

Q & A

for those who are importing medicines into Japan

**In case of bringing medicines, please read the following from Q1 to Q9 and Q11.
In case of sending medicines, please read the following Q1,3,4,6,8,9,10 and Q11**

Q1. Can I bring /send any prescription medicine into Japan from abroad?

A1. You can bring /send any prescription medicine into Japan without any special procedures on condition that

- (1) you bring/send it only for your own use
- (2) it is not any prohibited drug in Japan such as Methamphetamine,
- (3) it is not any especially controlled drug in Japan such as Narcotics,
- (4) quantity is up to one month supply.
- (5) it is not permitted to SEND Psychotropic drugs.

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

A2. You can bring more than one month supply of any prescription medicine, 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 and injector only for my own use into Japan with me?

A3. If you import medicines with syringes for them (permissive self-injection like insulin) at the same time for less than 1 month supplies, “Yakkan shoumei” is not required. (Regarding to efficacy and dosage)
And if you import syringe only (without medicines), you need to apply for “Yakkan shoumei” as medical devices even if you import 1 piece

Q4. How can I receive a certificated “Yakkan Shoumei”?

A4. You have to submit the application documents by Email in the PDF format. (If you don't have Email address, by post or FAX.

If the Pharmaceutical Inspector can confirm that your application documents are complete, he/she will send you a “Yakkan Shoumei” by Email in the PDF format. (If you don't have Email address, by post)

Q5. What kinds of documents are required in order to apply for a “Yakkan Shoumei” when I bring medicines with me?

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

- 1) **Import Report of Medication** [FORM 1] (with your signature, and 2 copies of this document), completed the blank application form (See the “Application Forms” attached.) according to the sample application document. (See the “Application Forms” attached.)
- 2) **Explanation of Product** [FORM 4 for medicines or FORM 5 for products except

medicines], filled in the blank application form (See the “Application Forms” attached.) according to the sample application document. (See the Application Forms” attached.) You have to fill out this document for each product.

(Alternative documents such as pamphlets by manufacturers can be accepted, if they show the descriptions required in Explanation of Product.)

(If you apply for 3 kinds of medicines, you need to fill out 3 "Explanation of Pharmaceutical Products” forms.)

3) **Copy of Prescription or Direction for medicines** with a name of the Dr. who prescribed your medicines, by which the Pharmaceutical Inspector can confirm the name and the quantity of each medicine only for your own use clearly.

4) **Document indicating Arrival Date and Place** (ex. Copy of Airline Ticket or Flight Itinerary.)

5) **Return Envelope** (If you can't send application documents by Email or FAX, you need send it by post with application.) It's required with Japanese Postal Stamps and 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.

Place of arrival: Narita International Airport, Haneda International Airport, etc.

Kanto-Shin'etsu Regional Bureau of Health and Welfare

Saitama-Shintoshin Godochosha 1, 7th floor,

1-1Shintoshin, Chuo-ku, Saitama City,

Saitama Prefecture, JAPAN 330-9713

TEL: +81-48-740-0800 / FAX:+81-48-601-1336

Email: yakkan@mhlw.go.jp

Place of arrival: Kansai International Airport, Chubu Centrair, Naha Airport, etc.

Kinki Regional Bureau of Health and Welfare

Ooe Building,7th floor, 1-1-22 Nonin Bashi,

Osaka City, Chuo-ku, Osaka Prefecture, JAPAN 540-0011

TEL: +81-6-6942-4096 / FAX:+81-6-6942-2472

Email: kiyakuji@mhlw.go.jp

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

A7. A “Yakkan Shoumei” is the Import Report of Medication, on which one of the Pharmaceutical Inspectors put confirmation seals, certificate numbers, his/her name, and so on.

You have to bring the “Yakkan Shoumei” with your medicines in order to show it to Customs on request when you arrive in Japan. The copy of “Yakkan Shoumei” is acceptable at-Customs.

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 certificated “Yakkan Shoumei”?

A8.

After we receive your completed application documents, we normally issue Yakkan shoumei in a few business days (not including Saturday, Sunday and National holidays

Q9. What shall I do, if my application is rejected because of lack of documents ?

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

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

Please write down your address, fax number or Email address correctly.

Q10. How do I apply for Yakkan shoumei when I send more than one month supply of prescription medicine to Japan from abroad?

A10. The required documents and the way to apply for a permit is different from the case to bring into as below,

At first, you (or your family) send medicines to the place where you are staying in Japan by postal service (or courier etc/) with the recipient as YOUR NAME.

Then IF you receive notice such as Customs notice (or Air Way Bill etc.) after your medicines arrive in Japan (which means if your parcel is held at the Customs clearance), you need to email us (the contact is described on the notice). Then you need to follow our instruction to receive your medicines.

Then we check the contents of your parcel to the Customs or courier company, and we will give you guidance whether you need to apply for Yakkan shoumei or not. If you need to apply, you have to send the application documents of Yakkan shoumei to us by Email, FAX or post.

After confirmation, we will send a certificated Yakkan Shoumei to you by Email (PDF file) or FAX. Then you will send the certificated Yakkan Shoumei" to the Customs or courier company by post or FAX. So you can receive your medicines from them.

The certificated "Yakkan Shoumei" is the Import Report of Medication, on which one of the Pharmaceutical Inspectors put confirmation seals, certificate numbers, his/her name, and so on. It will be valid only once 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.

Required documents for Yakkan shoumei when you send medicines are as follows, (It's different from the case of bringing.)

- 1) **Import Report of Medication** [FORM 1] (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) **Explanation of Product** [FORM 4 for medicines or FORM 5 for products except medicines], filled in the blank application form (See the "Application Forms" attached.) according to the sample application document. (See the Application Forms" attached.) You have to fill out this document for each product.
(Alternative documents such as pamphlets by manufacturers can be accepted, if they show the descriptions required in Explanation of Product.)
- (If you apply for 3 kinds of medicines, you need to fill out 3 "Explanation of Pharmaceutical Products" forms.)

3) **Copy of Prescription or Direction for medicines** with a name of the Dr. who prescribed your medicines, by which the Pharmaceutical Inspector can confirm the name of each medicine only for your own use clearly.

4) A copy of Invoice (if you have)

5) A copy of the postcard from a customhouse (with Notice number) (if by Air)

Or A copy of the bill of lading (B/L) (if by Ship)

Q11. What shall I do, if I have further questions regarding medicines which I am bringing/sending into Japan with me, or if I have little time before I leave home?

A11. Please contact any Pharmaceutical Inspector in your place of arrival's neighboring office by Email with the information including the name of International Airport (Place of Arrival), the product name of your medicines, the name and the amount of active ingredients (ex: XXmg / tablet etc.), figuration of medicines ("vial" or "tablets" etc.), the amount of medicines which you bring ("XXmonth supply" or XXtablets"etc.)

Place of arrival: Narita International Airport, Haneda International Airport, etc.

Kanto-Shin'etsu Regional Bureau of Health and Welfare

TEL: +81-48-740-0800 / FAX:+81-48-601-1336

Email: yakkan@mhlw.go.jp

Place of arrival: Kansai International Airport, Chubu Centrair, Naha Airport, etc.

• Kinki Regional Bureau of Health and Welfare

TEL: +81-6-6942-4096 / FAX:+81-6-6942-2472

Email: kiyakuji@mhlw.go.jp

[別紙第 1 号様式] [FORM 1]

※ () 輸入報告書 (Import Report of Medication)

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

(To Minister of Health, Labour and Welfare)
厚生労働大臣 殿

Name of Importer _____
 Importer's Signature _____
 Address of Importer _____

 Phone Number _____
 Fax Number _____
 e-mail _____@_____

品 名 (Name and Size of the Import Products)		数 量 (Quantity)
輸入の目的 (Purpose of Import)	<input checked="" type="radio"/> For Personal Use <input checked="" type="radio"/> Other Purpose ()	
誓約事項 (Oath)	<input type="checkbox"/> The import products above are solely for the purpose of import above, not for commercial use and/or gift for others.	
製 造 業 者 名 及 び 国 名 (Name of Manufacturer and Country of Origin)		
輸 入 年 月 日 (Import Date / Arrival Date)	AWB、B/L 等の番号 (AWB No. , B/L No. or Flight No.)	到着空港、到着港又は蔵置場所 (Arrival place (Airport, port or Storage place))
_____/_____/_____ (Year) (Month) (Date)		
備考	(Note)	
厚生労働省 確認欄	特記事項 厚生労働省 厚生局 薬事監視専門官 毒物劇物監視員	

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商 品 説 明 書 (Explanation of Pharmaceutical Product)

(Purpose of Import : For personal use or for treatment of patients)

<p>商 品 名 (Name of product)</p>	
<p>化学名、一般的 名称又は本質 (Chemical Name or Active Ingredients Name)</p>	<p>① ヒアルロン酸(Hyaluronic acid) ②ボツリヌス毒素(Botulinum toxin) ③ アスコルビン酸(Ascorbic acid) ④歯牙漂白剤(Dental bleach) ⑤ ミノキシジル(Minoxidil) ⑥ベバシズマブ(Bevacizumab) ⑦ サリドマイド(Thalidomide) ⑧ 不活化ポリオワクチン(Inactivated Poliovirus Vaccine) ⑨ リドカイン(Lidocaine) ⑩メラトニン(Melatonin) ⑪ ヨウ化カリウム(Potassium iodine) ⑫ オセルタミビルリン酸塩(Osetamivir Phosphate) ⑬ シルденаフィル(Sildenafil) ⑭漢方(Kampo products) ⑮その他(Other) ()</p>
<p>用 途 (Intended purpose)</p>	<p>① ガン治療(Cancer treatment) ②強壮剤・ED薬(Tonic medicine, ED medicine) ② うつ・気分障害・不眠治療(Treatment for Depression, Anxiety Disorder, Insomnia) ④ 栄養補充(Supplement) ⑤美容(Beauty) ⑥ 痩身効果(Slim figure,Weight Reduction) ⑦避妊(Birth control) ⑧アレルギー治療(Allergy treatment) ⑨育毛(Hair Restoration) ⑩ワクチン(Vaccine) ⑪皮膚麻酔(Topical anesthesia) ⑫眼科治療(Ophthalmology treatment) ⑬歯科治療(Dental treatment) ⑭ 特定疾病*治療(Specific disease treatment) ⑮震災関連(Earthquake disaster relations) ⑯動物の治療(Animal treatment) ⑰その他(Other)() ※特定疾病：介護保険法施行令第2条に規定する疾病（ガンを除く。） (※Specific disease; Disease prescribed in Nursing Care Insurance Law enforcement order Article 2. (Cancer is excluded.))</p>
<p>具体的な用途 (効能・効果、用法) (Efficacy, Dosage)</p>	
<p>規 格 (Specifications)</p>	

[別紙第 5 号様式] [FORM 5]

商 品 説 明 書 (Explanation of Product)

(Pharmaceutical Products are excluded)

商 品 名 (Name of product)	
化学名、一般的 名称又は本質 (Chemical Name or Active Ingredients Name)	
用 途 (効能・効果) (Efficacy)	
規 格 (Specifications)	

(Sample)

e.g. Medicine, Medical Device, Cosmetics etc.

[別紙第1号様式] [FORM 1]

Date of Request

※ (Medicine) 輸入報告書 (Import Report of Medication)

2016 / Jun / 1

(Year) (Month) (Date)

(To Minister of Health, Labour and Welfare)

厚生労働大臣殿

Sign here.

Name of Importer KANTO SHIN-ETSU

Importer's Signature _____

Address of Importer 1-1, Saitama-Shintoshin, Saitama

330-9713 JAPAN

Phone Number +81-48-740-0800

Fax Number +81-48-601-1336

e-mail kanto_shinetsu@mhlw.go.jp

Indicate the one we can reach.

List name and size of the product. Attach a separate sheet in case the space is short.

Write a unit.

Circle either one.

Check here.

品名 (Name and Size of the Import Products)		数量 (Quantity)
1. Aspirin tablet 200mg 2. K-PAP Machine Set • K-PAP Machine • K-PAP Mask (For replacement) • Tube(For replacement)		1. 100 tablets 2. (Details) • 1 unit • 3 sheets • 3 tubes
輸入の目的 (Purpose of Import)	<input checked="" type="radio"/> ⑤ For Personal Use <input type="radio"/> ⑨ Other Purpose ()	
誓約事項 (Oath)	<input checked="" type="checkbox"/> The import products above are solely for the purpose of import above, not for commercial use and/or gift for others.	
製造業者名及び国名 (Name of Manufacturer and Country of Origin)		
Kouseikyoku Co.Ltd. Japan		
輸入年月日 (Import Date / Arrival Date)	AWB、B/L等の番号 (AWB No. , B/L No. or Flight No.)	到着空港、到着港又は蔵置場所 (Arrival place (Airport, port or Storage place))
2016 / Jun / 19 (Year) (Month) (Date)	Japan Airlines JLXX	Narita International Airport
備考 (Note)	In the case of receiving, write "AWB No." or "B/L No." In the case of bringing, write "flight No. that you board".	
厚生労働省 確認欄 (For Official Use)	特記事項 厚生労働省 厚生局 薬事監視専門官 毒物劇物監視員	

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(Sample)

[別紙第4号様式] [FORM 4]

商 品 説 明 書 (Explanation of Pharmaceutical Product)

(Purpose of Import : For personal use or for treatment of the patient)

商 品 名 (Name of product)	Aspirin tablet 200mg
化学名、一般的 名称又は本質 (Chemical Name or Active Ingredients Name) Circle item.	① ヒアルロン酸(Hyaluronic acid) ②ボツリヌス毒素(Botulinum toxin) ③アスコルビン酸(Ascorbic acid) ④歯牙漂白剤(Dental bleach) ⑤ ミノキシジル(Minoxidil) ⑥ベバシズマブ(Bevacizumab) ⑦サリドマイド(Thalidomide) ⑧不活化ポリオワクチン(Inactivated Poliovirus Vaccine) ⑨リドカイン(Lidocaine) ⑩メラトニン(Melatonin) ⑪ヨウ化カリウム(Potassium iodine) ⑫オセルタミビルリン酸塩(Oseltamivir Phosphate) ⑬シルデナフィル(Sildenafil) ⑭漢方(Kampo products) ⑮その他(Other) (Acetyl Salicylic Acid)
用 途 (Intended purpose) Circle purpose.	① ガン治療(Cancer treatment) ②強壮剤・ED薬(Tonic medicine, ED medicine) ③うつ・気分障害・不眠治療(Treatment for Depression, Anxiety Disorder, Insomnia) ④ 栄養補充(Supplement) ⑤美容(Beauty) ⑥瘦身効果(Slim figure, Weight Reduction) ⑦避妊(Birth control) ⑧アレルギー治療(Allergy treatment) ⑨育毛(Hair Restoration) ⑩ワクチン(Vaccine) ⑪皮膚麻酔(Topical anesthesia) ⑫ 眼科治療(Ophthalmology treatment) ⑬歯科治療(Dental treatment) ⑭特定疾病*治療(Specific disease treatment) ⑮震災関連(Earthquake disaster relations) ⑯動物の治療(Animal treatment) ⑰その他(Other)(Antipyretic analgesics) *特定疾病：介護保険法施行令第2条に規定する疾病（ガンを除く。） (※Specific disease; Disease prescribed in Nursing Care Insurance Law enforcement order Article 2. (Cancer is excluded.))
具体的な用途 (効能・効果、用法) (Efficacy, Dosage)	【Efficacy】 Antipyretics, analgesics and anti-inflammatory agents 【Dosage】 Adults : 1 tablet every four hours as needed
規 格 (Specifications)	Aspirin tablets cases in a box aluminum laminate 10 tablets.

(Sample)

[別紙第5号様式] [FORM 5]

商 品 説 明 書 (Explanation of Product)

(Pharmaceutical Products are excluded)

<p>商 品 名 (Name of product)</p>	<p>K-PAP Machine Set</p> <ul style="list-style-type: none">• K-PAP Machine• K-PAP Mask• Tube
<p>化学名、一般的 名称又は本質 (Chemical Name or Active Ingredients Name)</p>	<ul style="list-style-type: none">• K-PAP Machine• K-PAP Mask (For replacement)• Tube(For replacement)
<p>用 途 (効能・効果) (Efficacy)</p>	<p>Treatment for sleep apnea syndrome</p>
<p>規 格 (Specifications)</p>	<ul style="list-style-type: none">• K-PAP Machine Model; XXX• K-PAP Mask Size; XXX• Tube Size; Taper:XX. Length:XX