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< *Date published:* DD Month YYYY>

FDA/XXX/GDL - ##/ZZ [XXX = initials of Dep’t, ## = serial No.; ZZ = Ver. No.]

<Name of adopting Committee (Committee abbreviation)>

Guidance Document on FDA Public Assessment Report

Draft[[1]](#footnote-1)

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| Draft written by <Drugs and Herbal Medicines Department> | <Month YYYY> |
| Draft reviewed by < Director, DCE, Legal, QMS >[[2]](#footnote-2) | <DD Month YYYY> |
| Start of public consultation | <DD Month YYYY>[[3]](#footnote-3) |
| Adopted by < Committee/Board> | <DD Month YYYY>3 |
| Date of coming into effect | <DD Month YYYY>[[4]](#footnote-4) |

This guideline replaces ‘<guideline>' (NMRA/…/…).[[5]](#footnote-5)

| Comments should be provided using this <link to comments page>. The completed comments form should be sent to hptd@fda.gov.gh |
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| **Keywords** | ***<Text>[[6]](#footnote-6)*** |
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Document Revision History

|  |  |  |
| --- | --- | --- |
| **Date of Revision** | **Version Number** | **Changes made and/or reasons for revision** |
| DD/MM/YYYY |  |  |
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**CONTENT AND PROCEDURE FOR DEVELOPMENT AND PUBLICATION OF PUBLIC ASSESSMENT REPORTS FOR REGISTERED MEDICINAL PRODUCTS BY THE FDA GHANA**

1. **INTRODUCTION**

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 is of great value for regulators and stakeholders. It 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.

Parts 3 and 4 of a 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)

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.

1. **INFORMATION FOR DEVELOPMENT OF A 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.

1. All proposed commercial presentation (including photo) of the finished pharmaceutical product. – as input for Part 2 of the FAPAR
2. 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
3. Information for the health care provider (Summary of Product Characteristics – SmPC) - as input for Part 4 of the FAPAR
4. 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.

1. **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.

1. **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.

1. **TRANSLATIONS**

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

1. **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.

1. Leave the wording ‘Draft’ if the guideline is adopted for release for public consultation. Delete the wording 'Draft' – but do NOT the delete the subtitle line it sits in. [↑](#footnote-ref-1)
2. If other parties have been involved in discussions this needs to be specified. [↑](#footnote-ref-2)
3. Date of publication on the FDA website. [↑](#footnote-ref-3)
4. First day of coming into effect. Latest 3 month after adoption. [↑](#footnote-ref-4)
5. If this supersedes a previous guideline – otherwise delete. [↑](#footnote-ref-5)
6. To be identified here during preparation of the guideline - keywords represent an internet search tool – Rapporteur(s) to propose and QA & TAC to adopt. [↑](#footnote-ref-6)