# Q & A

for those who are importing medicines into Japan

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

#### 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 "Yunyu Kakunin-sho", 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, "Yunyu Kakunin-sho" is not required. (Regarding to efficacy and dosage)And if you import syringe only (without medicines), you need to apply for "Yunyu Kakunin-sho" as medical devices even if you import 1 piece

#### Q4. How can I receive a certificated "Yunyu Kakunin-sho"?

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 "Yunyu Kakunin-sho" 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 "Yunyu Kakunin-sho" when I bring medicines with me?

- A5. The following documents are required in order to apply for a "Yunyu Kakunin-sho".
  - 1) **Import Confirmation Application Form** [FORM 12] (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 13 for medicines or FORM 14 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 "Yunyu Kakunin-sho". ("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 "Yunyu Kakunin-sho" by post?

A6.

<u> Place of arrival: Narita International Airport, Haneda International Airport, etc.</u>
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: <u>kiyakuji@mhlw.go.jp</u>

#### Q7. What shall I do, if I have received a certificated "Yunyu Kakunin-sho"?

A7. A "Yunyu Kakunin-sho" is the Import Confirmation of Medication issued by the Minister of Health, Labour and Welfare.

You have to bring the "Yunyu Kakunin-sho" with your medicines in order to show it to Customs on request when you arrive in Japan. The copy of "Yunyu Kakunin-sho" is acceptable at-Customs.

It will be valid only when your luggage contents are the same as indicated on the "Yunyu Kakunin-sho".

You have to take care never to correct the "Yunyu Kakunin-sho", or it becomes invalid.

#### Q8. How long does it take to receive a certificated "Yunyu Kakunin-sho"?

A8. After we receive your completed application documents, we normally issue Yunyu Kakunin-sho 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 Yunyu Kakunin-sho 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 Yunyu Kakunin-sho or not. If you need to apply, you have to send the application documents of Yunyu Kakunin-sho to us by Email, FAX or post.

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

The certificated "Yunyu Kakunin-sho" is the Import certificate 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 "Yunyu Kakunin-sho".

You have to take care never to correct the "Yunyu Kakunin-sho", or it becomes invalid.

Required documents for Yunyu Kakunin-sho when you send medicines are as follows, (It's different from the case of bringing.)

- 1) **Import Confirmation Application Form** [FORM 12] (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 13 for medicines or FORM 14 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

品 名(Name and Size of the Import Products)	数 量 (Quan	ntity)
輸入の目的 5. For Personal Use		
(Purpose of Import) 8. Other Purpose (		)
	of import above pat f	
<ul> <li>誓約事項</li> <li>□ The import products above are solely for the purpose</li> <li>(Oath)</li> <li>□ Use and /or gift for others.</li> </ul>	of import above, not i	or commercial
	1 1 1	1 . 1 .
確認事項 □Within the past two years, I have not violated th (Confirmation matter) □Pharmaceutical affairs stipulated by Cabinet Order or	_	
	_	
輸入しようとする品目の製造業者名及び国名 (Name of manufacturer and	Country Origin of Impor	t Products)
輸入年月日		
加彻証分、加全理込仏寺の留方   利復   (Import Data / Appind	空港、到着港又は蔵	
(AWB No., B/L No. or Flight No.) (Arrival	Place (Airport, port or Sto	orage place))
(Year) (Month) (Date)		
備 (Note)		
(For Official Use) 特記事項 確		
14月	4 巳 E )	(TT)
<sup>  欄</sup>   厚生労働大臣(地方厚	土 同 女 /	ED

( ) 輸力

) 輸入 確認申請書 (Import Confirmation Application Form)

I apply for confirmation which affects import by the above.

/ / (Year) (Month) (Date)

Name of Importer \_\_\_\_\_\_ Importer's Signature \_\_\_\_\_\_ Address of Importer \_\_\_\_\_\_ Phone Number \_\_\_\_\_\_ E-mail \_\_\_\_\_\_@

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

### 〔様式 13〕 [FORM 13]

#### 商 品 説 明 書 (Explanation of Pharmaceutical Product)

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

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

### 〔様式 14〕[FORM 14]

#### 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. 〔様式12〕 [FORM 12] Medicine ) ( 輸入 確認申請書 (Import Confirmation Application Form) 品 数 名(Name and Size of the Import Products) 量 (Quantity) Aspirin tablet 200mg 100 tablets 1. 1. List name and size of the product. Attach a 2. K-PAP Machine Set 2. (Details) Write a unit. separate sheet in case the space is short. • K-PAP Machine • 1 unit • K-PAP Mask (For replacement) • 3 sheets • Tube( For replacement) • 3 tubes Put "Circle" on either one. 5.) For Personal Use 輸入の目的 (Purpose of Import) 8. Other Purpose ( ) 誓約事項 The import products above are solely for the purpose of import above, not for commercial (Oath) use and /or gift for others. Check here. 確認事項 ZWithin the past two years, I have not violated the laws and regulations related to (Confirmation matter) pharmaceutical affairs stipulated by Cabinet Order or the disposition based thereon. Check here. の製造業者名及び国名 (Name of manufacturer and Country Origin of Import Products) 輸入 Kouseikyoku Co.Ltd. Japan 輸入年月 日 船荷証券、航空運送状等の番号 到着空港、到着港又は蔵置場所 (Import Date / Arrival (AWB No., B/L No. or Flight No.) (Arrival Place (Airport, port or Storage place)) Date) 2020 / Jun / 19 Japan Airlines JLXX Narita International Airport (Year) (Month) (Date) (Note) 備 If you are sending medication or are having medication sent to you by post, you 考 must include the AWB No. or the B/L No. If you are bringing medication with you to Japan, you must write your flight No. (For Official Use) 確 認 欄 厚生労働大臣(地方厚生局長) (EII)

I apply for confirmation which affects import by the above.

<u>2020 / Jun / 1</u>	
(Year) (Mon b) (Date)	
	Name of Importer <u>KANTO SHIN-ETSU</u>
Date of Request	Importer's Signature
	Address of Importer <u>1-1, Saitama-Shintoshin, Saitama</u>
	330-9713 JAPAN
	Phone Number <u>+81-48-740-0800</u>
	E-mail <u>kanto_shinetsu@mhlw.go.jp</u>
(To Minister of Health, Labour and Welfare) 厚生労働大臣(地方厚生局長) 殿	Indicate the one we can reach.

#### (Sample)

### 〔様式 13〕 [FORM 13]

商 品

説

明 書 (Explanation of Pharmaceutical Product)

Created for each item

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

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) Put "Circle" on item.	<ol> <li>1.ヒアルロン酸(Hyaluronic acid) 2.ボツリヌス毒素(Botulinum toxin)</li> <li>3.アスコルビン酸(Ascorbic acid) 4.歯牙漂白剤(Dental bleach)</li> <li>5.ミノキシジル(Minoxidil) 6.ベバシズマブ(Bevacizumab)</li> <li>7.サリドマイド(Thalidomide)</li> <li>8.不活化ポリオワクチン(Inactivated Poliovirus Vaccine)</li> <li>9.リドカイン(Lidocaine) 10.メラトニン(Melatonin)</li> <li>11.オセルタミビルリン酸塩(Oseltamivir Phosphate)</li> <li>12.シルデナフィル(Sildenafil) 13.漢方(Kampo products)</li> </ol>
用 途 (Intended purpose) Put "Circle" on purpose.	<ul> <li>(14)その他(Other)(Acetyl Salicylic Acid))</li> <li>1.ガン治療(Cancer treatment)2.強壮剤・ED 薬(Tonic medicine, ED medicine)</li> <li>3.うつ・気分障害・不眠治療(Treatment for Depression, Anxiety Disorder, Insomnia)</li> <li>4.栄養補充(Supplement)5.美容(Beauty)</li> <li>6.痩身効果(Slim figure,Weight Reduction)</li> <li>7.避妊(Birth control) 8.アレルギー治療(Allergy treatment)</li> <li>9.育毛(Hair Restoration) 10.ワクチン(Vaccine) 11.皮膚麻酔(Topical anesthesia)</li> <li>12.眼科治療(Ophthalmology treatment)</li> <li>13.歯科治療(Dental treatment)</li> <li>14.特定疾病*治療(Specific disease treatment)</li> <li>15.動物の治療(Animal treatment)</li> <li>16)その他(Other)(Antipyretic analgesics))</li> <li>※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。)</li> <li>(※Specific disease; Disease prescribed in Nursing Care Insurance Law enforcement order</li> <li>Article 2. (Cancer is excluded.))</li> </ul>
具体的な用途 (効能・効果、用法) (Efficacy, Dosage)	<pre>【Efficacy】 Antipyretics, analgesics and anti-inflammatory agents 【Dosage】 Adults : 1 tablet every four hours as needed</pre>
規   格 (Specifications)	Aspirin tablets cases in a box aluminum laminate 10 tablets.

### (Sample)

### 〔様式 14〕 [FORM 14]

商 品 説 明 書 (Explanation of Product)

(Pharmaceutical Products are excluded)

商 品 名 (Name of product)	K-PAP Machine Set • K-PAP Machine • K-PAP Mask • Tube
化学名、一般的 名称又は本質 (Chemical Name or Active Ingredients Name)	<ul> <li>K-PAP Machine</li> <li>K-PAP Mask ( For replacement )</li> <li>Tube( For replacement)</li> </ul>
用 途 (効能・効果) (Efficacy)	Treatment for sleep apnea syndrome
規   格 (Specifications)	<ul> <li>K-PAP Machine Model; XXX</li> <li>K-PAP Mask Size; XXX</li> <li>Tube Size; Taper:XX. Length:XX</li> </ul>