الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance for Priority Review of Product Registration

Version 5.3

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Saudi Food & Drug Authority

Drug Sector

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Please visit SFDA's website at
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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	24 October 2013	Draft for comments
1.1	Drug sector	25 February 2014	Final
2.0	Drug sector	11 July 2018	Update
3.0	Executive Directorate of Regulatory Affairs	13 May 2019	Update
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5.1	Executive Directorate of Regulatory Affairs	28 February 2022	Update
5.2	Executive Directorate of Regulatory Affairs	05 September 2022	Update
5.3	Executive Directorate of Regulatory Affairs	11 February 2024	Update (Next page shows the updated details)

What is New in version no. 5.2?

The following table shows the update to the previous version:

Section	Description of change
II. Criteria for Qualifying for Priority Review Designation	**Update:** - Criteria for biosimilar

What is New in version no. 5.3?

The following table shows the update to the previous version:

Section	Description of change
II. Criteria for Qualifying for Priority Review Designation	**Delete:** - Criteria for first generic
Application Form	**Update:** - Application form

Table of Contents

I. Introduction

This guidance has been developed to assist applicants in the preparation and submission of priority review applications.

This guidance is intended to facilitate and expedite the review of the human drugs[*] that are intended to treat serious or life threatening conditions, address unmet medical need and biosimilar for the innovated product. It is also intended for veterinary drugs according to the criteria outlined in these guidelines.

Priority review indicates that the review process of the application will be expedited by the concerned departments. However, the designation of a product as priority review does not alter any of the scientific standards and quality of evidence required for approval.

This document provides criteria for designation and process of submission of priority review applications.

II. Criteria for Qualifying for Priority Review Designation

A. New Drug & Biological:

The priority review process for New[†] & Biological drug are intended for the treatment of a serious or life-threatening condition and/or demonstrates the potential to address unmet medical needs.

1. Serious or Life-Threatening Condition:

Since the benefits of priority review designation apply to products for serious conditions as well as to products for life-threatening conditions, distinction between the two categories of conditions with regard to eligibility for priority review is unnecessary. Therefore, in the following discussion, all references to serious conditions will include life-threatening conditions.

[*] In the registration stage.
[†] A product that includes new chemical entity and introduced by the innovator company (or the partner).

1.1. Whether a condition is serious:

For a condition to be serious, the condition should be associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient but the morbidity need not to be irreversible, providing it is persistent or recurrent.

1.2. Whether the drug is intended to treat a serious condition:

For a product to be in a priority review, it must not only be used in patients with a serious condition, it must be intended to treat a serious aspect of that condition. Thus, in making a priority review determination, SFDA will assess whether the priority review program is designed to demonstrate an effect on a serious aspect of the condition. The following examples illustrate SFDA's approach:

- A therapeutic product directed at some aspect of a serious condition would be considered to treat a serious condition if it were being evaluated for effects on a serious manifestation(s) or serious symptom(s) of the condition.
- Drug product would be considered to treat a serious condition if it were being evaluated directly for its impact on a serious aspect of the condition or if it were being evaluated for its ability to improve diagnosis or detection of the condition and scientific data provided a strong basis for a presumption that the improvements in diagnosis or detection of the condition would lead to improved outcome.
- A preventive product would be considered to treat a serious condition if (1) it were being evaluated for its ability to prevent a serious manifestation(s) of the condition, or (2) it were being studied for its ability to prevent the condition and it was scientifically reasonable to assume that prevention of the condition would prevent its serious consequences.
- A product intended to improve or prevent a side effect of therapy of a condition would be considered to treat a serious condition if the side effect were serious (e.g. serious infections in patients receiving immunosuppressive therapy).
- A product intended and being studied for its ability to treat a condition while avoiding the side effects of currently accepted treatments of the condition might be considered to treat a serious condition if such side effects were serious (e.g. a less

myelosuppressive treatment for a tumor or an anti-inflammatory drug that does not cause gastrointestinal bleeding). Many therapies, even those intended to treat no serious conditions, are associated with rare, serious, adverse reactions, and new therapies, despite initial hopes, often are associated with their own set of serious reactions. Nonetheless, some adverse reactions are significant public health problems, and the development of therapies that do not cause such serious reactions would merit close attention. SFDA may designate the development of such a therapy as a priority review drug development program when (1) currently accepted therapy is widely used despite an unavoidable serious risk, (2) serious outcomes are a significant public health issue, and (3) the new therapy shows significant potential to have a substantially improved overall safety profile with at least similar efficacy.

Many conditions not generally considered to be serious have rare or distant serious sequelae (e.g. urinary tract infections or duodenal ulcers). Product for such conditions could be designated as priority review if the applicant demonstrates an effect on those serious sequelae. Conversely, some conditions that are generally considered to be serious have non-serious manifestations requiring symptomatic therapy (e.g. insomnia associated with schizophrenia, skin discoloration from Addison's disease, alopecia with lupus, subcutaneous nodules from rheumatoid arthritis). SFDA will not generally designate as priority review for a product whose effect has been measured in terms of non-serious manifestations unless the product's effect on those manifestations is reasonably likely to predict benefit on a serious manifestation.

2. Demonstrating the Potential to Address Unmet Medical Needs

SFDA will determine whether the drug has a potential to address unmet medical needs and whether the drug development program is designed to evaluate this potential:

2.1. Evaluation of whether the drug development plan addresses unmet medical needs

An unmet medical need is a medical need that is not addressed adequately by an existing therapy.

- Where there is no available therapy for the condition:
  - If no therapy exists for a serious condition, there is an obvious unmet medical need.

- Where there is available therapy for the condition:
  - When therapies exist for a condition, the developmental program for the new drug would address unmet medical needs if it evaluated any of the following:
    1. Improved effect(s) on serious outcomes of the condition that are affected by alternate therapies.
    2. Effect(s) on serious outcomes of the condition not known to be affected by the alternatives.
    3. Ability to provide benefit(s) in patients who are unable to tolerate or are unresponsive to alternative or an ability to be used effectively in combination with other critical agents that cannot be combined with available therapy.
    4. Ability to provide benefit(s) similar to those of alternatives while avoiding serious toxicity that is present in existing therapies, or avoiding less serious toxicity that is common and causes discontinuation of treatment of a serious disease.
    5. Ability to provide benefit(s) similar to those of alternatives but with improvement in some factor, such as compliance or convenience, that is shown to lead to improved effects on serious outcomes.

- Where the only available therapy is approved under the priority review designation (either on the basis of an effect on a surrogate endpoint or for restricted distribution).

2.2. Demonstration of the drug product's potential

The type of information needed to demonstrate the potential of a drug product to address unmet medical needs will depend on the stage of drug development. Data that become available during clinical development should support the drug's potential to address unmet medical needs and the development plan should be designed to assess this potential. SFDA will depend on the summaries of available data to determine whether the potential to address unmet medical needs has been demonstrated.

B. Biosimilar:

- The priority review process for the biosimilar drug is intended for the product considered the first biosimilar to the innovative product that already registered in SFDA or stringent regulatory authority.

C. Availability:

The priority review request for an unavailable drug will be evaluated according to the following criteria:

1. The product is included in one of the updated SFDA list for unregistered or unavailable products.
2. The alternative registered products don't cover the local market needs.
3. The product is included in one of the updated national product mandatory lists that are published on local content and government procurement authority websites.

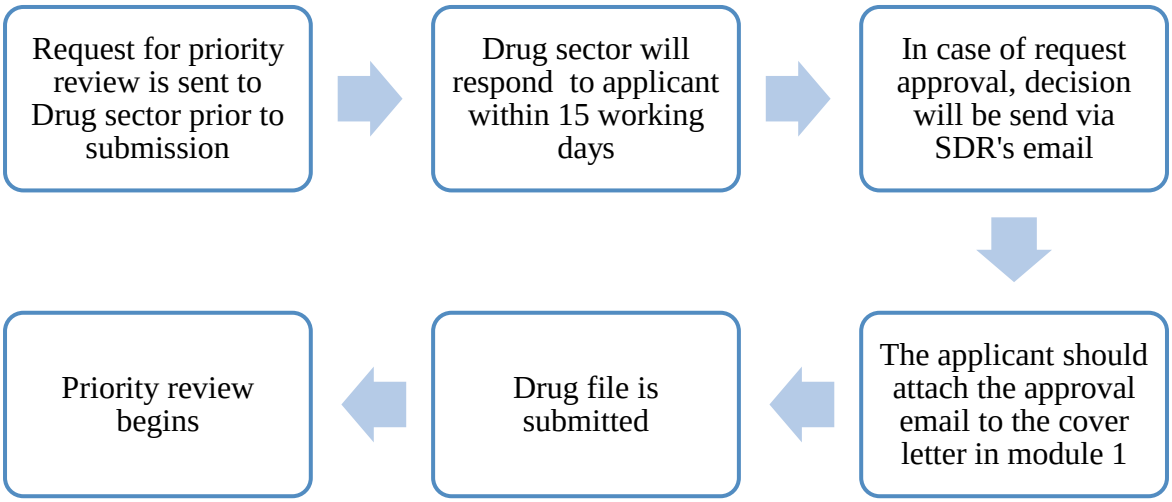
D. Veterinary products:

- New chemical entity:
    a. The product should be registered in stringent drug regulatory authority during last 3 years prior submission to SFDA.
- Vaccines:
    a. Isolated strain
    b. No alternative

III. Process for Designating a Drug for the Priority Review:

General procedures applicable to the submission of priority review designation request is described below:

A. For New & Biological Drug (human or veterinary):



1. When to send priority review designation submission

A request for priority review designation should be submitted **before** the original submission appointment. Taking in consideration, that request needs 15 working days for processing.

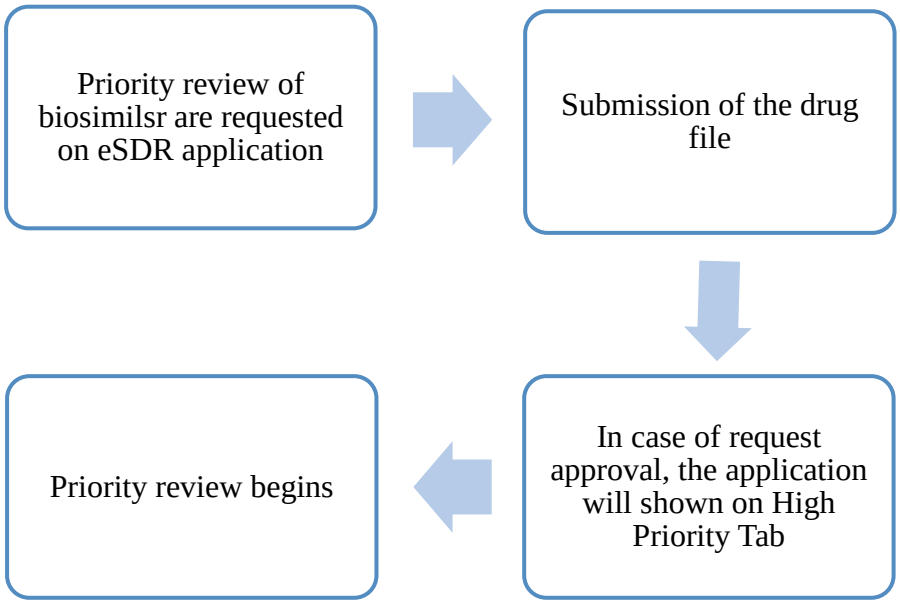
2. Where to send the priority review designation submission

An email for priority review designation should be sent to the Saudi Drug Registration SDR (SDR.Drug@sfda.gov.sa) as application form attached with the cover letter and documents support the request for priority review.

- In order to consider the product has a priority, the company must provide an image of this e-mail on 1.0 Cover letter in the initial submission (0000) otherwise the company will lose the opportunity.
- The applicant should request a prior approval if any of the CTD requirements are to be excluded or not available at the time of submission.

B. For biosimilar Drug

eSDR :



1. When to send priority review designation submission

eSDR:

The company should complete the relevant field on the eSDR Application as the picture below, otherwise SFDA will not accept priority review request after submitting the application.

- For first Biosimilar

2. Where to send the priority review designation submission

The company will receive the SFDA decision regarding the priority designation request within 5 days after the status of the application is "At the relevant department".

IV. Application Review:

A. Start of Review

Complete application according to the “Guidance for Submission” is essential in order to proceed the review. Actual start and scheduling of review will depend on many factors, including staffing, workload, competing priorities and other factors.

B. Review Time

The review clock will not begin until the product has been accepted to be priority reviewed. The total performance target is reduced by 40% of the normal registration process as described in “Regulatory Framework for Drug Approvals”.

V. Reference:

- The FDA Guidance for Industry on the Fast Track Drug Development Programs-Designation, Development, and Application Review, Jan.2006.

Application Form:

Request for Priority Review Designation	
Name of the company	
Trade name	
Active ingredient(s)	
Dosage form	
Strength/unit	
Drug type	☐ Human Drugs ☐ New drug. ☐ Biosimilar. ☐ Biologic. ☐ Veterinary product. ☐ New drug. ☐ Biologic. ☐ Radiopharmaceutical.
Criteria for requesting the priority review	
Proposed justification for requesting priority review	
List of document(s) attached to support the request	