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Guidelines for Import Authorisation Application for Glands and Other Organs for Organotherapeutic Uses, Blood Plasma, Human Blood, and Animal Blood

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1. Introduction

1.1. Pursuant to Article 9 of Law No. 7/2003 – *Foreign Trade Law*, an import license is required for foreign trade activities involving any goods listed in the Import List (Table B). The Import List (Table B) has been approved by the Chief Executive via his dispatch promogulated on the *Official Gazette of Macao SAR*.

1.2. The following goods are classified into the B2 category of the Import List (Table B):

1.2.1. Glands and other organs for organotherapeutic uses (Reference no. of The Nomenclature for the External Trade of Macao / Harmonized System: 3001.90.90)

1.2.2. Blood plasma (Reference no. of The Nomenclature for the External Trade of Macao / Harmonized System: 3002.12.10, 3002.12.90)

1.2.3. Human blood (Reference no. of The Nomenclature for the External Trade of Macao / Harmonized System: 3002.90.30)

1.2.4. Animal blood prepared for therapeutic, prophylactic or diagnostic uses (Reference no. of The Nomenclature for the External Trade of Macao / Harmonized System: 3002.90.40)

1.3. Pursuant to Article 3-A of Administrative Regulation No. 28/2003 – *Regulation*

on Foreign Trade Operations, the Health Bureau has the authority to issue import licenses for the goods listed in the Import List (Table B).

2. Basic Requirements for Import of the Goods to Macao

2.1. Goods and packaging

All imports (including the packaging) must comply with the quality and safety standards of the government of the place of origin or internationally observed standards.

2.2. Justified use of the goods

The applicant must specify the import purpose.

2.3. Compliance of the packaging

The external packaging of all the imports must comply to international technical standards and regulations, such as the WHO Guidance on Regulations for the Transport of Infectious Substances.

3. Documents Required for Prior Authorisation for Import

The following documents must be submitted (in Chinese or Portuguese) by the importer for import application:

3.1. A completed application form for the prior authorisation for import of glands and other organs for organotherapeutic uses, blood plasma, human blood, and animal blood;

3.2. A completed prior authorisation for import of glands and other organs for

organotherapeutic uses, blood plasma, human blood, and animal blood;

3.3. Samples of the goods' external packaging (descriptions or images);

3.4. Descriptions of the goods;

3.5. Written consent for export issued by the competent authority in the country/region of export;

3.6. Inspection documents[1)] or non-pollutant documents[2)] for the imports;

3.7. Information about the institution with confirmed users, location and scope of use (such as medical diagnosis, scientific research, educational experiments, industrial or examination purposes), and descriptions of the disposal solution;

3.8. Supporting documents for the institution receiving the human organs and tissue for diagnosis and transplant purposes[3)] (for applications for human transplant purposes only).

4. Procedures and Fees for Import Authorisation Application

4.1. Eligibility – Companies registered as a foreign trade operator with the Economic and Technological Development Bureau.

4.2. Prior authorisation for import (with a validity of 90 days starting from the issue date of the authorisation)

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1) The Health Bureau may require the importer to provide other relevant supporting documents on a case-by-case basis, especially those regarding blood-borne diseases such as hepatitis viruses and HIV.

2) Applicants for animal blood import must comply with Law No. 7/2020 – *Animal Pandemic Prevention Law* and Chief Executive's Dispatch No. 341/2007, and the Health Bureau has the right to review and approve the applications based on the advice from relevant departments.

3) Applicants for human organ and tissue transplant must comply with Law No. 2/96/M – *Regulations on the Donation, Removal and transplant of Human Organs and Tissue*.

4.2.1. The ‘Application for Prior Authorisation’ and ‘Prior Authorisation for Import’ must be completed and submitted together with the aforementioned documents to the Centre for Disease Control and Prevention of the Health Bureau for review and approval.

4.2.2. After all the required application documents have been submitted, a ‘Prior Authorisation for Import’ will be issued within 15 working days if the relevant conditions are satisfied.

4.2.3. Any additional documents that are required must be submitted within 15 working days after the date when the application is made. The application will be cancelled in the case of late submission of the documents. The submitted documents will be archived and will not be returned.

4.3. Import license (with a validity of 30 days starting from the effective date of the license)

4.3.1. Before importing the goods, the applicant must submit the original ‘Prior Authorisation for Import’ and the completed ‘Import License’ form to the Health Bureau.

4.3.2. The ‘Import License’ form is sold at the Printing Bureau. A maximum of 5 items of goods can be entered into one ‘Import License’ form; any others should be entered into the appendix.

4.3.3. Applicants must ensure the consistency of information provided in the ‘Import License’ form and the ‘Prior Authorisation for Import’; no changes can be made without approval.

4.3.4. The Health Bureau issues an 'Import License' (usually within 2 working days).

4.3.5. The applicant handles the customs declaration and clearance formalities.

4.4. The applicant must also enquire with the port transportation authority for any application formalities that may apply (Civil Aviation Authority (air) / Marine and Water Bureau (sea) / Public Security Police Force (land) / Macao Customs Services (customs formalities).

4.5. Pursuant to Article 10-A of Law No. 7/2003 – *Foreign Trade Law*, when applying to import goods that contain dangerous substances (infectious substances) as stipulated in Item 6.2 of Chief Executive's Dispatch No. 131/2023, the applicant must abide by Law No. 12/2022 – *Law on the Control of Dangerous Substances*, Administrative Regulation No. 27/2023 and its implementation rules.

4.6. Fees and taxes – no fees are charged for the application.

5. Where to submit the documents

Importers should submit all the aforesaid documents in person to the Centre for Disease Prevention and Control of the Health Bureau (Address: Avenida do Comendador Ho Yin, Edf. de Escritórios do Governo (Qingmao), 18º andar, Macau) for review and approval.

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