



<Supplementary information on import procedures for medicines, medical equipment, and cosmetics>

<Introduction>

The supplementary information is created for helping the Games Stakeholders can better understand about the import procedures mainly from the perspective of import way for medicines, medical equipment, and cosmetics.

< medicines that require application>

Japanese laws and regulations (laws on ensuring the quality, efficacy and safety of medicines, medical devices, etc.) comprehensively regulate general drugs to cosmetics that have effects on easing human body. In addition, please be aware that not only the nature of the ingredients, but also those that claim to have a pharmaceutical effect or that have a pharmaceutical form or dosage are, in principle, subject to the applicable laws and regulations and are subject to the application of this procedure.

(Examples)

Medications: OTC, Prescription drugs excluding narcotics and other controlled drugs **Medical equipment**: Thermometer, Emergency treatment kit, Massage bet, AED

Quasi drugs: Hand sanitizer, Vitamins, Insecticide

In vitro diagnostics: Medical test kits

Cosmetics: Toothpaste, Shampoo, Sunscreen lotion

- * No need to apply for masks (except for medical equipment such as for anesthesia).
- * Designated chemical substances such as nitrous oxide and isopentyl nitrite cannot be imported. (https://www.mhlw.go.jp/content/11120000/000563116.pdf)

<Important precautions when importing medicines, medical devices, and cosmetics for teams/groups>

When importing medicines, medical equipment, and cosmetics for teams/groups, as mentioned in 'Tokyo 2020 Customs & Freight Forwarding Guide', an accompanied medical doctor or medical specialist (healthcare professional) is required. In addition, the medical doctors or medical specialists must be present in Japan at the same time as the import customs clearance procedure.

Therefore, if you bundle (mix) medicines with other goods, the customs clearance procedures for those other goods can only be completed once the medical doctors or medical specialists arrive at Japan.

For above reason, when shipping medicinal products for teams/groups, Tokyo 2020 recommends shipping them separately from other goods.

<Explanation of import procedures for medicines, medical devices, and cosmetics>When importing medicines, medical equipment, and cosmetics, these goods will be divided into two (2) types.

Type 1 is,

- 'Hand-carried or Unaccompanied goods for team/group use'
 Type 2 is
- 'Goods for individual' which is namely for personal use.

In the case of importing goods as Type 1 'Hand-carried or Unaccompanied goods for team/group use', a medical doctor or medical specialist (In the case of NOC / NPC, it is mainly a team doctor and must be registered with the Tokyo 2020 Medical Service FA) shall be an importer. However, it is also possible to be imported as corporate cargo under the name of their team/group. It is necessary that the medical doctors or medical specialists do the import application by himself / herself in either case.

Please note that if there is no medical doctor or medical specialist, the only way is to import as 'Personal Luggage' within the usage allowance for individuals.

Whether it is imported as collective or individual case, it is necessary to bring unused medicines and medical devices back to your country after the Games.

The following explains the description of the specific import procedure when there is or there is no medical doctor or medical specialist in the team/group.

If there is a medical doctor or medical specialist, please follow 'Method A)' or 'Method B)'.

If there is no medical doctor or medical specialist, please follow 'Method C)'.

(* As mentioned above, <u>Cosmetics</u> are managed under the same strict laws as Japanese medicines, so please import them in the same way as medicines.)

Note: Strictly ruled drugs, such as narcotics and psychotropics, cannot be imported as 'for team/group use'. In addition, even for 'Individual Luggage', there are items which requires a permit, and some items are prohibited. For details, refer to Tokyo 2020 Customs & Freight Forwarding Guide at [Section 7.3.1.1, 7.3.1.2, Annex2].

1. If there is a medical doctor or medical specialist in the team/group

Method A): Medical doctors or medical specialists import as his/her belongings (= Hand-carried baggage)

- Step 1: Please follow the procedures described in P.50 [Section 7.3.2.2] of the Customs & Freight Forwarding Guide.
- Step 2: One or more medical doctors or medical specialists will make an application in advance, and the 'Import Confirmation Certificate will be issued by the Regional Health and Welfare Bureau (RHWB) which is required at the time of import.
- Step 3: Please show (Copy of) the Certificate with the item list to be imported issued by RHWB to the customs officer at the time of customs declaration after immigration,
 - *Please be aware that customs officer might check on medicines, medical devices, cosmetics, along with the item lists.

Method B): Import as Unaccompanied baggage under the name of medical doctors or medical specialists or Corporate Cargo under the name of the team/group

- Step 1: Please follow the procedures described in Customs & Freight Forwarding Guide P.50 [Section 7.3.2.2.].
- Step 2: One or more medical doctors or medical specialists need to apply for the importation of items in advance. With this procedure a 'Import Confirmation Certificate' will be issued by RHWB which is required when import the items.
 - Usually, the medical products should be imported as the medical doctors or medical specialists' unaccompanied baggage. However, it is also possible to be applied as a team/group corporate cargo. If you intend to declare the cargo as a team/group corporate cargo, it still should be received by the medical doctors or medical specialists and the medical doctors or medical specialists must take responsibility for managing the imported medicines, medical devices, and cosmetics. In either case, the medical doctors or medical specialists must be present in Japan at the same time as the import customs clearance procedures are ongoing.
 - ▶ If the medical products are imported as other than Hand-carried baggage (=unaccompanied baggage / general cargo), "Confirmation letter for Tokyo 2020 related goods" (=TOP-01-A) which can certify the cargo is related to the Games will be issued by Tokyo 2020 Logistics FA. Please refer to Chapter 6 of Tokyo 2020 Customs & Freight Forwarding Guide for details and send the necessary documents to [customs@tokyo2020.jp].

Step 3: 'Import Confirmation Certificate' (copy) issued by RHWB must be submitted to the customs broker. The customs broker must show it when performing import declaration. It should be kept after going through the Customs.

[Notes on customs clearance as 'Unaccompanied Baggage' and information of 'Customs Declaration Form']

(Customs Declaration Form)

 In order to proceed customs clearance as 'Unaccompanied Baggage', two copies of 'Customs Declaration Form' is required.

(Procedure for preparing and submitting 'Customs Declaration Form')

- The owner of the unaccompanied baggage is asked to prepare two (2) separate 'Customs Declaration Forms' when entering Japan. The information of both copies must be the same.
- (* Check 'Yes' for 3rd question of 'Unaccompanied Articles' and write 'Unknown' as packages (PKGS) on 'Customs Declaration Form')
- Hand over both copies of the 'Customs Declaration Form' to customs officials.
- A custom seal will be stamped on the forms and one (1) copy will be returned. Another copy will be collected by the customs.

The stamped 'Customs Declaration Form' is necessary for customs clearance. <u>Please be sure to pass</u> the original form to the customs broker.

2. If there is no medical doctor or medical specialist in the organization/group

Method C): Import as personal baggage (must be within allowed quantity)

- Step 1: Items cannot be imported as Cargo. However, each person who uses general drugs, medical equipment, and cosmetics can bring as 'Hand-Carried Baggage' as long as the quantity of items are within the amount allowed by Japanese law.
 - → (refer to Annex 1 on page 58 of Tokyo 2020 Customs & Freight Forwarding Guide for details of the usage allowance for individuals.)
 - If your team/group do not have a medical doctor or medical specialist, you can also set up a 'Japanese Resident Doctor (= doctor with a Japanese medical license)' as responsible for 'application' and 'management' of your medical products.
 - → In other words, a Japanese Resident Doctor will make an application in accordance with the procedures described in Tokyo 2020 Customs & Freight Forwarding Guide [Section 7.3.2.2.], and this Doctor will be responsible for the management of medicines, medical devices, and cosmetics during the Games.

<About Dangerous Goods and Luggage>

An 'Import Confirmation Certificate' will be issued after the approval of RHWB for the application of medical doctors or medical specialists, but this will only be the permission of 'Importation to Japan' only. Therefore, please note that this permission does not apply for the transportation of Dangerous Goods.

Depending on the goods, their shapes and substances may be treated as Dangerous Goods, and they might not be able to be transported by aircrafts or vessels. Therefore, judgment on the propriety is based on the airline, shipping company, or carrier used by each organization/group.

Please check with the airline, shipping company, or carrier directly. (E.g.: Sprays and flammable articles etc.)

The above information guides you through the procedures mainly from the perspective of import way for importing medicines, medical devices, and cosmetics. If you have any questions, please contact below.

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