الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Special Access Program

Version 1.0

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

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Special Access Program

Version 1.0

Saudi Food & Drug Authority

Drug Sector

For Inquiries *CT.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

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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
Draft	Executive Directorate of Products Evaluation	19 March 2019	Draft
1.0	Executive Directorate of Products Evaluation	10 October 2019	Final

Table of Content:

1. INTRODUCTION

The Saudi Food & Drug Authority (SFDA) regulations require that medicinal products are registered at SFDA before they are marketed in Saudi Arabia. Unregistered medicinal products may be available through an approved clinical trial protocol. A treatment option for patients in Saudi Arabia suffering from a serious or immediately life-threatening disease or condition, and there is no satisfactory authorized alternative therapy exists or who cannot be enrolled in a clinical trial, may be the use of an unauthorized medicinal product in a Special Access Program facilitate the availability to patients of new treatment options under development.

The SFDA considers requests from the treating physicians for access unregistered drugs for treatment, diagnosis or prevention of serious or life-threatening conditions when conventional therapies have been considered and ruled out, have failed, are unsuitable, and/or unavailable. The SFDA supporting the program is discretionary and a decision to authorize or deny a request is made on a case-by-case basis by taking into consideration the nature of the medical emergency, the availability of marketed alternatives and the information provided in support of the request regarding the use, safety and efficacy of the drug.

If access is granted, the physician agrees to report on the use of the drug including any adverse events encountered with such use, and must account for all quantities received to both the SFDA and the manufacturer/sponsor.

The SFDA does not conduct a comprehensive evaluation to ensure the validity of drug information or attestations of the sponsor respecting safety, efficacy and quality. These are important factors for physicians to consider when recommending the use of a drug and in making an appropriate risk/benefit decision in the best interests of the patient. The SFDA strongly required physicians treating individuals with drugs obtained through the Special Access Program to seek informed consent before treatment.

Physician are encouraged to contact individual sponsor to confirm the availability of a drug as well as to obtain the most up-to-date drug information such as prescribing information and other data supporting the use of the drug.

1.1. Scope

This guidance document is intended to:

- Clarify the mandate, intent and scope of the special access program.
- 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 in that process;
- Guidance, applied on "drug" include pharmaceuticals, radiopharmaceuticals, biologics and health products. It excludes medical devices and veterinary products.

1.2. Abbreviations

SFDA: The Saudi Food & Drug Authority

SAP: Special Access Program

ADR: Adverse Drug Reaction

SUSAR: Suspected Unexpected Serious Adverse Reaction

2. ROLES AND RESPONSIBILITIES

2.1 SFDA

Requests are received by the SFDA from 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 from the treating physician 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 SAP between sponsors, treating physicians and the SFDA;
- Monitoring issues and concerns pertaining to drugs available through the SAP;
- Reviewing documents supporting use of an unregistered drug prior to SAP approval;
- Working with the sponsors to gather and document information about a drug, its development and regulatory status; and
- Ensuring that the treating physicians have access to current and relevant information respecting a drug available through the program.

The SFDA reviews and tracks all Suspected Unexpected Serious Adverse Reactions (SUSARs) reports submitted by the treating physician. In addition, the 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 Treating Physician

The treating physician initiates a request and 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. After the SFDA

approval on the SAP program, it is the physician responsibility to fill the clearance form for his site.

The physicians are responsible for reporting to both the sponsor and the SFDA on the results of the use of the drug, including any adverse drug reactions encountered. The physician must also, upon request, provide an accounting for all drug supplies received.

2.3 Sponsors

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

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, SFDA must issue an Import Permit to the sponsor. This permit allows the drug supplies to be shipped without incident into Saudi Arabia and ensures that all appropriate authorities are so notified.

3. INITIATING A SPECIAL ACCESS REQUEST:

To initiate a SAP request the following criteria and requirements should be met:

3.1 Special Access Program Criteria:

i. The patient to be treated has an acute or chronic serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;

ii. The potential benefits justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated; and

iii. Providing the investigational drug for the requested use will not interfere with the initiation, conduct, 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.

3.2 Special Access Program Submission:

A. Pre SAP approval:

The manufacturer /sponsor or the licensed treating physician[1] should initiate the special access request and submit the following requirements:

i. An official and signed Arabic-Headed cover Letter to SFDA Executive Vice President for Drug Affairs.

ii. 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

iii. Investigator's Brochure includes the following:

- A brief description of the drug substance and the formulation, including the structural formula, if known.

[1] The physician should not submit the program on behalf of the sponsor. He can submit directly only if there is no sponsor of the program

- A summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans.
- A summary of information relating to safety and effectiveness in humans obtained from prior clinical studies. (Reprints of published articles on such 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.

iv. Informed Consent form must contain the following, but not limited to:

- A statement that the patient is aware of the SAP participation.
- The program expected duration. (if applicable)
- An explanation of the purposes of the program.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant which may reasonably be expected from the program.
- An 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.

B. Post SAP approval:

After obtaining SFDA approval on the SAP request, the licensed treating physician should submit the following (by email: ct.drug@sfda.gov.sa) to obtain clearance for his named patient/s:

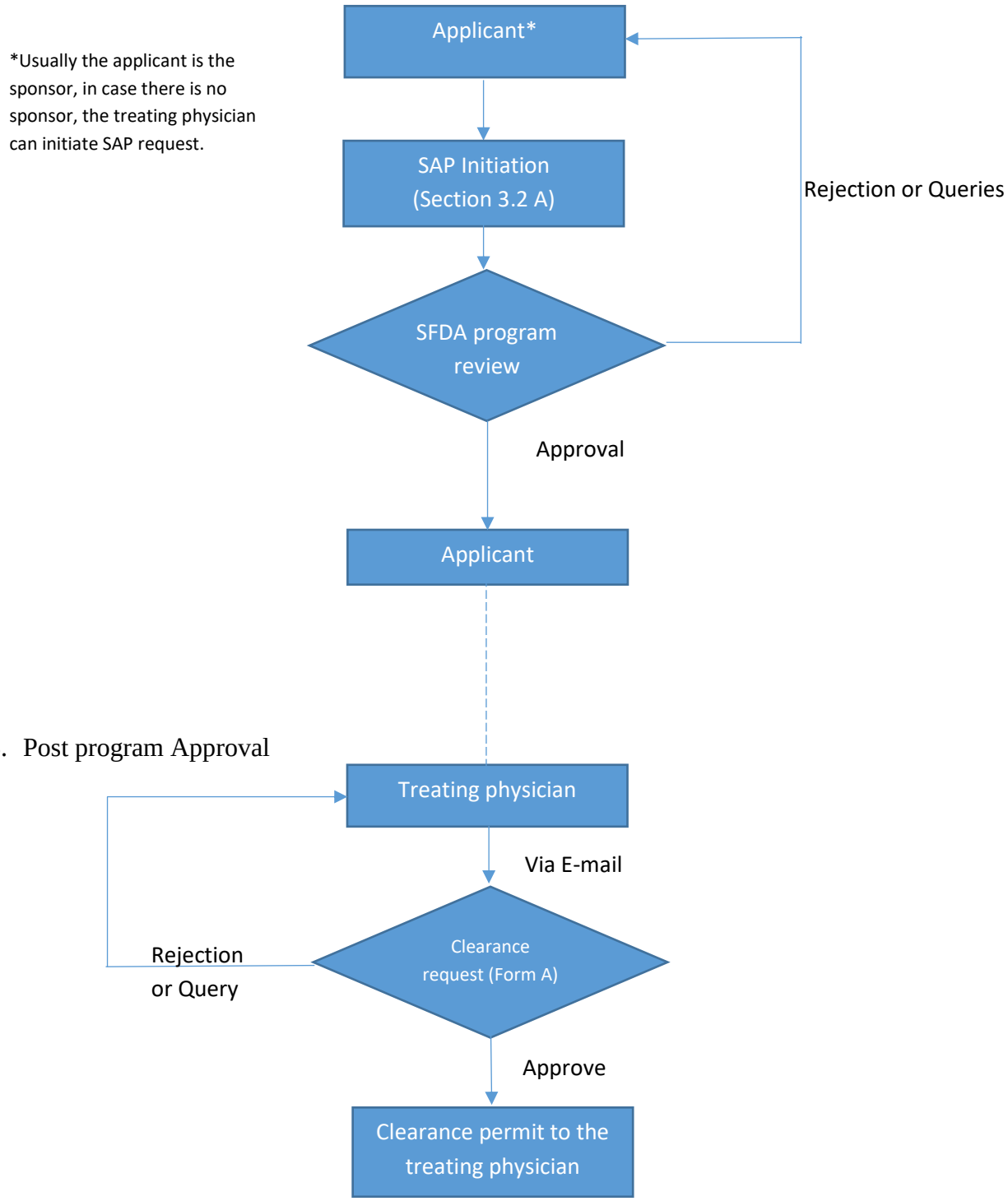
i. An official and signed Arabic-Headed cover Letter from beneficiary institution administration to Clinical Trials Department at SFDA/Drug Sector.

ii. Special Access Program Request (Appendix Form A) that completed and singed by the licensed treating physician.

iii. A copy of the official Informed Consent signed by each patient (by name) or by his\her legal guardian. In accordance with ICH guidelines.

iv. Any additional requirements or information that might be requested by SFDA.

A. Pre SAP program approval



B. Post program Approval

4. TIMELINES

4.1 Working Hours:

The Clinical Trials Department regular business working hours are from 07:30 am to 15:30 pm (GMT+3) Sunday to Thursday.

4.2 Processing Hours:

In case of all requirements were completed, the special access request will be processed within 24 working hours. However, given the mandate of the program and the volume of requests received, requests are triaged to ensure that urgent matters take precedence over less urgent matters. After processing, the request will be forwarded to an assessor for review.

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

5 REPORTING

5.1 Safety Reporting

i. It is mandatory to inform the SFDA immediately about any Suspected Unexpected Serious Adverse Reaction (SUSAR) that occurs in a SAP, using CIOMS FORM (appendix form B); as soon as possible, no later than 15 calendar 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 calendar days in 7 accordance with the ICH-E2A guideline, with a follow-up report succeeding it within 8 calendar days.

ii. SUSARs should be reported through the National Pharmacovigilance Center via e-mail (ICSR.DRUG@sfda.gov.sa). The e-mail subject must be “SAP.”

iii. The applicant must send SUSAR in XML format. Treating physician, however, may be exempted from reporting in XML format.

5.2 Progress Reporting

The applicant should submit written summaries of the program status to the SFDA every 3 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 CLEARANCE

When SFDA has granted the approval for a drug through Clinical Trial Department; then SFDA will issue an import letter leading the hospital or the sponsor to clear their product through SFDA ports. Upon applicant request in accordance with the requirements (3.2b)

7 ADVERTISING

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

8 GENERAL CONSIDERATION

8.1 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 sponsor 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.

8.2 Discontinued drugs

In circumstances where a drug is discontinued from the Saudi market, the SFDA will consider authorizing access to an alternative source 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 sponsor 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.

8.3 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 Moreover, excess products must be returned to the sponsor or destroyed and notify the SFDA.

9 Appendix[2]

FORM A (SPECIAL ACCESS PROGRAMME CLEARCANE REQUEST)

SECTION A: PHYSICIAN INFORMATION		
Physician's Name:		
Physician's ID #:		Physician's SCFHS Licensing #:
Hospital Name:		
Province:		City:
Contact Person: (if other than physician)		
Physician's Telephone #:	Extension #:	Physician's Mobil #:
Contact Telephone #:	Extension #:	Contact Mobil #:
Physician's Email Address:		Contact's Email Address:

SECTION B: DRUG AND MANUFACTURER INFORMATION	
Trade Name:	Other Name:
Manufacturer:	Sponsor: (if applicable)
Route of Administration: ORAL ☐ I.V. ☐ I.M. ☐ TOPICAL ☐ S.C. ☐ OTHER☐:	
Dosage Form: TAB ☐ CAP ☐ LIQUID ☐ POWDER ☐ CREAM ☐ OINT. ☐ PATCH ☐ OTHER:	

SECTION C: PATIENT INFORMATION

If you have supply of the drug on hand and would like to transfer it to another patient, thus requiring **authorization only**, please check here ☐ and complete the table below. Specify the amount being transferred in the quantity section.

Patient Initials (e.g. A.B.C.)	DOB (DD/MM/YYYY)	Gender	Indication for Use of Drug	New or Repeat patient for this drug?	Dosage and Duration (e.g. #mg bid x #days)	Strength (e.g. #mg)	Quantity (e.g. # tabs)
		M ☐ F ☐		N ☐ R ☐			
		M ☐ F ☐		N ☐ R ☐			
		M ☐ F ☐		N ☐ R ☐			
		M ☐ F ☐		N ☐ R☐☐			
Please specify the **EXACT AMOUNT** of drug requested (*e.g.* number of tabs, vials, units, etc.).							**Total:**
Please specify when the drug will be administered/dispensed? (i.e. a date):							

[2] Soft copy of the forms available under the drug sector page in "**Forms section**"

SECTION D: CLINICAL RATIONALE OF THE REQUEST
1. For **new** patients, provide specific information about your patient(s)'s medical history including conventional therapies considered, ruled out and/or failed or that are unsuitable and/or unavailable to achieve an adequate response. What specifically about this drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s)'s? Please explain.
2. For **repeat** patients, describe your patient(s)'s response to the drug relative to the initial treatment goal(s) and provide a rationale for requesting continued access.

SECTION E: PHYSICIAN'S ATTESTATION	
I, the treating physician, am accessing this non-marketed drug for use in the emergency treatment of a patient under my care in accordance with the Saudi *Food and Drug Authority Regulations.*	
I, the physician, agree to provide the progress report and a report on the results of the use of the drug including information on Adverse Drug Reactions and, on request, to account for quantities of the drug received.	
I, the physician, agree that all information provided in this form are correct and I am aware that any modifications or changes made on this form after issuing of SFDA decision will reject/cancel the request and I will subjected to legal action by SFDA.	
Treating physician's Signature:	**Date:**

SECTION F: SFDA'S DECISION		
Approve	☐	Without changes
Withhold Approval	☐	Changes, clarifications, or additional information requested
	Stipulations:	
Disapprove	☐	Risks significantly outweigh benefits or value of knowledge that may be gained Ethical issues preclude acceptability of the study
	Disapproval reasons:	

Signature: **Director of the Benefit Risk Assessment Department**	**Date:**

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

FORM B (CIOMS FORM)

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4–6 REACTION ONSET			8–12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										☐ PATIENT DEATH ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ THREAT TO LIFE

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO-DUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude drugs used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g., diagnostics, allergies, or pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOW-UP	

V. Treating physician information

26. Name of the treating physician		
27. Saudi Health Specialties Commission No.		
28. Qualified Area(s) of Specialty		
29. Place of Practice		
30 Address of Practice		
31. Telephone Number		
32. E-mail Address		

Email all clearance requests to ct.drug@sfda.gov.sa

For urgent requests requiring immediate attention please follow up with a call to the Clinical Trials Department at:

(+966) 11-2038222 Ext. 5773 or 5774