الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Verification and Abridged Pathways

Version 3.0

Date of Issue	1 February 2017

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Saudi Food & Drug Authority

Drug Sector

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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2.0	Executive Directorate of Regulatory Affairs	28 October 2019	Update and published for comment purposes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 (Next page shows the updated details)
2.2	Executive Directorate of Regulatory Affairs	1 May 2024	Updated the designation's contact email
3.0	Executive Directorate of Regulatory Affairs	20 October 2025	Updated Implantation date 20 January 2026

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- **What is new in version no. 3.0?**

The following table shows the updates to the previous version:

Section	Description of change
1. Introduction	**Update:** - Objective and Scope.
2. Definitions	**Add:** - Sameness of product
4. Submission Requirements	**Add:** - Variation application requirements
5. Procedure of submission	**Add:** - Procedure of variation submission
7. Regulatory Notes	**Add:** - Regulatory Notes for variation applications
9. Appendix	**Add:** - Application form for variation

1. INTRODUCTION

1.1. Objective

The Drug Sector at the Saudi Food & Drug Authority (SFDA) has developed this document to help the applicants on how to proceed with the registration and variation applications through verification or abridged pathways.

1.2. Background

The verification or abridged pathways established to facilitate the registration or variations process of products that are already approved by the United States (US) Food and Drug Administration (FDA), US Department of Agriculture (USDA), and/or European Medicines Agency (EMA).

1.3. Scope

The Verification and Abridged regulatory pathways apply to marketing authorization applications for new chemical entities and biologics of human and veterinary medicines.

The abridged pathway also applies to type II variation applications for new chemical entities and biologics of human and veterinary medicines.

Applications of blood products, advanced therapy medicinal products, and veterinary vaccines are excluded from the Verification and Abridged regulatory pathways.

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.
- Guideline for Variation Requirements

2. DEFINITIONS

- **Verification pathway**: The following drug regulatory agencies have approved and marketed the product:
    - For human medicinal products: EMA and FDA.
    - For veterinary medicinal products: EMA and FDA (for new veterinary products), USDA (for biological veterinary products).
- **Abridged pathway:** Either of the following drug regulatory agencies has approved and marketed the product and/or post-approval changes;
    - For human medicinal products: EMA or FDA.
    - For veterinary medicinal products: EMA or FDA (for new veterinary products), USDA (for biological veterinary products).
- **Sameness of product**: Compared to the reference agency, the submitted product application shall have identical essential characteristics. All relevant aspects of the product, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar (e.g., same qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, suppliers of active pharmaceutical ingredients, quality of all excipients). Additionally, the results of supporting studies of safety, efficacy, quality, indications, and conditions of use should be the same. The impact of potential and justified differences should be assessed by the marketing authorization holder and the SFDA to determine the possibility of using the reference agency's assessments or decisions.

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. Registration

4.1.1. A complete file:

- For **human products:** according to *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).

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

- In the cover letter: submit the requested pathway of registration and the reference(s) date of approval.
- 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 *stability requirements*.

- A 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 concerning 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 to be unacceptable.
  - **Abridged process:** It is similar to verification, but it requires only one of the two regulatory agencies referenced.
- 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.

4.1.3. Stability studies according to the *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 *Guidelines for Stability Testing*;

ii. An assurance letter must be provided stated that the applicant will report SFDA immediately if there are any Out of Specification (OOS) results

4.1.4. Price certificate (Form 16)[*].

4.1.5. 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.

4.2. Variation

4.2.1. Approval letter from reference agency.

4.2.2. Signed declaration of sameness of product must be provided including justifications for any potential differences.

4.2.3. A complete assessment report, unredacted and unedited, for the approved variation(s) by the reference agency.

4.2.4. Report that includes all questions and answers between the applicant and reference agency, including all annexes (unredacted/unedited), if applicable

[*] Refer to *the Guidance for Submission* for more information on this part

5. PROCEDURE OF SUBMISSION

5.1. For registration

Step 1: Submission

i. The applicant should submit the application form through SDR system and pay the fees.

ii. Upload the product's file.

iii. The applicant submit a designation request and checklist (see Appendix) to Designation.Drug@sfda.gov.sa

If necessary, SFDA will request a meeting with the applicant to verify eligibility and ensure that the application meets all requirements.

Step 2: Waiting for decision

- The applicant will receive the Drug Sector decision through Designation.Drug@sfda.gov.sa within ten working days;
- In case of non-eligibility, the application will be transferred to the other pathways (note: registration fees are non-refundable).

5.2. For variation

Step 1: Online submission

i. The applicant should submit the application form for variation by Abridged pathway (see Appendix), upload it through the SDR system and pay the fees.

ii. Upload the product's file.

Step 2: Business Validation

i. The product file will be validated to ensure that all information provided is according to the requirements and/or guidelines.

ii. In case of non-eligibility, the application will be proceeded according to the regular variation timeline.

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
Verification pathway	30 working days
Abridged pathway	60 working days.

7. REGULATORY NOTES

- The SFDA is not obligated to approve the application even if it receives approval by reference from a drug regulatory agency.
- 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.
- Applicants are required to adhere to the chosen reference agency throughout the product's lifecycle. For all variation requests, applicants must submit supporting documentation that conforms to the approvals issued by the chosen reference agency. For example, if an abridged pathway registration is based on an EMA decision, all subsequent variation requests must also utilize the EMA as the reference agency. Supporting documentation from the FDA will not be accepted.
- If the product was approved via the standard registration pathway, the abridged pathway for variations may be considered.
- SFDA reserves the right to reject the application if the applicant submits false or misleading information.

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 products that are 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 biological products.

8.2. File submission

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

  For human products: Refer to the SFDA data requirements section 1.7.2

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

- **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 requirements to submit the product through verification and abridged process?**

  Refer to the requirements section.

- **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 SFDA 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 SFDA 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. Designation Request for Verification or Abridged registration pathway

Applicants must use this form to send a Designation request by email to Designation.Drug@sfda.gov.sa being titled with "Designation request for **Verification** or **Abridged**"

نتقدم بطلب تعيين 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**
Reference agency		**الجهة المرجعية**
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.Application form for variation

The applicant shall apply through SDR system to fill the application form and pay the fees.

1. General information

Product type	☐ Human Medicinal Product ☐ Veterinary Product
Sub-product No.	
Request No.	
Registration No.	
Reference agency	☐ FDA ☐ EMA
Date of approval by reference agency	

2. Product information:

Trade Name	
Active Ingredient(s)	
Dosage Form	
Strength/Unit	
Package Size(s)	
Route of Administration	
Primary Packaging	
Secondary Packaging	
Approved Shelf Life	
Approved Storage Conditions	
Marketing Authorization Holder	
Agent	

3. **Does this change affect the last updated drug application form?**

☐ Yes
☐ No

4. **Type(s) of Variation(s):**

4.1. Variations included in this application:

Number and title of variation, as per the SFDA guidelines for the variation requirements	Procedure Type

4.2. Precise scope and background for change (Include a description and background of all the proposed changes with its proposed Classification):

Current	Proposed

Declaration:

- ✓ I hereby certify that the submitted information is true and accurate.
- ✓ The submitted variations in this application is only variations that will be studied by SFDA

- ✓ I declare that the SFDA application is for the same product as that approved by the reference agency.
- ✓ I declare that the variation request is identical to the approved variation(s) by the reference agency, and does not include any unapproved variation.

Title:

Name:

Signature:

Date:

Company stamp:

10. Checklist

10.1. Checklist for registration through the verification pathway

Verification	Yes	No
The applicant asks for verification process in the cover letter		
The product type is new chemical entitie or biological product (excluding blood product, advanced therapy medicinal product, and veterinary vaccines)		
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: 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		
- 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 Guidelines for Stability Testing, or the following requirements submitted: - A commitment letter to conduct stability studies according to the Guidelines for Stability Testing; - 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 16)		
Supporting documents on comparative safety and efficacy studies illustrating the added value from an economic perspective.		

10.2. Checklist for registration through the Abridged pathway

Abridged	**Yes**	**No**
The applicant asks for abridged process in the cover letter		
The product type is new chemical entity or biological product (excluding blood product, advanced therapy medicinal product, and veterinary vaccines)		
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: 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		
- 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 Guidelines for Stability Testing, or the following requirements submitted: - A commitment letter to conduct stability studies according to the Guidelines for Stability Testing; - 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 16).		
Supporting documents on comparative safety and efficacy studies illustrating the added value from an economic perspective.		