الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

# Registration According to Verification and Abridged

**Version 2.1**

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|---|---|
| Date of implementation | 1 February 2017 |

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Saudi Food & Drug Authority

# Registration According to Verification and Abridged

**Version 2.1**

Saudi Food & Drug Authority

Drug Sector

| | |
|---|---|
| *For Inquiries* | *Sdr.drug@sfda.gov.sa* |
| *For Comments* | *Drug.Comments@sfda.gov.sa* |

Please visit SFDA's website at
http://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx

for the latest update

**Saudi Food and Drug Authority**

**Vision and Mission**

## Vision

To be a leading international science-based regulator to protect and promote public health

## Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

## Document Control

| Version | Author | Date | Comments |
|---|---|---|---|
| 1.0 | Drug Sector | 1 February 2017 | Published as a memo |
| 1.1 | Standards Setting Directorate | 3 August 2017 | Update and including FAQs |
| 1.2 | Executive Directorate of Regulatory Affairs | 9 October 2018 | Including veterinary products and other update under the requirements section |
| 2.0 | Executive Directorate of Regulatory Affairs | 28 October 2019 | Update and published for comment purposes |
| 2.1 | Executive Directorate of Regulatory Affairs | 3 May 2020 | Final after public feedback<br>(Next page shows the updated details) |

- **What is new in version no. 2.1?**

The following table shows the update to the previous version:

| Section | Description of change |
|---|---|
| **3. Eligibility criteria** | Updating manufacturer sites criterion |
| **4. Submission Requirements** | Updating section 4.2 (assessment reports status and requirements of inspection) and section 4.4 |
| **5. Procedure of submission**<br>**6. Performance target** | General update for more clarification |

## Table of Contents

# 1. INTRODUCTION

## 1.1. Objective

The Drug Sector at Saudi Food & Drug Authority (SFDA) has developed this document to provide an assistance for the applicants on how to proceed the registration through verification and abridged.

## 1.2. Background

The registration process through verification and abridged evaluation routes are options meant to facilitate the product's registration that grants the approval of the US Food and Drug Administration (FDA), US Department of Agriculture (USDA) and/or European Medicines Agency (EMA), in a shorter timeframe.

## 1.3. Scope

Applicable for marketing authorization of both Human and Veterinary medicinal products for the following products:

- New Products (New Chemical Entity).
- Biological Products (excluding biosimilars, blood products, vaccines and advanced therapy medicinal products "for human").

## 1.4. Related guidelines

This document should be read in conjunction with the following Drug Sector documents:

- Regulatory Framework for Drug Approvals.
- Guidance for Submission.

## 2. DEFINITIONS

- **Verification Registration**: it is process where the product has been approved and marketed by both of the following drug regulatory agencies;
    - For human medicinal products: EMA **and** FDA.
    - For veterinary medicinal products: EMA **and** FDA (for new veterinary products), USDA (for biological veterinary products).

- **Abridged Registration:** it is a process where the product has been approved and marketed by either of the following drug regulatory agencies;
    - For human medicinal products: EMA **or** FDA.
    - For veterinary medicinal products: EMA **or** FDA (for new veterinary products), USDA (for biological veterinary products).

## 3. ELIGIBILITY CRITERIA

- The application must be submitted to the SFDA within two years from the date of approval by the reference agency.
- The product does not need a more stringent assessment as a result of different local disease patterns and/or medical practices.
- The product and its intended use (indications, dosage information, and patient groups (for human product) or target animal species (for veterinary product)) has not been rejected, withdrawn, suspended by **any drug regulatory agency** for safety or efficacy reasons.
- The manufacturer should be located in one of the following countries:

  USA, UK, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, Netherlands, Austria or Singapore.

  The level of manufacturing activity represents:
    - For Biologicals: Biological Substance and Finished product.
    - For Pharmaceuticals: Finished Product (bulk) and Primary Packaging.

## 4. SUBMISSION REQUIREMENTS

**4.1.** A complete file:

- For **human products:** according to the *GCC Data Requirements for Human Drugs Submission*, the eCTD submission should be the same as the reference drug regulatory agency (FDA or EMA) for Modules (2-5).
- For **veterinary products:** according to the *Data Requirements for Veterinary Medicinal Products*, the submission (vNees or CTD) should be the same as the reference drug regulatory agency (FDA, USDA or EMA).

**4.2.** In Module 1 (for human products) or Part 1 (for veterinary products) and under *Additional Data Section*, applicant must add the following:

1. In the cover letter: submit the requested route of registration and the reference(s) date of approval.
2. A declaration letter issued by the applicant stating that all aspects of the drug product's quality, including but not limited to, the formulation, manufacturing site(s), release and shelf life specifications, primary packaging and active pharmaceutical ingredient(s) source are identical to that currently approved by FDA / USDA and/or EMA at the time of submission. However, a different type of the container closure system (e.g. Alu/Alu blister vs. HDPE bottle) may be proposed to meet the *GCC stability requirements*.
3. Complete assessment report and other relevant supporting documents from the reference drug regulatory agency according to the following:
    - **Verification process:** the following/documents are required from both reference drug regulatory agencies:
        i. Complete clinical and quality assessment report along with if applicable assessment on the Question & Answer documents between the Sponsor and Agency and all annexes.
        ii. Assessment reports and/or documents pertaining to post-approval variations (if applicable).

iii. The submitted assessment reports should be unredacted or unedited, when possible, and should include details of imposed licensing conditions, final product labelling, chemistry and clinical review, and other information in relation to the product's approval. Redacted or edited reports might be acceptable if not related to the quality, safety or efficacy of the product. Trade secrets, confidential commercial and financial information, can be excluded from the submission. Reports obtained from the public domain are deemed unacceptable.

- **Abridged process:** Similar to verification but only from either of the two reference regulatory agencies.

4. For the inspection requirements; if the manufacturer is not registered in SFDA, then the company has to pay the fees and submit the following:
    - Valid GMP certificates from the local authority and other international authorities
    - A copy of Site Master File (SMF),
    - List of all products that manufactured at the site and supplied to Saudi Arabia,
    - Last Inspection Report - in English - from the local authority.
    - If available, last Inspection Report - in English - from other international authorities.

**4.3.** Stability studies according to the *GCC Guidelines for Stability Testing*.

If such studies are not available, the following requirements should be submitted:

i. A commitment letter to conduct stability studies according to the *GCC Guidelines for Stability Testing*;

ii. Assurance should be given that any Out of Specification (OOS) results should be reported immediately to the SFDA.

**4.4.** Price certificate (Form 30)[1].

**4.5.** Supporting documents on comparative safety and efficacy studies illustrating the added value from an economic perspective.

SFDA may request additional documentation not specifically outlined in this document, in order to adequately assess the safety, efficacy and quality of drug products. SFDA is committed to ensuring that such requests are justifiable.

## 5. PROCEDURE OF SUBMISSION

**Step 1: Online submission:**

i. The applicant should fill in the application form[2] through SDR system and pay the fees.

ii. Upload the product's file.

**Step 2: Request a pre-designation meeting:**

The meeting with Executive Directorate of Regulatory Affairs is mandatory to check the eligibility of the application and to ensure that the submission fulfils the requirements:

i. The applicant should fill in the meeting request with the checklist (see Appendix) and send them to SDR.Drug@sfda.gov.sa.

ii. The Regulatory Affairs staff will notify the applicant by email within five working days with the details of the meeting.

iii. During the meeting, the Regulatory Affairs staff will extensively assess the product file according to the guidance and the checklist.

**Step 3: Waiting for post-meeting decision:**

The applicant will receive the Drug Sector decision through SDR.Drug@sfda.gov.sa within five working days;

- In case of non-eligibility, the application will be transferred to the regular pathway (note: registration fees are non-refundable).

[1] Refer to *the Guidance for Submission* for more information on this part
[2] The applicant must select the requested pathway in the application form

## 6. PERFORMANCE TARGETS

Refer to the *Regulatory Framework for Drugs Approval* on target processing timelines for Drug Sector's registration steps.

The performance targets start when the Drug Sector approves the requested pathway by email.

| Process | Performance target |
|---|---|
| Registration through Verification | 30 working days |
| Registration through Abridged | 60 working days. |

## 7. REGULATORY NOTES

- Approval by reference drug regulatory agency does not oblige the SFDA to approve the application.
- During evaluation and for safety, efficacy or quality concerns, the related departments might request to transfer the application to the regular pathway. However, SFDA commits to clarify the decisions for any case.
- Confidential information which submitted by the companies to support their registration application is protected and will not be shared by any means with other parties.

# 8. FREQUENTLY ASKED QUESTIONS (FAQs)

This section includes answers of the most frequently asked questions about the verification and abridged:

## 8.1. Scope

- **Will SFDA accept the product registration via the decentralized procedure in Europe?**

  EMA registration means centralized procedure.

- **What is the situation for product approved by Health Canada, PMDA, Swiss Medic or TGA?**

  Only FDA, USDA and EMA are considered as reference agencies.

- **If the product is generic and it is lifesaving, is it possible to apply through verification and abridged?**

  The registration by verification and abridged is accepted only for new products (NCE) and new biological products.

- **Is it applicable for combination product (of well-known active ingredients) that have together a new indication and has received EMA and US registration approval?**

  Yes, it is.

- **Does the verification and abridged process apply to variations like new indications addition of already registered products with the SFDA?**

  Currently, verification and abridged only for product's registration.

## 8.2. File submission

- **What counts as proof of product registration?**

  For human products: Refer to the GCC data requirements section 1.7.2 (CPP or free sale).

  For veterinary products: Refer to the data requirements for veterinary medicinal products section 1a42 (CPP).

- **If conditional approval granted by FDA, USDA/ EMA, can the company apply to SFDA by using such conditional approval?**

  Yes and the applicant has to submit evidence of approval.

- **What are the file's requirements to submit the product through verification and abridged process?**

  Refer to the section of requirements.

- **For products which their manufacturing sites are not registered at SFDA, does SFDA approve the product without site inspection?**

  If the product manufacturing site is located in one of the countries mentioned in the Eligibility Criteria section, site inspection will not be a barrier for the product registration. SFDA will take the necessary actions to maintain the registration within the timeframe.

## 8.3. General

- **If company could not perform stability data on GCC zone according to the GCC guidelines on stability testing, can SFDA approve the data on Zone II?**

  The following should be submitted:

  - A commitment letter to conduct stability studies according to *the GCC Guidelines for Stability Testing*;
  - Assurance should be given that any out of specification results will be reported immediately to the SFDA.

- **For verification, what is the situation in case if there are any differences between Europe and US approved product (e.g. differences in approved indications, product label)?**

  In this case, SFDA will follow the applicant's chosen primary reference agency.

- **In case of differences for example: manufacturing site, release and shelf life specifications, primary packaging and API source; will the SFDA accept to register the product through verification and abridged procedure?**

  The submitted file must include a declaration letter stating that all aspects of the drug product's quality, including but not limited to the formulation, manufacturing site(s), release and shelf life specifications, primary packaging and API source are identical to that currently approved by the chosen reference drug regulatory agency.

- **Is the current pricing rules part of the verification and abridged?**

  Yes, it is.

- **Is the product testing part of the verification and abridged?**

  Yes, it is and refer to the Regulatory Framework for Drug Approvals.

- **Will SFDA review the Arabic translation of leaflet, label and carton during the registration process?**

  Yes, it will.

# 9. APPENDIX

## 9.1. Request for pre-designation meeting

Applicants must use this form to send a meeting request by email to SDR.Drug@sfda.gov.sa, being titled with "Pre-designation meeting for **Verification** or **Abridged**"

نتقدم بطلب الاجتماع لغرض تسجيل المستحضر الموضحة بياناته أدناه بآلية **(التجسير** أو **التوثيق)** علما بأنه تم تقديم جميع متطلبات دراسة المستحضر بناءً على ما ورد في دليل التسجيل بالتجسير والتوثيق:

| | | |
|---|---|---|
| **Ref. No.** | | **الرقم المرجعي** |
| **Registration Procedure** | | **آلية الدراسة** |
| **Certificate Date from USFDA or USDA** | | **تاريخ الحصول على الشهادة في USFDA or USDA** |
| **Certificate Date from EMA** | | **تاريخ الحصول على الشهادة في EMA** |
| **Trade Name** | | **الاسم التجاري** |
| **Generic Name** | | **الاسم العلمي** |
| **Strength** | | **التركيز** |
| **Dosage Form** | | **الشكل الصيدلاني** |
| **Pack Size** | | **حجم العبوة** |
| **Manufacturer** | | **الشركة الصانعة** |
| **MAH** | | **الشركة المسوقة** |
| **Agent** | | **الوكيل في السعودية** |

عليه نتعهّد نحن شركة (.....) بأنه تم الالتزام بما ورد في الدليل الخاص بذلك وللهيئة حق رفض الطلب إذا لم يتم التقيّد بالدليل المنشور وإحالة المستحضر للدراسة كما هو متبع في مسار التسجيل الاعتيادي.

**مدير شركة .....** **ختم الشركة**

**الاسم :**

**التوقيع:**

**التاريخ:**

## 9.2. Checklist

### 9.2.1. Checklist for Verification

| Verification | Yes | No |
|---|---|---|
| The applicant asks for verification process in the cover letter | | |
| The product type is New Chemical entity or Biological (excluding biosimilar, blood products, vaccines and advanced therapy medicinal products (for human products)) | | |
| The application submitted to SFDA within 2 years from the date of approval | | |
| The product or its intended use has not been rejected, withdrawn, suspended by any drug regulatory agency for safety or efficacy reasons. | | |
| The product does not need a more stringent assessment as a result of different local disease patterns and/or medical practices | | |
| - Manufacturing location is one of the following:<br>USA, UK, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, Netherlands, Austria or Singapore. | | |
| The applicant completes and submit the following from FDA / USDA and EMA in M1 under additional data: | | |
| - A declaration letter stating that all aspects of the drug product's quality, including but not limited to, the formulation, manufacturing site(s), release and shelf life specifications, primary packaging and active pharmaceutical ingredient(s) source are identical to that currently approved by FDA / USDA and EMA at the time of submission. | | |
| - Complete clinical and quality assessment report | | |
| - Assessment on the Question & Answer documents between the Sponsor and Agency and all annexes | | |
| - Assessment reports and/or documents pertaining to post approval variations | | |
| - Unredacted / unedited reports | | |
| - Payed inspection fees | | |
| - Valid GMP certificate from local authority | | |

| **Verification** | **Yes** | **No** |
|---|---|---|
| - Valid GMP certificate from other international authorities | | |
| - Copy of Site Master File (SMF) | | |
| - List of all products that manufactured at the site and supplied to Saudi Arabia | | |
| - Last inspection report - in English - from local authority. | | |
| - Last inspection report - in English - from other international authorities. | | |
| Stability studies according to the GCC Guidelines for Stability Testing, or the following requirements submitted:<br>- A commitment letter to conduct stability studies according to the GCC Guidelines for Stability Testing;<br>- Assurance that any out of specification results should be reported immediately to the SFDA. | | |
| A different type of container closure system is proposed. | | |
| Price certificate (Form 30) | | |
| Supporting documents on comparative safety and efficacy studies illustrating the added value from an economic perspective. | | |

### 9.2.2. Checklist for Abridged

| **Abridged** | **Yes** | **No** |
|---|---|---|
| The applicant asks for abridged process in the cover letter | | |
| The product type is New Chemical entity or Biological (excluding biosimilar, blood products, vaccines and advanced therapy medicinal products (for human products)) | | |
| The application submitted to SFDA within 2 years from the date of approval | | |
| The product or its intended use has not been rejected, withdrawn, suspended by any drug regulatory agency for safety or efficacy reasons. | | |
| The product does not need a more stringent assessment as a result of different local disease patterns and/or medical practices | | |
| - Manufacturing location is one of the following:<br>USA, UK, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, Netherlands, Austria or Singapore. | | |
| The applicant completes and submit the following from FDA, USDA or EMA in M1 under additional data: | | |
| - A declaration letter stating that all aspects of the drug product's quality, including but not limited to, the formulation, manufacturing site(s), release and shelf life specifications, primary packaging and active pharmaceutical ingredient(s) source are identical to that currently approved by FDA / USDA or EMA at the time of submission. | | |
| - Complete clinical and quality assessment report, | | |
| - Assessment on the Question & Answer documents between the Sponsor and Agency and all annexes | | |
| - Assessment reports and/or documents pertaining to post approval variations | | |
| - Unredacted /unedited reports | | |
| - Payed inspection fees | | |
| - Valid GMP certificate from local authority | | |
| - Valid GMP certificate from other international authorities | | |

| **Abridged** | **Yes** | **No** |
|---|---|---|
| - Copy of Site Master File (SMF) | | |
| - List of all products that manufactured at the site and supplied to Saudi Arabia | | |
| - Last inspection report - in English - from local authority | | |
| - Last inspection report - in English - from other international authorities | | |
| Stability studies according to the GCC Guidelines for Stability Testing, or the following requirements submitted:<br>- A commitment letter to conduct stability studies according to the GCC Guidelines for Stability Testing;<br>- Assurance that any out of specification results should be reported immediately to the SFDA. | | |
| A different type of container closure system is proposed. | | |
| Price certificate (Form 30). | | |
| Supporting documents on comparative safety and efficacy studies illustrating the added value from an economic perspective. | | |