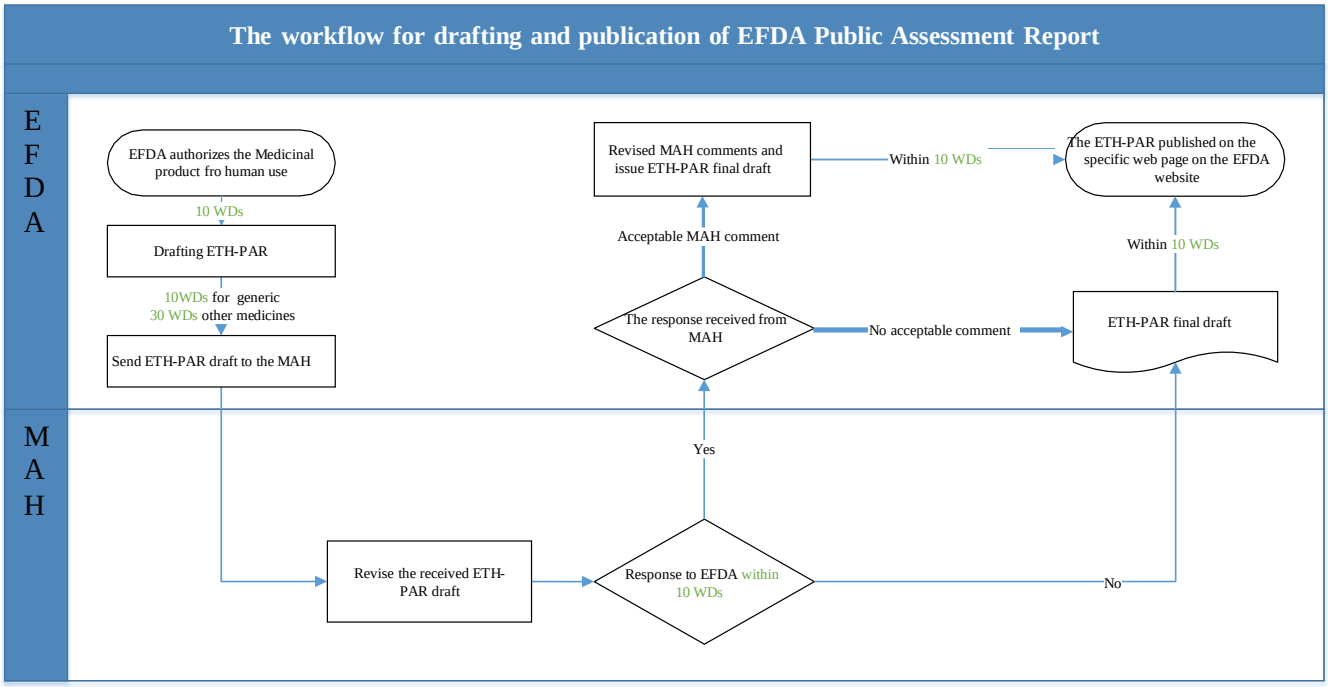
ETH-PARs published on the EFDA website are searchable by:

- Active ingredient
- Product name
- **MAH**

15) Product Information (PI)

A copy of the PI approved with the submission is included as an attachment to the ETH-PAR document when it is published by the EFDA

16) Publication process flow chart



17) References