## INSTRUCTIONS TO APPLY FOR PERMISSION TO IMPORT MEDICINE FOR PERSONAL USE\*

\*THE FOLLOWING INSTRUCTIONS DO NOT APPLY TO THOSE IMPORTING/BRINGING NARCOTICS INTO JAPAN; A SEPARATE FORM IS REQUIRED. PLEASE REFER TO THE 'NARCOTICS APPLICATION FORM'

1. Send the attached application forms directly to the Japanese Ministry of Health and Welfare at least three weeks before departing for Japan.

#### For your application you will need to send:

		Checklist
Application form 'Import Report of Medication'* ++	2 <b>signed</b> copies	
Declaration form	1 <b>signed</b> copy	
Explanation of the Products	1 copy per product	
Copy of your prescription**	1 copy per product	
Document stating your date of entry into Japan	1 copy	

# Please ensure that you have signed the appropriate forms. Forms without signatures will not be processed.

- \* For the purpose of completing this form 'Date of Import' will be the date you enter Japan. 'Place of Quarantine' will be the International Port in which you will be entering Japan.
- <sup>++</sup> If a family member is applying on your behalf, please ask them to write your name and their relationship to you in the section below 'Date of Import'.
- \*\*It may prove helpful to have a letter (on a letterhead) from your doctor explaining which medications are needed and why, and their required quantities.
- 2. From the list below, send by post your completed application to the closest Bureau of Health and Welfare to your point of arrival in Japan:

### Tokyo (Narita) International Airport (Kantou-Shinetsu office)

Kanto-Shinetsu Health and Welfare Bureau Saitama Shintoshin National Government Building No.1, 7F 1-1 Shintoshin, Chuo-ku, Saitama City, JAPAN 330-9713

Fax: 0011-81-4-8601-1336

#### **Kansai International Airport (Kinki office)**

Phone: 0011-81-6-6942-4096 Fax: 0011-81-6-6942-2472

### Naha International Airport (Okinawa branch office)

Phone: 0011-81-98-854-2584 Fax: 0011-81-98-834-8978 3. All enquiries regarding narcotics, psychotropic drugs, stimulants etc... should be directed to the following office:

Charge of Opium of Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Fax: 0011-81-3-3501-0034

- **4.** For further reference see, 'Importing or Bringing Medication into Japan for Personal Use' http://www.mhlw.go.jp/english/topics/import/index.html
- 5. Please keep a copy of your completed application for your records
- 6. After sending your application to the Ministry of Health and Welfare, it will be processed and you will be notified of the result of your application.

If the application has been successful, you will be sent a stamped copy of your application which you will need to take with you to Japan. Keep this document together with your medication to show at customs at your International Port of entry into Japan. Alternatively if you are sending medication, please include the stamped application form together with your medication.

If the application is rejected you will be notified directly.

**※** (

### ) 輸入報告書

Name of Importer\_\_\_

(Import Report of Medication)

(To Minister of Health,Labour and Welfare)

(Year) / (Month) / (Date)

印(Signature)

### 厚生労働大臣殿

								A	Address of I	mporter			
									Phone l	Number			
									Fax	Numbei	r		
			品	名					数	量	承認番号	<u>+</u>	許可登録年月日
	(Name	e and	d Size of t	ne In	nport	Product	s)		(Qua	ntity)		$/ \parallel$	
													/
					輸入	. (販売)	<b>坐</b> 許	<u>.</u>	登録番号	_ <del>有効期</del>	KR .	<u> </u>	
				)第		(AX)L)		平成	年月			月	日
	輸入	D E i	i/ı	) <del>//</del>	,		7	十八人	十 万	н	- +	Л	н
	(Purpose												
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				来 白	及び国	日名 (Na	ame o	or Manu	nacturer,an	a Count	try of Origin)		
+/	1 5 0 0	(D		.\					** == (8.50	/DI			
聊	i人年月日	(Da	te of Impo	rt)					<b>咸直場</b> 所	(Place o	of Quarantine)		
1													
備													
考													
	労働省に	1	輸入報告		2	念書	3	治験、	試験計画書	‡ 4	商品説明書	5	仕入書(Invoice)
	た資料	6	その他						)				
厚	(For Off	icial	Use)						特記事項				
生													
労													
働													
省													
確									厚生労働名	省関東信	越厚生局		
認									薬	事監視員	l		
欄									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 A 4 とすること。

### ※ ( Medicine ) 輸入報告書

(Import Report of Medication)

2007 / May / 30 (Year) / (Month) / (Date)

(To Minister of Health, Labour and Welfare)

厚生労働大臣殿

K Shiell

Name of Importer KANTO SHINETSU

Address of Importer 1-2-9 Nishi-Shinbashi, Minato-Ward, Tokyo

〒105-0003 JAPAN

Phone Number +81-3-5157-0516

Fax Number					r none Number		0 0107 00	
(Name and Size of the Import Products)  1. Aspirin Tablet 200mg 2. Anaphylaxis Emergency Treatment Kit ( containing 1 syringe of Epinephrine intermuscular injection 1ml and 4 tablets of chlopheniramine maleate 2mg)					Fax Number	+81	<del>-3-5157-0</del> 5	523
1. Aspirin Tablet 200mg 2. Anaphylaxis Emergency Treatment Kit ( containing 1 syringe of Epinephrine intermuscular injection 1ml and 4 tablets of chlopheniramine maleate 2mg)    株式 (販売) 業許可   登録番号   五分期限   上京 (W元) (W元) (W元) (W元) (W元) (W元) (W元) (W元)			品 名		数量		承認番号	/ 許可登録年月日/
2. Anaphylaxis Emergency Treatment Kit ( containing 1 syringe of Epinephrine intermuscular injection 1ml and 4 tablets of chlopheniramine maleate 2mg)    解人(販売) 業許可 登録番号 石効明限   接入(販売) 業許可 登録番号 石効明限   接入(販売) 業許可 登録番号 石効明限   接入(販売) 業許可 を経過等 石効明限   接入(販売) 業許可 を経過等 石効明限   接入(販売) 業計可   接入(販売) 業計可   接入(販売) 表		(Name	e and Size of the Impo	ort Products)	(Quantit	ty)		
Containing 1	1	Aspirin	Tablet 200mg		1. 100 Tal	olets		
intermuscular injection 1ml and 4 tablets of chlopheniramine maleate 2mg)    株人 (販売) 業許可 登録番号 石効即限   ※ ( ア ア Personal Use   日 月 日 年 月 日 年 月 日 年 月 日 年 月 日 年 月 日 年 月 日 年 月 日 年 月 日 年 月 日 年 月 日 日	2.	Anaphyla	axis Emergency Tr	eatment Kit	2. 1 Kit			
Manufacturer, and Country of Origin   War	( (	containir	ng 1 syringe	of Epinephrine				
輸入 (販売) 業許可   登録番号   1立期限	inter	muscula	r injection 1ml a	and 4 tablets of				
接入   日   日   日   日   日   日   日   日   日	chlo	pheniran	nine maleate 2mg)					
輸入の目的				入 (販売) 業許可	登録番号 有	効期限		
Purpose of Import		<b>※</b> (	)第	号 平成	年 月	目~	年	月日
大のUseikyoku Co. Ltd. Japan		輸入	の目的	For Personal Use				
Kouseikyoku Co. Ltd. Japan		(Purpose	of Import)					
輸入年月日 (Date of Import)   藤置場所 (Place of Quarantine)			製造業者及び	ブ国名 (Name of Mar	ufacturer,and C	ountry of	Origin)	
Result	K	ouseikyo	ku Co. Ltd. Japan					
備 考	輎	輸入年月日(Date of Import)						
厚生 * 働省に       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)         提出した資料 6 その他 (		2007/	July/29	Narita	International			
厚生労働省に 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) 提出した資料 6 その他(	備							
提出した資料 6 その他( )  厚 (For Official Use) 特記事項 生 労	考							
厚       (For Official Use)       特記事項         生       労         働       (4)         確       厚生労働省関東信越厚生局         認       薬事監視員	厚生的	労働省に	1 輸入報告書	2 念書 3 治験	、試験計画書	4 商品	品説明書	5 仕入書(Invoice)
生       労       働       省       確     厚生労働省関東信越厚生局       認     薬事監視員	提出)	した資料	6 その他(		)			
労働       省       確     厚生労働省関東信越厚生局       認     薬事監視員	厚	(For Offi	cial Use)		特記事項			
働       省       確 <u>厚生労働省関東信越厚生局</u> 認     薬事監視員	生							
省       確     厚生労働省関東信越厚生局       認     薬事監視員	労							
確 <u>厚生労働省関東信越厚生局</u> 認 薬事監視員	働							
認業事監視員	省							
	確				厚生労働省関	東信越厚	生局	
	認				薬事監	視員		
	欄				毒物像	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。

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

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	数量
(Name and Size of the Import Products)	(Quantity)

念

書

(To Minister of Health, Labour and Welfare) 厚生労働大臣殿 (Declaration) <u>2007 / May / 30</u> (Year) / (Month) / (Date)

輸入業者(受取人)氏名 (Name of Importer)

E garage

同住所 (Address of Importer)

1-2-9 Nishi-Shinbashi,Minato-Ward,Tokyo  $\mp$ 105-0003 JAPAN

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. )

SAMPLE

品名	数量
(Name and Size of the Import Products)	(Quantity)
1.ASPIRIN TABLET 200 mg	1. 100 Tablets
2.Anaphylaxis Emergency Treatment Kit	2. 1 Kit
(Cotaining 1 Syring of Epinephrine Intermuscular	
or subcutaneous) injection 1ml (1:1000) and 4 tablets of	
chlopheniramine maleate 2 mg)	

### 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)	
	(eg.Intended Health Effect)
効能又は効果	
(Efficacy)	
	(eg.Form)
規格	
(Specifications)	

### 商品説明書

 $(Explanation\ of\ the\ Products)$ 

商品名	ASPIRIN TABLET 200mg
(Name of Product)	
製造元名称	Kouseikyoku Co.Ltd. JAPAN
及び国名	
(Name of the	
Manufacture and	
Country of Origin)	
化学名、一般的	Acetyl Salicylic Acid
名称又は本質	(Analgesic
(Chemical Name	
or Active	
Ingredients Name)	
構造式及び剤型	Sugar coating white tablets, which are containing 200 mg Aspirin.
(成分分量)	
	$\Delta IMPIF$
(Ingredients and	
Quantity of them)	
	For pain:
効能又は効果	Adults - 1 tablet every four hours as needed.
(Efficacy)	
	Aspirin Tablets cases in a box alminium laminate 10 tablets.
規格	
(Specifications)	

### 商品説明書

(Explanation of the Products)

商品名	Anaphylaxis Emergency Treatment Kit
(Name of Product)	
製造元名称	Kouseikyoku Co.Ltd. JAPAN
及び国名	
(Name of the	
Manufacture and	
Country of Origin)	
化学名、一般的	Epinephrine and
名称又は本質	Chlorpheniramine Malate
H1774(0) 1 94	
(Chemical Name	(For Anaphylaxis + Antihistamine)
or Active	,
Ingredients Name)	
構造式及び剤型	Syringe is one self-injection which is containing 1 ml Epinephrine
(成分分量)	Solution(1:1000)and tablets are 4 white sugar corting pills which are
(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Containing chlopheniramine maleate 2 mg
(Ingredients and	
Quantity of them)	// \IVII
	For emergency treatment of anaphylaxis that results from accidental
効能又は効果	Injection of certain foods (nuts, peanuts)
(Efficacy)	
, , , , , , , , , , , , , , , , , , , ,	
	1 kit is containing 1 syringe of epinephrine intermuscular (or subcutaneous)
規格	injection 1 ml and 4 tablets of chlopheniramine maleate 2 mg
(Specifications)	

#### Importing or Bringing Medication into Japan for Personal Use

Section of Medicinal Inspection and Guidance,

Kantou-Shinetsu Regional Bureau of Health and Welfare,

Ministry of Health, Labour and Welfare

Saitama-shintoshin-Godochosha 1, 7<sup>th</sup> Floor, 1-1 Shintoshin,
Chuo-ku, Saitama City, Saitama Prefecture JAPAN ∓
330-9713

Tel. +81-48-740-0800 Fax. +81-48-601-1336

§ 1. In the case of quarantined medications for personal use at customs, you must get an import certification so-called 'Yakkan-Syoumei' from our office. The application should be satisfied with several guidelines. The application forms attach below.

The application of import certification is requiring the following documents;

- 1. Application Form (Import Report of Medication) ··· 2 copies with sign
- 2. Declaration ···1 copy with sign
- 3. Explanation of the Products
- 4. Prescription for Your Medication

[In the case of importing] (With the above 1 to 4 documents)

- 5. Copy of Notice Card from the Japanese Customs
- 6. Copy of Invoice
- 7. Copy of Air Way Bill (B/L)

[If you don't have 6. and/or 7., you have to have an inspection report on contents of imported goods so-called 'Horyu-Kokusai-Youbinbutsu-Jizen-Naiyo-Tenken-Negai(保留国際郵便物事前内容点検顧)' from a Customs where your medications were quarantined.]

[In the case of bringing] (With the above 1 to 4 documents)

- 8. Document Indicating Arrival Date (ex. Copy of Airline Ticket or Fright Itinerary)
- 9. The Notice from the Japanese Customs (If you get this, you must submit to our office)

You can get your medication due to submit the certification to the customs officer who quarantined your medication. Imported or brought medication into Japan for personal use must not be sold or given to others.

- § 2. An individual can import the following restricted quantities of medication without special procedures. You can't import exceeded quantities, without the above § 1 procedures. Imported or brought medication into Japan for personal use must not be sold or given to others.
  - 1. Drug or 'Iyakubugaihin' (quasi-drug): Up to 2 months' supply
    - · Prescription Drug: Up to 1 month's supply
    - Vitamin: Up to 4 months' supply
    - Drug or Iyakubugaihin' for External Use (excluding prescription drug): Up to 24 pieces

#### (Note)

Iyakubugaihin (quasi-drug):

'Iyakubugaihin' is a product that has restricted purpose of use, has a mild action on the human body, and is not categorized as a medical device.

e.g.) hair tonics, bath preparation, etc.

For external use:

e.g.) ointments, eye drops and etc.

2. Cosmetic: Up to 24 pieces per item

3. Medical Device (for home use only): 1 set

e.g.)electric massager

§ 3. An importer of medication (drug, 'quasi-drug (Iyakubugaihin)', cosmetic or medical device) for business purposes needs a License from the designated authority under the Pharmaceutical Affairs Law. If you want more information, please contact to a pharmaceutical affairs office of prefectural government in your Japanese office location.

### Import Prohibited Drugs

- § 4. Stimulants (Amfetamine and Metamfetamine) are nobody to import. Psychotropic drugs and Narcotics are strictly restricted. If you need further information, please contact following Narcotics Control Department.
- § 5. In accordance with CITES (Convention on International Trade in Endangered Species), import of drugs including the following substances is prohibited. If you need further information, please contact following Import Division.

e.g.)rhinoceros horn, musk, tiger bones and etc.

#### [Note]

The Convention on International Trade in Endangered Species (known as the "Washington Convention") was adopted in Washington, D.C., in March 1973 and came into effect in July 1975; its aim is to prevent the extinction of rare species of animals and plants.

#### **Further Information**

§ 6. Regarding Stimulants, Narcotics, Psychotropic drugs etc., please contact the following office;

Narcotics Control Department, Kanto-Shinetsu Regional Bureau of Health and Welfare Phone:+81-3-3719-8111, Fax:+81-3-3719-8116

§ 7. Regarding the CITES, please contact the following office;

Trade Licensing Division, Trade Control Department, Trade and Economic Cooperation Bureau, Ministry of Economy, Trade and Industry

Phone:+81-3-3501-1659

[Reference]http://www.mhlw.go.jp/english/topics/import/index.html