

Q&A

for those who are bringing prescription medicines into Japan with them

Q1. Can I bring any prescription medicine into Japan with me?

A1. You can bring any prescription medicine into Japan with you without any special procedure on condition that

- (1) you bring it only for your own use
- (2) it is an oral or an external medicine, not an injection,
- (3) it is not any prohibited drug such as Methamphetamine in Japan,
- (4) it is not any especially controlled drug such as Narcotics in Japan,
- (5) and its quantity is up to one month's supply.

Q2. How can I bring more than one month's supply of any oral or external prescription medicine only for my own use into Japan with me?

A2. You can bring more than one month's supply of any prescription medicine, except prohibited drugs and especially controlled drugs, only for your own use into Japan with you, if you apply for a so-called "Yakkan Shoumei", a kind of import certificate, and receive it before you leave home.

Q3. How can I bring any injection only for my own use into Japan with me?

A3. You can bring only a so-called "Pre-filled Syringe" or "Self-injection Kit" used under the direction of doctor into Japan with you, if you apply for a so-called "Yakkan Shoumei", a kind of import certificate, and receive it before you leave home.

Q4. How can I receive a "Yakkan Shoumei"?

A4. You have to submit the application documents by post.

If the Pharmaceutical Inspector can confirm that your application documents are complete and he admits that you speak the truth, he will send you a "Yakkan Shoumei" by post

Q5. What kinds of documents are required in order to apply for a "Yakkan Shoumei"?

A5. The following documents are required in order to apply for a “Yakkan Shoumei”.

- 1) Import Report of Medication (with your signature, and needed 2 copies only as to this document), filled in the blank application form (See the “Application Forms” attached.) according to the sample application document. (See the “Application Forms” attached.)
- 2) Declaration (with your signature), filled in the blank application form (See the “Application Forms” attached.) according to the sample application document. (See the “Application Forms” attached.), so that your filling may coincide with the Import Report of Medication.
- 3) Explanation of the Products, filled in the blank application form (See the “Application Forms” attached.) according to the sample application document. (See the “Application Forms” attached.)
(Alternative documents, pamphlets by manufacturers and so on, can be accepted, if they show the descriptions required in Explanation of the Products.)
- 4) Copy of Prescription or Direction for medicines with doctor’s signature, by which the Pharmaceutical Inspector can confirm the name and the quantity of each medicine only for your own use clearly.
- 5) Document indicating Arrival Date and Place (ex. Copy of Airline Ticket or Flight Itinerary.)
- 6) Return Envelope with Japanese Postal Stamps required and with Address where you want to receive a “Yakkan Shoumei”. (“Coupon –Réponse International” can be accepted instead of Japanese Postal Stamps required, and Return Envelope needs to have the length 14~23.5 cm and the width 9 ~12 cm.)

Q6. To which office can I submit application documents for a “Yakkan Shoumei” by post?

A6. If you arrive at Narita International Airport, you may submit the application documents to our office.

The following is our address.

Pharmaceutical Inspector

Section of Inspection and Guidance,

Kanto-Shin’etsu Regional Bureau,

Ministry of Health, Labour and Welfare

Saitama-shintoshin Godochosha 1, 7th floor,

1-1 Shintoshin, Chuo-ku, Saitama City,
Saitama Prefecture, JAPAN 330-9713

If you arrive at Kansai International Airport or Chubu International Airport, she has to submit the application documents to Kinki Regional Bureau, not to our office.

The following is their address.

Pharmaceutical Inspector
Section of Inspection and Guidance,
Kinki Regional Bureau,
Ministry of Health, Labour and Welfare,
Osaka Godochosha 4, 3th floor,
4-1-76 Ohtemae, Chuou-ku, Osaka City,
Osaka Prefecture, JAPAN 540-0008,

Q7. What shall I do, if I have received a “Yakkan Shoumei”?

A7. A “Yakkan Shoumei” is one of your original Import Report of Medication, where one of Pharmaceutical Inspectors on duty blue-stamps, numbers, red-seals with his name and so on.

You have to bring the “Yakkan Shoumei” with your medicines in order to show it to the Customs on request when you arrive in Japan.

It will be valid only when your luggage contents are the same as indicated on the “Yakkan Shoumei”.

You have to take care never to correct the “Yakkan Shoumei”, or it becomes invalid.

Q8. How long does it take to receive a “Yakkan Shoumei”?

A8. It depends on the completeness of your application documents and days by post required.

If you are in North America, Europe or Australia, they say that it takes the application documents about a week to reach Japan by post and it takes a “Yakkan Shoumei” about a week to reach you by post.

So it usually takes about two weeks totally to receive a “Yakkan Shoumei” there, even if your application documents are complete.

Q9. What shall I do, if my application is rejected because of lacks of documents or fillings required?

A9. If your application documents are not complete, the Pharmaceutical Inspector may request the additional or revised documents.

If you show your fax number, you can receive his request more rapidly to submit the additional or revised documents

If you show your address or fax number wrongly, you cannot receive his request.

Q10. How can I bring Narcotics, if I need them by all means in order to treat my disease?

A10. If you need to bring Narcotics (Hydrocodone, Fentanyl and so on) into Japan with you by all means in order to treat your disease, you have to apply for a Special Certificate issued by the Minister for Health, Labour and Welfare to Narcotics Control Department, which is a Special Police for Narcotics and to receive it before you leave home.

If you are found with Narcotics in Japan without a Special Certificate issued by the Minister for Health, Labour and Welfare, you can be arrested as a criminal on the spot, immediately, without a warrant in principle.

If you arrive at Narita International Airport, you can contact the following.

Narcotics Control Department,
Kanto-Shin'etsu Regional Bureau,
Ministry of Health, Labour and Welfare
(TEL ; +81- 3 -3512-8688)
(FAX ; +81- 3 -3512-8689)

Q11. Is Codeine Phosphate one of Narcotics in Japan?

A11. Any medicine containing Codeine Phosphate more than one percent is defined as one of Narcotics in Japan.

So you have to confirm that a medicine which you are bringing into Japan with you

contains Codeine Phosphate whether up to one percent or more than one percent on the basis of the label or package.

You may also consult with your doctor or the manufacturer.

Q12. Can I bring a stimulant into Japan with me?

A12. Any medicine containing Methamphetamine or Amphetamine is defined as one of “Prohibited Stimulants” and strictly restricted in Japan.

Nobody can bring any medicine containing Methamphetamine or Amphetamine (Adderall and so on) into Japan.

If you are found with any medicine containing Methamphetamine or Amphetamine illegally in Japan, you can be arrested as a criminal on the spot, immediately, without a warrant in principle.

Q13. Can I bring Pseudoephedrine into Japan with me?

A13. Any medicine containing more than 10 % of Pseudoephedrine is defined as one of Stimulant Raw Materials in Japan and you cannot bring it into Japan.

Q14. What shall I do, if I have further questions regarding medicines which I am bringing into Japan with me?

A14. Please contact any Pharmaceutical Inspector in our office by fax! (+ 81-48-601-1336).

Application Forms for “Yakkan Shoumei”

[別紙第1号様式]

※ () 輸入報告書

(Import Report of Medication)

(To Minister of Health, Labour and Welfare)

_____ (Year) / (Month) / (Date)

厚生労働大臣 殿

Name of Importer _____ 印(Signature)

Address of Importer _____

Phone Number _____

Fax Number _____

品名 (Name and Size of the Import Products)	数量 (Quantity)	承認番号	許可登録年月日
輸入(販売)業許可 登録番号 有効期限			
※ () 第 号 平成 年 月 日 ~ 年 月 日			
輸入の目的 (Purpose of Import)			
製造業者及び国名 (Name of Manufacturer, and Country of Origin)			
輸入年月日 (Date of Import)	蔵置場所 (Place of Quarantine)		
備考			
厚生労働省に提出した資料	1 輸入報告書 2 念書 3 治験、試験計画書 4 商品説明書 5 仕入書(Invoice) 6 その他 ()		
厚生労働省 確認欄	(For Official Use)	特記事項	
		厚生労働省関東信越厚生局 薬事監視員 毒物劇物監視員 印	

- 注 1 ※ () 欄には、医薬品、医薬部外品、化粧品、医療用具、毒物、劇物の別を記入すること。
2 「品名」欄に書ききれない場合は、別紙に記載のうえ添付すること。
3 「厚生労働省に提出した資料」欄は、添付した資料に○印を付し、又「その他」の場合は具体的に記入すること。
4 この報告書は正副2通作成すること。
5 この様式の大きさは日本工業規格A4とすること。

[別紙第2号様式]

念 書

(Declaration)

(To Minister of Health, Labour and Welfare)

(Year) / (Month) / (Date)

厚生労働大臣 殿

輸入業者 (受取人) 氏名 (Name of Importer)

印(Signature)

同住所 (Address of Importer)

今般、別紙輸入報告書により報告いたしました下記医療品、医療部外品、医療用具、化粧品、毒物、劇物は (個人) として使用するもので、他に販売、授与するものではありません。つきましては、本品の通関手続に関しよろしくお取り計らいお願いします。上述のとおり、後日のため念書を差し入れます。

(The purpose of the import of the products listed below is solely for use of myself, those are not for commercial use and/or not for present use.)

記

品 名 (Name and Size of the Import Products)	数 量 (Quantity)

[別紙第2号様式]

念 書

(Declaration)

(To Minister of Health, Labour and Welfare)

厚生労働大臣 殿

2005 / June / 6
(Year) / (Month) / (Date)

輸入業者 (受取人) 氏名 (Name of Importer)

Bob Smith (print & sign your name) 印(Signature)

同住所 (Address of Importer)

201 South Baker

Seattle, WA 98102 USA

今般、別紙輸入報告書により報告いたしました下記医療品、医療部外品、医療用具、化粧品、毒物、劇物は (個人) として使用するもので、他に販売、授与するものではありません。つきましては、本品の通関手続きに関しよろしくお取り計らいお願いします。上述のとおり、後日のため念書を差し入れます。

(The purpose of the import of the products listed below is solely for use of myself, those are not for commercial use and/or not for present use.)

記

品 名 (Name and Size of the Import Products)	数 量 (Quantity)
1. <u>ASPIRIN TABLET 200mg</u>	1. <u>100 Tablets</u>
2. <u>Anaphylaxis emergency Treatment Kit (containing 1 syringe of Epinephrine inter-muscular (or subcutaneous) injection 1 ml (1:1000) and 4 tablets of chlopheniramine maleate 2mg)</u>	2. <u>1 Kit</u>

[別紙第 6 号様式]

商 品 説 明 書

(Explanation of the Products)

商品名 (Name of Product)	
製造元名称 及び国名 (Name of the Manufacture and Country of Origin)	
化学名、一般的 名称又は本質 (Chemical Name or Active Ingredients Name)	
構造式及び剤型 (成分分量) (Ingredients and Quantity of them)	
効能又は効果 (Efficacy)	(e.g. Intended Health Effect)
規格 (Specifications)	(e.g. Form)

[別紙第 6 号様式]

商 品 説 明 書

(Explanation of the Products)

商品名 (Name of Product)	ASPIRIN TABLET 200mg
製造元名称 及び国名 (Name of the Manufacture and Country of Origin)	Kousaikyoku Co., Ltd. Japan
化学名、一般の 名称又は本質 (Chemical Name or Active Ingredients Name)	Acetyl Salicylic Acid (Analgesic)
構造式及び剤型 (成分分量) (Ingredients and Quantity of them)	Sugar coated white tablets, which contain 200 mg Aspirin
効能又は効果 (Efficacy)	(e.g. Intended Health Effect) For pain Adults – 1 tablet every four hours as needed
規格 (Specifications)	(e.g. Form) Aspirin Tablets cases in a box, aluminum laminate, 10 tablets

(see back for another example)

[別紙第 6 号様式]

商 品 説 明 書

(Explanation of the Products)

商品名 (Name of Product)	Anaphylaxis Emergency Treatment Kit
製造元名称 及び国名 (Name of the Manufacture and Country of Origin)	Kouseikyoku Co. Ltd., Japan
化学名、一般的 名称又は本質 (Chemical Name or Active Ingredients Name)	Epinephrine & Chlopheniramine Maleate (For Anaphylaxis + Antihistamine)
構造式及び剤型 (成分分量) (Ingredients and Quantity of them)	Syringe is one self-injection, which contains 1 ml Epinephrine solution (1:1000) and tablets are 4 white sugar coated pills, which contain chlopheniramine maleate 2 mg.
効能又は効果 (Efficacy)	(e.g. Intended Health Effect) For emergency treatment of anaphylaxis that results from accidental ingestion of certain foods (nuts, peanuts)
規格 (Specifications)	(e.g. Form) 1 kit is containing 1 syringe of Epinephrine inter-muscular (or subcutaneous) injection 1 ml and 4 tablets of chlopheniramine maleate 2 mg.