الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Special Access Program

Version No. 2

Date of publication	19 March 2019
Date of implementation	10 September 2019

Special Access Program

Version 2.0

Saudi Food & Drug Authority

Drug Sector

For Inquiries	*SFDA Call Center 19999*
For Comments	*Drug.Comments@sfda.gov.sa*

Please visit SFDA's website at
https://www.sfda.gov.sa/en/regulations?tags=2

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	Executive Directorate of Products Evaluation	9 September 2019	Final
2.0	Executive Directorate of Benefit-risk evaluation	25 October 2026	Update

- **What is new in version no. 2.0?**

The following table shows the updates to the previous version:

Section	Description of change
Introduction	**Add:** The mechanism for applying for rare disease medications, including SAP request.
Initiating a Special Access Program Request	**Update:** Change the roles and responsibilities for pre-SAP approval and post SAP approval (drug importation request)
Timelines	**Update:** The assessment of the program is expected to be responded to applicant within 7 working days.
Figure 1	**Update:** SAP Process
Termination of SAP	**Update:** Requirements for Termination of SAP
Appendix	**Delete**: Form A Form B Form C **Add**: Form X

Contents

Abbreviation list **6**

1. Introduction **8**

1.1. Rare diseases 8

1.2. Scope 9

2. Roles And Responsibilities **9**

2.1. SFDA 9

2.2. The applicant (Sponsors) 10

2.3. The Treating Physician 10

3. Initiating a Special Access Program Request **10**

3.1. Special Access Program Eligibility Criteria 11

3.2. Special Access Program Submission 11

A. Pre-SAP approval 11

B. Post SAP approval 13

4. Timelines **15**

4.1. Working Hours 15

5. Reporting **15**

5.1. Safety reporting 15

5.2. Completion, Termination or Suspension of SAP 15

5.3. Progress Reporting 16

6. Advertising **16**

7. General Consideration **16**

7.1. Registered drugs at SFDA with compliance actions 16

7.2. Discontinued drugs 17

7.3. Unused product 17

8. Appendix: Special Access Program Request Form **18**

Abbreviation list

SFDA	The Saudi Food & Drug Authority
Referenced Regulatory Authority (RRA)	- EMA: European Medicines Agency - US FDA: United States Food and Drug Administration-. - MHRA: United Kingdom's Medicines and Healthcare products Regulatory Agency - PMDA: Japanese Pharmaceuticals and Medical Devices Agency. - Health Canada - Swissmedic. - TGA: Australian Therapeutic Goods Administration.
SAP	Special Access Program
ADR	Adverse Drug Reaction
SUSAR	Suspected Unexpected Serious Adverse Reaction
Applicant (sponsor)	The pharmaceutical company or delegated vendor which take the responsibilities of starting, managing and financing the Special Access Program.

1. Introduction

The Saudi Food & Drug Authority (SFDA) regulations require that drugs are registered at SFDA before they are marketed in Saudi Arabia. Unregistered drugs may be available through an approved clinical trial protocol. A treatment option for patients with a serious, debilitating condition, where there is an unmet medical need or an immediate life-threatening condition, including patients affected by rare diseases, may be provided through a Special Access Program (SAP). This program facilitates the availability of unauthorized drugs under development when no satisfactory authorized alternative therapy exists or when the patient cannot be enrolled in a clinical trial.

The SFDA considers requests from applicant to access unregistered drugs for treatment, and/or prevention of serious debilitating condition with unmet medical need or life-threatening conditions when conventional therapies have been considered and ruled out, have failed, are unsuitable, and/or unavailable for any untreated health condition including patients affected by rare diseases. The SFDA supports the program is discretionary and a decision to authorize or deny a request is made on a case-by-case basis, taking into consideration the nature of the medical emergency, the availability of marketed alternatives, and the information provided supporting of the request regarding the use, safety and efficacy of the drug.

1.1. Rare diseases

Orphan and rare disease treatments may be requested through the Special Access Program, whether to treat the disease or to manage its symptoms. However, the Authority recommends enrolling the patient in a clinical trial, and encourages submitting the drug for registration with the Authority through one of the incentive programs it supports in the field of rare diseases, including: New Accelerator Program for Drugs in Rare Diseases (NADR), Orphan Drug Designation (ODD), Research and Investigational Drugs (RAID) Designation, or the Breakthrough Medicines Program (BMP).

Upon approval of the program, the applicant shall be required to report on the use of the drug, including any adverse events associated therewith, and shall account for all quantities received to the SFDA and the manufacturer/sponsor.

It is important to note that the SFDA does not bear responsibility for conducting a comprehensive evaluation to ensure the validity of the drug information or the sponsor's attestations concerning the safety, efficacy, and quality of the medication. Such considerations remain the responsibility of the treating physician, who must take them into account when recommending the use of a drug and rendering an appropriate risk/benefit determination in the best interests of the patient.

The SFDA requires that treating physicians of individuals using medications obtained through SAP obtain official informed consent, signed by the patient (full name) or the patient's legal guardian (full name), as well as the treating physician (full name). The signed consent form must be placed in the patient's hospital

medical record prior to the administration of treatment.

The applicant should be assured to confirm the availability of a drug as well as to provide the most up-to-date drug information such as prescribing information and other data supporting the use of the drug.

1.2. Scope

This guidance document is intended to:

- Clarify the mandate, intent and scope of SAP
- Describe the process to be followed to access a drug that cannot otherwise be sold or distributed in Saudi Arabia
- Illustrate the responsibilities of the treating physician, sponsor, and SFDA role
- Guidance, applied on "drug" include pharmaceuticals, radiopharmaceuticals, biologics and health products. It excludes medical devices and veterinary products.

2. Roles And Responsibilities

2.1. SFDA

Requests are received by SFDA from sponsors whom seeking approval for the access of an unregistered drug. SFDA may either authorize a sponsor to provide a drug to the treating physician, request additional information or deny the request. The SFDA undertakes the following risk management activities:

- Emphasizing that registered alternatives should always be considered and/or tried before considering the use of unauthorized drugs
- Recommending alternative mechanisms, such as clinical trials, to provide accelerated access to unregistered drugs
- Encouraging the exchange of information about drugs released through the program between applicant, treating physicians and the SFDA
- Monitoring issues and concerns pertaining to drugs availability through the SAP
- Reviewing documents which supports the use of an unregistered drug prior to SAP approval
- Working with the sponsors to gather and document information about a drug, its development, and its regulatory status
- Ensuring that the treating physicians have access to current and relevant information respecting a drug availability throughout the program.
- A thorough following up of the patient medical situation while using the drug.

The SFDA reviews and tracks all Suspected Unexpected Serious Adverse Reactions (SUSARs) reports

submitted by the applicant. In addition, SFDA may contact the manufacturer and recommend that information available on the drug be updated accordingly. The SFDA may also contact the treating physician in the event of (SUSAR).

2.2. The applicant (Sponsors)

The applicant (sponsor) may impose conditions on providing a drug to ensure that it is used in accordance with the latest information available. Applicant is also responsible for providing all relevant information, such as an Investigator's Brochure.

Applicants (sponsors) are responsible for ensuring that they meet the regulatory requirements of their own country with respect to the export of drugs to Saudi Arabia, especially in the case of a controlled drug. In addition, the applicant request an Import Permit to the SFDA for clearance of the drug. This permit allows the drug supplies to be shipped without incident into Saudi Arabia and ensures that all appropriate authorities are so notified.

The sponsor shall be required to comply with the SAP guidelines when importing an unregistered medication and must obtain approval directly from the Drug Permit Department at the SFDA via the Administrative Communication Department system.

2.3. The Treating Physician

The treating physician ensures that the decision to prescribe the drug is supported by credible evidence. Such evidence is usually found in an investigator's brochure, prescribing information from another jurisdiction, or publications in the medical literature.

Physicians must provide their patients with information about the drug's potential risks and/or benefits as well as alternative therapies available. It is mandatory that physicians seek informed consent from their patients or their legal guardian.

Physicians are responsible for reporting to the applicant/sponsor, who shall in turn be responsible for reporting to the SFDA, on the results of the drug's use, including any adverse drug reactions encountered. The applicant must also, upon request, provide an accounting of all drug supplies received.

3. Initiating a Special Access Program Request

To initiate SAP program request, the following criteria and requirements should be submitted by the applicant (sponsors).

3.1. Special Access Program Eligibility Criteria

3.1.1. The patient to be treated has an acute or chronic serious debilitating condition with unmet medical need or immediately life-threatening disease or health condition, and there is no comparable or satisfactory alternative therapy to treat or prevent the disease or condition;

3.1.2. The potential benefits justify the potential risks of the treatment use and those potential risks are considered reasonable in the context of the disease or the health condition to be treated;

3.1.3. Providing the drug for the requested use will not interfere with the initiation, conduction, or completion of clinical investigations that could support marketing approval of the special access use, or otherwise compromise the potential development of the special access use.

3.1.4. The SAP must fulfill one of the following conditions;

3.1.4.1 The drug has been registered for the same indication, dose and strength and route of administration in one of the Referenced Regulatory Authorities (RRA).

3.1.4.2 The SAP approved/permitted through one Referenced Regulatory Authorities (RRA).

3.1.4.3 The drug being under registration for the same indication, dose, strength, and route of administration as SFDA.

3.2. Special Access Program Submission

A. Pre-SAP approval

The applicant (sponsor) should initiate the special access request and submit the following requirements:

1. An official and signed Arabic-headed cover letter addressed to SFDA, Drug Sector, Clinical Trials Department.
2. SAP form (Annex SAP Request Form)
3. Special Access Program Protocol includes the following:

- The rationale for the intended use of the drug, including a list of available therapeutic options that would ordinarily be tried before resorting to the investigational drug or an explanation of why the use of the investigational drug is preferable to the use of available therapeutic options.
- The criteria for patient selection or, for an individual patient, a description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition.

- The method of administration of the drug, dose, and duration of therapy.
- A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.
- Any additional requirements or information that might be requested by SFDA, e.g. prescribing information/package insert from the jurisdiction where the drug may be marketed

4. **Investigator's Brochure includes the following:**

- A brief description of the drug substance and the formulation, including the structural formula, if known.
- A summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans.
- A summary of information related to safety and effectiveness in humans obtained from previous clinical studies such as reprints of published articles on related studies may be appended when useful.
- A description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and of precautions or special monitoring to be done as part of the investigational use of the drug.

5. **Informed Consent form should contain the following, but not limited to:**

- A statement that the patient is aware of the SAP participation.
- The program expected duration, if applicable.
- Explanation of the purposes of the program.
- Description of the procedures to be followed.
- Identification of any procedure which are experimental.
- Description of any reasonably foreseeable risks or discomforts to the participant.
- Description of any benefit to the participant which may reasonably be expected from the program.
- Explanation of whom to contact for answers to pertinent questions about the program, and whom to contact in the event of a program-related injury to the participant.
- A statement that participation is voluntary.

6. Institutional Review Board (IRB)/Research Ethics Committee (EC) or equivalent board or advisory such as Pharmacy and Therapeutics (P&T) committee. Including the list of documents reviewed with the version and date of each.

When the documents fulfill the requirements of SFDA, a “no objection letter” on the program of special

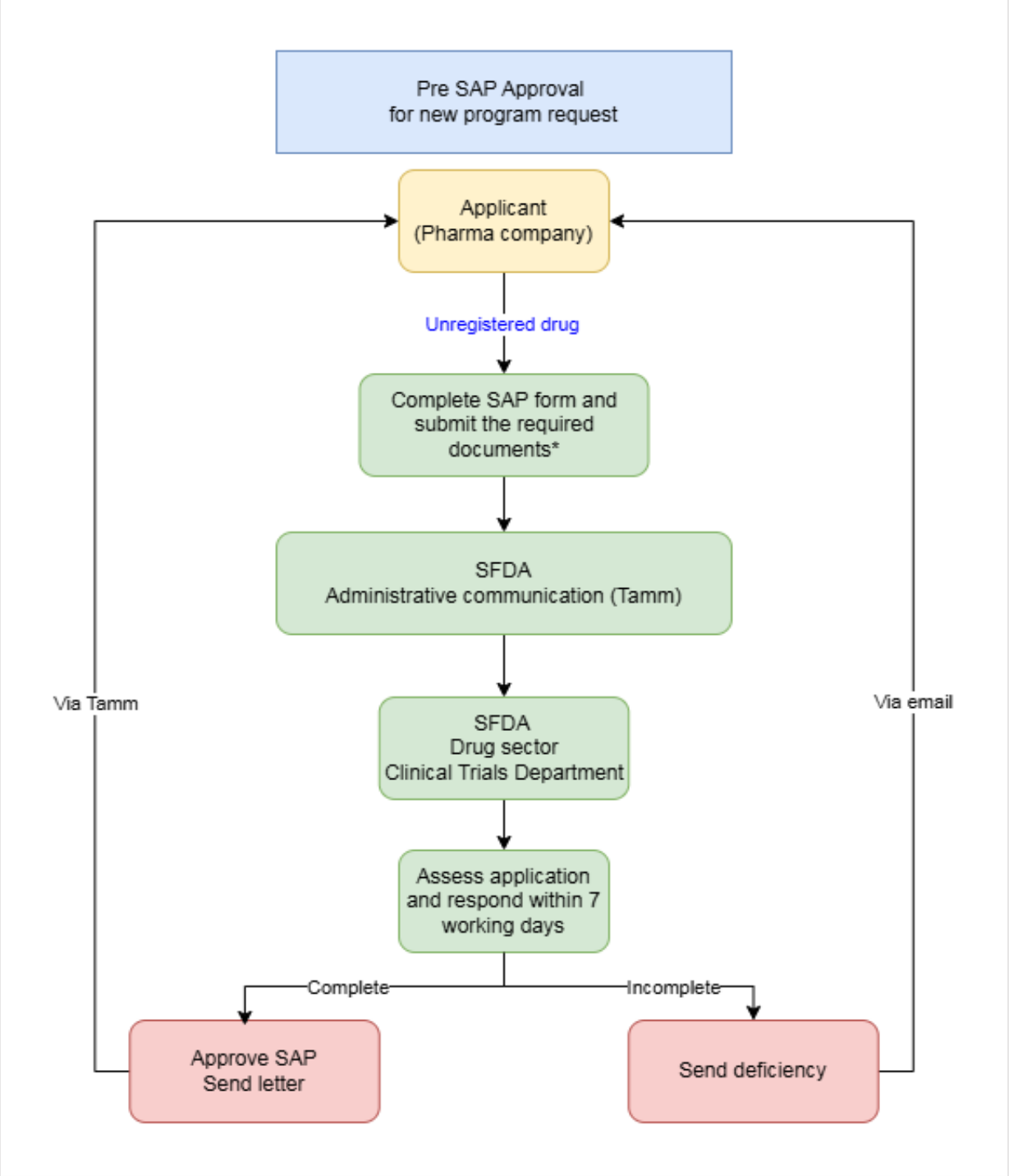
access program for the specified indication will be issued by Clinical Trial department in Drug Sector at SFDA.

B. Post SAP approval

For import license request, the requesting entity or the treating physician should directly submit the request to Drug Permits Department in Operations Sector at SFDA. Application can be submitted via one of the following channels:

1. Faseh System: https://faseh.sfda.gov.sa
2. Administrative Communications: Communications.Adm@sfda.gov.sa

Figure 1: SAP Process



4. Timelines

4.1. Working Hours

Applying for SAP: The Clinical Trials Department in Drug Sector at SFDA will assess the request on regular business working days, from Sunday to Thursday, throughout regular business working hours, which are from 07:30 am to 15:30 pm. The decision on the program is expected to be responded within 7 working days.

While reviewing the application, consideration takes into account that each request represents a unique set of circumstances and is supported to varying degrees by information provided by the applicant.

5. Reporting

5.1. Safety reporting

i. It is mandatory to inform the SFDA immediately about any suspected unexpected serious adverse reactions (SUSAR) as soon as possible, no later than 15 days followed by the follow-up report as soon as possible. If the SUSAR is fatal or life threating, SFDA must be informed as soon as possible, no later than seven days in accordance with the ICH-E2A guideline, with a follow-up report succeeding it within 8 days.

ii. SUSARs should be reported through the National Pharmacovigilance Center via email (icsr.drug@sfda.gov.sa). It is necessary to provide drug name and the e-mail must be titled as "SAP SUSAR."

iii. The applicant must send SUSARs in (XML) format in addition to complete the Council for International Organizations of Medical Sciences (CIOMS) Form.

iv. The applicant must send SUSAR in XML format.

5.2. Completion, Termination or Suspension of SAP

A. **Suspension of SAP program**: The SFDA has the right to temporarily suspend the SAP request in order to protect patients in case of the following:

- Safety concerns affecting participants.
- Non-compliance with SFDA regulations and requirements.

While the SAP is temporarily suspended, the SFDA will launch an investigation. Once the investigation is completed, the SFDA will decide one of the following:

1. Lift the suspension.
2. Terminate the SAP.

B. **Termination of SAP**: as an exit strategy for SAP, a close follow up for patients on medication is required to ensure patient safety.

Exit strategy should include the following requirements prior to SAP closure:

i. The global SAP closure plan includes the mechanism of transition for all the ongoing patients.
ii. A commitment letter that all patients will have a structured plan for receiving the medication, and will be monitored by the pharmaceutical company and/or by the treating physician for no less than two years after the closure of the program.
iii. A periodic follow up report regarding each patient health status and administration of the medication in a period of two years after the closure of the program submitted to SFDA.

C. The applicant must inform SFDA within 60 days with completing, terminating or suspending the program.

5.3. Progress Reporting

The applicant should submit written summaries of the program status to the SFDA every 12 months, or more frequently, if requested by the SFDA. The report may include the following:

i. Deviations from, or changes of, the protocol to eliminate immediate hazards to the patient.
ii. Changes increasing the risk to patient and/or affecting significantly the conduct of the program.
iii. All local adverse drug reactions (ADRs) that are both serious and unexpected.
iv. New information that may affect adversely the safety of the patient or the conduct of the program.

6. Advertising

In accordance to SFDA regulations, advertising of unauthorized drugs accessed through the SAP is strictly prohibited.

7. General Consideration

7.1. Registered drugs at SFDA with compliance actions

The SFDA will consider authorizing access to drugs following compliance action provided that:

- The drug is considered to be medically necessary for the treatment, diagnosis or prevention of a serious or life-threatening condition;
- The applicant is willing to publicly disclose the reasons for regulatory action;

- There are no other dosage forms of the drug on the market that would be considered a reasonable alternative;
- There are no other registered drugs or therapies that would be considered to be reasonable alternatives;
- A clinical trial is inappropriate under the circumstances for gathering new or confirmatory evidence of the safety and efficacy of the drug.

7.2. Discontinued drugs

In circumstances where a drug is discontinued from the market, the SFDA will consider authorizing access to an alternative source of another marketed drug in circumstances where:

- The drug is considered to be medically necessary for the treatment, diagnosis or prevention of a serious or life-threatening condition;
- The applicant is willing to disclose the reasons for the discontinuance of the drug;
- There are no other dosage forms of the drug on the market that would be considered a reasonable alternative;
- There are no other drugs or therapies that would be considered to be reasonable alternatives.

7.3. Unused product

Unused or excess medical products from SAP are subjected to approval/permission from the sponsor and SFDA to be used for another patient with the same medical condition. Furthermore, the treating physician requesting to transfer the supply of drug to another patient must receive authorization from SFDA prior to treatment.

The treating physician must reference the initial request (original patient) and indicate to whom and where the supply is being transferred. The amount being transferred will need to be specified in the quantity section and information provided to support the transfer of the drug for use to another patient(s). Consideration/authorization by the SFDA and the applicant is required prior to transferring the drug to initiate treatment. Moreover, excess products must be returned to the sponsor or destroyed. In addition, the treated physician should notify SFDA with the action that has been taken.

8. Appendix: Special Access Program Request Form

MUST BE ALL FILLED AND SUBMITTED WITH EACH REQUEST.	
SECTION A: APPLICANT AND CONTACT DETAILS	
A1. Cover letter number and date	Applicant reference number: Date: ____ / ____ / _____ (DD/MM/YYYY)
A2. Sponsor	Name:
A3. Local authorized representative in KSA	Name: License no.: Address:
A4. Contact person	Name: Position:
A5. Contact details	E-mail: Mobile: Landline:
A6. Request type (select ONE)	☐ Initial submission ☐ Amendment (amendment no. _____) ☐ Renewal ☐ Close-out ☐ Termination ☐ Cancellation
A7. Accompanying submission (select all that apply)	☐ Safety report ☐ Notification / update ☐ Response to SFDA query ☐ Other: _____
A٨. CRO (if applicable)	Name:
SECTION B: PROGRAM DETAILS	
B1. Program title	
B3. Program duration	Planned start date: ____ / ____ / _____ Planned end date: ____ / ____ / _____
B4. Requested approval validity	_____ months (maximum 12 months; renewable by submitting a renewal request before expiry)

MUST BE ALL FILLED AND SUBMITTED WITH EACH REQUEST.	
B5. Planned number of patients in KSA	
B6. Planned site(s)	Number of sites: _____ (attach the full list of sites with city and institution)
B7. Treating Physician (if applicable)	For each site: name, medical specialty, and SCFHS registration number (attach list if more than one site)
SECTION C: MEDICINAL PRODUCT (MP)	
C1. MP identification	Trade name: Other / code name: INN (generic name): Manufacturer and manufacturing site: ATC code: Strength:
C2. Route of administration	☐ Oral ☐ I.V. ☐ I.M. ☐ S.C. ☐ I.T. ☐ Topical ☐ Inhaled ☐ Ophthalmic ☐ Intranasal ☐ Intradermal ☐ Intravesical ☐ Other: _____
C3. Dosage form	☐ Tablet ☐ Capsule ☐ Oral liquid ☐ Powder for solution ☐ Solution for injection / vial ☐ Lyophilized powder ☐ Pre-filled syringe / autoinjector ☐ Cream ☐ Ointment ☐ Gel ☐ Transdermal patch ☐ Suppository ☐ Inhaler ☐ Other: _____
C4. Dosing regimen	Dose: Frequency: Planned treatment duration per patient: Other dosing notes:
SECTION D: CLINICAL JUSTIFICATION (MANDATORY)	
D1. Proposed indication	Indication: ICD-10 code:
D2. Seriousness of the condition (select ONE and justify)	☐ Life-threatening ☐ Seriously debilitating ☐ Chronically debilitating Justification, supported by objective and quantifiable medical or epidemiological data (e.g. median survival, rate of progression, disability burden):
D3. Registered therapeutic alternatives in KSA	List every therapy registered with SFDA for this indication and state, for each, whether it has failed, is unsuitable for the target patients, or is unavailable, and why:

MUST BE ALL FILLED AND SUBMITTED WITH EACH REQUEST.	
SECTION E: REGULATORY STATUS AND ELIGIBILITY	
E1. MP status at SFDA	Is the MP under registration at SFDA for the same indication, dose/strength and route of administration? ☐ Yes, SDR submission number: _____ date: ____ / ____ / _____ ☐ No
E2. MP status in a Reference Regulatory Authority (RRA)	Is the MP registered, or under registration, for the same indication, dose/strength and route of administration? ☐ No ☐ Yes, tick each applicable authority and give the identifier and decision date: ☐ US-FDA ☐ EMA ☐ MHRA ☐ Swissmedic ☐ Health Canada ☐ PMDA ☐ TGA
E3. Is this program itself approved or permitted by an RRA?	☐ No ☐ Yes, tick each applicable authority and give the registration / identifier number: ☐ US-FDA ☐ EMA ☐ MHRA ☐ Swissmedic ☐ Health Canada ☐ PMDA ☐ TGA
E4. Eligibility attestation	The request is eligible only if at least ONE of the conditions in Table 3 is met. Tick the condition(s) relied upon and attach the supporting evidence: ☐ Condition 1 ☐ Condition 2 ☐ Condition 3
E5. Clinical trial on the same MP in Saudi Arabia	☐ No clinical trial submitted ☐ Yes, SCTR number: Status: ☐ Approved ☐ Under review ☐ Recruiting ☐ Completed ☐ Terminated ☐ Rejected ☐ Suspended
E6. Justification where a trial is available (mandatory if E5 = Yes and the trial is under review, approved or recruiting)	Explain why the patients proposed for this program cannot be enrolled in that clinical trial. A special access program must not delay, replace or reduce enrolment into an ongoing trial.
SECTION F: SAFETY REPORTING AND RISK MANAGEMENT	
F1. Safety contact in KSA	Name: Position: E-mail: 24-hour telephone:
F2. Safety reporting commitments (tick each to acknowledge)	☐ Fatal or life-threatening SUSARs will be reported to SFDA within 7 calendar days of awareness, with a follow-up report within 8 further calendar days. ☐ All other SUSARs will be reported to SFDA within 15 calendar days of awareness.

MUST BE ALL FILLED AND SUBMITTED WITH EACH REQUEST.	
	☐ A periodic line listing of all adverse events, and a Development Safety Update Report, will be submitted annually or on SFDA request. ☐ SFDA will be notified within 15 calendar days of any regulatory or safety action taken on the MP by any regulatory authority worldwide (including suspension, restriction, withdrawal, or a new safety warning). ☐ SFDA will be notified within 24 hours if the program is suspended or terminated for safety reasons in KSA or in any other country.
F3. Risk minimization and monitoring	Describe the proposed risk minimization measures, required monitoring, and any controlled distribution or prescriber/site restrictions:
SECTION G: SUPPLY, COST AND TRANSITION	
G1. Free-of-charge supply	☐ Confirmed, the MP will be supplied free of charge to every patient enrolled in this program. Free supply will continue until the earliest of: (a) the treating physician documents that treatment is no longer clinically indicated or the patient withdraws; or (b) the product is registered with SFDA, commercially available in KSA and accessible to the patient through the normal supply and reimbursement route.
G2. Transition / exit strategy	Describe how continuity of treatment will be maintained for enrolled patients at program close-out, and how patients will be transferred to commercial supply following registration:
G3. Drug accountability	Describe the accountability records to be kept at each site, and the arrangements for the return or destruction of unused MP:
SECTION H: DATA PROTECTION	
☐ Acknowledged. No patient name or other direct identifier will be recorded on this form or in any submission made under this program; patients will be identified by code only.	
SECTION I: DECLARATION	
I, the undersigned, declare on behalf of the applicant that: 1. All information and documents submitted to SFDA in connection with this request are correct, accurate and complete. Providing inaccurate or misleading information may result in rejection of the application or in regulatory action in accordance with the applicable laws and regulations. 2. I have read and understood the information contained in this form and agree to its terms and conditions. 3. I will notify SFDA immediately if the status of this program changes at any time, during or after the SFDA review period, including suspension for safety reasons in KSA or in any other country. 4. I will comply with the safety reporting commitments set out in Section F. 5. The medicinal product will be provided to enrolled patients free of charge on the terms set out in Section G, including after the product is registered with SFDA and until the conditions in G1 are met. 6. The program will be conducted in accordance with the SFDA Guideline for Good Clinical Practice, the approved protocol, and the conditions of any SFDA approval issued for this program. 7. The product supplied under this program will not be advertised, promoted or supplied to any person outside the approved program. Name: _____ Position: _____ Entity: _____ Date: ____ / ____ / _____ Signature: _____ Official stamp:	

Table 2: Documents required at submission

#	Requirements	Enclosed
1.	Arabic-headed cover letter addressed to SFDA, Drug Sector, Clinical Trials Department, enclosing this completed form (E-mail or hard copy).	☐
2.	SAP protocol prepared in accordance with the SFDA SAP Guideline.	☐
3.	Investigator's Brochure, prepared in accordance with the SFDA SAP Guideline.	☐
4.	Informed Consent Form in Arabic and English, version-controlled and dated.	☐
5.	Approval letter: Institutional Review Board (IRB)/Research Ethics Committee (EC) or equivalent board or advisory such as Pharmacy and Therapeutics (P&T) committee. Including the list of documents reviewed with the version and date of each.	☐

Table 3: Eligibility conditions

The request is eligible for assessment only if at least ONE of the following conditions is met. Tick the condition(s) relied upon in Section E4 and attach the supporting evidence.

#	Condition	Evidence provided
1	The MP is registered for the same indication, dose/strength and route of administration by one of the following authorities: US-FDA, EMA, Health Canada, MHRA, TGA, PMDA, Swissmedic.	Authority: _____ Approval date: _____ Identifier: _____
2	The program has been approved or permitted by one of the following authorities: US-FDA, EMA, Health Canada, MHRA, TGA, PMDA, Swissmedic.	Authority: _____ Identifier: _____
3	The MP is under registration at SFDA for the same indication, dose/strength and route of administration.	SDR number: _____ Submission date: _____

Abbreviations

CRO: Contract Research Organization · GCP: Good Clinical Practice · ICD-10: International Classification of Diseases, 10th revision · MP: Medicinal Product · INN: International Non-proprietary Name · IRB: Institutional Review Board · RRA: Reference Regulatory Authority · SAP: Special Access Program · SCFHS: Saudi Commission for Health Specialties · SCTR: Saudi Clinical Trials Registry · SDR: Saudi Drug Registration system · SUSAR: Suspected Unexpected Serious Adverse Reaction