MANUAL ANVISA DE IMPORTAÇÃO DE MEDICAMENTOS E PRODUTOS AFINS

Gerência de Controle Sanitário de Produtos e Empresas em Portos, Aeroportos, Fronteiras e Recintos Alfandegados - GCPAF

Brasília, junho de 2024

ANVISA
Agência Nacional de Vigilância Sanitária

CEO

Antonio Barra Torres

Director of the Fifth Directorate – Dire5

Frederico Augusto de Abreu Fernandes (substitute)

General Management of Ports, Airports, Borders and Customs Areas – GGPAF

Bruno Gonçalves Araújo Rios

Management of Health Control of Products and Companies in Ports, Airports and Borders and Customs Areas - GCPAF

Elisa da Silva Braga Bowl

Import Authorization Office for Medication - PAFME

Ana Flavia Dias Vieira da Costa

Prepared by:

Ana Flavia Dias Vieira da Costa

Monica Cristina Antunes Figueirêdo Duarte

Reviewed by:

Patricia Basilio Medeiros Carpes

gcpaf@anvisa.gov.br

INDEX

1. OBJECTIVE AND SCOPE

This manual aims to guide importers on the rules for submission and specific procedures for analyzing import processes medicines and related products under the responsibility of the Import Authorization Office of Medicines (PAME). These are imports subject to non-licensing automatic in the Integrated Foreign Trade System (Siscomex), carried out exclusively by legal entities through the Single Foreign Trade Portal. The imports of medicines through other modalities described in RDC No. 81, of 2008, do not will be covered in this manual.

The subjects are organized into topics that help with consultation on regularization of companies and products, procedural instruction and analysis and control procedures inspection, indicating the legislation and specific situations applicable to each product and purpose of import.

This material is not intended to replace the guidelines on petitioning for import process already published by Anvisa or the Manual available on the Siscomex Portal, but complement them in specific aspects of the authorization to import medicines and related products in the context of Anvisa. The general rules and procedures for submitting import processes, applicable to all product categories, are listed in the Manual: Application for an Import License through an LPCO. It is suggested that you read of this document in advance. To access this and other documents related to Ports, airports and borders, please access the link: https://www.gov.br/anvisa/pt-br/contentcenters/publications/ports-airports-and-borders .

1.1. PRODUCTS UNDER PAFME APPROVAL

The following products are subject to PAFME approval for imports, in all countries: manufacturing stages, as well as their raw materials:

- Medicines, including advanced therapy products;
- Substances subject to special control under Ordinance No. 344/1998;
- Traditional Chinese Medicine products;
- Human cells and tissues for therapeutic purposes.

The import of these products, by a legal entity, in the form of raw material, semi-finished product, bulk product or finished product, must be subjected to inspection by PAFME before customs clearance. Furthermore, for substances subject to special control of lists A1, A2, A3, B1, B2, C3, D1, E and F of Ordinance No. 344/1998, and medicines containing them, prior authorization for boarding is required granted by Anvisa.

The procedures and documents required for the import of each category of product will be discussed later in this manual.

1.2. ADMINISTRATIVE TREATMENT ON IMPORTATION

The first step when import approval is required for a medicine and related products, regardless of the obligation or exemption from regularization, is checking whether the NCM (Common Nomenclature of Mercosur) has any highlight or Anvisa marking.

At the moment, a consultation he can to be carried out for the portal https://www.gov.br/siscomex/pt-br/informacoes/tratamento-administrativos/tratamento-administrative-in-import, consulting the Administrative Treatment Simulator Siscomex, or downloading the NCM and approving body consultation table.

The indication of the NCM for each good to be imported is not under the jurisdiction of the of Anvisa. The Agency is only responsible for analyzing the request for approval after the protocol of import process for the NCMs marked/highlighted for your evaluation.

Goods subject to health inspection that have treatment administrative of Anvisa, must have the highlight selected.

For products under PAFME approval we currently have:

MEDICINES

1) Highlight:

083 - Medicine (and supplies) for industry/human use

CONTROLLED SUBSTANCES

1) Highlights:

084 - Medicines or substances with a purpose controlled by Port. SVS/MS 344/1998

090 - Cannabis Product

2) Merchandise

HUMAN BLOOD, TISSUES, CELLS AND ORGANS

1) Highlight:

087 - Blood, tissues, cells and organs

For controlled substances, there is a marking of merchandise or two highlights to be selected, depending on the controls imposed by Ordinance No. 344/1998. Therefore, all imports of products containing substances controlled by Ordinance No. 344/1998, including medicines, reference material and reference standard, if merchandise is no longer marked for Anvisa, highlights 084 or 090. It is important to highlight that the addendums to the Ordinance exempt some from control. substances, depending on the purpose. The importer must be aware of this.

Regarding the highlighting of other medicines and pharmaceutical supplies, 083, this must be selected whenever a medicine is imported, in any manufacturing stage, for human use, or pharmaceutical inputs that are part of the formulation of medicines for human use. It should be clarified that the purpose given to the product by the importer does not change its category: medicine or pharmaceutical input. If it is a medicine indicated in its regulation for human use, regardless of the purpose of import, it is a product subject to sanitary intervention and must be included from Anvisa's highlight. The same applies to pharmaceutical inputs. Even if it is used for laboratory tests, the final product of which will not be used on humans, if it is an input pharmaceutical that integrates/will integrate the final composition of a medicine, is a product of Anvisa's health intervention. Now, if it is a medicine for exclusive use veterinarian, for example, that does not have a controlled substance, this is not an intervention Anvisa's health department.

ATTENTION

If the importing company verifies the need to include a highlight Anvisa in some NCM, or even review, must formalize the request through Contact Us of the Agency. The request must be sent with the indication of the NCM, type of product and motivation prior to carrying out the import.

Findings of non-selection of Anvisa highlights, for products that have The need for Anvisa's consent constitutes a health infraction under the terms of Law no. 6437/1977.

1.3. IMPORT PURPOSES

The import purposes under the responsibility of PAFME analysis are provided for in the regulations Resolutions of the Collegiate Board (RDC): RDC nº 81/2008, RDC nº 38/2013, DRC No. 08/2014, DRC No. 09/2015, DRC No. 172/2017, DRC No. 203/2017, DRC No. 488/2021, RDC nº 506/2021 and RDC nº 660/2022, arranged in subject codes specific terms under RDC nº 222/2006, described below:

1. Commercial/Industrial;
2. Tests - non-regularized products;
3. Proficiency Test;
4. Public Health Programs - Ministry of Health or public entities SUS members;
5. Exclusive use in healthcare units;
6. Clinical research and assistance programs;
7. Scientific, technological or human research, without registration purposes in the country;
8. *Cannabis-derived products,* by individuals, for their own use – import intermediated;

9. Human cells and tissues for therapeutic purposes;

10. Donation;

11. Supply of international transport means;

12. Exported goods or products produced in the national territory and returned.

The procedures and documentary instructions for each import purpose will be dealt with later in this manual. Purposes 9, 10, 11 and 12 are governed by the Chapter XXIII/DRC no 771/2002, Chapters X/XI, Chapter XXX and Chapter XXXII of DRC no 81/2008, respectively, and will be addressed in the next versions of this Manual.

2. COMPANIES INVOLVED IN IMPORT LOGISTICS

2.1. IMPORTERS

According to Law No. 6,360/1976, the import of medicines, drugs and supplies pharmaceuticals is an exclusive activity to be carried out by companies authorized by Anvisa, considering further that the link is established according to the specific category of product. It is important to note that as provided for in art. 9: “They are independent of a license for operation of the establishments covered by this Law that are part of the Administration Public or instituted by it, being subject, however, to the requirements pertinent to facilities, equipment and appropriate apparatus and assistance and technical responsibilities”.

Furthermore, Ordinance No. 344/1998 determines that for imports, for any purpose, of substances subject to special control (Annex I), their updates, or the For medicines containing them, it is mandatory to obtain a Special Authorization (AE) granted by Anvisa.

Currently, there are two Collegiate Board Resolutions (RDC) that govern the granting of Operating Authorization for Companies (AFE), for importers of medicines: RDC nº 16/2014 and RDC nº 61/2004. The AE grant is arranged in the DRC No. 16/2014.

Companies that operate in import operations on behalf of a third party or request, under the terms of the Federal Revenue Normative Instruction - IN RFB nº 1861/2018, must have AFE granted by RDC No. 61/2004 for the category of medicines. No

imports on behalf of a third party or order of products and substances
subject to special control, since the importer must have an AE.

The AFE, both from RDC nº 16/2014 is granted to the matrix and extends to its branches. The AFE of RDC nº 61/2004 is granted to the head office, and the branches are responsible for registering as a secondary petition in the AFE of the head office. The AE must be requested by each establishment importer.

2.1.1. Exemptions regarding AFE and AE

Regarding the scope of PAFME's activities, the exemptions for AFE and AE stand out. provided for in the regulations below.

As provided for in Ordinance No. 344/1998:

> *Art. 8 Companies, institutions and bodies are exempt from Special Authorization. in the execution of the following activities and categories linked to them:*
>
> *...*
>
> *II - Narcotics Repression Agencies;*
>
> *III - Clinical Analysis Laboratories that use substances covered by this Technical Regulation for diagnostic purposes only.*
>
> *IV - Reference Laboratories that use substances covered by this Technical Regulation for carrying out analytical tests to identify drugs.*

Furthermore, RDC nº 16/2014 provides for the following exemptions:

> *Art. 5º AFE is not required from the following establishments, companies or activities:*
>
> *...*
>
> *VII - import products intended exclusively for clinical trials, expanded access program, compassionate use program and provision of post-study medication, provided that the company is holder of an authorizing document necessary for the request import, issued by Anvisa, necessary for the execution of the certain program;*
>
> *VIII - import products intended exclusively for laboratory analysis for quality control or for developing new products;*

> *IX - Scientific, technological, innovation and development institutions experimental that exclusively carry out basic research activities or applied scientific, technological or new development nature products, services or processes.*
>
> ...
>
> *Art. 5º-A. The activity of importing into the AE of the holding companies is not required. of AE of Laboratory or Research Institution for import of products intended exclusively for own use in research activities.*

Importer regularization requirements will be addressed later in this manual, considering product and import purpose.

2.2. STORAGE IN CUSTOMS AREAS

RDC nº 346/2002 establishes what is understood as customs premises:

a) primary zone: duty-free stores, yards, warehouses, terminals and other locations intended for the movement and storage of imported goods or goods intended for exports that must move or remain under customs control, as well as the areas reserved for checking baggage destined for or coming from abroad;

b) secondary zone: warehouses, warehouses, terminals or other units intended for the storage of goods under the conditions of the previous item, as well as those facilities intended for the storage of international postal shipments and shipments expressed.

Companies that provide storage services for goods under surveillance sanitary, in establishments installed in Water Terminals, Organized Ports, Airports, Border Posts and Customs Areas must have AFE under the terms of RDC nº 346/2002. Furthermore, companies providing storage services for substances contained in the lists attached to Ordinance No. 344/1998, and its amendments, and the medicines that contain them, in establishments installed in Water Terminals, Ports Organized, Airports, Border Posts and Customs Areas must have AE, in terms of RDC nº 346/2002.

To be considered a bonded warehouse, the company must have permission or concession from the competent body of the Ministry of Finance to operate as a Precinct Customs.

The AFE for storage in a customs area is granted to the company's head office and will be valid throughout the national territory. Branches must have a registration linked to the matrix AFE process, granted and valid.

The AE granted to the company that operates substance storage activities subject to special control and medicines containing them, must be requested for each establishment where the service is provided.

2.3. TRANSPORTERS

2.3.1 During customs transit

Customs transit is a special regime that allows the transportation of goods, under customs control, from one point to another in the customs territory, with suspension of payment of taxes. In import customs transit, the goods in transport is not nationalized. For customs transit clearance to occur, it is necessary to processing of one of the following statements:

- Customs Transit Declaration (DTA);
- International Cargo Manifest - Customs Transit Declaration (MIC-DTA);
- International Waybill - Customs Transit Declaration (TIF-DTA);
- Transfer Transit Declaration (DTT);
- Container Transit Declaration (TCD); OR
- Declaration of International Transshipment or Transfer (DTI).

RDC nº 208/2018 extinguished the obligation to communicate to the health authority of customs transit. Therefore, Anvisa's statement regarding imported goods is restricted to import consent, which occurs after the transit regime, as well as well as the effective movement of the product.

However, it is up to the importer to adopt good transportation and storage, since it is responsible for preserving quality attributes, safety and efficacy of products and for maintaining transport conditions and storage established by the manufacturer. In this case, the hiring of companies regularized before health surveillance for transport activities and that meet the

Good transportation practices should always be a key point in medicine logistics and related products.

The application of customs transit regimes to the import of goods is prohibited. products belonging to the following classes and categories:

a) substances and medicines subject to special control, from lists A1, A2, A3, B1, B2, C3, D1, E and F from Portaria nº 344/1998;

b) thalidomide and medicines based on this active ingredient;

c) human cells and tissues for therapeutic purposes; and

d) goods or products suspected of having compromised their identity standard and quality, or in emergency and provisional situations, by measures related to the international health and epidemiological context.

ATTENTION

When storing dangerous, heat-sensitive or heat-requiring products of power generator, the importer must pay special attention to the AFE of the customs area, which must contemplate this differentiated condition of storage in your inspection report.

2.3.2 After customs clearance

Companies that transport nationalized goods, after once customs clearance has been completed, they must hold an AFE or AE, whichever is applicable, in the terms of RDC nº 16/2014.

This information is not subject to the assessment of import consent, as it refers to stage after the clearance of the goods. However, the importer is fully responsible responsibility in hiring authorized companies that comply with good practices transport practices in accordance with specific health legislation in force.

3. MEDICINES AND RELATED PRODUCTS

As already described in item 1.1., the import of the following is subject to PAFME approval: following products, at all stages of manufacturing, as well as their raw materials:

- Medicines, including advanced therapy products;
- Substances subject to special control under Ordinance No. 344/1998;
- Traditional Chinese Medicine products;
- Human cells and tissues for therapeutic purposes.

3.1. MEDICINES

According to concepts and definitions available on the Anvisa Portal, medicine is the pharmaceutical product, technically obtained or prepared, with prophylactic purposes, curative, palliative or for diagnostic purposes.

Regulatory categories of medicines are: new, similar, generic, biological, radiopharmaceuticals, specific, phytotherapeutics, dynamized, low-risk drugs and gases medicinal.

As provided for in art. 12 of Law No. 6,360/1976, none of the products covered this Law, including imported ones, may be industrialized, exposed for sale or delivered to the consumption before being registered with the Ministry of Health. Thus, the medicines marketed in Brazil are subject to notification, authorization or registration with Anvisa, registration being the most frequent form of regularization:

- Medicines with health authorization: the following are subject to Health Authorization: *Cannabis* product for medicinal purposes, under the terms of RDC nº 327/19;
- Notified drugs: low-risk drugs, some drugs dynamized, some medicinal gases and traditional herbal products are subject to notification, as provided for in the specific regulations of each category;
- Registered medicines: other medicines are registered with the Anvisa.

In the case of importing a finished product, the registration number must be informed. or the health authorization of the presentation being imported. If the importer does not

is the registration holder, the Registration Holder Declaration (DDR) must be attached to the LPCO. The conditions of the imported product such as: the description of the presentation, the validity of the registration, the shelf life of the product, the storage conditions, the manufacturer and product formula, must be in accordance with its regularization with the Anvisa.

In the case of importing medicine in bulk, in addition to the information above, It will be verified whether the importer, orderer or purchaser is listed as the manufacturer in the regularization of the product for the packaging stage.

For drugs subject to notification, there must be active notification for that product/company. Likewise, the conditions of the imported product such as, description of the presentation, the shelf life of the product, storage conditions, the manufacturer and formula of the product, must be in accordance with the regularization of this with to Anvisa.

ATTENTION

The conditions of the imported product must be the same as those for regularizing the product in force with Anvisa at the time of manufacture of the imported batch. In In case of discrepancies, the import is subject to rejection and prohibition.

3.1.1. Biological medicines

As set out in RDC nº 55/2010, the categories of biological medicines are:

1. Vaccines:

Immunobiological drugs containing one or more antigenic substances which, when inoculated, are capable of inducing active specific immunity in order to protect against, reduce the severity of or combat the disease(s) caused by the agent that caused the antigen(s).

2. Hyperimmune serums:

They are whole or fragmented, purified heterologous immunoglobulins, obtained from from plasma of animals hyperimmunized with toxic substances originating from animals, microorganisms or viruses.

3. Blood products:

They are pharmaceutical products obtained from human plasma, subjected to industrialization and standardization processes that give them quality, stability, activity and specificity.

4. Biomedicines – classified into:

a) medicines obtained from biological fluids or tissues of origin animal; and

b) medicines obtained through biotechnological procedures;

5. Monoclonal Antibodies:

They are immunoglobulins derived from the same clone of B lymphocyte, whose cloning and propagation takes place in continuous cell lines;

6. Medicines containing live, attenuated or dead microorganisms;

7. Probiotics:

They are preparations or products containing defined and viable microorganisms in sufficient quantity to alter the microbiota, by implantation or colonization, of a compartment of the host and thus exert a beneficial effect on the health of that host.

8. Allergens (allergenic products):

They are substances, generally of protein origin, present in animals or plants, capable of inducing an IgE response and/or a type I allergic reaction.

The documents and procedures for importing biological products vary, depending on according to the product category as described later in this manual.
Therefore, the importer must identify the category of the biological medicine or input. imported active pharmaceutical to correctly classify it in the procedures import.

Furthermore, RDC No. 669/2022 provides for the minimum requirements to guarantee the quality of imported biological products and exempts imported biological products finished or in their primary packaging from quality control tests in the country, as long as certain requirements are met.

Considering that most imported organic products are not submitted for analysis in Brazil, the documents and requirements are required in all imports of products regularized by Anvisa. Furthermore, the same is also adopted rational for imports with authorization from Anvisa for non-regularized products,

since the authorization exempts the product from being regularized with Anvisa, maintaining the other legal provisions in force.

One of the documents to be verified when authorizing the import of these products are continuous temperature records of the transport chain. Thus, the products imported finished or primary packaged biological products for industrial purposes, commercial or other human use, except for those used in research, has the process of import granted under health pending, for subsequent release of the Custody Term and Responsibility.

3.2. PHARMACEUTICAL SUPPLIES

3.2.1 Active pharmaceutical ingredients

Regarding regularization, all companies that import pharmaceutical inputs (IFAs) must register them with Anvisa, in accordance with art. 1 of RDC nº 637/2022.

The registration of inputs of plant origin is mandatory, as long as they are classified as active pharmaceutical ingredients. It is not necessary to register homeopathic APIs and Imported IFAs for qualification testing of new suppliers or development of new products. Furthermore, it is not possible to register *pellets* as IFAs, as they are already medicines intermediaries.

In addition to registration, according to art. 5 of RDC nº 204/2006: “The following are prohibited: import and sale of pharmaceutical inputs intended for the manufacture of medicines whose therapeutic efficacy has not yet been evaluated by the Agency National Health Surveillance Agency”. This determination is ratified by RDC No. 81/2008. In other words, so that an input can be used in the manufacture of medicine or formulas magistral, it is necessary that a medicine based on the substance has already been registered, since therapeutic efficacy is evaluated during the registration process. The records canceled may be considered, as long as they were not canceled due to problems of safety or efficacy.

Therefore, the import of IFAs must meet the criteria below, taking into account the two import types:

Import by IFA distributors

For import by a distribution company, the IFA must: (I) be registered with the Anvisa and (II) have had therapeutic efficacy assessed by Anvisa.

(I) RDC nº 637/2022 determines that all companies that import inputs active pharmaceutical ingredients (APIs) must register them with Anvisa, according to art. 1 of RDC nº. 637/2022. Therefore, the importer must inform the IFA registration process with Anvisa at the time of import.

For imports outsourced by distributors, in cases of import by order or on behalf of and order, the registration must be carried out by the orderer or the purchaser of the IFA. The presentation of an Import Authorization is not admissible by Predetermined Intermediation or DDR. Furthermore, the IFA registration in compliance with RDC No. 637/2022 is considered for the head office and its branches.

(II) Before importing the IFA, the importer must check whether there is or has been drug registered with the IFA to be imported. The importer must be careful to check it is the same substance, that is, the same Brazilian Common Denomination (DCB) and/or CAS *(Chemical Abstracts Service) number.*

To check registered medicines, simply search for active ingredient in Anvisa Portal, through the link https://consultas.anvisa.gov.br/#/medicamentos/ . The list of Brazilian Common Denominations (DCB), with the respective CAS *(Chemical Abstracts Service),* this available at https://www.gov.br/anvisa/pt-br/subjects/pharmacopoeia/dcb .

For specific medicines, herbal medicines, dynamized and notified of low risk there are other criteria for proving IFA with therapeutic efficacy assessed by Anvisa, as described below:

Specific medications:

- Medicine already registered with the IFA;
- IFAs that make up medicines that have a standard package insert.

Herbal medicines:

- Medicine already registered with the IFA;
- IFAs listed in IN nº 02/2014;
- IFAs that have a published monograph from the Committee on Herbal Medicinal Products – HMPC European Medicines Agency – EMA;

-IFAs with monograph in the Brazilian Pharmacopoeia Phytotherapeutic Formulary - FFFB;

- IFAs that make up medicines that have a standard package insert or leaflet computerized.

Dynamized medicines:

- Medicine already registered with the IFA;

- Drug notified with the IFA;

- IFAs listed in IN No. 25/2018 and IN No. 26/2018;

- IFAs with monograph in the Homeopathic Formulary of the Brazilian Pharmacopoeia;

- IFAs listed in one of the references of IN nº 27/2018.

Notified low-risk drugs:

- IFAs listed in IN nº 106/2021.

Import by/for drug manufacturer

For importation by or for a drug manufacturing company, the IFA must: (I) be registered with Anvisa and (II) be approved in the regularization of the medication for which will be used.

(I) RDC nº 637/2022 determines that all companies that import inputs active pharmaceutical ingredients (APIs) must register them with Anvisa, according to art. 1 of RDC nº. 637/2022. Therefore, the importer must inform the IFA registration process with Anvisa at the time of import.

(II) In the case of import of IFA for the manufacture of medicines regularized with Anvisa must be informed of the regularization number of the finished product. The importer must ensure that the IFA manufacturer is registered for the product informed.

If the importer is the holder of the drug registration or manufacturer of the medicine, it is not a case of outsourced import. In other cases, if the company declares importing IFA for the manufacture of a medicine manufactured/registered by another company, it is necessary to present the DDR to prove the agreement of the recipient with the operation and Import Authorization by Intermediation Predetermined, if this is the type of intermediation.

3.2.2 Other pharmaceutical inputs

The import of excipients is also subject to intervention by Anvisa, and is not applicable registration or verification of therapeutic efficacy. Therefore, when importing these inputs the company must justify their use in the production process of a medicine and/or master formula. It should be clarified that for the import of inputs pharmaceuticals, active or not, the import AFE is required, as provided in RDC no. 16/2014. Substances considered pharmaceutical inputs are available in the DCB list, available at https://www.gov.br/anvisa/pt-br/assuntos/farmacopeia/dcb .

For the import of excipients, the characteristics of the imported product to be included in the procedure of Chapter XXXIX of the RDC No. 81/2008 to be used. That is, if it is not a substance subject to special control or biological origin, the import procedure to be used is 5.3, as described later in this manual, regardless of the finished product that will be manufactured.

The import of intermediate substances used as input for manufacturing of medicines or active pharmaceutical ingredients, **but which are not part of the final composition of the finished product,** are not subject to sanitary intervention, as long as it is not substance subject to special control. Therefore, it will not be possible to select Anvisa's highlight for the import of such substances.

ATTENTION

The import of drug packaging material is not under approval of PAFME. Packaging materials that are classified as medical devices must be imported in accordance with the procedure of this category of products. The others are not subject to Anvisa's health intervention.

3.3. SUBSTANCES SUBJECT TO SPECIAL CONTROL

As provided for in Ordinance No. 344/1998, for the import, for any purpose, of substances subject to special control, or medicines containing them, is It is mandatory to obtain a Special Authorization (AE) granted by Anvisa.

Thus, the import of any substance subject to special control, regardless of purpose, would be subject to health intervention by Anvisa, given the need if the importing company has an AE granted by the Agency.

Anvisa periodically updates the Annex to Ordinance No. 344/1998, with the following inclusions/changes of substances subject to special control, as well as reviews of their addenda. The most current version of the lists and the update history are available in https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/controlados/lista-substances. Therefore, all substances/purposes listed in Annex I of Ordinance no. 344/1998, indicated as subject to special control, must be submitted for approval from Anvisa at the time of import. For medicines and pharmaceutical inputs, if the provisions of items 3.1 and 3.2 also apply.

3.3.1. Cannabidiol and *Cannabis* Products

The import of cannabidiol and *cannabis* products can be carried out by more than a procedure, depending on the purpose and imported product.

They are only subject to the controls of List C1 of Ordinance No. 344/1998 and, therefore, fall under procedure 3 of Chapter XXXIX of the Annex of RDC nº 81/2008, the synthetically obtained cannabidiol products, provided that no other products are present controlled substances, and primary cannabidiol standards. It is noteworthy that products even though they are purified, free of THC, they do not fall under list C1 because they are of origin vegetable.

Cannabis products regulated by Anvisa, registered or with Authorization Health under the terms of RDC nº 327/2019 and updates, as well as inputs pharmaceuticals, in the form of plant derivatives, phytopharmaceuticals and in bulk, based on derivatives of *Cannabis sativa,* to be used in its manufacture or testing is subject to the Procedure 1 of RDC nº 81/2008. Furthermore, exceptional authorization was granted to import of plant derivatives of *Cannabis spp.* for purification and obtaining, in the territory

national, of the pharmaceutical grade CBD phytopharmaceutical to be used in the manufacture of products of *Cannabis,* until the review and reformulation of art. 18 of RDC nº 327/2019 and updates. This import is also subject to Procedure 1 of RDC No. 81/2008.

RDC nº 660/2022 establishes that the import of products derived from *Cannabis* may occur, by an individual, for personal use, upon prescription of legally qualified professional, for health treatment. This is a product industrialized, intended for medicinal purposes, containing derivatives of the *Cannabis* plant *spp..* For these cases there is a specific procedure for import determined by RDC no. 660/2022, which will be described later in this manual.

Other imports of cannabidiol or *cannabis* products that do not qualify in the situations mentioned above they are included in List E (proscribed plants) and List F2 (proscribed psychotropic drugs) of Annex I of Ordinance No. 344/1998, being prohibited, except for teaching and research purposes. In cases of import for teaching and research purposes, they must the requirements of RDC nº 172/17 or Procedure 1A of RDC nº 81/2008 must be met.

Therefore, the importer must carry out the appropriate classification of the product to be imported in the lists of Ordinance No. 344/1998, considering its characteristics (synthetic, primary standard or plant origin), regularization with Anvisa and import purpose, to identify the most appropriate procedure for importing the following items of cannabidiol and *Cannabis products.*

The import procedures mentioned above are detailed later in this manual.

3.4. ADVANCED THERAPY PRODUCTS

As stated in RDC nº 505/2021, advanced therapy products are a special category of new drugs comprising cell therapy product advanced, the tissue engineering product and the gene therapy product. The products of advanced therapies are subject to registration with Anvisa as well as the others medicines and, therefore, follow the same criteria described in item 3.1.

3.5. TRADITIONAL CHINESE MEDICINE PRODUCTS

According to RDC nº 901/2024, Traditional Chinese Medicine (TCM) products are not are subject to health registration. However, as already mentioned, according to art. 10 of Law No. 6,360/1976, the import of medicines, drugs, supplies is prohibited pharmaceuticals and other products covered by this Law, for industrial and commercial purposes, without prior and express favorable manifestation of the Ministry of Health. Furthermore, according to art. 7 of Law No. 9,782/1999, Anvisa is responsible for consenting to the import and export of goods and products that involve a risk to public health. Therefore, even if it is not subject to registration or notification, the import of MTC products is subject to sanitary intervention by the Anvisa, given that there are already health criteria determined by the Agency.

In this case, the “regularization of the product” must fully comply with the provisions of Chinese Pharmacopoeia, as provided for in RDC No. 901/2024. For this, the composition qualitative and quantitative (proportionally) of the imported MTC product should be identical to the product monograph in the Chinese Pharmacopoeia.

Furthermore, product labeling must comply with the provisions of RDC No. 901/2024. In addition to the composition of the product, which must comply with the monograph of the Chinese Pharmacopoeia, products marketed as TCM cannot claim on their packaging indications or therapeutic claims. Furthermore, TCM products must have trade names according to their traditional designation described in references on TCM.

Importation of TCM product APIs is permitted. Similarly, the API must be described in the Chinese Pharmacopoeia and must be registered with Anvisa, under the terms of DRC No. 637/2022.

3.6. HUMAN CELLS AND TISSUES FOR THERAPEUTIC PURPOSES

As provided for in Chapter XXIII of RDC No. 81/2008, the import of human cells and tissues for therapeutic purposes, provided that their purpose is proven therapeutics by the importer.

The goods in this category are:

- Skin, musculoskeletal tissue and heart valves for therapeutic purposes;
- Hematopoietic progenitor cells for therapeutic purposes;
- Human germ cells and tissues and pre-embryos for therapeutic purposes;

• Human corneas for therapeutic purposes.

These assets are not subject to registration, authorization or notification with Anvisa. In these cases, a favorable technical opinion is issued by the Blood, Tissue, and Biotechnology Management. Cells, Organs and Advanced Therapy Products (GSTCO) or importer qualification by Anvisa, in the case of germ cells, germ tissues and human embryos, own, as provided for in RDC No. 771/2022.

It should be clarified that advanced therapy products, despite being originating from human cells and tissues, do not fall into this category. These are special category of new medicines regulated by Anvisa, as described in item 3.4.

3.7. LABELING OF MEDICATIONS AND IDENTIFICATION OF LOAD

Chapter XV of RDC No. 81/2008 establishes, in item 2.6, the minimum information of labeling of medicines that must appear on the primary or secondary packaging or of transport, when the product enters the national territory:

a) Commercial name;

b) Name of manufacturer and place of manufacture;

c) Lot or batch number or code;

d) Date of manufacture; and

e) Expiry date.

For regulated medicines, the labeling must be in accordance with RDC no. 768/2022, which provides for the labeling of medicines, or regulations specific to the product category, and are authorized or notified in the regularization of the product with Anvisa.

The external packaging of each volume of imported product, regardless of the manufacturing stage, must be identified with the following information, as per Chapter V from RDC nº 81/2008:

• commercial name, when dealing with a finished or bulk product;

• name of the active ingredient underlying the formulation;

• common name or technical, chemical or biological name of the product, when it is of input or raw material intended for the production of medicines;

• batch number or code or production batch of the packaged products;

- manufacturer name, city and country;
- special care for storage, including those related to maintenance of the identity and quality of the good or product, such as temperature, humidity, luminosity, between others.

For products on lists A1, A2, A3, B1, B2, C3, D1, E and F of Ordinance No. 344/1998 It is not necessary to identify the imported volumes as set out above.

4. ANVISA IMPORT APPROVAL

The administrative procedures for classifying products with the Siscomex are described in Chapter XXXIX of RDC No. 81/2008. For products subject to With PAFME's consent, the following procedures apply for most purposes:

Substances subject to special control and medicines containing them:

- Procedure 1: raw material, semi-finished product or finished product of listas "A1", "A2", "A3", "B1", "B2", "C3" e "D1" da Portaria nº 344/1998;
- Procedure 1A: raw material, semi-finished product or finished product from lists “F” and “E” of Ordinance No. 344/1998, exclusively for teaching purposes and search;
- Procedure 3: raw material, semi-finished product or finished product of lists “C1” “C2” and “C5” of Ordinance No. 344/1998.

Exceptions to the controls of the Lists of Ordinance No. 344/1998, as well as prohibitions on import, are described in the respective addendums, considering some purposes. Therefore, we suggest that the importer consult the lists in Ordinance No. 344/1998, as well as your addendums, available in https://www.gov.br/anvisa/pt-br/subjects/medicines/controlled/substances-list, for correct framing of import.

ATTENTION

Failure to comply with the minimum labeling requirements set out in Chapter XV of RDC nº 81/2008 or specific legal provisions for labeling The medicine is subject to import denial and cargo prohibition.

Biological medicines:

- Procedure 2: raw material, semi-finished product, bulk product or finished blood product;
- Procedure 2A: raw material, semi-finished product, bulk product or finished product of serums and vaccines;
- Procedure 2B: raw material, semi-finished product, bulk product or finished product of biological products derived from source fluids or tissues animal and allergens;
- Procedure 2C: raw material, semi-finished product, bulk product or finished product of biological products obtained by procedures biotechnological, antibodies monoclonals, drugs containing live, attenuated or dead microorganisms and probiotics.

Other medicines:

- Procedure 5.3: raw material, semi-finished product, bulk product or finished product of medicines in general, not classified under previous procedures. Therefore, it applies to the importation of medicines uncontrolled synthetics (new, generic and similar), specific, notified, phytotherapeutics, dynamized, radiopharmaceuticals, medicinal gases and products of advanced therapies.
- TCM: although it is not called a medicine, for the purposes of framing of the matter in the import process requested with the Anvisa, it was decided that the best framework for the subject would be in Procedure 5.3.

The following will describe the criteria and mandatory documents for importing medicines and related products for each import purpose.

4.1. COMMERCIAL/INDUSTRIAL PURPOSE

As provided for in RDC nº 81/2008, only the import, delivery consumption, exposure for sale or human health in any capacity, of goods and products under health surveillance, which meet the health requirements set out in this Regulation and relevant health legislation. Goods and products under health surveillance, intended for trade, industry or direct consumption, should have their import authorized as long as are formally regularized before the National Health Surveillance System in concerning the obligation, where applicable, of registration, notification, registration, authorization of model, exemption from registration, or any other form of control regulated by National Health Surveillance Agency.

Therefore, the import of medicines, related products, and raw materials for their manufacturing, duly regularized with Anvisa, for sale, use and distribution, are framed within the industrial/commercial purpose.

ATTENTION

Somatropin is a substance on list C5 of Ordinance No. 344/1998 and an input active biological drug. For imports that follow the criteria of the Chapter XXXIX of RDC 81/2008, the requirements of the following must be met: biological drug procedures, except for the regularization of company, which must have AE.

4.1.1. Substances and medicines subject to special control - lists A1, A2, A3, B1, B2, C3 and D1 from Portaria nº 344/1998

The import of medicines, at any stage of manufacturing, raw materials and other products containing substances from lists A1, A2, A3, B1, B2, C3 and D1 of the Ordinance nº 344/1998 is subject to Procedure 1 of RDC nº 81/2008.

Applicable subject codes
Medicines (at all production stages), raw materials and other substances under special control: - 90311: Anvisa Import Permission, of 11 to 20 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by a legal entity for industrial or commercial purposes, in post-shipment LI/LPCO; - 90312: Anvisa Import Permission, of 11 to 20 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by a legal entity for industrial or commercial purposes, in post-shipment LI/LPCO; - 90313: Anvisa Import Permission, of 21 to 30 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by a legal entity for industrial or commercial purposes, in post-shipment LI/LPCO; - 90314: Anvisa Import Permission, of 31 to 50 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by a legal entity for industrial or commercial purposes, in post-shipment LI/LPCO; - 90315: Anvisa Import Permission, of 51 to 100 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by a legal entity for industrial or commercial purposes, in LI/LPCO post-shipment.
Applicable LPCO model
I00049
Company regularization
a) **Importation of pharmaceutical input, subject to special control, by a distributor inputs:** the company must have AE granted to the importing establishment, to import pharmaceutical inputs; b) **Importation of pharmaceutical input, subject to special control, by manufacturer medicines:** the importing company must have an AE granted for the establishment importer, to import pharmaceutical inputs and/or to manufacture medicines; c) **Importation of bulk medicine, subject to special control, by manufacturer medicines:** the importing company must have AE to import and package or manufacture medicines; d) **Importation of finished medicine (human or veterinary), subject to control special, by pharmaceutical industry or drug distributor:** the importing company must have AE to import medicines;

e) **Importation of substance, subject to special control:** the importing company must have AE to import active pharmaceutical ingredient.

Product regularization

Medicines (at all production stages):

a) Present product regularization, as explained in item 3.1.

Active pharmaceutical ingredient:

a) Present IFA registration and regularization of the finished product, when applicable, as per explained in item 3.2.

Other pharmaceutical inputs:

a) Present regularization of the finished product, when applicable, and justification for use of the product as explained in item 3.2.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Quality control analytical report;

d) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa;

e) Export Authorization (AEX) or No Objection Certificate issued by the authority competent non-external;

f) Endorsement document regarding proof of docking of the goods and products: With the integration of LPCO/LI there is no longer sending proof of cargo docking. The information of presence of the load is shown in the LPCO, in a specific field.

Mandatory documents – depending on the situation

In the case of outsourced imports:

a) DDR;

b) Import Authorization Carried Out by Predetermined Intermediation of Chapter VIII of the RDC No. 81/2008: this document is not applicable to imports of controlled products, as since every importer must have AE.

If a quantity lower than that authorized in the AI has been imported:

a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements
a) Prior boarding authorization granted by Anvisa; b) Authorized entry points, except list C3: I - Port of Rio de Janeiro, Rio de Janeiro/RJ; II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ; III - Port of Santos, Santos/SP; and IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP. In the case of products and substances on the C3 list, there is no restriction on the place of entry.
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 659/2022

Note 1: The import of all substances on the lists is subject to Procedure 1 A1, A2, A3, B1, B2, C3 and D1 of Ordinance No. 344/1998 and products that contain them. If not if it is a product subject to regulation by Anvisa, as a medicine for exclusive use veterinarian, registered with Mapa, the importer must present the number of such regularization, as justification. It should be clarified that in the case of pharmaceutical inputs, if for common human and veterinary use, imported by a distributor, it is necessary to comply with the criteria for human use.

4.1.2 Reference material and standard – lists A1, A2, A3, B1, B2, C3 and D1 of Ordinance No. 344/1998

The import of standard and reference material for proficiency testing is subject to to Anvisa's health intervention, as provided for in Chapter XX of RDC nº 81/2008. Already the The use of these products in tests other than proficiency tests is a not subject to sanitary intervention, however, considering it to be a product of intervention sanitary, Anvisa's approval is required regardless of the purpose.

Only the import of standards and samples containing substances subject to special control, according to Ordinance No. 344/1998, is subject to the approval of PAFME.

The import of reference materials and standards containing substances from the lists A1, A2, A3, B1, B2, C3 and D1 of Ordinance No. 344/1998, are also subject to Procedure 1 by RDC nº 81/2008.

Applicable subject codes
Industrial purpose – quality control: - 90408 - Anvisa Approval for Import of reference standard, material or substance, containing substance of procedure 1 or 1A by legal entity, for proficiency testing or Quality Control, in LI/LPCO. Commercial purpose: - 90520 - Anvisa approval for import of up to 10 items of standard, material or substance of reference, containing controlled substance of procedure 1 and 1A, by legal entity, for marketing, in LI/LPCO. - 90521 - Anvisa approval for import of 11 to 20 items of standard, material or substance of reference, containing controlled substance of procedure 1 and 1A, by legal entity, for marketing, in LI/LPCO. - 90522 - Anvisa approval for import of 21 to 30 items of standard, material or substance of reference, containing controlled substance of procedure 1 and 1A, by legal entity, for marketing, in LI/LPCO. - 90523 - Anvisa approval for import of 31 to 50 items of standard, material or substance of reference, containing controlled substance of procedure 1 and 1A, by legal entity, for marketing, in LI/LPCO. - 90524 - Anvisa approval for import of 51 to 100 items of standard, material or substance reference, containing controlled substance of procedure 1 and 1A, by legal entity, for marketing, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) Import for industrial purposes – quality control: the importing company must have AE to import pharmaceutical inputs, import medicines or manufacture medicines;

b) Import for industrial purposes – quality control, by Laboratory or Institution

Research: case intended exclusively for personal use in research activities, which includes new product development.

c) Import for commercial purposes: the importing company must have an AE to import pharmaceutical inputs or import medicines.

Product regularization

Not applicable

If it is a “reference sample” of a product regularized by Anvisa, the import must follow the provisions set out in item 4.1.1.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Analytical quality control report, except when it concerns imports of primary reference standards; (even if not mandatory, we suggest presenting a form technique or certificate of analysis for primary standards, to enable the analysis of product framing)

d) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa. Check the addenda of the aforementioned lists for exceptions regarding quantities;

e) Export Authorization (AEX) or No Objection Certificate issued by the authority competent authority abroad. Check the addenda of the aforementioned lists for exceptions regarding quantities.;

f) Endorsement document regarding proof of docking of the goods and products: With the integration of LPCO/LI there is no longer sending proof of cargo docking. The information of presence of the load is shown in the LPCO, in a specific field;

g) Term of Responsibility of Chapter XXXVIII of RDC nº 81/2008, declaring the purpose import, given that it is not a Reference Standard for Proficiency testing.

Mandatory documents - depending on the situation

If a quantity lower than that authorized in the AI has been imported:

a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.

Mandatory requirements

a) Prior boarding authorization granted by Anvisa;

b) Authorized entry points, except list C3: I - Port of Rio de Janeiro, Rio de Janeiro/RJ; II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ; III - Port of Santos, Santos/SP; and IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP. In the case of products and substances on the C3 list, there is no restriction on the place of entry.
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 81/2008, DRC No. 659/2022

Note 1: Impurity standards

Impurities in controlled substances are not necessarily subject to same control as the original substance. Therefore, if the importer does not know the classification of the impurity standard to be imported, you must consult the Coordination of Control and International Trade of Controlled Products (Cocic), through Fale With us, to fit into the correct procedure. If it is not a substance subject to special control, the import is not approved by PAFME and must be carried out as per Reference Standard Import Manual.

Note 2: Reference material and standard for drug enforcement agencies

Imports intended for research and laboratory analysis carried out by law enforcement agencies drugs when carrying out their activities must follow the provisions of RDC nº 172/17 and, therefore, it will be addressed in item 4.7.4.1.3. Substances and medicines subject to control special - lists C1, C2 and C5 of Ordinance No. 344/1998

The import of medicines, at any stage of manufacturing, raw materials and other products containing substances from lists C1, C2 and C5 of Ordinance No. 344/1998 is subject to Procedure 3 of RDC nº 81/2008.

Applicable subject codes
Medicines (at all production stages), raw materials and other substances under special control: - 90321: Anvisa Import Authorization for up to 10 items of medicines and substances that compose, subject to special control, of procedure 3, by legal entity for industrial purposes or commercial, in LI/LPCO; - 90322: Anvisa Consent for the Import of 11 to 20 items, of medicines and substances that compose, subject to special control, of procedure 3, by legal entity for industrial purposes or commercial, in LI/LPCO; - 90323: Anvisa Consent for the Import of 21 to 30 items, of medicines and substances that compose, subject to special control, of procedure 3, by legal entity for industrial purposes or commercial, in LI/LPCO; - 90324: Anvisa Consent for the Import of 31 to 50 items, of medicines and substances that compose, subject to special control, of procedure 3, by legal entity for industrial purposes or commercial, in LI/LPCO; 90325 - Anvisa Consent for the Import of 51 to 100 items, of medicines and substances that compose, subject to special control, of procedure 3, by legal entity for industrial purposes or commercial, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) **Importation of pharmaceutical input, subject to special control, by a distributor inputs:** the company must have AE granted to the importing establishment, to import pharmaceutical inputs; b) **Importation of pharmaceutical input, subject to special control, by manufacturer medicines:** the importing company must have an AE granted for the establishment importer, to import pharmaceutical inputs and/or to manufacture medicines; c) **Importation of bulk medicine, subject to special control, by manufacturer medicines:** the importing company must have AE to import and package or manufacture medicines; d) **Importation of finished medicine (human or veterinary), subject to control special, by pharmaceutical industry or drug distributor:** the importing company must have AE to import medicines;

e) **Importation of substance, subject to special control:** the importing company must have AE to import active pharmaceutical ingredient.

Product regularization

Medicines (at all production stages):

a) Present product regularization, as explained in item 3.1.

Active pharmaceutical ingredient:

a) Present IFA registration and regularization of the finished product, when applicable, as per explained in item 3.2.

Other pharmaceutical inputs:

a) Present regularization of the finished product, when applicable, and justification for use of the product as explained in item 3.2.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Quality control analytical report.

Mandatory documents – depending on the situation

In the case of outsourced imports:

a) DDR;

b) Import Authorization Carried Out by Predetermined Intermediation of Chapter VIII of the RDC No. 81/2008: this document is not applicable to imports of controlled products, as since every importer must have AE.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.

Legal basis

DRC No. 68/2003, DRC No. 81/2008, DRC No. 659/2022

Note 1: The import of all substances on the lists is subject to Procedure 3 C1, C2 and C5 of Ordinance No. 344/1998 and products containing them. If it is not a product subject to regularization by Anvisa, as a medicine for exclusive veterinary use, registered with Mapa, the importer must present the number of such regularization, as justification. It should be clarified that, in the case of pharmaceutical inputs, if they are in common use human and veterinary, imported by distributor, must comply with the criteria for use human.

4.1.4 Reference material and standard – lists C1, C2 and C5 of Ordinance No. 344/1998

Import of materials and reference standards containing substances listed C1, C2 and C5 of Ordinance No. 344/1998 is also subject to Procedure 3 of RDC No. 81/2008.

Applicable subject codes
Industrial purpose – quality control: - 90423 - Anvisa Approval for Import of reference standard, material or substance, containing substance of procedure 3 by legal entity, for proficiency testing or Quality Control, in LI/LPCO.. Commercial purpose: - 90525 - Anvisa approval for import of up to 10 items of standard, material or substance of reference, containing controlled substance of procedure 3, by legal entity, for marketing, in LI/LPCO. - 90526 - Anvisa approval for import of 11 to 20 items of standard, material or substance of reference, containing controlled substance of procedure 3, by legal entity, for marketing, in LI/LPCO. - 90527 - Anvisa approval for import of 21 to 30 items of standard, material or substance of reference, containing controlled substance of procedure 3, by legal entity, for marketing, in LI/LPCO. - 90528 - Anvisa approval for import of 31 to 50 items of standard, material or substance of reference, containing controlled substance of procedure 3, by legal entity, for marketing, in LI/LPCO. - 90529 - Anvisa approval for import of 51 to 100 items of standard, material or substance of reference, containing controlled substance of procedure 3, by legal entity, for marketing, in LI/LPCO.
Applicable LPCO model

I00049
Company regularization
a) **Import for industrial purposes – quality control:** the importing company must have AE to import pharmaceutical inputs, import medicines or manufacture medicines; b) **Import for industrial purposes – quality control, by Laboratory or Institution Research:** case intended exclusively for personal use in research activities, the which includes new product development. c) **Import for commercial purposes:** the importing company must have an AE to import pharmaceutical inputs or import medicines.
Product regularization
Not applicable If it is a “reference sample” of a product regularized by Anvisa, the import must follow the provisions set out in item 4.1.3.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical quality control report, except when it concerns imports of primary reference standards; (even if not mandatory, we suggest presenting a form technique or certificate of analysis for primary standards, to enable the analysis of product framing) d) Term of Responsibility of Chapter XXXVIII of RDC nº 81/2008, declaring the purpose import, given that it is not a Reference Standard for Proficiency testing.
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 81/2008, DRC No. 659/2022

Note 1: Impurity standards

Impurities in controlled substances are not necessarily subject to same control as the original substance. Therefore, if the importer does not know the classification of the impurity standard to be imported, you must consult COCIC in advance, through the Contact Us to follow the correct procedure. If this is not the case, substance subject to special control, the import is not approved by PAFME and must be carried out according to the Reference Standard Import Manual.

Note 2: Reference material and standard for drug enforcement agencies

Imports intended for research and laboratory analysis carried out by regulatory bodies drug repression in the conduct of its activities must follow the provisions of RDC No. 172/17 and will therefore be addressed in item 4.7.

4.1.5. Biological medicines – blood products

The import of biological blood-derived medicines, at any stage of manufacturing, and raw material is subject to Procedure 2 of RDC nº 81/2008.

Applicable subject codes
- 90374: Anvisa Import Authorization for up to 10 items of biological products or raw materials. raw materials that compose them, of procedure 2, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90381: Anvisa Import Authorization for 11 to 20 items of biological products or raw materials. raw materials that compose them, of procedure 2, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90382: Anvisa Import Authorization for 21 to 30 items of biological products or raw materials. raw materials that compose them, of procedure 2, by a legal entity for industrial or commercial purposes me LI/LPCO; - 90383: Anvisa Import Authorization for 31 to 50 items of biological products or raw materials. raw materials that compose them, of procedure 2, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90384: Anvisa Import Authorization for 51 to 100 items of biological products or raw materials. raw materials that compose them, of procedure 2, by a legal entity for industrial purposes or commercial, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization

a) **Import of active ingredient or semi-finished product by blood product manufacturer:** the company must have AFE granted to the parent company, to manufacture medicines;

b) **Import of finished blood products by the pharmaceutical industry:** the company must have AFE granted to the parent company, to import medicines;

c) **Third party import - account and order of third party or order:** the company Importer must have AFE for import on behalf of and order of third party for medicines (RDC nº 61/2004). The purchaser/orderer must have the corresponding AFE, according to items a e b.

Product regularization

Medicines (at all production stages):

a) Present product regularization, as explained in item 3.1.

Active pharmaceutical ingredient:

a) Present IFA registration and regularization of the finished product, as explained in item 3.2.

Other pharmaceutical inputs:

a) Present regularization of the finished product, when applicable, and justification for use of the product as explained in item 3.2.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture.

Mandatory documents – depending on the situation

In the case of importing a finished product or in primary packaging:

a) Good Manufacturing Practices Certificate (CBPF);

b) Custody and Responsibility Term (TGR);

c) Analytical report on quality control of the bulk product, for imported products in primary packaging.

In the case of outsourced imports:

a) DDR;

b) Import Authorization Carried Out by Predetermined Intermediation of Chapter VIII of the RDC No. 81/2008, if importing by order or order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

In the case of import in primary packaging:

a) Imported biological products in their primary packaging must contain the identification on each container - number or alphanumeric code - that identifies the production batch.

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality;
- 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;
- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state.

Mandatory documents:

a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt;

b) Certificate of release of the finished biological product batch;

c) Satisfactory analytical report, issued by INCQS.

Mandatory documents – depending on the situation:

- If a temperature excursion occurs during the transportation of imported cargo

a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.

Legal basis

DRC No. 68/2003, DRC No. 81/2008, DRC No. 900/2024, DRC No. 412/2020, DRC No. 669/2022

4.1.6. Biological medicines – serums and vaccines

The import of biological medicines – serums and vaccines, at any stage of manufacturing, and raw material is subject to Procedure 2A of RDC nº 81/2008.

Applicable subject codes
- 90376: Anvisa Import Authorization for up to 10 items of biological products or raw materials. raw materials that compose them, of procedure 2A, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90377: Anvisa Import Authorization for 11 to 20 items of biological products or raw materials. raw materials that compose them, of procedure 2A, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90385: Anvisa Import Authorization for 21 to 30 items of biological products or raw materials. raw materials that compose them, of procedure 2A, by a legal entity for industrial purposes or commercials in LI/LPCO; - 90386: Anvisa Import Authorization for 31 to 50 items of biological products or raw materials. raw materials that compose them, of procedure 2A, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90387: Anvisa Import Authorization for 51 to 100 items of biological products or raw materials. raw materials that compose them, of procedure 2A, by a legal entity for industrial purposes or commercial, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) **Import of active ingredient or semi-finished product by serum/vaccine manufacturer:** company must have AFE granted to the parent company, to manufacture medicines; b) **Import of finished serum/vaccine, by pharmaceutical industry:** the company must have AFE granted to the parent company, to import medicines; c) **Third party import - account and order of third party or order:** the company Importer must have AFE for import on behalf of and order of third party for medicines (RDC nº 61/2004). The purchaser/orderer must have the corresponding AFE, according to items a e b.
Product regularization
Medicines (at all production stages):

a) Present product regularization, as explained in item 3.1.

Active pharmaceutical ingredient:

a) Present IFA registration and regularization of the finished product, as explained in item 3.2.

Other pharmaceutical inputs:

a) Present regularization of the finished product, when applicable, and justification for use of the product as explained in item 3.2.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture.

Mandatory documents – depending on the situation

In the case of importing a finished product or in primary packaging:

a) Good Manufacturing Practices Certificate (CBPF);

b) Custody and Responsibility Term (TGR);

c) Analytical report on quality control of the bulk product, for imported products in primary packaging.

In the case of outsourced imports:

a) DDR;

b) Import Authorization Carried Out by Predetermined Intermediation of Chapter VIII of the RDC No. 81/2008, if importing by order or order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

In the case of import in primary packaging:

a) Imported biological products in their primary packaging must contain the identification on each container - number or alphanumeric code - that identifies the production batch.

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in

next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days. - The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.
TGR Release
Applicable secondary subject codes: - 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality; - 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State; - 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state. Mandatory documents: a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch. Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 412/2020, DRC No. 669/2022

Seasonal influenza vaccine

Annually, seasonal influenza vaccine strains are updated, which requires a change in the product's registration with Anvisa.

According to the new post-registration regulations for biological products, RDC nº 413/2020 and IN nº 65/2020, all seasonal influenza vaccines that have a Production strain update protocol approved by Anvisa may have post-strain update record classified as a minor, implementation change immediately, as long as the conditions set out in the aforementioned regulations are met. Case

If this update protocol is not approved, the post-registration petition remains subject to prior manifestation of Anvisa for its implementation.

Thus, during the period of adaptation for the registration of seasonal influenza vaccines, due to to the update of strains, there will be two possibilities for import approval:

• Registration process subject to minor quality changes

- If there is already a protocol for the annual update petition and it is approved, the import of the product will be deferred.

- If there is no protocol for the annual update petition or it has not yet been approved by the Biological Products Evaluation Management (GPBIO), the import will be granted, but will be included as a health issue to be resolved when releasing the TGR.

• Registration process subject to moderate quality changes

- If there is already a protocol for the annual update request and it is approved, the import of the product will be deferred.

- If there is already a protocol for the annual update petition and it has not yet been analyzed by GPBIO, the import will be approved, but will be included as a pending health issue to be remedied upon release of the TGR.

- If there is no protocol for the annual update petition, a requirement will be issued sanitary, subject to rejection and prohibition of the cargo.

4.1.7. Biological medicinal products – derived from fluids or tissues of animal origin and allergens

The import of biological medicinal products derived from source fluids or tissues animal and allergens, at any stage of manufacturing, and raw material is subject to Procedure 2B of RDC nº 81/2008.

Applicable subject codes
- 90378: Anvisa Import Authorization for up to 10 items of biological products or raw materials. raw materials that compose them, of procedure 2B, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90379: Anvisa Import Authorization for 11 to 20 items of biological products or raw materials. raw materials that compose them, of procedure 2B, by a legal entity for industrial purposes or commercial, in LI/LPCO;

- 90388: Anvisa Import Authorization for 21 to 30 items of biological products or raw materials. raw materials that compose them, of procedure 2B, by a legal entity for industrial purposes or commercials in LI/LPCO; - 90389: Anvisa Import Authorization for 31 to 50 items of biological products or raw materials. raw materials that compose them, of procedure 2B, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90390: Anvisa Import Authorization for 51 to 100 items of biological products or raw materials. raw materials that compose them, of procedure 2B, by a legal entity for industrial purposes or commercial, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) **Import of active input or semi-finished product by product manufacturer biological:** the company must have AFE granted to the parent company, to manufacture medicines; b) **Import of finished biological product, by pharmaceutical industry:** the company must have AFE granted to the parent company, to import medicines; c) **Third party import - account and order of third party or order:** the company Importer must have AFE for import on behalf of and order of third party for medicines (RDC nº 61/2004). The purchaser/orderer must have the corresponding AFE, according to items a e b.
Product regularization
Medicines (at all production stages): a) Present product regularization, as explained in item 3.1. Active pharmaceutical ingredient: a) Present IFA registration and regularization of the finished product, as explained in item 3.2. Other pharmaceutical inputs: a) Present regularization of the finished product, when applicable, and justification for use of the product as explained in item 3.2.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product.

Mandatory documents – depending on the situation
In the case of importing a finished product or in primary packaging: a) Good Manufacturing Practices Certificate (CBPF); b) Custody and Responsibility Term (TGR); c) Analytical report on quality control of the bulk product, for imported products in primary packaging. In the case of outsourced imports: a) DDR; b) Import Authorization Carried Out by Predetermined Intermediation of Chapter VIII of the RDC No. 81/2008, if importing by order or order. If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
In the case of import in primary packaging: a) Imported biological products in their primary packaging must contain the identification on each container - number or alphanumeric code - that identifies the production batch.
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days. - The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.
TGR Release
Applicable secondary subject codes: - 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality; - 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;

- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state. Mandatory documents: a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch. Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 412/2020, DRC No. 669/2022

4.1.8. Biological medicines – obtained by biotechnological procedures, antibodies monoclonal, containing live, attenuated or dead microorganisms and probiotics

The import of biological medicines – obtained through procedures biotechnological, monoclonal antibodies, containing live microorganisms, attenuated or dead and probiotics, at any stage of manufacturing, and raw material is subject to Procedure 2C of RDC nº 81/2008, including somatropin and the products that contain.

Applicable subject codes
- 90380: Anvisa Import Authorization for up to 10 items of biological products or raw materials. raw materials that compose them, of procedure 2C, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90375: Anvisa Import Authorization for 11 to 20 items of biological products or raw materials. raw materials that compose them, of procedure 2C, by a legal entity for industrial purposes or commercial, in LI/LPCO; - 90391: Anvisa Import Authorization for 21 to 30 items of biological products or raw materials. raw materials that compose them, of procedure 2C, by a legal entity for industrial purposes or commercials in LI/LPCO; - 90392: Anvisa Import Authorization for 31 to 50 items of biological products or raw materials. raw materials that compose them, of procedure 2C, by a legal entity for industrial purposes or commercial, in LI/LPCO;

- 90393: Anvisa Import Authorization for 51 to 100 items of biological products or raw materials.
raw materials that compose them, of procedure 2C, by a legal entity for industrial purposes or
commercial, in LI/LPCO.

Applicable LPCO model

I00048

Company regularization

Somatropin (list C5, Ordinance No. 344/1998):

a) **Importation of active pharmaceutical ingredients, by an input distributor:** the company must have an AE granted to the importing establishment, to import pharmaceutical inputs;

b) **Importation of active pharmaceutical ingredient, by manufacturer of biological products :** The company must have an AE granted to the importing establishment to import inputs pharmaceuticals or to manufacture medicines;

c) **Importation of medicine in bulk, by a manufacturer of biological products:** the company must have AE granted to the importing establishment to import and package medicines or to manufacture medicines;

d) **Importation of finished biological product, by pharmaceutical industry or distributor medicines:** the company must have an AE granted to the importing establishment to import medicines;

Other biological products:

a) **Importation of active pharmaceutical ingredients, by an input distributor:** the company must have AFE granted to the parent company, to import pharmaceutical inputs;

b) **Importation of active pharmaceutical ingredient, by manufacturer of biological products :** company must have AFE granted to the parent company, to import pharmaceutical inputs or to manufacture medicines;

c) **Import of biological product in bulk, by manufacturer of biological products :** company must have AFE granted to the head office, to import and package medicines or to manufacture medicines;

d) **Importation of finished biological product, by pharmaceutical industry or distributor medicines:** the company must have AFE granted to the parent company, to import medicines;

e) **Third party import - account and order of third party or order:** the company Importer must have AFE for import on behalf of and order of third party for medicines (RDC nº 61/2004). The purchaser/orderer must have the corresponding AFE, according to items of “a”, “b”, “c” and “d”.

Product regularization

Medicines (at all production stages):

a) Present product regularization, as explained in item 3.1.

Active pharmaceutical ingredient:

a) Present IFA registration and regularization of the finished product, when applicable, as per explained in item 3.2.

Other pharmaceutical inputs:

a) Present regularization of the finished product, when applicable, and justification for use of the product as explained in item 3.2.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

d) summary protocol for the production of the product (according to the WHO standard protocol, if the product is included in it).

Mandatory documents – depending on the situation

If the product contains blood derivatives in its formulation:

a) Certificate of release of the finished product batch, issued by the country's health authority manufacturing. (the batch number on the certificate must match the batch number of the blood derivative used in the formulation);

b) Technical documents of the blood product used as a stabilizer: (1) declaration of origin of the plasma used, (2) certificate of analysis of the quality control of the plasma used and (3) certificate of release of the serology of the plasma used.

In the case of importing a finished product or in primary packaging:

a) Good Manufacturing Practices Certificate (CBPF);

b) Custody and Responsibility Term (TGR);

c) Analytical report on quality control of the bulk product, for imported products in primary packaging.

In the case of outsourced imports:

a) DDR;

b) Import Authorization Carried Out by Predetermined Intermediation of Chapter VIII of the RDC No. 81/2008, if importing by order or order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

In the case of import in primary packaging:

a) Imported biological products in their primary packaging must contain the identification on each container - number or alphanumeric code - that identifies the production batch.

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality;
- 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;
- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state.

Mandatory documents:

a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt;

b) Certificate of release of the finished biological product batch.

Mandatory documents – depending on the situation:

- If a temperature excursion occurs during the transportation of imported cargo

a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.

Legal basis

DRC No. 68/2003, DRC No. 81/2008, DRC No. 412/2020, DRC No. 669/2022

4.1.9. Other medicines

The import of other medicines, at any stage of manufacture, and raw material, which do not contain substances subject to special control of Ordinance No. 344/1998 and are not inputs or finished products of biological medicines, are subject to Procedure 5.3 of RDC No. 81/2008, including MTC products.

Applicable subject codes
Considering the short shelf life of some radiopharmaceuticals and therapy products advanced, there are separate codes for these product categories. Therefore, despite all be subject to Procedure 5.3, the importer must pay attention to the full description of the subject code. RADIOPHARMACEUTICAL drugs (at all production stages) and raw materials: - 90316: Anvisa Consent for the Import of up to 10 items of radiopharmaceuticals and raw materials that compose them, of procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO; - 90317: Anvisa Consent to Import up to 11 to 20 items of radiopharmaceuticals and raw materials that compose them, of procedure 5.3, by a legal entity for industrial or commercial purposes, in LI/LPCO; - 90318: Anvisa Consent to Import up to 21 to 30 items of radiopharmaceuticals and raw materials that compose them, of procedure 5.3, by a legal entity for industrial or commercial purposes, in LI/LPCO; - 90319: Anvisa Consent to Import up to 31 to 50 items of radiopharmaceuticals and raw materials that compose them, of procedure 5.3, by a legal entity for industrial or commercial purposes, in LI/LPCO; - 90320 - Anvisa Consent for Import of up to 51 to 100 items of radiopharmaceuticals and raw materials that compose them, of procedure 5.3, by a legal entity for industrial or commercial purposes, in LI/LPCO. ADVANCED THERAPY PRODUCTS: - 90291 - Anvisa Import Authorization for up to 10 items of advanced therapy products, from procedure 5.3, by legal entity, for industrial or commercial purposes, in LI/LPCO. Other drugs subject to procedure 5.3 and (at all production stages) and raw material: - 90331 - Anvisa approval for the import of up to 10 items of medicines and raw materials that compose them, of procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO;

- 90332 - Anvisa Consent for the Import of 11 to 20 items of medicines and raw materials that compose them, of procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO;

- 90333 - Anvisa Consent for the Import of 21 to 30 items of medicines and raw materials that compose them, of procedure 5.3, by legal entity, for industrial or commercial purposes, in LI/LPCO;

- 90334 - Anvisa Consent for the Import of 31 to 50 items of medicines and raw materials that compose them, of procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO;

- 90335 - Anvisa Consent to Import 51 to 100 items of medicines and raw materials that compose them, of procedure 5.3, by a legal entity for industrial or commercial purposes, in LI/LPCO.

Applicable LPCO model

I00048

Company regularization

a) **Importation of active pharmaceutical ingredients, by an input distributor:** the company must have AFE granted to the Head Office, to import pharmaceutical inputs;

b) **Importation of active pharmaceutical ingredient, by drug manufacturer:** the company must have AFE granted to the parent company, to import pharmaceutical inputs or to manufacture medicines;

c) **Importation of medicine in bulk, by a medicine manufacturer:** the company must have AFE granted to the Head Office, to import and package medicines or to manufacture medicines;

d) **Importation of finished medicine, by pharmaceutical industry or distributor medicines:** the company must have AFE granted to the Head Office, to import medicines;

e) **Importation on behalf of and by order of a third party of a product not subject to special control :** importing company must have AFE for import on behalf of and order of a third party medicines (RDC nº 61/2004). The purchaser must have the corresponding AFE, according to items of “a”, “b”, “c” and “d”.

f) **Importation of TCM product:** there is no requirement for AFE for the importation of products of the MTC, given that they are not classified as products subject to AFE established in the art. 3º of RDC nº 16/2014.

Product regularization

Medicines (at all production stages):

a) Present product regularization, as explained in item 3.1.

Active pharmaceutical ingredient:

a) Present IFA registration and regularization of the finished product, when applicable, as per explained in item 3.2.

Other pharmaceutical inputs:

a) Present regularization of the finished product, when applicable, and justification for use of the product as explained in item 3.2.

TCM Products

a) Composition of the product according to the Chinese Pharmacopoeia monograph, as per explained in item 3.5.

Mandatory documents

d) Commercial invoice;

e) Bill of lading or extract from the CCT (air transport);

f) Analytical quality control report.

Mandatory documents – depending on the situation

In the case of outsourced imports:

a) DDR;

b) Import Authorization Carried Out by Predetermined Intermediation of Chapter VIII of the RDC No. 81/2008, if importing by order or order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

If it is a TCM product:

a) Labelling statements, labelling model or other equivalent document.

This is not a mandatory document provided for in the regulations, but it is suggested that it be presented. document to enable the analysis of the qualitative and quantitative composition of the product in relation to product monograph in the Chinese Pharmacopoeia.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.

- For radiopharmaceuticals, as provided for in RDC No. 738/2022, it is necessary to attach to the dossier import documentation after cargo clearance. However, these are requirements for purposes of inspection and monitoring, and a secondary petition is not allowed to be filed with the import process or release of cargo subject to health requirements for this purpose.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 901/2024

4.2. PURPOSE OF TESTING – UNREGULATED PRODUCTS

The import of samples of finished products, in bulk or raw materials, belonging to the class of drugs not regulated by Anvisa for testing must comply with the provisions of Chapter XXI of RDC No. 81/2008.

Tests for raw materials and medicines are considered: control test of quality; testing for approval of registration, post-registration or regularization of the product with to Anvisa, which includes bioavailability, bioequivalence or equivalence tests pharmaceutical; operational testing on industrial or laboratory equipment. There is no provision of importing unregulated medicine for training and teaching. Furthermore, the Chapter XXI prohibits the import of medicines not regulated by Anvisa, intended for market research.

As provided for in the aforementioned Chapter, the import of drug samples unregulated must meet the health requirements set out in Chapter XXXIX of the RDC No. 81/2008, where applicable. Furthermore, it is important to emphasize that the imported quantity must be compatible with the stated purpose.

Products that are regularized in the country may be imported under Chapter XXI. Anvisa, but they are divergent/irregular. As an example, we have the import of expired products for validating a new route in the product transport chain biologicals. It is up to the importer to describe the situation clearly in the Declaration of Use document. and Purpose.

ATTENTION

The import of products regulated by Anvisa for testing purposes does not is subject to Chapter XXI (unregulated products). It must be carried out according to industrial purpose.

Furthermore, the import of raw materials for manufacturing drugs exclusively international is also considered unregulated, since only would be responsible for importing the finished product. Therefore, the import of these products to quality control, for example, is also subject to Chapter XXI of RDC No. 81/2008.

The importation of placebos for testing purposes is also considered in Chapter XXI. For cases of placebos of controlled or biological medicines, but which do not contain controlled substances or substances of biological origin, may be classified under Procedure 5.3, upon presentation of justification.

4.2.1. Substances and medicines subject to special control - lists A1, A2, A3, B1, B2, C3 and D1 from Portaria nº 344/1998

The import of medicines, at any stage of manufacturing, raw materials and other products containing substances from lists A1, A2, A3, B1, B2, C3 and D1 of the Ordinance nº 344/1998 is subject to Procedure 1 of RDC nº 81/2008.

Applicable subject codes
90425- Anvisa Approval for Importation of Raw Materials and Products Containing Substances Subject to special control of Ordinance SVS/MS nº 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, F), not regularized in the SNVS, for testing purposes, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) **Import of pharmaceutical input, subject to special control, by manufacturer medicines:** the importing company must have an AE granted for the establishment importer, to import pharmaceutical inputs and/or to manufacture medicines;

b) **Importation of bulk medicine, subject to special control, by manufacturer medicines:** the importing company must have AE to import and package or manufacture medicines;

c) **Importation of finished medicine, subject to special control, by industry pharmaceutical:** the importing company must have an AE to import medicines;

d) **Importation of products, subject to special control, by a Laboratory or Institution Research:** case intended exclusively for personal use in research activities, which includes development of new products.

Product regularization

Not applicable

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Analytical quality control report, except for tests with finished products that do not involve human beings;

d) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa;

e) Export Authorization (AEX) or No Objection Certificate issued by the authority competent non-external;

f) Endorsement document regarding proof of docking of the goods and products: With the integration of LPCO/LI there is no longer sending proof of cargo docking. The information of presence of the load is shown in the LPCO, in a specific field;

g) Terms of Responsibility of Chapter XXII;

h) Declaration of Use and Purpose as per Section VI of Chapter XXI.

Mandatory documents - depending on the situation

If a quantity lower than that authorized in the AI has been imported:

a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

In the case of importing a reference drug that is unavailable on the national market:

a) Authorization described in paragraph 4, art. 9 of RDC nº 35/2012, for the acquisition of the medicine in international territory;

b) In this case, the non-presentation of the quality control analytical report is justified and documents from RDC nº 68/2003 (Tables Q1, Q2 and documents from Table Q3).
Mandatory requirements
a) prior authorization for boarding granted by Anvisa; b) Authorized entry points, except list C3: I - Port of Rio de Janeiro, Rio de Janeiro/RJ; II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ; III - Port of Santos, Santos/SP; and IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP. In the case of products and substances on the C3 list, there is no restriction on the place of entry.
Observations
Not applicable
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 659/2022

4.2.2. Substances and medicines subject to special control - lists C1, C2 and C5 of the Ordinance No. 344/1998

The import of medicines, at any stage of manufacturing, raw materials and other products containing substances from lists C1, C2 and C5 of Ordinance No. 344/1998 is subject to Procedure 3 of RDC nº 81/2008.

Applicable subject codes
- 90347: Anvisa Approval for Importation of raw materials, non-controlled drugs or products containing substances subject to special control of Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), not regularized in the SNVS, for testing purposes, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) **Import of pharmaceutical input, by drug manufacturer:** the company The importer must have an AE granted to the importing establishment to import inputs pharmaceuticals and/or to manufacture medicines;

b) **Importation of medicine in bulk, by a medicine manufacturer:** the company importer must have AE to import and package or manufacture medicines;

c) **Importation of finished medicine, subject to special control, by industry pharmaceutical:** the importing company must have an AE to import medicines;

d) **Importation of products, subject to special control, by a Laboratory or Institution Research:** case intended exclusively for personal use in research activities, which includes development of new products.

Product regularization

Not applicable

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport);

c) Analytical quality control report, except for tests with finished products that do not involve human beings;

d) Terms of Responsibility of Chapter XXII;

e) Declaration of Use and Purpose as per Section VI of Chapter XXI.

Mandatory documents – depending on the situation

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

In the case of importing a reference drug that is unavailable on the national market:

a) Authorization described in paragraph 4, art. 9 of RDC nº 35/2012, for the acquisition of the medicine in international territory;

b) In this case, the non-presentation of the quality control analytical report is justified and documents from RDC nº 68/2003 (Tables Q1, Q2 and documents from Table Q3).

Mandatory requirements

Observations

Legal basis

DRC No. 68/2003, DRC No. 81/2008, DRC No. 659/2022

4.2.3. Biological medicines – blood products

The import of biological blood-derived medicines, at any stage of manufacturing, and raw material is subject to Procedure 2 of RDC nº 81/2008.

Applicable subject codes
- 90347: Anvisa Approval for Importation of raw materials, non-controlled drugs or products containing substances subject to special control of Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), not regularized in the SNVS, for testing purposes, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable or If it is not a matter of importing products intended exclusively for laboratory analysis for quality control or for new product development: a) **Importation of pharmaceutical input:** the importing company must have AFE to import pharmaceutical inputs or manufacture medicines; b) **Import of bulk product:** the importing company must have AFE to import and packaging or manufacturing medicines; c) **Import of finished product:** the importing company must have AFE to import medicines.
Product regularization
Not applicable
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product, except for tests with finished products that do not involve human beings; d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture; e) Chapter XXI Disclaimer; f) Declaration of Use and Purpose.
Mandatory documents – depending on the situation
If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
Legal basis
DRC No. 68/2003, DRC No. 81/2008

4.2.4. Biological medicines – serums and vaccines

The import of biological medicines – serums and vaccines, at any stage of manufacturing, and raw material is subject to Procedure 2A of RDC nº 81/2008.

Applicable subject codes
- 90347: Anvisa Approval for Importation of raw materials, non-controlled drugs or products containing substances subject to special control of Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), not regularized in the SNVS, for testing purposes, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable or If it is not a matter of importing products intended exclusively for laboratory analysis for quality control or for new product development: a) **Importation of pharmaceutical input:** the importing company must have AFE to import pharmaceutical inputs or manufacture medicines; b) **Import of bulk product:** the importing company must have AFE to import and packaging or manufacturing medicines; c) **Import of finished product:** the importing company must have AFE to import medicines.
Product regularization
Not applicable
Mandatory documents
a) Commercial invoice;

b) Bill of lading or extract from the CCT (air transport); c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product, except for tests with finished products that do not involve human beings. humans; d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture; e) Chapter XXI Disclaimer; f) Declaration of Use and Purpose.
Mandatory documents – depending on the situation
If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
Legal basis
DRC No. 68/2003, DRC No. 81/2008

4.2.5. Biological medicinal products – derived from fluids or tissues of animal origin and allergens

The import of biological medicinal products derived from source fluids or tissues animal and allergens, at any stage of manufacturing, and raw material is subject to Procedure 2B of RDC nº 81/2008.

Applicable subject codes
- 90347: Anvisa Approval for Importation of raw materials, non-controlled drugs or products containing substances subject to special control of Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), not regularized in the SNVS, for testing purposes, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable or

If it is not a matter of importing products intended exclusively for laboratory analysis for quality control or for new product development: a) **Importation of pharmaceutical input:** the importing company must have AFE to import pharmaceutical inputs or manufacture medicines; b) **Import of bulk product:** the importing company must have AFE to import and packaging or manufacturing medicines; c) **Import of finished product:** the importing company must have AFE to import medicines.
Product regularization
Not applicable
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product, except for tests with finished products that do not involve human beings; d) Terms of Responsibility of Chapter XXII; e) Declaration of Use and Purpose as per Section VI of Chapter XXI.
Mandatory documents – depending on the situation
If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
Legal basis
DRC No. 68/2003, DRC No. 81/2008

4.2.6. Biological medicines – obtained by biotechnological procedures, antibodies monoclonal, containing live, attenuated or dead microorganisms and probiotics

The import of biological medicines – obtained through procedures biotechnological, monoclonal antibodies, containing live microorganisms, attenuated or dead and probiotics, at any stage of manufacturing, and raw material is subject to

Procedure 2C of RDC nº 81/2008, including somatropin and the products that contain.

Applicable subject codes
- 90347: Anvisa Approval for Importation of raw materials, non-controlled drugs or products containing substances subject to special control of Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), not regularized in the SNVS, for testing purposes, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Somatropin (list C5, Ordinance No. 344/1998): a) **Import of pharmaceutical input, by drug manufacturer:** the company The importer must have an AE granted to the importing establishment to import inputs pharmaceuticals and/or to manufacture medicines; b) **Importation of medicine in bulk, by a medicine manufacturer:** the company importer must have AE to import and package or manufacture medicines; c) **Importation of finished medicine, by pharmaceutical industry:** the importing company must have AE to import medicines d) **Importation of products, subject to special control, by a Laboratory or Institution Research:** case intended exclusively for personal use in research activities, which includes development of new products. Other biological products: Not applicable or If it is not a matter of importing products intended exclusively for laboratory analysis for quality control or for new product development: a) **Importation of pharmaceutical input:** the importing company must have AFE to import pharmaceutical inputs or manufacture medicines; b) **Import of bulk product:** the importing company must have AFE to import and packaging or manufacturing medicines; c) **Import of finished product:** the importing company must have AFE to import medicines.
Product regularization
Not applicable
Mandatory documents

a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product, except for tests with finished products that do not involve human beings; d) summary protocol for the production of the product (according to the WHO standard protocol, if the product is included in it); e) Terms of Responsibility of Chapter XXII; f) Declaration of Use and Purpose as per Section VI of Chapter XXI.
Mandatory documents – depending on the situation
If the product contains blood derivatives in its formulation: a) Certificate of release of the finished product batch, issued by the country's health authority manufacturing. (the batch number on the certificate must match the batch number of the blood derivative used in the formulation); b) Technical documents of the blood product used as a stabilizer: (1) declaration of origin of the plasma used, (2) certificate of analysis of the quality control of the plasma used and (3) certificate of release of the serology of the plasma used. If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
Legal basis
DRC No. 68/2003, DRC No. 81/2008

4.2.7. Other medicines

The import of other medicines, at any stage of manufacture, and raw material, which do not contain substances subject to special control of Ordinance No. 344/1998 and are not inputs or finished products of biological medicines, are subject to Procedure 5.3 of RDC No. 81/2008.

Considering that TCM products are not regulated by Anvisa, they are not import for “testing” purposes.

Applicable subject codes
- 90347: Anvisa Approval for Importation of raw materials, non-controlled drugs or products containing substances subject to special control of Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), not regularized in the SNVS, for testing purposes, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable or If it is not a matter of importing products intended exclusively for laboratory analysis for quality control or for new product development: a) **Importation of pharmaceutical input:** the importing company must have AFE to import pharmaceutical inputs or manufacture medicines; b) **Import of bulk product:** the importing company must have AFE to import and packaging or manufacturing medicines; c) **Import of finished product:** the importing company must have AFE to import medicines.
Product regularization
Not applicable
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical quality control report, except for tests with finished products that do not involve human beings; d) Terms of Responsibility of Chapter XXII; e) Declaration of Use and Purpose as per Section VI of Chapter XXI.
Mandatory documents – depending on the situation
If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4. In the case of importing a reference drug that is unavailable on the national market: a) Authorization described in paragraph 4, art. 9 of RDC nº 35/2012, for the acquisition of the medicine in international territory;

b) In this case, the non-presentation of the quality control analytical report is justified and documents from RDC nº 68/2003 (Tables Q1, Q2 and documents from Table Q3).
Mandatory requirements
Observations
Legal basis
DRC No. 68/2003, DRC No. 81/2008

4.2.8. Additional clarifications – testing documents

Statement of Use and Purpose

As stated in Chapter XXI of RDC No. 81/2008, it must be presented document, signed by the technical and legal manager of the importing company, where must contain the following information:

a) purpose of import;

The intended purpose of the import must be described, taking into account the tests provided for medicines and their raw materials. It is not enough to describe only "testes".

b) total quantity, justified, for the number of samples imported;

The importer must inform the quantity imported, and justify it in view of the declared tests that will be carried out. If there is any doubt that the imported quantity is compatible with the tests to be carried out, the import process is subject to requirement or refusal and prohibition.

c) details of the qualitative and quantitative formula of the imported sample;

e) batch or lot numbers and number of units produced per batch;

For this item, the company must indicate the identification of the imported batches, as well as as the total size of each batch. If the total size information is unknown, justification may be provided.

f) description of the tests to be carried out in the national territory, with a summary of the protocol justifying the quantity requested, when applicable;

The importer must inform which test(s) will be carried out on the product. imported, presenting the summary of the protocol of each of them. It should be

demonstrated the need to use the entire imported quantity of the product not regularized. If there are doubts that the imported quantity is compatible with the tests to be carried out, the import process is subject to requirement or rejection and interdiction.

h) occurrence of waste resulting from the operation of the import purpose proposal, methodology for appropriate treatment inactivation;

i) name of the person responsible for the imported product and respective information relating to the Individual Taxpayer Registry and the professional council of your registration, with identification of the registration number.

It should be noted that this is an import of a product not regularized by Anvisa. Therefore, the purpose of the import, the tests to be carried out and the demonstration of import of a quantity compatible with the purpose informed through this document It is essential for the approval of the import process.

Disclaimer

The Term of Responsibility (TR) to be presented is that provided for in Chapter XXII of the RDC nº 81/2008, with no changes to its text.

The art. 13 of IN nº 158/2022 allows the commercialization of pilot batches whose records are granted and that meet the conditions required in this Normative Instruction, but this is a step after carrying out the tests referred to in the TR of Chapter XXII. Therefore, it is not there are irregularities in the marketing of approved pilot batches, as provided for in IN No. 158/2002, having presented the TR of Chapter XXII.

4.3. PURPOSE OF PROFICIENCY TEST

The import of standard and reference material for proficiency testing is subject to to Anvisa's health intervention, as provided for in Chapter XX of RDC nº 81/2008. Just the import of standards and samples containing substances subject to control special, according to Ordinance No. 344/1998, is subject to the approval of PAFME.

This item lists the requirements for direct import by the laboratory. proficiency test provider or the company that will perform the proficiency tests. In the case of import for commercialization, item 4.1 must be checked.

4.3.1 Material and reference standard subject to special control – lists A1, A2, A3, B1, B2, C3 and D1 from Portaria nº 344/1998

Applicable subject codes
- 90408 - Anvisa Approval for Import of reference standard, material or substance, containing substance of procedure 1 or 1A by legal entity, for proficiency testing or Quality Control, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import pharmaceutical inputs, import medicines or manufacture medicines; or b) Laboratory or Research Institution: Laboratory or Research Institution AE, if applicable. intended exclusively for own use in research activities.
Product regularization
Not applicable. If it is a “reference sample” of a product regularized by Anvisa, the import must follow the provisions set out in item 4.1.1.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical quality control report, except when it concerns imports of primary reference standards; (even if not mandatory, we suggest presenting a form technique or certificate of analysis for primary standards, to enable the analysis of product framing) d) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa. Check the addenda of the aforementioned lists for exceptions regarding quantities; e) Export Authorization (AEX) or No Objection Certificate issued by the authority competent authority abroad. Check the addenda of the aforementioned lists for exceptions regarding quantities.; f) Endorsement document regarding proof of docking of the goods and products: With the integration of LPCO/LI there is no longer sending proof of cargo docking. The information of presence of the load is shown in the LPCO, in a specific field;

g) Term of Responsibility of Chapter XX-A of RDC nº 81/2008.
Mandatory documents - depending on the situation
If a quantity lower than that authorized in the AI has been imported: a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.
Mandatory requirements
a) Prior boarding authorization granted by Anvisa; b) Authorized entry points, except list C3: I - Port of Rio de Janeiro, Rio de Janeiro/RJ; II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ; III - Port of Santos, Santos/SP; and IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP. In the case of products and substances on the C3 list, there is no restriction on the place of entry.
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 81/2008, DRC No. 659/2022

4.3.2 Material and reference standard subject to special control – lists C1, C2 and C5 of the Ordinance No. 344/1998

Applicable subject codes
- 90423 - Anvisa Approval for Import of reference standard, material or substance, containing substance of procedure 3 by legal entity, for proficiency testing or Quality Control, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import pharmaceutical inputs, import medicines or manufacture medicines;

or b) Laboratory or Research Institution: Laboratory or Research Institution AE, if applicable. intended exclusively for own use in research activities.
Product regularization
Not applicable If it is a “reference sample” of a product regularized by Anvisa, the import must follow the provisions set out in item 4.1.3.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Analytical quality control report, except when it concerns imports of primary reference standards; (even if not mandatory, we suggest presenting a form technique or certificate of analysis for primary standards, to enable the analysis of product framing) d) Term of Responsibility of Chapter XX-A of RDC nº 81/2008.
Mandatory documents - depending on the situation
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 81/2008, DRC No. 659/2022

4.4. PURPOSE OF PUBLIC HEALTH PROGRAMS - MINISTRY OF HEALTH OR ENTITIES PUBLIC MEMBERS OF ITS

As provided for in RDC No. 81/2008, the purpose is to import for use exclusive in public health programs with acquisition by a multilateral organization international and by the Ministry of Health or its linked entities. We will deal here with the second situation, which is more routine.

Therefore, they are imports carried out directly by the Ministry of Health or public entities that are part of the SUS, with the purpose and proof of use in programs public health. This is exclusively the import of finished products. It is not applies the provisions of this item to imports of products subject to health inspection, carried out by private entities, even when linked to the SUS, with products intended for public health programs.

Mandatory requirements and documents for importing medicines and related products by the Ministry of Health and related public entities are the same as those already listed in item 4.1 for commercial/industrial purposes.

In cases of import by these entities, there are different procedures for prioritization of analysis, exception of presentation of documents in the procedural instruction initial and forecast of exceptional authorization for the import of non-regularized products, upon prior request to the Anvisa Board of Directors, as provided for in RDC No. 203/2017.

4.4.1. Medicinal products subject to special control - lists A1, A2, A3, B1, B2, C3 and D1 of the Ordinance No. 344/1998

The import of medicines containing substances from lists A1, A2, A3, B1, B2, C3 and D1 of Ordinance No. 344/1998 are subject to Procedure 1 of RDC No. 81/2008.

Applicable subject codes
- 90410: Anvisa Import Authorization for the Ministry of Health or public entities members of the SUS, of substances subject to special control, of procedure 1 and 1A, in stage of finished product, intended for public health program, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import medicines. Considering that the Ministry of Health and entities linked to the SUS do not have AE, such Importation can only occur with authorization from the Anvisa Board of Directors.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines:

a) Present a valid exceptional import authorization issued by Anvisa.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft may be presented;*

c) Quality control analytical report;

d) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa;

e) Export Authorization (AEX) or No Objection Certificate issued by the authority competent non-external;

f) Endorsement document regarding proof of docking of the goods and products: With integration of LPCO/LI no longer sends proof of cargo docking. The information the presence of the load is presented in the LPCO, in a specific field.

Mandatory documents - depending on the situation

In the case of a regularized medication:

a) DDR.

If a quantity lower than that authorized in the AI has been imported:

a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

a) Prior boarding authorization granted by Anvisa;

b) Authorized entry points, except list C3:

I - Port of Rio de Janeiro, Rio de Janeiro/RJ;

II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ;

III - Port of Santos, Santos/SP; and

IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP.

In the case of products and substances on the C3 list, there is no restriction on the place of entry.

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 203/2017, DRC No. 659/2022

4.4.2. Substances and medicines subject to special control - lists C1, C2 and C5 of the Ordinance No. 344/1998

The import of medicines containing substances from lists C1, C2 and C5 of the Ordinance No. 344/1998 is subject to Procedure 3 of RDC No. 81/2008.

Applicable subject codes
- 90464: Anvisa import approval for the Ministry of Health or public entities members of the SUS, of medicines, except procedure 1 and 1A, in the product stage finished, intended for public health program, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import medicines. Considering that the Ministry of Health and entities linked to the SUS do not have AE, such Importation can only occur with authorization from the Anvisa Board of Directors.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued by Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft may be presented;* c) Quality control analytical report.
Mandatory documents – depending on the situation
In the case of outsourced imports:

a) DDR. If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 203/2017, DRC No. 659/2022

4.4.3. Biological medicines – blood products

The import of blood-derived biological medicines is subject to Procedure 2 of RDC nº 81/2008.

Applicable subject codes
- 90464: Anvisa import approval for the Ministry of Health or public entities members of the SUS, of medicines, except procedure 1 and 1A, in the product stage finished, intended for public health program, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued by Anvisa.
Mandatory documents
a) Commercial invoice;

b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft may be presented;*

c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture;

e) Good Manufacturing Practices Certificate (CBPF);

f) Custody and Responsibility Term (TGR).

Mandatory documents – depending on the situation

In the case of outsourced imports:

a) DDR.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of finished imported biological medicines is deferred pending sanitary, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality;
- 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;
- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state.

Mandatory documents: a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch; c) Satisfactory analytical report, issued by INCQS. Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 900/2024, DRC No. 203/2017, DRC No. 412/2020, DRC No. 669/2022

4.4.4. Biological medicines – serums and vaccines

The import of biological medicines – serums and vaccines are subject to Procedure 2A of RDC nº 81/2008.

Applicable subject codes
- 90464: Anvisa import approval for the Ministry of Health or public entities members of the SUS, of medicines, except procedure 1 and 1A, in the product stage finished, intended for public health program, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued by Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft may be presented;*

c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture:

e) Good Manufacturing Practices Certificate (CBPF);

f) Custody and Responsibility Term (TGR).

Mandatory documents – depending on the situation

In the case of outsourced imports:

a) DDR;

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality;
- 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;
- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state.

Mandatory documents:

a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch. Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 203/2017, DRC No. 412/2020, DRC No. 669/2022

Seasonal influenza vaccine

In the case of importing seasonal influenza vaccine regularized by Anvisa, if applies the provisions of item 4.1.6, serums and vaccines for commercial/industrial purposes.

4.4.5. Biological medicinal products – derived from fluids or tissues of animal origin and allergens

The import of biological medicinal products derived from source fluids or tissues animal and allergens is subject to Procedure 2B of RDC nº 81/2008.

Applicable subject codes
- 90464: Anvisa import approval for the Ministry of Health or public entities members of the SUS, of medicines, except procedure 1 and 1A, in the product stage finished, intended for public health program, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued by Anvisa.
Mandatory documents
d) Commercial invoice;

e) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft may be presented;*

f) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

g) Good Manufacturing Practices Certificate (CBPF);

h) Custody and Responsibility Term (TGR).

Mandatory documents – depending on the situation

In the case of outsourced imports:

a) DDR;

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality;
- 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;
- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state.

Mandatory documents:

a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch. Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 203/2017, DRC No. 412/2020, DRC No. 669/2022

4.4.6. Biological medicines – obtained by biotechnological procedures, antibodies monoclonal, containing live, attenuated or dead microorganisms and probiotics

The import of biological medicines – obtained through procedures biotechnological, monoclonal antibodies, containing live microorganisms, attenuated or dead and probiotics is subject to Procedure 2C of RDC nº 81/2008, including the products containing somatropin.

Applicable subject codes
- 90464: Anvisa import approval for the Ministry of Health or public entities members of the SUS, of medicines, except procedure 1 and 1A, in the product stage finished, intended for public health program, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Somatropin (list C5, Ordinance No. 344/1998): a) the importing company must have an AE to import medicines. Considering that the Ministry of Health and entities linked to the SUS do not have AE, such Importation can only occur with authorization from the Anvisa Board of Directors. Other biological products: Not applicable
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued by Anvisa.

Mandatory documents
e) Commercial invoice; f) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft may be presented;* g) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product; h) summary protocol for the production of the product (according to the WHO standard protocol, if the product is included in it); i) Good Manufacturing Practices Certificate (CBPF); j) Custody and Responsibility Term (TGR).
Mandatory documents – depending on the situation
If the product contains blood derivatives in its formulation: a) Certificate of release of the finished product batch, issued by the country's health authority manufacturing. (the batch number on the certificate must match the batch number of the blood derivative used in the formulation); b) Technical documents of the blood product used as a stabilizer: (1) declaration of origin of the plasma used, (2) certificate of analysis of the quality control of the plasma used and (3) certificate of release of the serology of the plasma used. In the case of outsourced imports: a) DDR; If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days. - The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.
TGR Release
Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality; - 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State; - 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state. Mandatory documents: a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch. Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 203/2017, DRC No. 412/2020, DRC No. 669/2022

4.4.7. Other medicines

The import of other medicines, which do not contain substances subject to special control of Ordinance No. 344/1998 and are not biological medicines, are subject to Procedure 5.3 of RDC No. 81/2008.

Applicable subject codes
- 90464: Anvisa import approval for the Ministry of Health or public entities members of the SUS, of medicines, except procedure 1 and 1A, in the product stage finished, intended for public health program, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Not applicable
Product regularization
Regularized medicines:

a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued by Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft may be presented;* c) Quality control analytical report.
Mandatory documents – depending on the situation
In the case of outsourced imports: a) DDR. If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 203/2017

4.4.8. Additional clarifications – documents and requirements for health programs public

Exceptional import of products not regulated by Anvisa

RDC No. 203/17 establishes criteria and procedures for import, on a of exceptionality, of products subject to health surveillance without registration with Anvisa, intended exclusively for use in public health programs by the Ministry of Health and its related entities.

These entities must request authorization from the Anvisa Board to import products subject to health surveillance, which includes medicines and related products,

prior to import. The request must be made via the Electronic Import System Information (SEI) meeting the criteria and presenting supporting documents described in the aforementioned standard.

After the granting of the exceptional import authorization, the applicant for this may proceed with the import of the non-regularized product and must attach the Official Letter authorizer in LPCO.

Loading of cargo

In LPCOs integrated with LI, the “Load” button is available for the importer inform the shipment of the cargo and this field is mandatory. For the Ministry of Health and entities linked to the SUS, in addition to the import of radiopharmaceuticals and advanced therapy products, this field can be filled with the *draft* date of the bill of lading or, in cases where the *draft* is not available, it must be the invoice date is informed. This date must be updated when the shipment is made of the cargo and presenting the valid bill of lading or extract of the CCT (modal air).

Ministry of Health import processes

OS No. 123/2023, which provides operational guidelines for the analysis of import processes carried out directly by the Ministry of Health, determines differentiated procedures for the analysis of import processes submitted by this organ:

- **Bill of lading**

In the initial procedural instruction, the presentation of the *draft* of the knowledge of shipped cargo. If the import processes are approved without the need for health requirement, the valid bill of lading, original, non-original or non-negotiable copy, or extract of the CCT in the case of air transport, must be presented in addition to the import process or at the time of the request for release of the Custody and Responsibility Term (TGR), in the case of biological products.

For import processes in which health requirements are issued, it will already be A valid bill of lading or extract from the CCT (air mode) is requested.

- **Summary dismissal**

There will be no summary rejection when there is a need to adapt the procedural instruction and/or request for necessary clarifications to be provided in the import process, with the issuance of up to two health requirements being possible.

It should be noted that mistakes that cannot be corrected, such as protocol of import process in wrong subject code, are subject to rejection summary.

Import processes for entities linked to the SUS

As expected for the Ministry of Health, the presentation of the *draft* of the knowledge of cargo shipped in the procedural instruction of import processes of entities linked to the SUS. The valid, original, bill of lading, not original or non-negotiable copy, or extract of the CCT in the case of air transport, must be presented in addition to the import process or at the time of the request for release of the Custody and Responsibility Term (TGR), in the case of biological products.

4.5. PURPOSE EXCLUSIVE USE IN HEALTHCARE UNIT

The import of products subject to health surveillance by a health unit, for its exclusive use, is regulated by RDC No. 488/2021. As provided for in this Resolution, the import can be carried out by the health unit itself, through an operation of importation on behalf of a third party and by order or by institutions to which the health unit is linked.

For the purposes of this Resolution, a health unit is a health establishment intended to provide assistance to the population in the prevention, treatment and diagnosis of diseases, in the recovery and rehabilitation of patients.

RDC No. 488/2021 provides for the possibility of importing non-commercial products. regularized by Anvisa and unavailable on the national market, upon prior request and exceptional authorization from the Agency's Board of Directors. In these cases, the interested party must register as an external user in Anvisa's SEI, carry out the electronic petition with the documents indicated in art. 4th of RDC nº 488/2021 and await manifestation from the Anvisa Board, before filing the import process.

It is worth noting that RDC No. 08/2014 already authorizes the importation of medicines not regularized as set out in IN No. 01/2014 intended for the exclusive use of health units. Therefore, if the drug is listed in IN nº 01/2014, same active ingredient, form pharmaceutical and concentration, the import of this product not regularized by Anvisa is already authorized, with no prior request to the Anvisa Board of Directors.

4.5.1. Medicinal products subject to special control - lists A1, A2, A3, B1, B2, C3 and D1 of the Ordinance No. 344/1998

The import of medicines containing substances from lists A1, A2, A3, B1, B2, C3 and D1 of Ordinance No. 344/1998 are subject to Procedure 1 of RDC No. 81/2008.

Applicable subject codes
Public health units: - 90356: Anvisa approval for the import of medicines, by public health units, in finished product stage, for your exclusive use, in LI/LPCO. Private health units: - 90532: Anvisa approval for the import of medicines, by private health units, in finished product stage, for your exclusive use, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import medicines. Considering that health units do not have AE, such importation can only occur in exceptional situations authorized by Anvisa.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued to Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is a public entity linked to the SUS; c) Quality control analytical report;

d) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa;

e) Export Authorization (AEX) or No Objection Certificate issued by the authority competent non-external;

f) Endorsement document regarding proof of docking of the goods and products: With the integration of LPCO/LI there is no longer sending proof of cargo docking. The information of presence of the load is shown in the LPCO, in a specific field.

Mandatory documents - depending on the situation

In the case of a private healthcare unit:

a) License or Health Permit of the recipient health unit, which covers the health care activity.

In the case of import by institutions such as foundations, civil society organizations, public interest (OSCIPs), health plan operators, state and municipal secretariats of health and military organizations:

a) Document proving the link between the health unit and its linked entity.

In the case of a regularized medication:

a) DDR.

If a quantity lower than that authorized in the AI has been imported:

a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

a) prior authorization for boarding granted by Anvisa;

b) Authorized entry points, except list C3:

I - Port of Rio de Janeiro, Rio de Janeiro/RJ;

II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ;

III - Port of Santos, Santos/SP; and

IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP.

In the case of products and substances on the C3 list, there is no restriction on the place of entry.

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 488/2021, DRC No. 659/2022

4.5.2. Substances and medicines subject to special control - lists C1, C2 and C5 of the Ordinance No. 344/1998

The import of medicines containing substances from lists C1, C2 and C5 of the Ordinance No. 344/1998 is subject to Procedure 3 of RDC No. 81/2008.

Applicable subject codes
Public health units: - 90356: Anvisa approval for the import of medicines, by public health units, in finished product stage, for your exclusive use, in LI/LPCO. Private health units: - 90532: Anvisa approval for the import of medicines, by private health units, in finished product stage, for your exclusive use, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import medicines. Considering that health units do not have AE, such importation can only occur in exceptional situations authorized by Anvisa.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Present a valid exceptional import authorization issued to Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is a public entity linked to the SUS;

c) Quality control analytical report.
Mandatory documents – depending on the situation
In the case of a private healthcare unit: a) License or Health Permit of the recipient health unit, which covers the health care activity. In the case of import by institutions such as foundations, civil society organizations, public interest (OSCIPs), health plan operators, state and municipal secretariats of health and military organizations: a) Document proving the link between the health unit and its linked entity. In the case of a regularized medication: a) DDR. If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 488/2021, DRC No. 659/2022

4.5.3. Biological medicines – blood products

The import of blood-derived biological medicines is subject to Procedure 2 of RDC nº 81/2008.

Applicable subject codes
Public health units: - 90356: Anvisa approval for the import of medicines, by public health units, in finished product stage, for your exclusive use, in LI/LPCO. Private health units:

- 90532: Anvisa approval for the import of medicines, by private health units, in finished product stage, for your exclusive use, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) AFE of RDC nº 61/2004, if it is import on behalf of a third party and by order.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Proof of registration of the product in the country of origin or in the country in which it is marketed, or equivalent document in Portuguese, English or Spanish, if applicable. medicine from IN nº 01/2014. or b) Present a valid exceptional import authorization issued to Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is a public entity linked to the SUS; c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product; d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture; e) Good Manufacturing Practices Certificate (CBPF); f) Custody and Responsibility Term (TGR).
Mandatory documents – depending on the situation
In the case of a private healthcare unit: a) License or Health Permit of the recipient health unit, which covers the health care activity. In the case of import by institutions such as foundations, civil society organizations, public interest (OSCIPs), health plan operators, state and municipal secretariats of health and military organizations: a) Document proving the link between the health unit and its linked entity.

In the case of a regularized medication:

a) DDR.

In the case of imports on behalf of a third party and by order:

a) Contract proving the commercial relationship between the health unit and the importer by account and order of a third party or by order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of finished imported biological medicines is deferred pending sanitary, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality;
- 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;
- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state.

Mandatory documents:

a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt;

b) Certificate of release of the finished biological product batch;

c) Satisfactory analytical report, issued by INCQS.

Mandatory documents – depending on the situation:

- If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 900/2024, DRC No. 488/2021, DRC No. 412/2020, DRC No. 669/2022

4.5.4. Biological medicines – serums and vaccines

The import of biological medicines – serums and vaccines are subject to Procedure 2A of RDC nº 81/2008.

Applicable subject codes
Public health units: - 90356: Anvisa approval for the import of medicines, by public health units, in finished product stage, for your exclusive use, in LI/LPCO. Private health units: - 90532: Anvisa approval for the import of medicines, by private health units, in finished product stage, for your exclusive use, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) AFE of RDC nº 61/2004, if it is import on behalf of a third party and by order.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Proof of registration of the product in the country of origin or in the country in which it is marketed, or equivalent document in Portuguese, English or Spanish, if applicable. medicine from IN nº 01/2014. or b) Present a valid exceptional import authorization issued to Anvisa.
Mandatory documents
a) Commercial invoice;

b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is a public entity linked to the SUS;

c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

d) Certificate of release of the finished product batch, issued by the health authority of the country of manufacture:

e) Good Manufacturing Practices Certificate (CBPF);

f) Custody and Responsibility Term (TGR).

Mandatory documents – depending on the situation

In the case of a private healthcare unit:

a) License or Health Permit of the recipient health unit, which covers the health care activity.

In the case of import by institutions such as foundations, civil society organizations, public interest (OSCIPs), health plan operators, state and municipal secretariats of health and military organizations:

a) Document proving the link between the health unit and its linked entity.

In the case of a regularized medication:

a) DDR.

In the case of imports on behalf of a third party and by order:

a) Contract proving the commercial relationship between the health unit and the importer by account and order of a third party or by order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

a) b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes: - 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality; - 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State; - 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state. Mandatory documents: a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch; Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 488/2021, DRC No. 412/2020, DRC No. 669/2022

Seasonal influenza vaccine

In the case of importing seasonal influenza vaccine regularized by Anvisa, if applies the provisions of item 4.1.6, serums and vaccines for commercial/industrial purposes.

4.5.5. Biological medicinal products – derived from fluids or tissues of animal origin and allergens

The import of biological medicinal products derived from source fluids or tissues animal and allergens is subject to Procedure 2B of RDC nº 81/2008.

Applicable subject codes
Public health units: - 90356: Anvisa approval for the import of medicines, by public health units, in finished product stage, for your exclusive use, in LI/LPCO.

Private health units: - 90532: Anvisa approval for the import of medicines, by private health units, in finished product stage, for your exclusive use, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) AFE of RDC nº 61/2004, if it is import on behalf of a third party and by order.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Proof of registration of the product in the country of origin or in the country in which it is marketed, or equivalent document in Portuguese, English or Spanish, if applicable. medicine from IN nº 01/2014. or b) Present a valid exceptional import authorization issued to Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is a public entity linked to the SUS; c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product; d) Good Manufacturing Practices Certificate (CBPF); e) Custody and Responsibility Term (TGR).
Mandatory documents – depending on the situation
In the case of a private healthcare unit: a) License or Health Permit of the recipient health unit, which covers the health care activity. In the case of import by institutions such as foundations, civil society organizations, public interest (OSCIPs), health plan operators, state and municipal secretariats of health and military organizations: a) Document proving the link between the health unit and its linked entity. In the case of a regularized medication:

a) DDR.

In the case of imports on behalf of a third party and by order:

a) Contract proving the commercial relationship between the health unit and the importer by account and order of a third party or by order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.

Mandatory requirements

Observations

- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
- The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.

TGR Release

Applicable secondary subject codes:

- 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality;
- 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State;
- 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state.

Mandatory documents:

a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt;

b) Certificate of release of the finished biological product batch.

Mandatory documents – depending on the situation:

- If a temperature excursion occurs during the transportation of imported cargo

a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.

Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 488/2021, DRC No. 412/2020, DRC No. 669/2022

4.5.6. Biological medicines – obtained by biotechnological procedures, antibodies monoclonal, containing live, attenuated or dead microorganisms and probiotics

The import of biological medicines – obtained through procedures biotechnological, monoclonal antibodies, containing live microorganisms, attenuated or dead and probiotics is subject to Procedure 2C of RDC nº 81/2008, including the products containing somatropin.

Applicable subject codes
Public health units: - 90356: Anvisa approval for the import of medicines, by public health units, in finished product stage, for your exclusive use, in LI/LPCO. Private health units: - 90532: Anvisa approval for the import of medicines, by private health units, in finished product stage, for your exclusive use, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
Somatropin (list C5, Ordinance No. 344/1998): a) the importing company must have an AE to import medicines. Considering that health units do not have AE, such importation can only occur in exceptional situations authorized by Anvisa. Other biological products: a) AFE of RDC nº 61/2004, if it is import on behalf of a third party and by order.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Proof of registration of the product in the country of origin or in the country in which it is marketed, or equivalent document in Portuguese, English or Spanish, if applicable. medicine from IN nº 01/2014.

or

b) Present a valid exceptional import authorization issued to Anvisa.

Mandatory documents

a) Commercial invoice;

b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is a public entity linked to the SUS;

c) Analytical report on quality control of the active pharmaceutical ingredient(s) and finished product;

d) summary protocol for the production of the product (according to the WHO standard protocol, if the product is included in it);

e) Good Manufacturing Practices Certificate (CBPF);

f) Custody and Responsibility Term (TGR).

Mandatory documents – depending on the situation

If the product contains blood derivatives in its formulation:

a) Certificate of release of the finished product batch, issued by the country's health authority manufacturing. (the batch number on the certificate must match the batch number of the blood derivative used in the formulation);

b) Technical documents of the blood product used as a stabilizer: (1) declaration of origin of the plasma used, (2) certificate of analysis of the quality control of the plasma used and (3) certificate of release of the serology of the plasma used.

In the case of a private healthcare unit:

a) License or Health Permit of the recipient health unit, which covers the health care activity.

In the case of import by institutions such as foundations, civil society organizations, public interest (OSCIPs), health plan operators, state and municipal secretariats of health and military organizations:

a) Document proving the link between the health unit and its linked entity.

In the case of a regularized medication:

a) DDR.

In the case of imports on behalf of a third party and by order:

a) Contract proving the commercial relationship between the health unit and the importer by account and order of a third party or by order.

If any component may originate from a ruminant animal, for human use:

a) Tables Q1 and Q2 completed, as described in item 5.4;

b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days. - The import of imported biological medicines, finished or in primary packaging, is granted pending health issues, for subsequent release of the TGR.
TGR Release
Applicable secondary subject codes: - 90286 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same municipality; - 90287 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in the same State; - 90288 - Verification of compliance with health requirements relating to the Release of Term of Custody and Responsibility of products in the Anvisa import approval process, in LI/LPCO, stored outside the bonded warehouse, but in a different state. Mandatory documents: a) Continuous temperature records of the transport chain, which must identify the name of the product, batch number, time and date of shipping and receipt; b) Certificate of release of the finished biological product batch. Mandatory documents – depending on the situation: - If a temperature excursion occurs during the transportation of imported cargo a) Temperature cycling study, according to art. 28 of RDC nº 412/2020.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 488/2021, DRC No. 412/2020, DRC No. 669/2022

4.5.7. Other medicines

The import of other medicines, which do not contain substances subject to special control of Ordinance No. 344/1998 and are not biological medicines, are subject to Procedure 5.3 of RDC No. 81/2008.

Applicable subject codes
Public health units: - 90356: Anvisa approval for the import of medicines, by public health units, in finished product stage, for your exclusive use, in LI/LPCO. Private health units: - 90532: Anvisa approval for the import of medicines, by private health units, in finished product stage, for your exclusive use, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) AFE of RDC nº 61/2004, if it is import on behalf of a third party and by order.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1. Unregulated medicines: a) Proof of registration of the product in the country of origin or in the country in which it is marketed, or equivalent document in Portuguese, English or Spanish, if applicable. medicine from IN nº 01/2014 or b) Present a valid exceptional import authorization issued to Anvisa.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is a public entity linked to the SUS; c) Quality control analytical report.
Mandatory documents – depending on the situation
In the case of a private healthcare unit: a) License or Health Permit of the recipient health unit, which covers the health care activity.

In the case of import by institutions such as foundations, civil society organizations, public interest (OSCIPs), health plan operators, state and municipal secretariats of health and military organizations: a) Document proving the link between the health unit and its linked entity. In the case of a regularized medication: a) DDR. If any component may originate from a ruminant animal, for human use: a) Tables Q1 and Q2 completed, as described in item 5.4; b) Documents indicated in Table Q3 as described in item 5.4.
Mandatory requirements
Observations
- The import of finished, semi-finished or bulk products or raw materials is prohibited, for industrial, commercial and international donation purposes, with a validity period expiring in next 30 (thirty) days from its health release, except for the period defined in its regularization with Anvisa or by the manufacturer takes less than 180 days.
Legal basis
DRC No. 68/2003, DRC No. 81/2008, DRC No. 488/2021

4.6. PURPOSE OF CLINICAL RESEARCH AND ASSISTANCE PROGRAMS

Importation of drugs subject to clinical research and access programs expanded, compassionate use and post-study supply must comply with the provisions of Chapter XXVI of RDC nº 81/2008 and Chapter IX of RDC nº 09/2015. For therapy products advanced the requirements of Chapter XXVI of RDC No. 81/2008 and Chapter VII of RDC nº 506/2021.

It should be noted that this is an import of a product not regularized by Anvisa, upon presentation of an authorization document - Special Communication (CE), Specific Special Communication (CEE), Import Document (DI) or Official Letter, issued by Anvisa, after analysis and approval of the Product Clinical Development Dossier. Therefore, products imported for clinical research, expanded access programs, use compassionate and post-study provision, should have characteristics that correspond to the described in these import authorization documents. For any discrepancies, Regardless of the justification, the document must be updated with the area

competent technique, Coordination of Clinical Research in Medicines and Products Biologicals (Copec) (medicines) or GSTCO (advanced therapy products), before proceed with the import.

ATTENTION

The import of medicines for clinical trials involving human beings, without registration purposes with Anvisa, is not included in this purpose. It is of scientific/technological research.

According to OS No. 03/2024 and reported on the Anvisa portal, authorization is no longer permitted boarding for the import of medicines subject to clinical research or for assistance programs, except those containing substances subject to special control of Lists A1, A2, A3, B1, B2, C3, D1, E and F of the Portaria no 344/1998.

Thus, in the case of imports relating to medicines from assistance programs approved prior to the validity of this OS, as well as clinical trials approved during the validity of RDC nº 39/2008, the importer must request COPEC to update the document authorizer via Contact Us or carry out the petition protocol with subject code 10823 – CLINICAL TRIALS – Change of Clinical Trial Submission Form. Only After issuing the updated document, the import process must be registered.

4.6.1. Medicinal products subject to special control - lists A1, A2, A3, B1, B2, C3 and D1 of the Ordinance No. 344/1998

Applicable subject codes
Clinical research: - 90409: Anvisa Approval for Importation of drug samples under or for monitoring of Clinical Research containing substance from procedure 1 or 1A, in LI/LPCO. Assistance programs: - 90488: Anvisa approval for the import of medicines intended for access programs expanded, compassionate use, post-study drug provision and clinical trials containing substance from procedure 1 or 1A, in LI/LPCO.

Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import medicines; or b) Laboratory or Research Institution: Laboratory or Research Institution AE, if applicable. intended exclusively for own use in research activities.
Product regularization
Not applicable
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa; d) Export Authorization (AEX) or No Objection Certificate issued by the authority competent non-external; e) Endorsement document regarding proof of docking of the goods and products: With the integration of LPCO/LI there is no longer sending proof of cargo docking. The information of presence of the load is shown in the LPCO, in a specific field; f) Special Communication (EC), Specific Special Communication (CEE), Document for Import (DI) of Product(s) under investigation or Official Letter when it involves the supply of post-study medication, updated, issued by COPEC; g) Term of Responsibility of Chapter XXVII of RDC nº 81/2008.
Mandatory documents - depending on the situation
In the case of import by someone other than the DDCM holder: a) Import responsibilities delegation document. If a quantity lower than that authorized in the AI has been imported: a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.
Mandatory requirements
a) Prior boarding authorization granted by Anvisa; b) Authorized entry points, except list C3: I - Port of Rio de Janeiro, Rio de Janeiro/RJ;

II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ; III - Port of Santos, Santos/SP; and IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP. In the case of products and substances on the C3 list, there is no restriction on the place of entry.
Observations
Legal basis
DRC No. 81/2008, DRC No. 38/2013, DRC No. 09/2015 and DRC No. 659/2022

4.6.2. Medicines subject to special control - lists C1, C2 and C5 of Ordinance No. 344/1998

Medicines containing somatropin are included in this procedure.

Applicable subject codes
- 90424: Anvisa Approval for Importation of Drug Samples under or for monitoring of Clinical Research or expanded access programs, compassionate use and post-study supply containing procedure 3 substance, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
a) the importing company must have an AE to import medicines; or b) Laboratory or Research Institution: Laboratory or Research Institution AE, if applicable. intended exclusively for own use in research activities.
Product regularization
Not applicable
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport);

c) Special Communication (EC), Specific Special Communication (CEE), Document for Import (DI) of Product(s) under investigation or Official Letter when it involves the supply of post-study medication, updated, issued by COPEC; d) Term of Responsibility of Chapter XXVII of RDC nº 81/2008.
Mandatory documents - depending on the situation
In the case of import by someone other than the DDCM holder: a) Import responsibilities delegation document.
Mandatory requirements
Observations
Legal basis
DRC No. 81/2008, DRC No. 38/2013, DRC No. 09/2015 and DRC No. 659/2022

4.6.3. Other medicines, except advanced therapy products

Criteria and procedures for importing drugs under clinical research or for assistance programs, with the exception of advanced therapy products, which do not contain substances subject to special control under Ordinance No. 344/1998 are the same. Therefore, the provisions of this item apply to other categories of medicines, except advanced therapy products.

Applicable subject codes
Clinical research: - 90350: Anvisa Authorization for Importation of Medicines under or for Monitoring Clinical Research, except procedure 1, 1A and 3, in LI/LPCO. Assistance programs: - Anvisa approval for the import of medicines intended for expanded access programs, compassionate use, post-study drug supplies and clinical trials, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) AFE to import medicines, if the importer is not the company holding the DDCM.
Product regularization
Not applicable

Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Special Communication (EC), Specific Special Communication (CEE), Document for Import (DI) of Product(s) under investigation or Official Letter when it involves the supply of post-study medication, updated, issued by COPEC; d) Term of Responsibility of Chapter XXVII of RDC nº 81/2008.
Mandatory documents – depending on the situation
In the case of import by someone other than the DDCM holder: a) Import responsibilities delegation document.
Mandatory requirements
Observations
Legal basis
DRC No. 81/2008, DRC No. 38/2013, DRC No. 09/2015

4.6.4. Advanced therapy products

Applicable subject codes
- 90292: Anvisa approval for the import of advanced therapy products under clinical research, in LI/LPCO.
Applicable LPCO model
I00048
Company regularization
a) AFE to import medicines, if the importer is not the company that owns the DDCTA/DSCTA.
Product regularization
Not applicable
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Special Communiqué (SC), Specific Special Communiqué (SSC) issued by GSTCO.
Mandatory documents – depending on the situation

In the case of import by someone other than the DDCTA/DSCTA holder:
a) Import responsibilities delegation document.
Mandatory requirements
Observations
- The packaging, packing, documentation and transportation of the biological material to be used in a clinical trial with an investigational advanced therapy product must be performed in order to guarantee and maintain the integrity of these products, in an appropriate and exclusive container for import purposes, at the appropriate temperature, and duly identified, in accordance com RDC nº 504/2021 e IN nº 270/2023.
Legal basis
DRC No. 81/2008, DRC No. 506/2021

4.6.5. Additional clarifications – documents and requirements for clinical research and assistance programs

Expiration date

The shelf life of the imported product must correspond to the shelf life indicated in the CE, CEE or authorization document issued by the competent technical area of Anvisa. The import of products with a shorter expiration date will only be approved if the document if the validity period is described as “up to XX months/years”.

In the case of medication kits used in double-blind studies, in which can identify the components of these kits to protect the blinding of the clinical trial, The kit's manufacturing date and expiration date must be informed in the LPCO/LI, as a single item. However, as the Clinical Trial Submission Form (CEF) must be each component of the kit is listed, with their respective expiration dates, recommended if there is a discrepancy in information between the CE/CEE and the import documents.

Import Responsibility Delegation Document

As provided for in RDC No. 09/2015, the document delegating responsibility import document is a document issued by the research sponsor, which contains the

indication of the authorized importer and the responsibilities regarding transportation and clearance of imported goods. Therefore, whenever the import is carried out by company that is not the holder of the Clinical Development Dossier, must be presented this document.

It should be clarified that this is a document submitted electronically and, therefore, must contain an electronic signature as provided in item 5.5 of this manual.

4.7. PURPOSE SCIENTIFIC, TECHNOLOGICAL OR RESEARCH INVOLVING HUMAN BEINGS, WITHOUT REGISTRATION PURPOSE IN THE COUNTRY

The import of products intended for scientific or technological research and research involving human beings must follow the provisions of RDC No. 172/2017. According to definitions of this regulation:

- Scientific, Technological and Innovation Institution: body or entity of the direct or indirect public administration or legal entity under private law without for-profit legally constituted under Brazilian laws, with headquarters and jurisdiction in Country, which includes in its institutional mission or in its social objective or statutory basic or applied research of a scientific or technological nature or the development of new products, services or processes;
- Scientific or Technological Research: research whose results are applied in health sector and ultimately aimed at improving the health of individuals and population groups;
- Scientific or technological research involving human beings: research that, individually or collectively, interacts with human beings, directly, **without the purpose of registering the product under investigation.**

Imports intended for research and laboratory analysis carried out by regulatory bodies drug enforcement in the conduct of its activities must also follow the provisions of the DRC No. 172/17.

4.7.1. Substances, standards and drugs subject to special control - lists A1, A2, A3, B1, B2, C3, D1, E and F from Portaria nº 344/1998

Applicable subject codes
- 90407: Anvisa approval for import of samples and standards of products subject to control special of Ordinance 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, F), of procedures 1 and 1A, intended for scientific or technological research; - 90406: Anvisa approval for import of samples and standards of products subject to control special of Ordinance 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, F), of procedures 1 and 1A, imported by drug enforcement agencies.
Applicable LPCO model
I00049
Company regularization
a) Simplified Special Authorization (AEP). or b) AE to import medicines, in the case of intermediated import.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Import Authorization (AI) or No Objection Certificate issued by the area competent at Anvisa; d) Export Authorization (AEX) or No Objection Certificate issued by the authority competent non-external; e) Endorsement document regarding proof of docking of the goods and products: With the integration of LPCO/LI there is no longer sending proof of cargo docking. The information of presence of the load is shown in the LPCO, in a specific field.
Mandatory documents - depending on the situation
In the case of research involving human beings, with non-regularized medication: a) CEP or CONEP opinion. In the case of a regularized medication: a) DDR.

If the import is not carried out by the person responsible for the research and the Institution a) Term of Responsibility signed by the researcher responsible for the research and Scientific, Technological and Innovation Institution, as per Annex I of RDC No. 172/2017. If a quantity lower than that authorized in the AI has been imported: a) Customs Clearance Authorization (ADA). Note: There is no obligation to rectify the AEX issued by the exporter.
Mandatory requirements
a) Prior boarding authorization granted by Anvisa; b) Authorized entry points, except list C3: I - Port of Rio de Janeiro, Rio de Janeiro/RJ; II - Rio de Janeiro International Airport - Maestro Antonio Carlos Jobim Airport, Rio de Janeiro January/RJ; III - Port of Santos, Santos/SP; and IV - Sao Paulo International Airport - Governor André Franco Montoro Airport, Guarulhos/SP. In the case of products and substances on the C3 list, there is no restriction on the place of entry.
Observations
- The quantity of each product to be imported must be compatible with the study approved by CEP and/or CONEP.
Legal basis
DRC No. 172/2017, DRC No. 659/2022

4.7.2. Substances, standards and drugs subject to special control - lists C1, C2 and C5 of Ordinance No. 344/1998

Included in this procedure are imports of somatropin and medicines that contain it.

Applicable subject codes
- 90371: Anvisa approval for import of samples and standards of products subject to control special referred to in Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), procedure 3, intended to scientific or technological research, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization

a) Simplified Special Authorization (AEP). or b) AE to import medicines, in the case of intermediated import.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport).
Mandatory documents - depending on the situation
In the case of research involving human beings, with non-regularized medication: a) CEP or CONEP opinion. In the case of a regularized medication: a) DDR. If the import is not carried out by the person responsible for the research and the Institution a) Term of Responsibility signed by the researcher responsible for the research and Scientific, Technological and Innovation Institution, as per Annex I of RDC No. 172/2017.
Mandatory requirements
Observations
- The quantity of each product to be imported must be compatible with the study approved by CEP and/or CONEP.
Legal basis
DRC No. 172/2017, DRC No. 659/2022

4.7.3. Other medicines

Criteria and procedures for importing drugs for research scientific and technological, which do not contain substances subject to special control of Ordinance No. 344/1998, are the same. Therefore, the provisions of this item apply to the other drug categories.

Applicable subject codes
- 90399: Anvisa approval for importing medicines, except procedures 1, 1A and 3, intended for scientific or technological research, in LI/LPCO.

Applicable LPCO model
I00048
Company regularization
a) Not applicable or b) AFE to import medicines, in the case of intermediated imports.
Product regularization
Regularized medicines: a) Present product regularization, as explained in item 3.1.
Mandatory documents
a) Commercial invoice; b) Bill of lading or extract from the CCT (air transport); c) Term of Responsibility - Annex I of RDC nº 172/2017.
Mandatory documents – depending on the situation
In the case of research involving human beings, with non-regularized medication: a) CEP or CONEP opinion. In the case of a regularized medication: a) DDR.
Mandatory requirements
- The quantity of each product to be imported must be compatible with the study approved by CEP and/or CONEP. The quantities of each product previously imported, referring to the same research, must be informed, according to the model in Annex I.
Observations
Legal basis
DRC No. 172/2017

4.8. PRODUCTS DERIVED FROM CANNABIS, BY INDIVIDUALS, FOR THEIR OWN USE – INTERMEDIATE IMPORTATION

Initially, it should be noted that the import of *Cannabis* products per person physics can be carried out formally through registration in the computerized system of foreign trade, by accompanied baggage or by express shipment and must follow the

provided for in RDC No. 660/2022. However, only imports into the computerized system foreign trade are subject to PAFME approval.

The import of *Cannabis* products by individuals can be carried out by the patient's legal guardian or by his/her legally appointed attorney. In addition, may also be mediated by a hospital entity, a government unit linked to the area health, health plan operator for exclusive and targeted care for patient previously registered with Anvisa.

Applicable subject codes
- 90223: Anvisa approval for the import of cannabis-derived products for the service of a patient previously registered with Anvisa, linked or not to the obligation of judicial compliance, in LI/LPCO.
Applicable LPCO model
I00049
Company regularization
Not applicable
Product regularization
Not applicable
Mandatory documents
a) “Proof of registration for exceptional import of Cannabis-derived product” valid and with updated information on the imported product; b) Bill of lading or extract from the CCT (air mode) – in the instruction initial procedural *draft* may be presented if it is the Ministry of Health or a public entity linked to SUS; c) Commercial invoice; d) Valid medical prescription; e) Proof of patient's address: despite being described in RDC No. 660/2022, the absence of this document does not give rise to rejection or sanitary requirement in imports via LPCO/LI.
Mandatory documents - depending on the situation
Mandatory requirements
Observations

- RDC No. 660/2022 does not establish exclusive entry points, just as there is no prohibition on customs transit. In this way, imports can be carried out through any point of entry and there may be customs transit for clearance in another location. However, it is up to highlight that it is necessary for the storage environment to have AE for this purpose.
Legal basis
DRC No. 660/2022

Medical prescription and imported quantities: The importer must present a prescription valid from a legally qualified professional who, according to RDC nº 660/2022, is valid six months. The quantity and presentation imported must be compatible with the prescription. In case of discrepancy, a requirement may be issued. While the registration is in force, the same prescription can be presented in more than one health inspection for the purposes of import approval by Anvisa, provided that the imported quantities do not exceed the prescribed quantity.

Proof of registration for exceptional import of Cannabis-derived product: proof of registration presents the product information consisting of “name” and “company”, which, according to COCIC guidelines, may be the exporting company, distributor or manufacturer of the product. Therefore, considering that in LPCO the data of company to be informed are the exporter and manufacturer, we suggest that importer provide clarifications and a photo of the product label, if possible, when this is registered with the company responsible for distribution, to make the analyses more fast, considering that in LPCO there is no field to inform the distributor.

4.9. OTHER PURPOSES

4.9.1. Imports of non-regularized products linked to the obligation of compliance with legal actions

As amended by RDC No. 262/2019 to RDC No. 81/2008:

*8. The import of goods or products **not regularized by ANVISA,** linked to mandatory compliance with **legal actions granted in the interest of treatment clinical patient care,** in which the importing legal entity is **a public institution member of the organizational structure of the Unified Health System (SUS),** will be granted*

automatic import licensing in SISCOMEX, regardless of whether it was carried out of any other technical or procedural analysis, being the responsibility of the importer guarantees the quality and safety of the products purchased.

Therefore, there is a specific subject code for these imports, with a view to need for automatic deferral. However, it is necessary to verify whether the protocol under this subject code has been done properly and whether the import meets the requirements of the RDC No. 262/2019. Considering that most imported products are medicines, the audit of this procedure is under the approval of PAFME.

It is important to highlight that importing substances subject to control is not permitted. special of lists A1, A2, A3, B1, B2, C3, D1, E and F of Ordinance No. 344/1998, including products *Cannabis* derivatives for individuals, per this subject code, even if it is a import linked to the obligation to comply with legal actions, considering it is a substance subject to international control. The importer must use the codes: 90223 (Cannabis products for individuals), or 90410 (other substances subject to special control).

ATTENTION

Imports by SUS member institutions must fully comply with the provisions of this item. Even if it is an import linked to mandatory compliance with legal actions, there is no protocol under subject code 90418.

Applicable subject codes
90418 - Anvisa approval for the import of goods or products not regularized by ANVISA, by institutions that are part of the SUS, linked to the obligation to comply with legal action, except procedure 1 and 1A, in LI/LPCO.
Applicable LPCO model
I00044 – if it is a medical device; I00045 – if it is a cosmetic or hygiene product; I00046 – if it is food;

I00047 – if it is a sanitizing agent; I00048 – if it is a medicine; I00049 – if it is a medicine from list C1, C2 and C5 of Ordinance No. 344/1998; I00050 – in the case of other goods subject to health intervention.
Company regularization
Not applicable
Product regularization
Product not regularized by Anvisa
Mandatory documents
a) Court decision to be complied with by the importer. In this document, there must be identified the product subject to import, the importer (or health entity linked to it) as defendant in the court decision, and the individual to whom the product is intended.
Optional documents
a) Medical prescription; b) Regularization of the product in the country of origin; c) Quality control report; d) Bill of lading or extract from the CCT (air transport); e) Commercial invoice.
Mandatory requirements
- The importer must be a public institution that is part of the SUS.
Observations
- If it is a regularized product, even if it is to comply with a legal demand, it is not applicable import by this subject code. It should be clarified that the regularized product is considered product with the same characteristics as regularization with Anvisa, such as validity, labeling language, registration number described on the packaging. - If there are any doubts regarding the correct classification of the import in RDC nº 262/2019, you can be issued health requirement. - If it is found that the import does not fall within RDC nº 262/2019, it will be rejected.
Legal basis
DRC No. 262/2019 (DRC No. 81/2008)

4.9.2. Procedure 1A

As provided for in Section II of Chapter XXXIX of RDC No. 81/2008, it is prohibited to import of products subject to special control as set out in Ordinance No. 344/1998,

at any stage of manufacture, as listed in List F, unless intended for teaching and research. Considering the provisions of RDC No. 659/2022, the same applies to plants subject to under special control (List E). Therefore, if it is not an import for scientific research/ technological, as per item 4.7, must be imported under Procedure 1A.

The documents and requirements for Procedure 1A are the same as for Procedure 1. and, therefore, the importer must follow the provisions of item 4.1.1.

4.9.3. Importation for exclusive export purposes

The import of active or semi-finished pharmaceutical ingredients for the manufacture of medicines for exclusive export purposes, that is, whose medicine is not regularized in Brazil, is a purpose not subject to Anvisa's health intervention, but the imported product is subject to intervention. In these cases, the importer must use the code of the subject and procedure of the imported product/medicine to be manufactured, considering the industrial purpose. To justify the lack of regularization of the product with Anvisa, the importer must present the Manufacturing Authorization for Exclusive Export Rights (AFFEE) issued by Anvisa and the Terms of Responsibility of Chapter XXXVIII of DRC no 81/2008.

4.9.4. Exceptional import of unregulated industrialized radiopharmaceuticals

Until 03/31/2025, RDC nº 567/2021 is in force, which provides for the criteria and temporary and exceptional procedures for the import of radiopharmaceuticals industrialized products contained in IN nº 81/2020, due to the risk of shortages in national territory. Therefore, as long as the requirements of this standard are met, it is authorized to Importation of products not regulated by the Ministry of Health and SUS entities (as per item 4.4.7), by health units (as per item 4.5.7) or by legal entities under private law, which are not health units (as per item 4.1.9).

Additional requirements for importing radiopharmaceuticals from each purpose to be presented, with reference to the above-mentioned items, in the case of importing a product not regularized under the terms of RDC nº 567/2021:

Mandatory documents
a) Proof of regularization of the product in the country of origin or in the country where it is marketed, in Portuguese, English or Spanish (in lieu of regularization of the product at Anvisa); b) Proof of compliance with good manufacturing practices in the country; c) Declaration attesting to the adoption of monitoring and compliance strategies pharmacovigilance guidelines, according to the model contained in Annex I of RDC No. 567/2021; d) Declaration certifying that it is an import of essential medicine, regularized in foreign health authority and authorized for distribution in their respective country, as per model Annex II of RDC No. 567/2021; e) Technical report containing the number and description of the DCB of the radiopharmaceutical of IN nº. 81/2020, to which the imported product refers and justification for the need for importation, including discussion of the unmet medical need with the registered products and available on the national market.
Mandatory documents - depending on the situation
If the purchase order number was provided in the declaration in Annex II (d): a) copy of the purchase order in the import file.
Mandatory requirements
- Industrialized radiopharmaceuticals listed in Section 1 may be imported without registration with Anvisa. II of the Annex to IN No. 81/2020, and its updates; - The description of the goods in the import license must contain the inscription "AUTHORIZED IN ACCORDANCE WITH THE COLLEGIATE BOARD RESOLUTION - Nº 567, OF SEPTEMBER 29, 2021.
Observations
Legal basis
DRC No. 567/2021

5. REQUIREMENTS AND MANDATORY DOCUMENTS – DETAILED INFORMATION

5.1. COMMERCIAL INVOICE

Also known as *an invoice,* it is a contractual document that reflects the purchase and sale transaction between the Brazilian importer and the foreign exporter. In document must contain, at a minimum, the full name and address of the exporter and the

importer, description of the goods, quantity and type of volumes. The proforma invoice is not accepted.

In outsourced imports, by order or on behalf of third parties, commercial invoice must identify the purchaser or the person ordering the goods. In this In this sense, only two companies may be indicated on the invoice in the commercial transaction:

I. Account and order of third party: Importer on account and order is the third party company. The purchaser is the holder of the regularization;

II. Order: Importer by order is the third party company. Ordering party is the holder of the product's regularization.

5.2. SHIPPING BILLS

Also known as a bill of lading, it is a document issued by the carrier, which defines the contracting of the international transport operation, proves receipt of the goods at origin and the obligation to deliver them to the place of destination, constitutes proof of possession or ownership of the goods and is a document that covers the merchandise and describes the transport operation.

For the purposes of analyzing the import process, only knowledge of the type "puppy" and "single" are accepted to support import licensing clearance. To the information about storage conditions (temperature, humidity) of products heat-sensitive and dangerous goods must be expressly indicated in the document. The knowledge to be presented in the import process may be original or copy not negotiable, as long as it has the identification of the knowledge number and is signed by the carrier.

For air transport, with the evolution of the CCT (Cargo and Transit Control), the document to be attached to the LPCO must be the extract of the CCT with proof of effective shipment of cargo.

5.3. DECLARATION OF THE RREGULARIZATION HOLDER (DDR)

The Declaration of the holder of regularization (DDR) authorizing the import by third party according to the model available on the Anvisa portal, Forms and models, it must be attached to the LPCO by a company or establishment that is not the holder of the regularization of the imported product. The DDR model to be used is exclusively the one indicated on the website

Anvisa's electronic form, with no changes being authorized to the form and content of the text published. The exception is imports carried out by health units, which have models themselves described in RDC No. 488/2021.

A DDR for Import Licensing must be requested, containing only the products listed in the respective LI.

5.4. PRODUCTS CONTAINING DERIVATIVES FROM RUMINANT ANIMALS – RDC Nº 68/2003

Medicines for human use, except for research purposes, which have its composition starting material obtained from tissues/fluids of ruminant animals must present information and documentation in accordance with RDC No. 68/2003, in addition to the documents already provided for in current legislation.

Therefore, the importer must indicate YES in the field “Contains animal derivatives ruminant?" of the LPCO and present tables Q1 and Q2, indicated in the annex to RDC no. 68/2003, as well as the documents defined by Table Q3 of the regulation.

In relation to Table Q1, the model in the annex of RDC No. must be presented. 68/2003. The fields “Product Identification” to “Expiration Date” must be filled in with the information about the imported product. Fields 1 to 9 must be filled with the data of each substance of ruminant animal origin. It is important the correct and complete filling out of this document, so that the correct classification of the substance in terms of geographic risk and degree of infectivity. Dwarf presentation of table Q1 leads to summary rejection. The presentation of the document incomplete or with inconsistencies in filling, gives rise to a technical requirement.

Table Q2 must be presented in accordance with the model in the annex to RDC no. 68/2003. The external packaging of the goods must bear a similarity to table Q2 in a location visible, easy to read and access for health inspection. The information in table Q2 refer to the imported product. Failure to submit table Q2 will result in rejection summary. The presentation of the document incompletely or with inconsistencies filling, gives rise to technical requirements.

The importer must assess the classification of the fabric/fluid in the respective infectivity category, and the respective geographic risk of the country of origin of the animals, observing Annex 5 of RDC No. 305/2002 and the classification made available by the Office The geographical risk of each country should be consulted in the

address electronic https://www.woah.org/en/disease/bovine-spongiform-encephalopathy/

Note that the geographic risk division indicated in Annex 5 of RDC nº 305/2002 presents a nomenclature and division different from that established by the OIE. For this reason, it was the following correlation was drawn up between the risk grading described in RDC No. 305/2002 and the currently used by the OIE:

Classification RDC nº 305/2002	**OIE Classification***
Risk 1 – BSE-free country or zone	Country with negligible risk
Risk 2 – BSE-free country or zone in which no case has been declared autochthonous	Country with controlled risk
Risk 3 – Country or area provisionally free of EBB in which have declared an autochthonous case	Country with unknown risk
Risk 4 – Country or area in which the incidence of BSE is low	Country with unknown risk
Risk 5 – Country or area in which the incidence of EBB is high	Country with unknown risk

* Countries not classified by the OIE are considered to be at maximum risk

Since the category of tissue infectivity and the geographic risk of country, the importer must use Table Q3 to define which documents and/or certificates proving control associated with Bovine Spongiform Encephalopathy (EEB). Thus, the documentation will be defined by crossing the infectivity category of the fabric (columns I, II, III and IV) with the country's geographic risk (lines 1 to 5).

Risco Geográfico	Categoria de Tecido / Fluido			
	I	II	III	IV
1	BPF*+CVI ou CFE	BPF*+CVI ou CFE	BPF*+CVI ou CFE	B
2	PROIBIDO	BPF*+CVI ou CFE	BPF*+CVI ou CFE	B
3	PROIBIDO	PROIBIDO	PROIBIDO**	D
4	PROIBIDO	PROIBIDO	PROIBIDO**	D
5	PROIBIDO	PROIBIDO	PROIBIDO**	D

Where:

GMP - Manufacturer's Good Manufacturing Practices Certificate or Analytical Control Report Quality of the finished product shipped by the Manufacturer

CVI - International Veterinary Certificate

CFE - Certificate of Conformity - European Pharmacopoeia

B - CVI or CFE or official document from the local health authority attesting to the origin of the raw material

D - Certificate of Conformity - European Pharmacopoeia + GMP

* - Required for finished and bulk products / Note: in the case of product in the processing stage semi-finished production will require the presentation of the GMP or the Analytical Report of Control of Quality issued by the manufacturer for each component.

** - Except pulmonary surfactants, as long as they present CFE

Documents and certificates established by Table Q3

CFE - Certificate of Conformity - European Pharmacopoeia – EDQM: In this case it must the valid EDQM certificate must be presented to the supplier of the raw material originating from tissue or fluid from ruminant animals. The data in the EDQM certificate must be compared with the data provided in table Q1. The validity of the certificate must be consulted in website https://extranet.edqm.eu/publications/Recherches_CEP.shtml.

CBPF - Good Manufacturing Practices Certificate: The CBPF must be presented referring to the manufacturer of the imported product.

CVI – International Veterinary Certificate: Each country has its own model document, however it is important to be able to identify the origin of the raw material used, indicating batch and place of manufacture.

Analytical Report of Quality Control of the finished product issued by

Manufacturer: This document must be issued by the manufacturer, per batch or lot, based on in the quality control analyses carried out on the product. The document must include product name, batch, expiration date or best before date, date of manufacture, name from the manufacturer and the results of the analyses, which must be in accordance with the limits specified.

5.5. ELECTRONIC SIGNATURE

All documents constituting the import process to be submitted for analysis by Anvisa, which have mandatory signature in current regulations, such as Declarations and Terms of Responsibility, must be legible and signed electronically with a digital certificate as provided for in art. 3 of RDC No. 74/2016 and in art. 5 of Decree No. 10,278/2020. Company representatives must be registered at Anvisa or a legal representation document must be presented. The signatures of the legal and technical representative must be digital, using e-CNPJ type certificates or e-CPF, issued by certifying authorities recognized by the Key Infrastructure Brazilian Public - ICP/Brazil, according to art. 3 of RDC nº 74/2016. Documents with digital signature, when printed, scanned and attached will not be accepted, since it is not possible to verify the authenticity of the signature. Proof of validation of the digital signature can be carried out by consulting the VALIDAR system - https://validar.iti.gov.br/.

5.6. SHIPMENT AUTHORIZATION AND DEADLINES

The import of substances from lists A1, A2, A3, B1, B2, C3, D1, E and F of Ordinance no. 344/1998 and products containing them are subject to prior shipping authorization to be granted by Anvisa, except for exceptions described in the addenda of the aforementioned lists.

For such a request, the company must petition, as a secondary petition or tertiary, linked to the Import Authorization process, the subject code “70873 - Request for authorization to ship substances and products subject to control special of Ordinance SVS/MS nº 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, E and F)”. Only After the shipping authorization is issued and the cargo is shipped, the importer must file the import process, which will be analyzed by PAFME.

For reference standards exempt from Import Authorization (AI), the company must file the primary petition requesting boarding authorization with the code subject “70874 – Request for shipping authorization for reference standards of controlled products exempt from Import Authorization”.

The procedures for registering LPCO and LI are detailed in the Manual: Petition for Import License through LPCO.

ATTENTION

The “Primary Petition Subject Code” field does not allow editing after the LPCO record. Wrong subject code protocols even in status of “Import authorization issued” will be rejected by code incorrect subject.

It is worth noting that when an LPCO/LI with already authorized shipment (Authorization of import issued) is rejected, it is necessary to start the entire procedure again: register new LI, new LPCO, request boarding authorization and file the process import, after shipping authorization is issued. The shipping authorization granted for the rejected LPCO/LI, even if it is for the same load, it is not valid for the new LI/LPCO/import process. Therefore, it is up to the importer to pay attention to the adequate and mandatory procedures and documents, to prevent a process of import of cargo with shipping authorization issued is denied.

The same happens when the LI is automatically cancelled by Siscomex. There is no more indication of the deadline for loading the cargo after shipping authorization granted (Import authorization issued). However, the importer must pay attention for the deadline for final manifestation in the LI which is up to 150 days (60 days that the LI remains “for analysis” + 90 days which remains an automatic requirement), as provided for in the Ordinance Secex nº 249/2023, since the status “Import authorization issued” does not migrate for the LI. Therefore, it is up to the importer to plan to ship the cargo in a timely manner. for analysis and final conclusion of the request by Anvisa, approval/rejection, within the within 150 days of LI registration.

If the LI is automatically canceled by the system before the analysis is completed or before cargo clearance, the company must carry out the entire procedure again: register new LI, new LPCO, request boarding authorization and file import process, after shipping authorization is issued. In these cases, it is necessary that the importer cancels the LPCO linked to the LI canceled by the system, before starting the new procedure, to formalize that the AI that had the boarding authorized was not used.

5.7. TERM OF CUSTODY AND RESPONSIBILITY (TGR)

The document must be presented according to the model available on the Anvisa portal, Forms and templates, in which the company undertakes to store and preserve the product at the specified address until the health requirement is met and the TGR is released. It must contain at least the information about the product, batch, LI number and quantity. The document must be signed by the company's legal representative.

The place indicated for storing the cargo must be the company importer/purchaser/orderer or a branch thereof. If a warehouse is indicated thirdly, the contract proving such outsourcing must be presented storage.

5.8. CONTINUOUS TEMPERATURE RECORDS AND BATCH RELEASE CERTIFICATE

As provided for in art. 7 of RDC nº 669/2022, for the complete release of batches of imported finished biological products or in their primary packaging must be presented to Anvisa: (a) copy of temperature records and (b) certificate of release of the imported batch, issued by the quality assurance of the importing company.

(a) copy of temperature records

Continuous temperature records of the supply chain must be presented. transport that prove that the product was kept within the conditions of storage and transportation recommended by the manufacturer. The presentation is not only a summary of the maximum and minimum temperatures reached, being necessary present temperature records of the entire transport.

Furthermore, the temperature records must coincide with the date on which the temperature appears. the delivery of the cargo to the carrier, considering the documents presented in the initial procedural instruction.

(b) certificate of release of the imported batch, issued by the company's quality assurance importer

As provided for in RDC nº 669/2022, the importer must be able to:

- technically evaluate all documentation relevant to the product batch imported;

- technically evaluate the temperature records that prove that the product was maintained within the conditions recommended in the product registration, in order to guarantee the quality, efficacy and safety; and

- issue the release certificate for the finished biological product batch under the responsibility of the responsible pharmacist.

Therefore, the certificate to be presented in TGR release requests biological products is a document issued by the importer (or holder of the regularization), with the evaluation of the imported product, especially regarding issues relating to temperature monitoring, possible excursions suffered and the conclusions regarding the impact on product quality, based on thermal cycling studies be presented.

It is not necessary to present a certificate issued by the exporter and/or manufacturer of the product.

5.9. TEMPERATURE CYCLING STUDY

The temperature cycling study is provided for in Section VI of RDC nº 412/2020 and is a study carried out to evaluate the effect of the biological product remaining in conditions other than those defined for transport or storage. Therefore, This study must be presented for cargo release purposes when excursions occur temperature during transport or storage of the biological product and must be representative of the worst case (time and temperature).

According to RDC nº 412/2020, the cycling study must comply with the following criteria:

a) It must be carried out with at least 1 (one) representative batch of the commercial scale;

b) It must be representative of the temperature deviation that occurred during transportation or storage;

c) Samples subjected to temperature cycles must be kept in the long-term storage conditions and evaluated until the end of the shelf life product validity;

d) Exceptionally, in the case of an ongoing cycling study, the following must be partial data are presented, accompanied by a technical justification that gives support for verified deviation.

6. IMPORT CONSENT – DETAILED INFORMATION

6.1. SUMMARY REJECTION

When the process does not meet mandatory legal requirements, it is rejected. summarily, without technical requirement. Summary rejection occurs, for example, when there is an absence of mandatory documents or in cases of petition protocol with incorrect subject code, as per item II, art. 2 of RDC nº 204/2005, or even by discrepancy in information between the petition and the health inspection, as per item 1.3 of Chapter II of Annex to DRC No 81/2008.

6.2. TECHNICAL REQUIREMENTS

The technical requirement is a measure that can be used as due diligence procedural when the health authority deems it necessary to request information or additional clarifications on the documentation supporting the petitions registered with Anvisa.

The deadline for compliance with the requirement, as per paragraph 2 of art. 6 of RDC No. 204/2005 is 30 (thirty) days, non-extendable, counted from the date of registration/issue of the requirement in the computerized system for consenting import processes. Once once the established deadline has expired, if the petition for compliance does not occur requirement, as instructed in the Manual: Petitioning for an Import License by By means of LPCO, the import process will be rejected due to non-compliance with the demands made within the established deadline.

If the company fails to comply with the requirements formulated, it will be up to the rejection for not having fully met the requirements formulated, as per paragraph I, of art. 7th of RDC nº 204/2005.

We emphasize that additional documents may be requested to those provided for in the RDC. No. 81/2008, as well as other current regulations, for analysis of the claim and upon technical justification, and the company must present them when requested (Chapter XXXVII, item 3 of RDC nº 81/2008).

If correction of information in the Import Licensing is necessary, the The importer must register a replacement LI, correcting this information.

The procedures for complying with the requirement and registering a replacement LI are described in the Manual: Petitioning for an Import License through an LPCO.

ATTENTION

Accelerated stability studies do not serve as a guarantee of maintenance of quality in cases of temperature excursion, since they are not conducted until the end of the product's validity period.

6.3. SUBSTITUTIVE LI

The procedures for registering a replacement LI are described in the Manual: Petition for Import License through LPCO.

Petitions arising from changes to information in import processes, whose initial petition has not been finalized (accepted or not), they will be analyzed on a case-by-case basis.

LI petitions replacing already completed processes (consented or not approved) do not may be in disagreement with the inspection and/or conclusion of the inspection previous health report, as provided for in Subsection V, Section I, Chapter III of RDC No. 81/2008.

Therefore, they cannot be changed, for example:

- Product registration;
- Name;
- Commercial presentation;
- Batch;
- Inclusion/exclusion of product, item or batch.

Furthermore, regarding ILs that require prior boarding authorization, there is no need for a new request for boarding authorization in cases of replacement of the LI resulting from specific changes in monetary, exchange rate and information tax, without implications for health inspection and whose shipment has already been authorized in the replaced LI.

6.4. INSPECTION OF GOODS

Inspection of goods is a procedure to be carried out on a discretionary basis by Anvisa in import approval, according to inspection channels for import approval imports provided for in RDC No. 228/2018.

If there is a need to inspect the cargo, the approving body will insert text in the LI/LPCO, indicating to the importer that the products have been highlighted for inspection. This form, it will be up to the importer to inform the presence of the cargo in the LPCO, via compliance with requirement, and other information that may be requested.

In the case of in-person physical inspection of the cargo, the Anvisa Office responsible for the inspection of the customs area where the cargo is stored will schedule the inspection with the importer or his legal representative. This appointment will be recorded on the Single Portal or other means chosen by the Post.

In the case of remote inspection of the cargo, the approving body will record in the LI/LPCO the proposed date and time, as well as the system indicated for remote inspection. This form, it will be up to the importer to request the faithful depositary to position the cargo and the scheduling of remote inspection. For this scheduling, the importer or his/her trusted depositary must contact the customs area where the merchandise to be inspected. Depending on the scheduling system used at the site customs, the inspection schedule can be requested directly in the system by Anvisa server, specifying date and time.

The legal representative, whose power of attorney must be previously attached to the LPCO, carrying an identification document, must be present at the time of inspection, according to RDC nº 597/2022 and questions and answers https://www.gov.br/anvisa/pt-br/contentcenters/publications/ports-airports-and-borders/guides-and-manuals/questions_and_answers__remote_inspection_siscomex_final-version.pdf/view.

A

power of attorney must grant specific powers to the legal representative to represent the importer with Anvisa.

ATTENTION

If the imported product does not appear for the scheduled remote inspection, either due to lack of access to the link sent or scheduling with the system, a new attempt will be made scheduling, with a proposal for a new date and time. If the importer does not appear to the second appointment, without providing the appropriate justification in the process of import (addition or compliance with requirement), the import process will be rejected, the cargo was precautionarily banned and the importer was fined.

6.5. LOADING INTERDICTION

The Terms of Prohibition of irregular products will be attached to the LI LPCO rejected and banned by Anvisa. The deadline for compliance with demands included in the Interdiction Terms are counted from the date of receipt of the Interdiction Term sent to the importer via Electronic Letter linked to the rejected import process and interdicted. If there is no confirmation of the reading of the Official Letter, the Interdiction Term will be sent via Receipt Notice (AR) with the term counting from the receipt of the document by the importer.

The issuance of a Sanitary Interdiction Term will always be subject to the verification of an occurrence classified as a health irregularity, under the terms of Law no. 6.437/1977.

The Interdiction Term will contain the data on the health irregularity, the term and the type of destination (rejection or destruction).

The importer whose import was not authorized by Anvisa is obliged to return the goods abroad, within 30 (thirty) days of becoming aware of the non-authorization, as determined by Law No. 12,715/2012 and updates. The general rule is to proceed with return to the country of origin of the banned imported good or product, as stated in the Chapter XXXIII of RDC nº 81/2008. However, there are some situations in which it is possible

proceed with the destruction of the merchandise, and these situations are assessed on a case-by-case basis by the Anvisa.

It should be clarified that the determination of return of goods, instead of destruction, is in line with the National Solid Waste Policy established by Law No. 12,305/2010, in which the determination of return to the origin of merchandise unauthorized foreigner is always used as the first option by this consenting body.

Therefore, the importer, in order to change the destination of the cargo, must present a refusal justified by the exporter, considering customs or health rules of the country of origin, upon presentation of documentary proof, or present proof of impossibility of returning the goods (example: bankruptcy and closure of the exporting company).

To request a change in the destination of the banned merchandise, the importer must do so by means of an addendum petition, with the respective justification, before finalization the destination period initially defined in the Interdiction Term. Requests without due justification will be rejected.

Once the prohibited goods have been disposed of (returned or destroyed), the The importer must submit, by means of an addendum, proof of destination within the deadline determined by Anvisa. If the destination is destruction, it is necessary to contact the Post/Coordination responsible for the premises to verify the procedures for fulfillment of the demand. Proof of destination must be attached to the Single Portal, in the “Attached Documents” tab. Additionally, the importer must request the code of attachment not requested.

ATTENTION

If the importer does not present proof of destination of the cargo (return or destruction) within the period defined by Anvisa, will be fined for a health violation, under the terms of Law no. 6,437/1977.

6.5.1. Unblocking cargo at the Airport Concessionaire's cargo terminal Guarulhos International

For cargo stored in the Guarulhos airport warehouse, it is necessary to unlocking the load in a proprietary system, CMS, for the purpose of moving it to its destination final, return or destruction. In these cases, the importer must do so by means of a petition of addition, with the respective justification, requesting the release of the load in the CMS for purposes of movement for return or destruction.

7. SERVICE CHANNELS FOR SOCIETY

Contact with PAFME is made exclusively through the communication channels. service available on the Anvisa website.

If you identify any inconsistencies in this document or if you still have questions, Please contact us through this channel.

8. REVISION HISTORY

Version	Date	Item	Change
1.0	June/2024	N/A	- Initial issuance
1.1	September/2024	1.2. 3.2.2 3.5. 4.1.2. 4.1.4.	- Inclusion of highlights with the approval of PAFME and clarifications on the topic. - New Anvisa definition of importing inputs that are not part of the final composition of the finished product. - Update from RDC nº 21/2014 to RDC nº 901/2024. - Update of subject code 90408 and inclusion of subject codes 90520 to 90524; - Clarifications regarding quality control and commercial purposes; - Inclusion of Note 2. - Update of subject code 90423 and inclusion of subject codes 90525 to 90529; - Clarifications regarding quality control and commercial purposes; - Inclusion of Note 2.

			- Update from RDC nº 58/2010 to RDC nº 900/2024.
		4.1.5.	- Update from RDC nº 21/2014 to RDC nº 901/2024.
		4.1.9.	- Inclusion of placebos.
		4.2.	- Clarifications for item e).
		4.2.8.	- Clarifications regarding importers.
		4.3.	- Title update; - Updated subject code 90408.
		4.3.1.	- Title update; - Updated subject code 90423.
		4.3.2.	- Update from RDC nº 58/2010 to RDC nº 900/2024.
		4.4.3.	- Update of subject code 90356 and inclusion of subject code 90532.
		4.5. – all items	- Update from RDC nº 58/2010 to RDC nº 900/2024.
		4.5.3.	- Clarifications on Proof of registration for exceptional import of Cannabis-derived products.
		4.8.	- Inclusion of clarification on CCT extract for air transport. (This change was included in all items that mentioned knowledge of shipped cargo).
		5.2.	- Change of title; - Inclusion of clarification on LI cancellation.
		5.6.	- Item inclusion.
		5.8.	- Item renumbering. In the previous version it was 5.8.
		5.9.	