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 Q8, Q10 and Q11.</u>

In case of <u>sending medicines</u>, please read the following Q1,3,4, Q7 to Q11.

Q1. Can I bring /send general prescription medicine into Japan from overseas?

- A1. You can bring /send general prescription medicine into Japan without any special procedures on condition that
 - (1) you bring/send it only for personal 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 (e.g. Morphine) and Stimulants' Raw Materials (e.g. Lisdexamfetamine),
 - (4) quantity is up to one month supply.
 - (5) it is not permitted to SEND Psychotropics, Narcotics and Stimulants' Raw Materials.

Q2. How can I bring more than one month supply of general prescription medicine only for personal use into Japan?

A2. You need to apply for Import Confirmation before entering Japan.

Q3. How can I bring/send injection and injector only for personal use into Japan?

A3. If you bring/send medicines with syringes for them (permissive self-injection like insulin) at the same time for less than 1 month supply, Certificate for Import Confirmation is not required. (Regarding to efficacy and dosage)

However, if you import syringe only (without medicines), you need to apply for Import Confirmation as medical devices even if you import 1 piece.

Q4. How can I obtain a Certificate for Import Confirmation?

A4. Online application is available by clicking the blue bottom below. Certificate for Import Confirmation (PDF) to the email address you registered, if there are no problems with your application.



https://impconf.mhlw.go.jp/aicpte/page/login.jsp?lang=en/

The manual for online applications is

https://impconf.mhlw.go.jp/manual/manual application en.pdf

For inquiries regarding the operation of this system, etc.

Please contact the following for the operation and specifications of the system.

Email: TDEN-aic-helpdesk (at) ml.toshiba.co.jp

*Replace (at) with @.

Q5. What documents are required to attach an application for import confirmation to bring into Japan?

- A5. The following documents are required in order to apply for Import Confirmation.
 - 1) A valid prescription (or a doctor's note) indicating 3 items of the patient, medicine and doctor's name issued by your doctor FOR ALL MEDICINES or MEDICAL DEVICES you apply.
 - 2) A Document indicating 4 items of arrival date, arrival place (airport or port), flight (Cruise) No., and passenger's name (applicant's name) issued by airline (or cruise) company. (For example: itinerary, the copy of airplane ticket)

Q6. What shall I do if I have received Certificate for Import Confirmation?

A6. Please show the Certificate for Import Confirmation if requested by customs, when you arrive in Japan.

You have to take care never to correct the Certificate for Import Confirmation, or it becomes invalid.

Q7. How long does it take to receive Certificate for Import Confirmation?

A7. It will be normally issued in a few business days (not including Saturday, Sunday and National holidays), if your application form is completed.

Q8. What shall I do if my application is returned or rejected?

A8. Please confirm your registered email address for the reason why your application was not approved or instructions on how to correct the issue.

Q9. What documents are required to attach an application for import confirmation if the medicine I sent to Japan is stopped at customs?

- A9. Please apply online application. (See Q4 for more information on online application.) For Applying Application, you need to attach the documents below.
 - 1) Invoice
 - 2) Air Waybill from courier service / A postcard from customs.
 - 3) A valid prescription (or a doctor's note) indicating 3 items of the patient, medicine and doctor's name issued by your doctor FOR ALL MEDICINES or MEDICAL DEVICES you apply.
- *The importer name and patient's name on the prescription must be the same.
- **Narcotics, psychotropics and stimulant raw materials are **prohibited to send** from overseas to Japan.

Q10. What should I do if I have a trouble with my online application?

A10. Please contact help desk if you have any questions about the online system.

Email: TDEN-aic-helpdesk (at) ml.toshiba.co.jp

*Replace (at) with @.

If you are still unable to resolve your trouble, please submit the following form along with the necessary documents (see Q5 and Q9) to the email address listed below (the address varies depending on your arrival place).

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

Email: yakkan (at) mhlw.go.jp *Replace (at) with @.

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

• Kinki Regional Bureau of Health and Welfare

Email: kiyakuji (at) mhlw.go.jp *Replace (at) with @.

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

品 名 (Name and Size of the Import Products)			数 量(6	(uantity)
 輸入の目的	5. For Personal Use	I		
(Purpose of Import)	8. Other Purpose ()
誓約事項 (Oath)	☐ The import products above are solely for the purpose of import above, not for commercia use and /or gift for others.			
確認事項 (Confirmation matter)	□Within the past two years, I have not violated the laws and regulations related to pharmaceutical affairs stipulated by Cabinet Order or the disposition based thereon.			
輸入しようとする	I 品目の製造業者名及び国名 (Name of manu	ıfacturer and Countr	ry Origin of Im	port Products)
			-	=
輸入年月日	船荷証券、航空運送状等の番号	列美党洪	到着港又は	
(Import Date / Arrival	何何ய分、加工建込れ寺の笛り (AWB No., B/L No. or Flight No.)	到有主他、 (Arrival Place (A		
Date)	1113 1101, 212 1101 01 1 1 1 1 1 1 1 1 1 1 1 1 1 1	(2111141111400 (2		
(Year) (Month) (Date)				
備 (Note)				
考				
(For Official U	se) 特記事項			
確	14,12,3			
認				
欄	厚生労働大臣	1(地方厚生局長	麦)	(EII)
I apply for confirm	ation which affects import by the above			_
- or p-3				
//	<u> </u>			
(Year) (Month) (Da	,			
	Name of Importer			
	Address of Impor	ter		
	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)	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.オセルタミビルリン酸塩(Oseltamivir Phosphate) 12.シルデナフィル(Sildenafil) 13.漢方(Kampo products) 14.その他(Other) (
用 途 (Intended 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.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.動物の治療(Animal treatment) 16.その他(Other)()
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)

〔様式 12〕 [FORM 12]

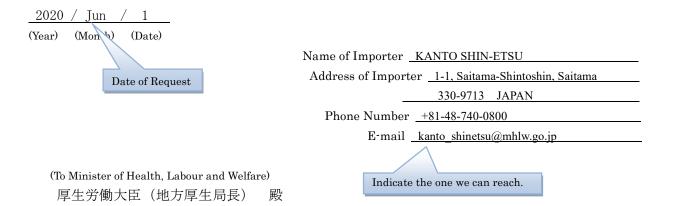
e.g. Medicine, Medical Device, Cosmetics etc.

(Medicine)

輸入 確認申請書 (Import Confirmation Application Form)

品名	(Name and	Size of the Import Products)		数	量 (Quantity)
Aspirin tablet 200 K-PAP Machine S K-PAP Machine	omg Lis	t name and size of the product. At		 1. 100 tablets 2. (Details) 1 unit 	Write a unit.
• K-PAP Mask (For replacen	nent)		• 3 sheets	
• Tube(For repla	cement)			• 3 tubes	
Put "Circle" on either one.					
輸入の目的	5. For Pe	rsonal Use			
(Purpose of Import)	8. Other	Purpose ()
誓約事項 (Oath) Check here.					
確認事項 (Confirmation matter) Within the past two years, I have not violated the laws and regulations related to pharmaceutical affairs stipulated by Cabinet Order or the disposition based thereon.					
輸入しよ Check her	e. の製造	業者名及び国名 (Name of man	ufacture	r and Country Orig	in of Import Products)
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		B No., B/L No. or Flight No.)	1		, port or Storage place))
Date) 2020 / Jun / 19					
(Year) (Month) (Date)	Ja	npan Airlines JLXX		Narita Interna	ntional Airport
備 (Note) 考		If you are sending medication or a must include the AWB No. or the B		ng medication sent	to you by post, you
(For Official Us	se)	If you are bringing medication with you to Japan, you must write your flight No.			
確 認 欄		厚生労働大日	三(地)	方厚生局長)	(ii)

I apply for confirmation which affects import by the above.



(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.	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.オセルタミビルリン酸塩(Oseltamivir Phosphate) 12.シルデナフィル(Sildenafil) 13.漢方(Kampo products) 14.その他(Other) (Acetyl Salicylic Acid)
用 途 (Intended purpose) Put "Circle" on 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.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.動物の治療(Animal treatment) 15.動物の治療(Animal treatment) 16.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)

〔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)	 K-PAP Machine K-PAP Mask (For replacement) Tube(For replacement)
用 (効能・効果) (Efficacy)	Treatment for sleep apnea syndrome
規 格 (Specifications)	 K-PAP Machine Model; XXX K-PAP Mask Size; XXX Tube Size; Taper:XX. Length:XX