



Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Regulations and Requirements

for the clearance of medicines,
pharmaceutical preparations,
devices, medical supplies and food
supplies for the use of pilgrims

Regulations and Requirements for the clearance of medicines, pharmaceutical preparations, devices, medical supplies and food supplies for the use of pilgrims

Version number 2.2

For inquiries and Comments

19999

And suggestions

Drug.Comments@sFDA.gov.sa

Please visit the Saudi Food and Drug Authority website

<https://www.sFDA.gov.sa/ar/regulations?tags=2>

For more information
Saudi Food & Drug Authority

Mission and Vision

Vision

To be a leading global body based on scientific foundations to promote and protect public health

Vision

Protecting society through legislation and an effective regulatory system to ensure the safety of food, medicine, medical devices, cosmetic products, pesticides, and feed



Index

Section One:	06 - 10
Imported products such as medicines, medical devices and supplies that are in the possession of Pilgrims Affairs Offices or official government agencies coming to the Kingdom for the use by patients of the mission.	
Section Two:	11 - 12
Products of medicines, pharmaceutical preparations, or medical devices and supplies received with doctors accompanying upcoming Hajj campaigns coming through air, sea or land ports for emergency use by pilgrims during the duration of movement to reach the holy sites.	
Section Three:	13 - 17
Incoming products of medicines, devices, medical supplies and foodstuffs in the possession of pilgrims for personal use	
Section Four:	18 - 23
Forms, pledges and lists	

Documentation

Version	Date	Publisher	Note
1	1\10\1439	Ports directorate in drug sector	initiation
2	11\10\1442	Inspection support executive directorate	Update
3	11\10\1443	Inspection support executive directorate	Update (The following page explains the terms of update)
4	28\08\1444	Inspection support executive directorate	Update (The following page explains the terms of update)

What is the update in this version (Number (2.2) ?

Below is a table showing the updates:

Title	Update type
<ul style="list-style-type: none">• Dedicate the email to the central clearance section.• Replace a clearance request letter addressed to the Saudi Food and Drug Authority Office at the port of arrival with the central clearance email• Electronic path• Adding responsibility for dispensing restricted drugs in the electronic system (CDS: Controlled Drug System) to the custody officer.	<ul style="list-style-type: none">• Dedicate an email to receive requests received during the Hajj season Hajj@sfda.gov.sa• Replace a clearance request letter addressed to the Saudi Food and Drug Authority Office with an email for central clearance to the following mailing address: Hajj@sfda.gov.sa• Clarifying that requests will be received through the electronic path of the Ministry of Hajj• Adding a requirement for the custody officer for narcotic drugs and psychotropic substances to complete the procedures for dispensing them through the electronic system (CDS: Controlled Drug System) for restricted drugs.

Section One:

Section One: Imported products of medicines, devices, and medical supplies in the possession of Pilgrims Affairs Offices or official government agencies coming to the Kingdom for the use of patients affiliated with the mission, and contraindications to the supply of foodstuffs.

First: Conditions and Rules

These requirements will be submitted electronically through the Ministry of Hajj and Umrah portal to streamline and expedite the process. If this system is implemented before the start of this year's Hajj season, all applications and documents must be submitted electronically, without the need for paper copies.

2. Commitment to providing medicines, devices, and medical supplies through approved airports:

- King Abdulaziz International Airport in Jeddah
- Prince Mohammed bin Abdulaziz Airport in Medina

Clearance for the import of medicines, devices, and medical supplies for Hajj will only be granted for shipments arriving between Shawwal 15th and Dhul-Qi'dah 30th. This is in accordance with the regulations outlined in the Hajj Affairs instructions booklet by the Ministry of Hajj and Umrah.

1. Pilgrims Affairs Offices shall submit official documents and data regarding medicines, devices and medical supplies to the Ministry of Hajj and Umrah no less than fifteen (15) days before the shipment arrives, via the electronic route for pilgrims abroad. Some requests can be exempted by the Ministry and allowed to be sent. An electronic copy of the documents described in the second paragraph, the required documents, on the following email (hajj@sfda.gov.sa)

2. The dispensing of narcotic drugs and psychotropic substances will be monitored through the electronic system (CDS: Controlled Drug System) for restricted drugs at the following link: <https://cds.sfda.gov.sa>

3. When supplying controlled medications with the mission, Pilgrims Affairs Offices shall adhere to the following:

- a) Attach a copy of the medical licenses of the medical mission headquarters in Mecca and Medina.
- b) The custody officer for narcotic drugs and psychotropic substances is obligated to enter the quantities dispensed for each prescription dispensed through the electronic system (CDS: Controlled Drug System) for restricted drugs at the following link (<https://cds.sfda.gov.sa>), through an account provided by the Saudi Food and Drug Authority, Pilgrims Affairs Offices.
- c) **Provide proof of the need to supply restricted medicines by providing the following requirements:**

1. Medical prescriptions for the mission's pilgrims explaining their need for these medications
2. Number of beneficiaries of restricted medications and their medical condition.

4. The import of medicines and medical supplies for Pilgrims Affairs Offices through King Abdulaziz Airport in Jeddah shall be by airfreight only and according to a bill of lading so that regular customs procedures are applied in clearing medicines and medical devices.

5. Pilgrims Affairs Offices must have a licensed medical team on staff. The head of this team is responsible for overseeing and managing all medications.

6. The supply of X-ray machines or medical devices and supplies containing radioactive materials is prohibited.

7. The supply of medicines and pharmaceutical preparations containing substances prohibited by local and international regulations is strictly forbidden.

8. Verify that the packing statement for the attached list of products accurately reflects the actual contents of the shipments received through the port. The list and boxes should be numbered sequentially to streamline inspection and auditing processes.

9. All Pilgrims Affairs Offices shall do the following upon departure:

- Re-exporting the remaining quantities of medicines and medical supplies when the mission leaves the Kingdom, according to a customs declaration.
- A copy of the statement of what was dispensed, what is remaining and what was damaged shall be submitted.

Due to the non-compliance of some missions with the pledges submitted annually, the custody officials will not be allowed to leave the Kingdom until their commitment to the pledges that were signed is confirmed, and the remaining quantities of medicines, devices, and medical supplies are re-exported. Upon departure, he is required to submit a letter from the Saudi Food and Drug Authority to the Passport

Department at the port stating its commitment to the pledges referred to above.

10. It is prohibited to distribute excess or remaining quantities of medicines, devices and medical supplies to any party, and it is not allowed to keep them in residential buildings after the end of the Hajj season, and they shall be re-exported so that they are not exposed to damage.

11. The mission shall import only the necessary medicines, devices and supplies for the use of mission personnel by estimating annual consumption based on what was consumed during previous years and not supplying large quantities in excess of the need. The Authority has the right to reject any product or quantity that it deems to be in excess of the mission's need.

12. It is prohibited to supply foodstuffs with Pilgrims Affairs Offices for the purpose of catering, which are provided by catering contractors in accordance with the

Instructions Manual regulating Hajj Affairs and the minutes of the agreement concluded between the Ministry of Hajj and the Pilgrims Affairs Office.

13. It is prohibited to import foodstuffs from the list of countries from which imports are prohibited, published on the Authority's website.

14. It is prohibited to import food items shown in the list of food commodities prohibited from importing according to the customs provisions published on the Authority's website (the list attached).

Second: Documents required for permission:

a) E-mail addressed to Hajj@sFDA.gov.sa requesting clearance, indicating the name of the person responsible for entrusting medicines and medical supplies and for re-exporting the remaining ones after the end of Hajj, and the transaction registration number at the Ministry of Hajj, and attaching a

copy of the medical licenses for the headquarters of Pilgrims Affairs Offices (in the case of medicine subject to monitoring) and the minutes of the agreement concluded with the number of pilgrims, and the completion of the forms and pledges described in Chapter Four:

b) Undertake to restrict the use of medicines, devices and medical supplies to mission personnel only and to their responsibility. They shall not be sold or disposed of by any means whatsoever and undertake to commit to the introduction of quantities of narcotic drugs and psychotropic substances through the Restricted Drug System (CDS: Controlled Drug System) for each prescription dispensed and to return the remainder with the mission upon return. Submit a statement of expenditure, residual and damaged prior to the Mission's departure from the Kingdom to the branch of the Saudi Food and Drug Authority at the Customs Port and undertake to contract with an accredited

company for the destruction of medical wastes (attached is the pledge form required to be submitted with the Pilgrims Affairs Offices or official missions).

c) Filling statement for the following:

- Narcotic and controlled medications.
- Required medications (unmonitored)
- Medical devices and supplies

Certified by the competent authority in the country to which the mission is located and certified by the Saudi Embassy.

Regarding medicines, the packing statement shall contain the following:

- Scientific name
- Pharmaceutical form

- Concentration
- Size
- Quantity required
- Number of cases being treated
- For medical devices and supplies, the packing statement shall contain the following:
- Name of the substance or device
- Quantity required

Fill out the attached form and provide it in an electronic copy on the Excel program, attaching the invoices indicating the quantity, weight and value, with the need to ensure that the approved quantities and items in the lists are compatible with the incoming shipment and that the lists and cartons contain explanatory numbers to facilitate inspection procedures.

Section Two:

Products of medicines, pharmaceutical preparations, medicines, and medical supplies received with doctors accompanying Hajj campaigns coming through air, sea, or land ports for emergency use by pilgrims during the period of movement to the holy sites and food supply sites.

First: Conditions and controls:

These requirements will be submitted electronically through the Ministry of Hajj and Umrah portal to streamline and expedite the process. If this system is implemented before the start of this year's Hajj season, all applications and documents must be submitted electronically, without the need for paper copies.

1. We are working to ensure that these requirements are not the electronic path of the Ministry of Hajj and Umrah to facilitate and speed up the procedures
If this is completed before the beginning of this year's Hajj season, in this case it is necessary to adhere to submitting applications and documents electronically, without the need to submit them on paper.
2. The medicines and medical supplies received with the doctor shall be for emergency cases only and in quantities that cover the needs of the campaign members accompanying the doctor for their personal use during the trip and transportation to residential headquarters or holy sites and until they are connected with the Pilgrims Affairs Office later.
3. It is prohibited to supply narcotic or controlled medications with a doctor for the use of pilgrims during the period of transportation to the destinations.
4. It is prohibited to supply products containing substances that fall within the prohibited lists locally and internationally.
5. It is prohibited to supply x-ray machines or medical devices and supplies that contain radioactive materials.

Second: Documents required for clearance:

1. A letter from the Ministry of Health to which the doctor accompanying the campaign is affiliated stating that he is assigned to accompany the campaign to provide the necessary emergency treatment services during the campaign's travel until it reaches the holy sites.
2. In the event that the letter referred to above is not available, medical prescriptions\ reports shall be attached explaining the need for emergency products for patients accompanying the doctor during the period of transportation to the headquarters.
3. A pledge from the doctor stating that he is responsible for medicines and medical supplies and that they will only be dispensed to campaign pilgrims, and that the remainder of them will be re-exported upon leaving the Kingdom according to the pledge form required to be submitted with the doctor accompanying the campaign.

Section Three:

Incoming products of medicines, devices, medical supplies, and foodstuffs in the possession of pilgrims for personal use

First: Controlled narcotic drugs and uncontrolled drugs and pharmaceutical preparations:

These requirements will be submitted electronically through the Ministry of Hajj and Umrah portal to streamline and expedite the process. If this system is implemented before the start of this year's Hajj season, all applications and documents must be submitted electronically, without the need for paper copies.

Terms and controls:

- Clearance of controlled narcotic drugs shall be approved for a quantity that is adequate for a maximum of thirty days or the patient's stay in the Kingdom, whichever is less, provided that the expiration date is valid for the pilgrim's personal use only and under his responsibility.
- Clearance of non-controlled drugs shall be approved for a quantity that does not exceed one month use or the duration of the pilgrim's stay, whichever is less, for the pilgrim's personal use only and under his responsibility.
- If the quantity of medication required to be cleared exceeds the patient's need, the remaining quantity will be destroyed.
- It is prohibited to enter medicines and pharmaceutical preparations that are brought with pilgrims without their original packaging or those issued by the treatment institution.
- It is prohibited to enter expired medications and pharmaceutical preparations.

- The medicines and pharmaceutical preparations required to be cleared shall be free of internationally and locally banned substances and radioactive materials.
- The Authority does not allow the entry of products of unknown composition, as well as those with misleading medical claims such as (weight loss, weight gain, whitening, sexual claims, etc.)
- The Authority advises that you consult a doctor before using any pharmaceutical preparation

Narcotic and controlled drug clearance requirements:

1. Attach a detailed medical report certified by the treatment institution in which the patient is being treated and no more than a year or months old from the date of its issuance, provided that the report includes the following:

- a) personal information about the patient
- b) Medical diagnosis
- c) The treatment plan and its duration.
- d) Medical recommendation.
- e) The scientific name of the drug, the pharmaceutical form, and the prescribed dosage

2. Or attach a prescription made out with the patient's name, approved by the same treatment institution, and not more than six months old, provided that it contains the following information:

- a) Diagnosis of the disease.
- b) The scientific name of the drug, the pharmaceutical form, and the prescribed dosage
- c) Method of use and duration of treatment.
- d) The stamp of the treatment institution

Requirements for clearing uncontrolled drugs and pharmaceutical preparations

- 1.A copy of the medical report or prescription for prescription medications, which states the medical condition and the medication required for treatment,

indicating the duration of treatment and the recommended dose, and no more than six months have passed since its issuance date.

Second: Medical devices and supplies

Terms and controls:

- Clearance of medical devices and supplies shall be approved for a quantity not exceeding one month’s use or the duration of the pilgrim’s stay, whichever is less, for the pilgrim’s personal use only and under his responsibility.
- If the quantity of medical devices and supplies required to be cleared exceeds the patient’s need, the remaining quantity shall be destroyed.
- It is prohibited to enter medical devices and supplies that are brought with pilgrims without their original packaging or those provided by the treatment institution.
- Expired medical devices and supplies are prohibited from entering.
- The medical devices and supplies required to be cleared shall be free of internationally banned materials and radioactive materials.

Requirements

1. A copy of the medical report or prescription for descriptive medical devices and supplies, which states the medical condition and the need for the medical device or product required for treatment, indicating the duration of treatment, and no more than six months have passed since the date of its issuance

Second: Medical devices and supplies

Terms and controls:

- It is prohibited to import foodstuffs shown in the list of food goods prohibited from importing according to customs provisions published on the Authority's website (list attached).
- Any food item shall contain a nutritional label, regardless of the type of food product (dairy, cheese, meat, poultry, or canned fish).
- The entry of any food items that have expired or do not contain an expiration date is prohibited.
- The entry of any food items that show signs of damage or spoilage is prohibited, for example (the presence of mold, an unpleasant odor, or changes in color or physical properties of the food item).
- The entry of any food items that have been warned about through the Saudi Food and Drug Authority website due to their violation of the technical regulations and approved standard specifications is prohibited.
- The entry of any food items that contain any of the following ingredients on their food label (alcohol, fats, pork derivatives, and additives forbidden to use) is prohibited.
- The food item received with the pilgrim shall be preserved according to the appropriate preservation method, especially food items that need either cooling or freezing.
- It is prohibited to enter any food item that is contaminated with insects or any other contaminants that have been in contact with the food item or the food product packaging.
- It is prohibited to enter any food item that contains health or nutritional claims or contains images that suggest medical or nutritional claims on the food product.

- Food items brought with pilgrims are prohibited from being brought in containers not designated for storing food items or in unclean containers.
- It is prohibited to enter food items that are brought with pilgrims in commercial quantities, and food items brought with pilgrims shall be in quantities that cover the need until arriving at the residences only.

Section Four:

The forms required to be specified when sending or submitting the application to the Authority’s office at the port of arrival

The data is submitted through the electronic platform for pilgrims abroad of the Ministry of Hajj and Umrah (Medical Supplies Services), In the event of technical challenges, a report is filed and requests are completed via email and the Excel file is sent and can be accessed through the following link:

<https://www.sfda.gov.sa/ar/forms/79535>

Medical Devices List	Drug List	Controlled Drug List
Medical Device Name	AtcCode	AtcCode
Package Size (per Box)	Generic Name	Generic Name
Quantity (Number Of Boxes)	Trade Name	Trade Name
Total Quantity smallest Unit	Strength	Batch number
	Dosage Form	Expiry
	Number Of Boxes	Voulme ml
	Package Size (EX: Number of tablets in each Box)	Strength
	Total Quantity smallest Unit	Dosage Form
	No. of patients using the product for Chronic Disease	Number Of Boxes
		Package Size (EX: Number of tablets in each Box)
		Total Quantity smallest Unit
		No. of patients using the product

The pledge required to be submitted with the Pilgrims Affairs Offices or official missions

COUNTRY NAME
Total number of pilgrims – according to the agreement
Shipment Port of Entry
Date of Shipment arrived
Makkah Medical headquarters (LOCATION – DATE OF OPENING AND CLOSED)
Makkah Number of clinics
Madinah Number of clinics
I, the undersigned, pledge that all the above-mentioned information is correct and that the Pilgrims Affair Office is responsible for adhering to the following items:
The Medications and medical devices and materials, which are imported under our responsibility and commit that it will be used by the members of the campaign only, and it will not be sold or used in any manner whatsoever and the remaining quantities will be returned when the campaign depart to their country.
We also commit to add the dispensed quantities of narcotic and psychotropic medications through the Controlled Drug System (CDS) for each prescription dispensed and submit to Saudi Food & Drug Authority a list of control drugs and narcotics, including the stock, used, and the remaining quantity after the end of the Hajj period and before departure.
We also commit to take full responsibility to Sign contract with approved medical waste Company.
With my full knowledge I am the undersigned that I will be prevented from leaving the Kingdom if I do not comply with the above.
The name of the person responsible for the medication: Job title: Passport number: E-mail: Mobile number: Signature:
Name of the head of the medical team: Job title: Passport number: E-mail: Mobile number: Signature:
Stamp

List of food commodities prohibited from being imported* according to the terms of the customs tariff

Item	HS number	food commodities
0203		Pork meat (fresh, chilled or frozen)
		fresh, chilled or frozen:
	02031100	Whole carcasses and semi-carcasses
	02031200	Thighs, shoulders, to be cut including bones
	02031900	--- other
	02032100	Whole carcasses and semi-carcasses
	02032200	Thighs, shoulders, to be cut including bones
	02032900	Other
0205		Meat of horses, donkeys, mules and hinnies (fresh, frozen or chilled)
0206	02050090	--- other
		Edible offal and limbs from species of cattle, pigs, sheep, goats, horses, donkeys, mules and hinnies (fresh, frozen or chilled)
	02063000	--- from species of pigs (fresh or chilled)
	02064100	--- Livers
0208	02064900	--- other
		Edible flesh, offal, legs (fresh, frozen or chilled)
0209	02089091	---- frog thighs
0210		Pure pork fat and poultry fat, not extracted by melting or other extraction methods, fresh, chilled, frozen, salted, in brine, dried or smoked.
	02091000	--- from pigs
		Meat, offal and edible limbs, salted or brine, dried or smoked, edible flour and powders of meat, offal and limbs.
		Pork meat
0908	02101100	Thighs, shoulders, chops and bones

	02101200	Breasts with lard and pieces
	02101900	--- other
0908		Nutmeg and its husk, cardamom
	09081100	Nutmeg not crushed or powdered
	09081200	Nutmeg, crushed or powdered
	09082100	The nutmeg husk not crushed or powdered
	09082200	Nutmeg husk, crushed or powdered
1207		Other fruits and oil seeds, whether crushed
	12079100	--- Poppy seeds
	12079910	--- Poppy
	12079920	--- Hemp seeds
1211		Plants and their parts
	12113000	Coca leaves...
	12114000	Poppy straw ...
	12119020	... Black poppy
	12119060	... marijuana
1302		Plant juices and extracts
		Plant juices and extracts
	13021100	. . Opium.....
		--other
	13021910	--- Hashish
1501		Pig fat, including pork fat
	15011000	Pig fat
Item	HS number	food commodities
	15012000	Other pork fats
1503		Stearin, lard and lard oil
	15030011	. . . From a pig.....
	15030021	. . . From a pig.....

	15030091	. . . From a pig
1518		Animal oils, fats and grease
	15180011	-- From a pig
1601		Thick or thin sausage and similar products made from meat, entrails, limbs or animal blood. Food preparations based on these products.
	16010010	“...from a pig or animal blood
1602		Other preparations and articles made of meat, entrails and limbs, or animal blood
	16024100	Pork thigh or pieces of it..
	16024200	Pork shoulder or pieces of it
	16024900	Others, including mixtures..
	16029030	Preparations from animal blood..
1702		Sugar products, including white chocolate, that do not contain cocoa
	17049080	White chocolate containing alcohol
1806		Chocolate and other food preparations containing cocoa
	18063110	Filled with alcohol
	18063210	Not filled with alcohol
2203	22030000	Beer made from malt barley
2204		Wines from fresh grapes, including wines fortified with alcohol; Grape peels, excluding those included in heading 20.09
	22041000	Sparkling wine
	22042100	Other grape wines whose fermentation has been prevented or stopped by adding alcohol in containers with a capacity not exceeding 2 liters
	22042900	Other grape wines whose fermentation has been prevented or stopped by adding other alcohol
	22043000	Other wines, grape juice whose fermentation has been prevented or stopped by adding alcohol. Other types of grape juice.
2205		Vermouth and other wines from fresh grapes flavored with plants or aromatic substances

	22051000	In containers with a capacity not exceeding 2 liters
	22059000	Others
2206	22060000	Other fermented beverages (for example, apple, pear, or honey syrup), fermented beverage mixtures, and fermented beverage mixtures with non-alcoholic beverages not included or specified elsewhere.
1602		Undenatured ethyl alcohol of which the standard of alcohol by volume is not less than 80% by volume; Denatured ethyl alcohol and other denatured denatured spirits of any caliber.”
	22072090	Denatured ethyl alcohol and other denatured spirits of any caliber: other
2208		Undenatured ethyl alcohol with a volumetric alcohol content of less than 80% by volume; Spirits, scented alcoholic beverages (liquor) and other spirits.
	22082000	Alcoholic beverages resulting from distillation of wine or grape pomace
	22083000	Whiskey
	22084000	Rum and other spirits resulting from the distillation of fermented sugarcane products
	22085000	Jinn and Geneva
	22086000	Vodka
	22087000	Scented alcoholic beverages (liquor)
	22089090	Other ...
	23070010	Wine sediment.

