

Regulations and Requirements for the clearance of medicines, pharmaceutical products, medical devices and supplies, and food products that arrive for pilgrims' use

Version 2.2

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Saudi Food & Drug Authority

For inquiries and suggestions

19999

CEC@sfda.gov.sa

For more information visit the official website

https://www.sfda.gov.sa/ar/regulations?tags=2



Saudi Food & 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



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
4	28/08/1444	Inspection operation Department	update
5	21/08/1446	Governance and Clearance Development directorate	update



• The update in this version

Title	update		
• Section one.	• **Addition:**		
	Compliance with the provisions outlined in the Medical Hajj		
	Offices Permits document issued by the Ministry of Health.		
	• **Addition:**		
	Attach a copy of the Health Affairs license for the medical facilities		
	where medicines will be stored and preserved during the season.		
	• **Deletion:**		
	Requirements for supplying controlled medicines with the		
	mission and related commitments.		
	 Deletion and Replacement: 		
	Delete: "Due to the failure of some missions to comply with		
	the commitments submitted annually, the custodians will not be		
	allowed to leave the Kingdom"		
	Replace with: "The list of compliant and non-compliant		
	offices will be shared with the Ministry of Health and the Ministry		
	of Hajj and Umrah to take the necessary actions accordingly."		
• Section three.	Narcotic drugs and psychotropic substances carried by pilgrims		
	for personal use are exempt from this requirement, provided that		
	prior approval is obtained from the Saudi Food and Drug		
	Authority through the Controlled Drugs System (CDS) program		
	via the following link:		
	https://cds.sfda.gov.sa.		
• Section four	Delete the page related to narcotic drugs in the Excel file.		



Index

Section One: Imported products such as medicines, medical devices and supplies that are in the
possession of Pilgrim Affairs Offices or official government agencies coming to the
Kingdom for the use by patients of the mission.
Section Two: Products such as medicines, pharmaceutical products or medical devices and
supplies that arrive with doctors accompanying Hajj campaigns coming through
air, sea or land ports for emergency use by pilgrims during the period of travel to
reach the holy sites.
Section Three: Products such as medicines, medical devices and supplies, and food items that
arrive and are in the possession of pilgrims for personal use.
Section Four: Forms, Pledge and Lists



Section One: Imported products such as medicines, medical devices and supplies that are in the possession of Pilgrim Affairs Offices or official government agencies coming to the Kingdom for the use by patients of the mission and impediments to the supply of food items.

First: Conditions and Rules:

- 1- These requirements are to be executed through the External Hajj Unified System of the Ministry of Hajj and Umrah in order to facilitate and accelerate procedures, and if it was completed before the beginning of the Hajj season for this year, then in this case it is necessary to submit applications and documents electronically, with no need of hard copy submission.
- 2- Compliance with the provisions outlined in the Medical Hajj Offices Permits document issued by the Ministry of Health regarding contracting with a licensed service provider in the Kingdom of Saudi Arabia to supervise or provide services. This includes the responsibility of verifying the transportation, storage, dispensing, and reexport of medicines. The service supervisor has the right to contract with a third party to fulfill all the requirements of the authority related to the importation of medicines and medical supplies for the Hajj Affairs Offices.
- 3- Compliance with the supply of medicines, medical equipment and supplies via the accredited airports.
 - (King Abdul Aziz International Airport in Jeddah.
 - Prince Mohammed bin Abdul Aziz Airport in Madinah.

during the period from 15 Shawwal to 30 Dhu al-Qa'da Clearance of anything that arrives outside this period shall not be approved in accordance with the conditions contained in the booklet of instructions governing Hajj affairs issued by the Ministry of Hajj and Umrah.

4- Hajj Affairs Offices must submit official documents and details on medicines, medical devices and supplies to the Ministry of Hajj and Umrah at least fifteen (15) days prior to the arrival date of the shipment, and also send an electronic copy of the documents set forth in the second paragraph (Documents Required) via email to the office of the Food and Drug Authority at the port of arrival at western central clearance section (Hajj@sfda.gov.sa)



- 5- Attach a copy of the Health Affairs license for the medical facilities where medicines will be stored and preserved during the season.
- 6- The importation of narcotic drugs and psychotropic substances is not permitted. The attached schedules of the Narcotic Drugs and Psychotropic Substances Control System can be accessed through the following link: https://www.sfda.gov.sa/ar/regulations/62877.
- 7- The import of medicines and medical devices relating to Pilgrim Affairs Offices arriving via King Abdul Aziz
 International Airport in Jeddah shall be by airfreight only and under a bill of lading in order for the formal
 customs procedures to be applied for the clearance of medicines and medical devices.
- 8- The staff of the Hajj Affairs Office shall have a licensed medical team and the required medicines shall be under the supervision and responsibility of the head of the medical team.
- 9- The supply of medical devices and supplies containing radioactive materials shall not be permitted.
- 10- It is prohibited to import the medicines and pharmaceutical products containing substances that fall within the banned lists locally and internationally.
- 11- The contents of the packing statement of the attached list of products to be imported and submitted for clearance must be verified in accordance with the actual content of shipments received through the port, with the provision that the lists and cartons shall be numbered in such a way as to facilitate the procedures of inspection and checking of items.
- 12- All Pilgrim Affairs Offices upon leave must do:
 - re-export the remaining quantities of medicines and medical devices upon departure of the mission from the Kingdom, under a customs declaration.
 - A copy of the statement of what was dispensed, what is remaining and what was damaged must be submitted.
- 13- The distribution of excess or unnecessary quantities of medicines, medical devices and supplies to any entity shall not be permitted. They shall not be allowed to be kept in the residential premises after the end of the Hajj season and must be re-exported so as not to be damaged.
- 14- The mission must import the necessary medicines, medical devices and supplies only for the use of the personnel of the mission by estimating the annual consumption based on what was consumed during the



- previous years, and it must not supply large quantities in excess of the need. The SFDA has the right to reject any product or quantity that it deems to be in excess of the need of the mission.
- 15- The supply of food items to the Pilgrim Affairs Offices for the purpose of catering shall not be permitted, as this is provided by the catering operators in accordance with the booklet of instructions regulating Hajj affairs and the memorandum of agreement between the Ministry of Hajj and the Pilgrim Affairs Office.
- 16- The import of food items from the list of countries from which import is prohibited as published on the Authority's website shall not be permitted.
- 17- The import of food items listed in the list of food items prohibited for import shall not be permitted to be imported according to the customs terms published on the Authority's website (List attached).

Second: Documents Required for Clearance:

- a. EMAIL addressed to Hajj@sfda.gov.sa indicating the name of the responsible personal for the imported medicines, pharmaceutical products, medical devices and supplies and the re-export of the remaining quantities, the record number of the transaction at the Ministry of Hajj, and a copy of the concluded memorandum of agreement with the total number of pilgrims, And complete the forms and commitments outlined in section Four.
- **b.** A pledge to limit the use of the medicines, medical devices and supplies to the personnel of the mission only and under their responsibility, that these shall not be sold or disposed of in any manner whatsoever, and that the remaining amounts thereof shall be returned together with the mission when it returns; also submitting a statement of what was dispensed, what is remaining and what was damaged, prior to the mission's departure from the Kingdom to the branch of the Food and Drug Authority at the customs port; a pledge to delete contract with an accredited company to dispose medical waste (Attached is the form for the pledge that is required to be submitted with the Pilgrim Affairs Offices or the official missions).
- c. Packing statement of:
 - (non-controlled) drugs.
 - medical devices and supplies.



approved by the competent authority in the mission's country and endorsed by the Saudi Embassy.

For non-controlled drugs statement containing:

- the scientific name
- pharmaceutical form
- concentration
- size
- required quantity
- number of cases treated

For medical devices and supplies statement containing:

- the name of the item or device.
- the required quantity.

together with filling out the attached form and providing it in an electronic format in Excel, and attaching the invoices showing the quantity, weight and value, with the need to ensure that they conform to the quantities and items approved within the lists with the shipment received and that the lists and cartons contain explanatory numbers to facilitate inspection procedures.



Section Two: Products such as medicines, pharmaceutical products or medical devices and supplies

that arrive with doctors accompanying Hajj campaigns coming through air, sea or

land ports for emergency use by pilgrims during the duration of travel to reach the

holy sites and impediments to the supply of food items.

First: Conditions and Rules:

- 1- These requirements are to be executed through the External Hajj Unified System of the Ministry of Hajj and Umrah in order to facilitate and accelerate procedures, and if it was completed before the beginning of the Hajj season for this year, then in this case it is necessary to submit applications and documents electronically, with no need of hard copy submission.
- 2- The medicines and medical supplies that arrive with the doctor must be for emergency cases only and in quantities that will cover the needs of the members of campaign accompanying the doctor for their personal use during the journey and the transfer to the residential premises or holy sites and until they are connected to the Pilgrim Affairs Office later.
- 3- The supply of narcotic or controlled drugs with the doctor for the use of pilgrims during the period of movement up to the holy sites shall be prohibited.
- 4- The supply of products containing substances that fall within the banned lists locally and internationally shall be prohibited.
- 5- The supply of medical devices and supplies containing radioactive materials shall not be permitted.
- 6- The supply of food items to Hajj campaigns and offices shall be prohibited and there is no need to transport them with the doctor accompanying the campaign.
- 7- The medicines and medical supplies must be under the responsibility of the doctor accompanying the campaign, and he must re-export the remaining quantities thereof when departing from the Kingdom.

Second: Documents Required for Clearance:

- 1- A letter from the Ministry of Health of the doctor accompanying the campaign stating that he is charged with accompanying the campaign to provide the necessary emergency treatment services during the journey of the campaign until it reaches the holy sites.
- 2- In the event that the above-mentioned letter is not available, medical reports / prescriptions indicating the need of the patients accompanying the doctor shall be attached to the emergency products during the period of transfer to the premises.



3- A pledge from the doctor stating his responsibility for the medicines and medical supplies, that they will only be dispensed to pilgrims of the campaign, and that the remaining amounts shall be re-exported when leaving the Kingdom in accordance with the undertaking form required to be submitted by the doctor accompanying the campaign.

<u>Section Three:</u> Products such as medicines, medical devices and supplies, and food items that arrive and are in the possession of pilgrims for personal use.

* First: Controlled and narcotic drugs and non- controlled drugs and pharmaceutical products:

• Regulations and Requirements:

- 1. Clearance of controlled narcotic drugs shall be approved for a quantity that is adequate for a maximum of 30 days or the duration of the patient's stay in the Kingdom, whichever is lesser, provided that the Expiry date is valid and only for the personal use of the pilgrim 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 patient's stay in the Kingdom, whichever is lesser, for the personal use of the pilgrim under his responsibility.
- 3. If the quantity of medicine required to be cleared is more than the patient's need, the remaining quantity shall be disposed.
- 4. The entry of medicines and pharmaceutical preparations that arrive with pilgrims without their original packaging or that dispensed from the medical institution shall be prohibited.
- 5. The entry of expired medicines and pharmaceutical products shall be prohibited.
- 6. The medicines and pharmaceutical products required to be cleared must be free of internationally and locally banned substances and radioactive materials.
- 7. The Authority shall not permit the entry of preparations with an unknown formulation, as well as those that have falsified medical claims such as (weight loss, weight gain, whitening, sexual claims).
- B. The Authority recommends that you consult your doctor before using any pharmaceutical preparation.



• Requirements for the clearance of controlled narcotic drugs:

- 1. Providing a detailed medical report approved by the institution treating the patient, which shall not be more than six months old, and which must contain the following:
 - **a.** Personal information about the patient.
 - **b.** Medical diagnosis.
 - c. Treatment Plan and Duration.
 - d. Medical Recommendations.
 - e. Scientific name of the drug, pharmaceutical form and prescribed dosage.
- **2.** Or Providing a medical prescription made out in the patient's name approved by the same treatment institution, which shall not be more than six months old, and which must contain the following information:
 - **a.** Diagnosis of the disease.
 - **b.** Scientific name of the drug, pharmaceutical form and prescribed dosage.
 - **c.** How to use and duration of treatment.
 - d. Seal of the Treatment Institution.

Requirements for the release of non-controlled Drugs and pharmaceutical products:

1. A copy of the medical report or prescription for the prescribed medicines, indicating the diagnosis and the medicine required for treatment, indicating the duration of treatment and the recommended dosage, which shall not be more than six months old.



Second: Medical devices and Supplies:

• Regulations and Requirements:

- Clearance of medical devices and supplies shall be approved for a quantity that does not exceed one
 month use or the duration of the pilgrim's stay in the Kingdom, whichever is lesser, for the personal use
 of the pilgrim only and under his responsibility.
- 2. If the quantity of medical equipment and supplies required to be cleared is more than the patient's need, the remaining quantity shall be disposed.
- 3. The entry of medical devices and supplies that arrive with pilgrims without their original packaging or that dispensed from the medical institution shall be prohibited.
- 4. The entry of expired medical devices and supplies shall be prohibited.
- The medical devices and supplies required to be cleared must be free of internationally banned substances and radioactive materials.

• Requirements:

1. A copy of the medical report or prescription for prescribed medical equipment and supplies, indicating the diagnosis and the need for the medical equipment or product required for treatment, indicating the duration of treatment, which shall not be more than six months old.

Third: Food Items:

• Conditions and Rules:

- 1. The import of food items listed in the list of food items prohibited for import shall not be permitted to be imported according to the customs terms published on the Authority's website (list attached).
- 2. Any food item must contain a food label irrespective of the type of food product (dairy, cheese, meat, poultry, fish, canned).
- 3. The entry of food items that are expired or that do not bear an expiry date shall be prohibited.
- 4. The entry of any food items showing signs of damage or spoiling, for example (presence of mould, bad smell, discoloration and change of the food's physical properties).



- 5. The entry of any food items that have been warned about via the website of the Food and Drug Authority due to their violation of technical regulations and approved standard specifications, shall be prohibited.
- 6. The entry of any food items whose food card contains any of the following ingredients (alcohol, pig fats and derivatives, prohibited additives) shall be prohibited.
- 7. The food item that arrives with the pilgrim must be preserved according to the appropriate preservation method and especially food items that require cooling or freezing.
- 8. The entry of any food item that is contaminated with insects or any other contaminants in contact with the food item or the packaging of the food product shall be prohibited.
- 9. The entry of any food item containing health or nutritional claims or containing images that suggest medical or nutritional claims on the food product shall be prohibited.
- 10. The entry of food items that arrive with pilgrims in containers that are not intended to store food items or that are found to be in unclean containers shall be prohibited.
- 11. The entry of food items that arrive with pilgrims in commercial quantities and in excess of their needs shall be prohibited.

Section Four: Forms, Pledge and Lists

The data must be submitted through the Ministry of Hajj and Umrah's electronic platform for overseas pilgrims (Medical Supplies Services). In case of technical challenges, a report should be submitted, and requests should be completed via email by sending the Excel file, which can be accessed through the following link:

.https://www.sfda.gov.sa/sites/default/files/2024-04/Drug-hajj-522_0.xlsx



The commitment required to be submitted with the Hajj Affairs Offices or official .missions

COUNTRY NAME			اسم الدولة
Total number of pilgrims - according to the agreement			اجمالي عدد الحجاج وفق الاتفاقية
Shipment Port of Entry			منفذ وصول الشحنة
Date of Shipment arrived			تاريخ وصول الشحنة
Makkah Medical headquarters (LOCATION – DATE OF OPENINIG AND CLOSING)			بيانات المقر الطبي الرئيسي بمكة (العنوان/تاريخ بداية ونهاية عمل المقر)
Madinah Medical headquarters (LOCATION – DATE OF OPENINIG AND CLOSING)			بيانات المقر الطبي الرئيسي بالمدينة المنورة (العنوان/ تاريخ بداية ونهاية عمل المقر)
Makkah Number of clinics			عدد المقرات الطبية بمكة المكرمة
Madinah Number of clinics			عدد المقرات الطبية بالمدينة
I, the undersigned, pledge that all information is correct and that the P responsible for adhering to the following	Pilgrims Affairs Office is	ـد أنـا الموقـع أدنـاه بصـحة جميـع المعلومـات المـذكورة أعـلاه	
	only, and it will not r whatsoever and the e returned when the	our فلال موسم حج هذا العام هي تحت مسؤوليتنا ولن by التصرف التصرف المنافية فقط ولن يتم بيعها أو التصرف المنافية وسيلة كانت، ومسؤوليتنا الكاملة عن أي اضرار المنافية عن استخدامها وبأنه سيتم إعادة الكميات المتبقية	
• we also commit to take full recontract with approved medic	• •	5 (to 5 5 t) S (a) 5 5 t) S (b) 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	
With my full knowledge I am I will be prevented from leav do not comply with the above	ing the Kingdom if I	مع كامل علمي أنا الموقع أدناه بأنه سيتم منعي من مغادرة المملكة في حال عدم التزامي بما ذكر أعلاه.	



The name of the newson responsible for the	إسم المسؤول عن عهدة الأدوية:
The name of the person responsible for the medication:	
	التخصص الصحي:
Job title:	التخصص الصعي: رقم الجواز:
Passport number: E-mail:	البريد الالكتروني:
Mobile number:	رقم الجوال:
Signature:	التوقيع:
	إسم رئيس الفريق الطبي:
Name of the head of the medical team:	ي ۱۳۰۰ کري د کې د کې
Traine of the head of the medical team.	التخصص الصحى::
Job title:	التخصص الصحي: رقم الجواز:
Passport number:	
E-mail: Mobile number:	البريد الالكتروني:
Signature:	رقم الجوال: التوقيع:
	التوقيع:
Stamp	
	الختم:



List of Prohibited Food Items for Import* According to Customs Tariff Codes.

ltem	HS Code	**Item
		Code**
لحوم فصيلة الخنازير، طازجة أو مبردة أو مجمدة.		0203
طازجة أو مبردة او مجمدة:		
ذبائح كاملة وأنصاف ذبائح	02031100	
أفخاذ وأكتاف وقطعها بعظمها	02031200	
غيرها	02031900	
ذبائح كاملة وأنصاف ذبائح	02032100	
أفخاذ وأكتاف وقطعها بعظمها	02032200	
غيرها	02032900	
لحوم فصائل الخيول والحمير والبغال والنغال طازجة أو مجمدة أو مبردة		0205
غيرها	02050090	
أحشاء وأطراف صالحة للأكل من فصائل الأبقار والخنازير والضأن والماعز والخيل والحمير		0206
والبغال والنغال، طازجة أو مبردة أو مجمدة.		
من فصيلة الخنازير طازجة او مبردة	02063000	
أكباد	02064100	
غيرها	02064900	
لحوم وأحشاء وأطراف صالحة للأكل طازجة أو مبردة أو مجمدة		0208
افخاذ ضفادع	02089091	
شحم خنزير صرف وشحم طيور دواجن، غير مستخلص بالإذابة أو بطرق الاستخلاص		0209
الاخرى طازجة أو مبردة أو مجمدة أو مملحاً أو في ماء مملح أو مجففا أو مدخنا		
-من خنزير	02091000	
لحوم وأحشاء وأطراف صالحة للأكل مملحة أو ماء مملح مجففة أو مدخنة دقيق ومساحيق		0210
صالحة للأكل من لحوم وأحشاء أو أطراف.		
لحوم فصيلة الخنازير		
أفخاذ وأكتاف وقطعها وعظمها	02101100	



صدور يتخللها شحم وقطعها	02101200	
غيرها	02101900	
جوز الطيب وبسباسته وحب الهال (قاقلة)		0908
جوز الطيب غير مجروش ولا مسحوق	09081100	
جوز الطيب مجروش أو مسحوق	09081200	
بسباسة جوز الطيب غير مجروشة ولا مسحوقة	09082100	
بسباسة جوز الطيب مجروشة أو مسحوقة	09082200	
أثمار وبذور زيتية أخر وإن كانت مكسرة		1207
بذور <i>خشخ</i> اش	12079100	
خ <i>ش</i> خاش	12079910	
بذور قنب	12079920	
"نباتات وأجزاءها،		1211
. أوراق الكوكا	12113000	
قش خشخاش	12114000	
<i>خشخ</i> اش أسود	12119020	
قنب هندي	12119060	
عصارات وخلاصات نباتية،		1302
عصارات وخلاصات نباتية:		
أفيون	13021100	
غيرها		
حشیش	13021910	
شحوم خنزير (بما فها دهن الخنزير		1501
دهن خنزير	15011000	
شحوم خنزير أخر	15012000	
ستيارين دهن وشحم الخنزير وزيت دهن الخنزير		1503
من خازير	15030011	
من خازير	15030021	
من خازير	15030091	
زيوت ودهون وشحوم حيوانية		1518
من خازير	15180011	



سجق (غليظ أو رفيع) ومنتجات مماثلة من لحوم أو من أحشاء وأطراف أو من دم حيواني؛		1601
محضرات غذائية أساسها هذه المنتجات		
"من خنزبر أو دم حيو اني	16010010	
محضرات وأصناف محفوظة أخر من لحوم أو من أحشاء وأطراف أو من دم حيواني		1602
فخذ الخنزير وقطعه	16024100	
كتف الخنزير وقطعه	16024200	
غيرها بما فيها المخاليط	16024900	
محضرات من دم الحيوانات	16029030	
مصنوعات سكرية (بما فيها الشوكلاته البيضاء)، لا تحتوي على الكاكاو		1704
. شوكلاته بيضاء محتوية على كحول	17049080	
شوكلاته ومحضرات غذائية أخر تحتوي على كاكاو		1806
محشوة تحتوي على كحول	18063110	
غير محشوة تحتوي على كحول	18063210	
جعة بيرة مصنوعة من شعير الناشط (الملت)	22030000	2203
نبيذ من عنب طازج بما في ذلك الانبذة المقواة بالكحول؛ سلافه العنب عدا الداخل منها في		2204
البند ٢٠,٠٩		
نبيذ فوار	22041000	
أنبذه أخر، سلافه عنب منع أو أوقف اختمارها بإضافة كحول في أوعية لا تزيد سعتها عن	22042100	
٢ لتر		
. أنبذه أخر، سلافه عنب منع أو أوقف اختمارها بإضافة كحول غيره	22042900	
أنبذه أخر، سلافه عنب منع أو أوقف اختمارها بإضافة كحول أنواع أخر من سلافه العنب	22043000	
فيرموث وأنبذه أخر من عنب طازج منكهة بنباتات أو مواد عطرية		2205
في أوعية لاتزيد سعتها عن ٢ لتر	22051000	
غيرها	22059000	
مشروبات مخمرة أخر (شراب تفاح أو كمثرى أو عسل مثلا)؛ مخاليط مشروبات مخمرة	22060000	2206
ومخاليط مشروبات مخمرة مع مشروبات لا كحولية غير داخلة أو مذكورة في مكان آخر		
كحول ايثيل غير معطل لا يقل معيار الكحول الحجمي فيه عن ٨٠% حجماً؛ كحول ايثيل		2207
معطل وغيره من المشروبات الروحية المعطلة المحولة، من أي عيار كان"		
. كحول ايثيل معطل وغيره من المشروبات الروحية المعطلة من أي عيار كان: غيره	22072090	
كحول ايثيل غير معطل يقل عيار الكحول الحجمي فيه عن ٨٠% حجما؛ مشروبات روحية		2208



ومشروبات كحولية معطرة (ليكور) ومشروبات روحية أخر		
مشروبات كحولية ناتجة عن تقطير النبيذ أو تفل العنب	22082000	
ويسكي	22083000	
. روم ومشروبات روحية أخر ناتجة عن تقطير منتجات قصب السكر المخمرة	22084000	
. جن و جنيفا	22085000	
فودكا	22086000	
مشروبات كحولية معطرة (ليكور)	22087000	
غيره	22089090	
رواسب نبیذ.	23070010	

^{*}المصدر : مصلحة الجمارك السعودية، كتاب التعريفة الجمركية الطبعة الخامسة عشر ١٤٣٣هـ-٢٠١٢م.

^{*}Source: Saudi Customs Authority, Customs Tariff Book, 15th Edition, 1433 H-2012G.