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Agency: Ministry of Health/National Health Surveillance Agency/Collegiate Board

RESOLUTION RDC Nº 488, OF APRIL 7, 2021

Provides for the import of products subject to health surveillance by a health unit, for its exclusive use.

The Collegiate Board of the National Health Surveillance Agency, in exercise of the powers conferred upon it by art. 15, III and IV, in conjunction with art. 7, III and IV of Law No. 9,782, of January 26, 1999, and art. 53, VI, §§ 1º and 3º of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 255, of December 10, 2018, resolves to adopt the following Resolution, as deliberated at a meeting held on April 7, 2021, and I, the Chief Executive Officer, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Art. 1 This Resolution establishes the requirements for the import of products subject to health surveillance by health units, for their exclusive use.

§1º The import referred to in the caput may be carried out through an import operation on behalf of a third party and by order, in accordance with Collegiate Board Resolution - RDC No. 81, of November 5, 2008, and its updates.

§2º The import referred to in the caput may be carried out by institutions such as foundations, civil society organizations of public interest (OSCIPs), health plan operators, state and municipal health departments and military organizations, provided that it is for the exclusive use of a linked health unit.

§3º The import referred to in the caput must be preceded by import licensing, by through SISCOMEX, with imports being prohibited through other methods.

§4º The distribution, donation, resale or trade of imported products is not permitted. terms of this Resolution.

Art. 2 For the purposes of this Resolution, a health unit is a health establishment designed to provide assistance to the population in the prevention, treatment and diagnosis of diseases, and in the recovery and rehabilitation of patients.

CHAPTER II

PROCEDURAL INSTRUCTION

Art. 3 The import process covered by this Resolution must be accompanied by the following: following documents:

I - proof of regularization of the product with Anvisa or, in the case of an unregulated product, authorization from the Collegiate Board or the reporting Board, as the case may be, for import on an exceptional basis;

II - Health License or Permit of the health unit receiving the import by the health authority competent health surveillance, in the case of private health units;

III - Business Operating Authorization (AFE) of the import service provider on behalf of a third party and by order, for the activity of importing products subject to health surveillance, if applicable;

IV - contract proving the commercial relationship between the health unit and the importer on behalf of a third party or by order;

V - document proving the link between the health unit and its linked entity; and

VI - declaration by the legal entity holding the product's regularization (DDR) with Anvisa authorizing the import in accordance with the models in Annexes I, II and III of this Resolution, and must:

a) be linked to 1 (one) single and exclusive health unit, with the transfer of this authorization;

b) in the case of import on behalf of a third party and by order placed through an entity linked to the health unit, the declaration must specify this situation, citing all the bodies involved in the operation;

c) have legal validity, valid for up to 90 (ninety) days from the date of signature;

d) be signed by the legal guardian or legal representative of the holder of the regularization; and

e) express a commitment to observe and comply with the rules and procedures established by health legislation, as well as being aware of the penalties to which they are subject, in accordance with Law No. 6,437 of August 20, 1977.

§1º The procedural instruction referred to in the caput must be carried out in accordance with the provisions of Chapter XXXIX of the Collegiate Board Resolution - RDC No. 81, of November 5, 2008, and its updates.

§2 Documents submitted electronically must be digitally signed by the legal guardian or legal representative of the importing company, using e-CNPJ or e-CPF certificates, issued by certifying authorities recognized by the Brazilian Public Key Infrastructure - ICP/Brasil.

CHAPTER III

IMPORTATION OF PRODUCTS NOT REGULARIZED BY ANVISA

Art. 4º The import of products not regularized by Anvisa and unavailable on the national market, intended for clinical use, must be submitted for assessment and authorization by the Anvisa Board of Directors on an exceptional basis, with the submission of the following documents:

I - Import License (LI);

II - letter from the health unit containing the quantity of the product to be imported with justification for the unavailability of an equivalent product on the national market, as per the model in Annex IV;

III - proof of registration of the product in the country of origin or in the country where it is marketed, or equivalent document, in Portuguese, English or Spanish;

IV - product leaflet/instructions for use;

V - scientific technical report containing justification for the need for import, including discussion of the medical need not met by the products registered and made available on the national market; and

VI - in the case of importation by a health plan operator, the link must be proven of the operator with the health unit that will use the product.

§1º The import referred to in the caput applies in the event of unavailability of the regularized product in the national market, characterized by the temporary or permanent inability to meet national demand by registration holders duly regularized in the country.

§2 In the case of medicines, the unavailability provided for in §1 of this article must refer to a product with the same active ingredient, concentration and pharmaceutical form regularized in the national market.

§3 In cases where requests for exceptional import authorization have an identical purpose, that is, the same product from the same manufacturer that has already been authorized by the Anvisa Collegiate Board, the Board reporting on the analysis of the request may grant authorization based on a previous decision.

§4º For the authorization provided for in §3º, the condition of unavailability must be maintained in the national market and the status of the product's registration in the country of origin or its commercialization.

§5º The importation of a product authorized on an exceptional basis, granted by the Collegiate Board or the reporting Board, is subject to verification, by the health authority of ports, airports and borders, of the regularization of the importer and compliance with the other requirements set out in art. 3º.

§6 If the requirement of unavailability on the national market or justification of unmet medical need is not proven, the request for exceptional import may be closed before assessment by the Board of Directors.

Art. 5º The process of importing medicines not regularized by Anvisa, authorized on an exceptional basis under the terms of the Normative Instruction - IN nº 1, of February 28, 2014, or its updates, must be accompanied by proof of registration of the product in the country of origin or in the country where it is marketed, or an equivalent document in Portuguese, English or Spanish.

Art. 6º For products not regularized by Anvisa, the health unit receiving the import is responsible for:

I - be responsible for the quality, effectiveness and safety of the product to be imported;

II - check validity periods and establish mechanisms to ensure the necessary conditions for maintaining the quality of imported products;

III - ensure that health professionals and patients have clear and precise information on the use and conservation care of imported products and on the notification of technical complaints and adverse events related to them; and

IV - be responsible for the destruction of imported products under the terms of this Resolution, when determined by Anvisa.

CHAPTER IV

FINAL PROVISIONS

Art. 7º Changing the purpose of the import described in this Resolution is prohibited.

Art. 8º The authorization to import on an exceptional basis under the terms of this Resolution does not exempt the importer from complying with the requirements set forth in the Collegiate Board Resolution - RDC No. 81, of November 5, 2008, and other applicable standards, which will be assessed in the import process by the technical area of ports, airports and borders.

Art. 9 The Collegiate Board Resolution - RDC No. 383, of May 12, 2020, published in the Official Gazette of the Union No. 90, of May 13, 2020, Section 1, page 119, is hereby revoked.

Art. 10. This Resolution shall come into force on the date of its publication and art. 5 shall come into force on May 3, 2021.

ANTONIO BARRA TORRES

ANNEX I

Direct import by health unit

The company (name of the registration holder)....., CNPJ no. ....., duly authorized by ANVISA - AFE nº listed below, covered by ....., holder of the regularization of the the Import License nº by its legal representative and its technical representative, in accordance with product(s) ....., represented the provisions of the Collegiate Board Resolution - RDC nº 81, of November 5, 2008, authorizes the health unit. ..... , CNPJ nº. ..... to carry out the direct import of the product for its exclusive use.

Commercial name of the product	Commercial presentation of the product	Anvisa regularization number

We declare that after importation, the products will not be destined for trade, thus ensuring the traceability of these products, as established in article 56 of Law No. 6360, of 23 September 1976 and paragraph 1 of article 15 of Decree No. 8,077 of August 14, 2013.

We are committed to strictly observing the rules and procedures established by health legislation, and we are aware of the penalties to which we will be subject in terms of Law No. 6437, of August 20, 1977, whenever non-compliance with these provisions is proven. standards.

This declaration is valid for 90 days from the date of signature.

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Signature of the Legal Representative

ANNEX II

Importation to the health unit through its linked entities

The company (name of the registration holder)....., CNPJ no. ..... , duly authorized by ANVISA - AFE nº....., holder of the regularization of the product(s) listed below, covered by Import License No. ..... , represented by its legal representative and its technical representative, in accordance with the provisions of Resolution of the Collegiate Board of Directors - RDC No. 81, of November 5, 2008, authorizes the unit of health....., CNPJ nº. ..... to carry out the direct import of the product, through its linked entity ....., CNPJ nº. ..... , for exclusive use by the health unit.

Commercial name of the product	Commercial presentation of the product	Anvisa regularization number

We declare that after importation, the products will not be destined for trade, thus ensuring the traceability of these products, as established in article 56 of Law No. 6360, of 23 September 1976 and paragraph 1 of article 15 of Decree No. 8,077 of August 14, 2013.

We are committed to strictly observing the rules and procedures established by health legislation, and we are aware of the penalties to which we will be subject in terms of Law No. 6437, of August 20, 1977, whenever non-compliance with these provisions is proven. standards.

This declaration is valid for 90 days from the date of signature.

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Signature of the Legal Representative

ANNEX III

Importation to a health unit through an operation

import on behalf of and by order of a third party and by order

The company (name of the registration holder)....., CNPJ no....., duly authorized by ANVISA - AFE no. listed below,), covered....., holder of the regularization of the product(s) by the Import License no. ..... , represented by its legal representative and its technical representative, in accordance with the provisions of Resolution of the Collegiate Board of Directors - RDC No. 81, of November 5, 2008, authorizes the company. ..... , CNPJ nº....., AFE nº....., to carry out the exclusive import activity on behalf of and order/order for exclusive use by the health unit....., CNPJ no..... .

Commercial name of the product	Commercial presentation of the product	Anvisa regularization number

We declare that after importation, the products will not be destined for trade, thus ensuring the traceability of these products, as established in article 56 of Law No. 6360, of September 23, 1976 and paragraph 1 of article 15 of Decree No. 8,077, of August 14, 2013.

We are committed to strictly observing the rules and procedures established by health legislation, and we are aware of the penalties to which we will be subject under Law No. 6437, of August 20, 1977, whenever non-compliance with these rules is proven.
standards.

This declaration is valid for 90 days from the date of signature.

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Signature of the Legal Representative

ANNEX IV

HEALTH UNIT LETTER

_____(name of the health unit receiving the import), by means (if any), duly registered with the CNPJ of its linked institution no. _____, established at_____(address) hereby requests this import, on an exceptional basis through the importer_____(name of the importer on behalf of and by order of a third party, if any), under the terms of the Collegiate Board Resolution - RDC No. 488, of April 7, 2021.

I declare that I need to import_____(units: vials, tablets) of the product_____(active ingredient), in the concentration_____, from the company_____, located at the address _____in_____(country), for my own use, not for resale or trade. The object of this exceptional authorization is LI No...., of.....

I declare that no product with the same characteristics available on the national market was identified (include evidence such as: brief report on the cause of the shortage if it is already routine, proof of acquisition attempts or a letter from the registered company communicating the discontinuation).

I declare that I assume all responsibilities for the use of the product and that I am aware that as the product subject to import is not regularized by Anvisa, this health unit is responsible for evaluating the benefit-risk of using the medicine in its patients, including monitoring any adverse events or technical complaints and other responsibilities set forth in art. 6 of the Collegiate Board Resolution - RDC No. 488, of April 7, 2021.

I declare that I am aware that the authorization for exceptional import by the Anvisa Board of Directors does not exempt the importer from complying with the other requirements set forth in the Board of Directors Resolution - RDC No. 81, of November 5, 2008 and other applicable standards, which will be assessed in the import process by GGPAF, the technical area responsible for the assessment and sanitary release of imported products.

I declare that I am aware that failure to comply with the provisions contained in this Resolution and other related provisions constitutes a health infraction, in accordance with Law No. 6437 of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liabilities.

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Signature of the Legal Representative of the Health Unit