FOOD AND DRUGS AUTHORITY

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Technical Advisory Committee on Clinical Trials

Guidelines on FDA Public Assessment Report

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This guideline is the initial issue.

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8th January 2024	01	Initial issue of Guideline

Guidelines on FDA Public Assessment Report

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Acknowledgments

This guideline was developed based on the European Medicines Agency's Guideline on the public assessment report of medicinal products processed through the centralized procedure as well as the WHO Guideline on public assessment guideline for the assessor and the applicant.

Executive Summary

The FDA public assessment report (FAPAR) will be published for every medicinal product that will be granted approval by the FDA. The FAPAR will include a description of the quality, safety and efficacy of the registered product.

The FAPAR will also summarize the data and information submitted by the applicant from the manufacturer(s) which defines the vital components of the registered FPP.

There are eight (8) sections of the FAPAR as captured in Section 3.1. The guidance for the development of the FAPAR as well as some notable translations have been duly captured.

All FAPARs will be published on the FDA website and can be viewed under Drug registration.

1. Introduction (background)

The Food and Drugs Authority (FDA) Public Assessment Reports (FAPARs) are a key registration output, providing insight and transparency to the processes followed to register the finished pharmaceutical products (FPPs) concerned.

FAPAR describes the quality, safety and efficacy of the registered product and summarizes the assessment of the data and information provided by the manufacturer which are essential components of a registered FPP.

1.1. Legal Basis

In pursuance of Section 118 and 128 of the Public Health Act, 2012, Act 851, this guideline is hereby made to provide a procedure for processing and publishing Public Assessment Report information on registered medicinal products on the website of the FDA.

1.2. Scope

This guideline is applicable to registered drugs which includes the following:

a. Allopathic drugs for Human Use

b. Vaccines

c. Biological products

Note: This guideline also covers the publication of information on rejected and deferral applications. The content of information to be published on rejected and deferred applications are defined below and does not follow the format laid out below in the guideline.

- *Rejected application: The FDA will publish lists of rejected applications with details of the application and the reason for the rejection.*
- *Deferral applications: The FDA will publish lists of deferred applications where the applicant has not been able to address issues regarding safety, efficacy and quality through 5 rounds of submission.*

2. Definitions and Abbreviations

API- Active pharmaceutical ingredient

EMA- European Medicines Agency

FAPAR- FDA Public Assessment Report

FDA- Food and Drugs Authority

FPP- Finished Pharmaceutical Product

MS- Microsoft

PIL- Patient information leaflet

SmPC- Summary of product characteristics

WHO- World Health Organization

3. Content And Procedure for Development and Publication Of Public Assessment Reports For Registered Medicinal Products By The FDA Ghana

There are eight (8) parts to a FAPAR list in section 3.1

Parts 3 and 4 of the FAPAR – product information for the user and the health care provider – have been quality assured by FDA. In effect, they form a component of the registered medicinal product. Therefore, they may be altered only after an application for variation has been accepted by FDA. If a product (including its information) is altered outside this procedure it can no longer be considered to be registered. (But see also the section on deviations below)

3.1. Content: Parts of a FAPAR

A FAPAR consists of eight parts:

Part 1: Abstract

Part 2: All accepted presentations (including photo)

Part 3: Product information for the user (Patient Information Leaflet - PIL)

Part 4: Information for the health care provider (Summary of Product Characteristics – SmPC)

Part 5: Labelling

Part 6: Scientific discussion (Quality, Safety and Efficacy)

Part 7: Steps taken for registration

Part 8: Steps taken following registration.

3.2. Information For Developing FAPAR

In submitting a product for evaluation for registration an applicant must contribute the information and/or documents that will be needed – in the event of registration – for development of or inclusion in the FAPAR.

The following documentation should therefore be drafted (in MS-Word format) by the applicant and included in Module 1 of the initial application submission.

a) All proposed commercial presentation (including photo) of the finished pharmaceutical product. – as input for Part 2 of the FAPAR
b) Product information for the user (Patient Information Leaflet - PIL) - as input for Part 3 of the FAPAR prepared as per the published template for PIL. Applicant will also be required to include a mock-up of the patient information leaflet (PIL), taking into consideration the recommendations as described in the Food and Drugs Authority's guideline on the readability of the labelling and the package leaflet of medicinal products for human use.
c) Information for the health care provider (Summary of Product Characteristics – SmPC) - as input for Part 4 of the FAPAR
d) Labelling - as input for Part 5 of the FAPAR

The FDA will also generate initial draft for **Part 1, 6, 7** and **8** of the FAPAR.

Failure to submit the required documentation to be included in a FAPAR may result in rejection of the application.

3.3. Steps In Developing A FAPAR

The sequence for developing a FAPAR following registration of an FPP is as follows:

Step 1: The applicant submits documents required for the FAPAR as part of the initial submission for evaluation for registration to FDA.

Step 2: FDA compiles the draft FAPAR when the assessment and inspections have been completed successfully.

Step 3: FDA forwards the draft FAPAR to the applicant for review. (Documents are exchanged in electronic format by the applicant and FDA, generally by email.)

Step 4: The applicant reviews and comments on (annotates) the draft FAPAR, in particular to ensure that the FAPAR does not contain any proprietary or confidential information.

Step 5: The applicant returns the annotated draft FAPAR to FDA.

Step 6: FDA reviews the annotated text – Steps 3 to 6 may need to be repeated if an item requires further clarification – and finalizes the FAPAR.

Step 7: If the FPP, as produced at the specified manufacturing site(s), meets the registration requirements, FDA accepts the FPP for inclusion in the FDA List of Registered Medicinal Products (i.e. registers it) publishes the FAPAR and informs the applicant accordingly.

3.4. Guidance Relating to Development of Contents of FAPAR

FDA registration guidance documents should be consulted before preparing the Patient Information Leaflet (PIL), the Summary of Product Characteristics (SmPC) and the Labelling document that will form the basis for Parts 3, 4 and 5, respectively of the FAPAR for a registered product.

These documents include the following templates:

- PIL template (for part 3 of a FAPAR)
- SmPC template (for part 4 of a FAPAR)
- Labelling template (for part 5 of a FAPAR)

The templates provide the structure for the relevant sections of a FAPAR while the guidelines for SmPC, PIL and Labelling provide guidance on the content and level of detail required in those sections.

3.5. Translations

All information related to registered products must be provided in English.

3.6. Deviations From Registered Product Information

Some deviations from the SmPC and PIL published with the FAPAR are acceptable:

- Combining the PIL with the SmPC is acceptable if both are included in their entirety and any parts intended for professionals only are clearly marked.
- Making available only the SmPC (and not also PIL) is acceptable for products that are administered in hospital/by a health care professional only
- Changing the order of items in the SmPC /PIL is NOT acceptable. The standard format as per the FDA template for a PIL and SmPC remains strongly recommended.
- Aligning the product information with the corresponding texts in a more recently published FAPAR of a comparable product (e.g. Same API, comparable pharmaceutical formulation, same dosage strength) is possible.

The reason for any deviation from the product's registered texts must be clearly stated by the company whenever such a deviation applies.

Following posting of the FAPAR on the FDA website, updating of the PIL and SmPC may be necessary. For example:

- when Ghana's treatment recommendations changes
- the corresponding text for the innovator product has undergone significant updating
- new and relevant scientific data have become available.

In these cases, the applicant should submit the new texts to FDA with a tabular overview of the changes (pre-change/post-change) together with the reasons for any changes, a short expert statement, and any references. A statement from FDA as to the acceptability of the new texts must be received before either the PIL and or the SmPC can be changed.

References

1. EMA. (2006). Reflection Paper on European Public Assessment Report Summary for the Public.
2. WHO website: http://www.who.int/en/

Annex 1

Information to be provided by applicant for development of FAPAR

INFORMATION TO BE PROVIDED BY APPLICANT FOR DEVELOPMENT OF FOOD AND DRUGS AUTHORITY PUBLIC ASSESSMENT REPORT (FAPAR) FOR A FINISHED MEDICINAL PRODUCT						
Part	**Title**	**Drafted by**	**Type and /or format of information**	**Source of information for innovator or generic product, approved by WHO listed reference Authorities**		**Source of information for generic product**
				…for which a public assessment report is available	**…for which NO public assessment report is** available **(if a confidential report is available the** applicant **may enclose it with the submission or FDA can request it from the reference authority concerned)**	**…for which acceptable comparator / reference product is available**
1	Abstract	FDA	Overview of key information			
2a	All Accepted Presentations	FDA	Description of all accepted presentations and dosages, as given in the product dossier			
2b	Appearance of Product	FDA	Photograph of formulation (solid forms) or other product characteristics (liquid forms)			
3	Product Information for the User (in English)	Applicant	Practical, easily understandable information for the user of the product and that the user can act upon directly, if necessary	As approved by the reference authority (in English, or as authorized English translation	As approved by reference authority (in English, or as authorized English translation	The text should reflect the information available for the innovator / comparator product. The comparator product must be one that is acceptable to the FDA. In particular, the indication and safety profile should be the same as for the approved

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Part	**Title**	**Drafted by**	**Type and /or format of information**	**Source of information for innovator or generic product, approved by WHO listed reference Authorities**		**Source of information for generic product**
				…for which a public assessment report is available	**…for which NO public assessment report is** available **(if a confidential report is available the** applicant **may enclose it with the submission or FDA can request it from the reference authority concerned)**	**…for which acceptable comparator / reference product is available**
4	Information for the Health Care Provider (in English)	Applicant (FDA)	All practical and essential medical (background) information on the product for healthcare providers	Summary of Product Characteristics (SmPC) as approved by reference authority, in English, or as authorized English translation	SmPC approved by reference authority, in English, or as authorized English translation	comparator / reference product(s). However, special reference may be made by FAPAR committee to National treatment guidelines, which may result in deviations from the reference product's information.
5	Labelling (in English)	Applicant (FDA)	All text for packaging (primary and secondary)	As approved by reference authority, in English, or as authorized English translation	As approved by reference authority, in English, or as authorized English translation See guidance: 9	
6	Scientific Discussion	FDA, based on • assessment reports on quality	Outcome of quality and bioequivalence evaluation (where applicable) and, if required, the overview of			

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				…for which a public assessment report is available	**…for which NO public assessment report is** available **(if a confidential report is available the** applicant **may enclose it with the submission or FDA can request it from the reference authority concerned)**	**…for which acceptable comparator / reference product is available**
		• bioequivalence (where applicable) study and/or summary of product safety and efficacy	current product safety and efficacy	Summary of product safety and efficacy can be submitted *voluntarily* or link provided to relevant section of public assessment report on website of a reference authority See guidance: 12	Summary of product safety and efficacy, as contribution to Part 6, can be submitted *voluntarily* See guidance: 12	Note: Not required since relevant information on safety and efficacy is generally available for this type of product
7	Steps taken for registration	FDA	Chronological description of main steps of assessment of product			
8	Steps taken following registration	FDA	Chronological description of main steps after registration of product			

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