**The National Agency of Sanitary Surveillance**



[**www.anvisa.gov.br**](http://www.anvisa.gov.br)

**Public Consultation No. 587, 24 December 2018**

**D.O.U of 27/12/2018**

**The  Board of the National Agency of Sanitary Surveillance**, using the powers conferred upon it by Article 15, III and IV, allied to the art. 7º, III and IV of Law no. 9,782, of 26 January 1999, and the art. 53, III, Parapgraphs 1º and 3º of internal rules adopted pursuant to Annex I of resolution of the Board - RDC No. 255 of 10 December 2018, resolves to submit to public consultation, for comments and suggestions from the general public, proposal for a normative act in an Annex, as discussed in the meeting held on 11 December 2018, and i, CEO, determine its publication.

Art. 1º is established within 30 (thirty) days to send comments and suggestions to the text of the public consultation which features on the control of imports and exports of plants, substances and medicinal products subject to special control, and takes other measures.

Sole Paragraph. The term of this article will start 7 (seven) days after the date of publication of this public consultation in the Diário Oficial da União.

Art. 2 The proposed normative act is available in its entirety at Anvisa's portal on the internet and the suggestions should be sent electronically through the fulfillment of specific form, available at the following address:  [http://formsus.datasus.gov.br/site/formul ari o.php ?id \_a plicacao=4 41 09](http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=44109)

§1 The contributions received are considered public and will be available to any interested party by means of tools contained in electronic form, in the menu "result", including during the consultation process.

§2 At the   end of the filling in the electronic form will be made available to the interested protocol number of the record of your participation, being dismissed the postal or classroom protocol documents in a physical environment with the Agency.

§3 In the case of restriction of access of the citizen to computerized resources will be allowed to send and receive suggestions in writing, in a physical environment, during the consultation period, to the following address: National Agency of Sanitary Surveillance/Management of Controlled Products - GPCON, SIA EXCERPT 5, Special Area 57, Brasília-DF, CEP 71.205-050.

§4 Exceptionally, international contributions can be forwarded in the physical environment, to the following address: National Agency of Sanitary Surveillance/Bake ssoria International Affairs - AINTE, SIA EXCERPT 5, Special Area 57, Brasília-DF, CEP 71,205-

050.

Art. 3 After the deadline stipulated in Article 1, the National Agency of Sanitary Surveillance will promote the analysis of the contributions and, in the end, to publish the results of the public consultation on the portal of the Agency.

Sole Paragraph. The Agency may, according to the need and reasons of convenience and opportunity, articulate with organs and entities involved with the issue, as well as those who have expressed an interest in the matter, to subsidize further technical discussions and the final deliberation of the Board.

**WILLIAM DIB**

Ceo

**Annex**

**Proposal ON PUBLIC CONSULTATION**

Case No: 25351.490965/2015-07

Subject: Proposal for a resolution of the Board - DRC which features on the control of imports and exports of plants, substances and medicinal products subject to special control, and takes other measures.

Regulatory Agenda 2017-2020: Issue #1.13 - Control and supervision on import action,

Export and research with substances under special control and plants that can originating them. Common arrangements for processing:

Responsible area: GPCON/GGMON/Fifth Board

Chief Rapporteur: Renato Alencar Porto

Resolution of the Board - DRC NO XXX XXXXX XXXX

**The Board of the National Agency of Sanitary Surveillance**, in the use of the assignment that gives you the art. 11, Item IV, of Regulation of the National Agency of Sanitary Surveillance, approved by Decree no. 3,029, of 16 April 1999, and in view of the provisions laid down in section V And Parapgraphs 1º and 3º of art. 53 of the internal rules adopted pursuant to Annex I of the RDC No. 61 of the Anvisa, 03 February 2016, at a meeting held on 11 December 2018, adopts the following Resolution of the Board and i, Director- President, determine its publication:

**Chapter I**

**The INITIAL PROVISIONS**

**Section I Objective**

Art. 1º establishes controls for the import and export, for any purpose, of substances, plants and medicinal products subject to special control, as well as defines the criteria for the granting of special permit simplified for Institution of Education and Research (AEP).

Sole Paragraph. The lists of substances subject to special control and plan tas proscribed listed in Annex I of the SVS/MS Decree No 344 of 12 May 1998, and its updates.

**Section II Scope**

Art. 2º are covered by this resolution any legal person who import or export, for any purpose, substances, plants and medicinal products subject to special control, and the teaching and research institutions that perform any activity with these products.

Art. 3 Except the controls referred to in this Resolution: I - the patterns of isotopes and radioisotopes;

II - the patterns of organic substances marked isotopicamente;

III - kits for  *in vitro diagnostics*and for detection of controlled substances in the environment; IV - the drug formulations not containing substances in list D1; and

V - the substances in list D2, which are subject to the control and supervision of the

The Ministry of Justice.

Sole Paragraph. The provisions in paragraph 4 of this Article shall not apply to the Analytical Standards on the basis of substances in list D1.

**Section III Definitions**

Art. 4 For the purpose of this resolution, adopted the following definitions:

I - Export Authorisation (AEX): act exercised by Anvisa, through the issuance of a document authorizing the export of substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and plants from the list and/or plants that can cause substances subject to special control, as well as the medications that contain it;

II - Import Authorization (AI): act exercised by Anvisa, through the issuance of a document authorizing the import of substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and plants from the list and/or plants that can cause substances subject to special control, as well as the medications that contain it;

III - Import authorisation is intended solely for the purposes of teaching or research: ato exercised by Anvisa, through the issuance of a document authorizing the import of substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and plants from the list and/or plants that can cause substances subject to special control, as well as the medications that contain, intended solely for the purpose of teaching, research, analysis or for the production, importation and distribution of analytical standards;

IV - Specific Import authorisation: ato exercised by Anvisa, through the issuance of a document authorizing the import of substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and plants from the list and/or plants that can cause substances subject to special ole control, as well as the medications that contain, when intended to units of forensic science officers, analytical reference laboratory, educational institution or research, including their foundations of support;

V - manufacturing authorization for the sole purpose of export (AFEX): act exercised by Anvisa, through the issuance of a document authorizing the manufacture of medicinal products and presentations not registered in Brazil, on the basis of substances or plants subject to special control, with the sole purpose of exportation;

VI - Special Permit for Institution of Education and Research (AEP): act exercised by

Anvisa, through the issuance of a document authorizing the teaching and research institutions to acquire and use plants, substances and medicinal products subject to special control, to develop teaching activity and research;

VII - Authorisation for the purpose of Customs Clearance (ADA): act exercised by Anvisa, through the issuance of a document amending the quantitative data or units of prod uto contained in the import authorization;

VIII - Balance of psychoactive substances and other subject to special control (BSPO): document that demonstrates the movement of substances subject to special control and  imported medicinal products containing them;

IX - Certificate of no objection for export (CNE): a document issued by the Anvisa, when required by the health authority of the importing country, which tells not be requested authorization to export to the substances listed in Schedule C1, C2, C3 and C5 and for those not subject to special control, as well as to the medicinal products containing them;

X - Certificate of non-objection to import (CNI): a document issued by the Anvisa, when required by the health authority of the exporting country, which tells not be required import authorization for the substances listed in Schedule C1, C2, C3 and C5 and for those not subject to special control, as well as to the medicinal products containing them;

XI - Import Quota: The quantity of the substance of the Lists A1, A2, A3, B1, B2 and plants subject to special control, that the legal person may import, upon request of the import authorization;

XII - Additional import quota: the quantity of the substance of the Lists A1, A2, A3, B1, B2, and plants are subject to special control, that the legal person may import, in additional to import quota, upon request of the import authorization;

XIII - Endorsement: confirmation, by the competent sanitary authority, of the quantitative effectively joined or exported by the country, in comparison with the first authorised;

XIV - Import License (LI): electronic document filed by the importer in SISCOMEX, which contains information about the goods to be imported and the import operation in a general way, such as importer, exporter, country of origin, provenance and acquisition, the tax system,  exchange coverage, among others;

XV - Electronic Petitioning: application held in Internet environment, by means of the form of petition is identified by a number of transaction, whose data are sent directly to the information system of the Anvisa, without the need to send physical documentation to the Agency;

XVI - Legal Guardian: físic the person designated in statute, social contract or ata constitution mandated to represent the legal person, actively and passively, in acts of judicial and extrajudicial documents;

XVII - technical responsible: professional lawfully authorized by their respective professional advice to exercise technical responsibility for the legal person;

18Th CENTURY - Integrated Foreign Trade System (Siscomex): is a computerised instrument by means of which it is exercised the government control of foreign trade in Brazil;

XIX - NDS System: management information system that automates steps of control of substances and plants subject to special control of the SVS/MS Decree No 344 of 12 May 1998, and its updates, at national and international levels, and allows the sun icitação and the issuing of permits for Import and Export of electronic form;

XX - Substances subject to special control include those listed in Annex I lists

SVS/MS Decree No 344 of 12 May 1998, and their updates; and

XXI - plants subject to special control include those listed in the list of Annex I of the SVS/MS Decree No 344 of 12 May 1998, and its updates, as well as plants that can cause substances subject to special control.

**Chapter II**

**The INTERNATIONAL TRADE SECTION I**

**The points of entry and exit**

Art. 5 (1) The substances of lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4 and the plants subject

The special control, as well as the medications that contain, can enter into national territory and exit this only by ports and airports listed in Annex I to this resolution.

**Section II**

**The Import**

Art. 6 (1) The importer must request to Anvisa, at any time, import quota of substances in lists A1, A2, A3, B1, B2 and plants subject to special control eitas, as well as the medications that contain it.

§ 1A analysis of the application of the import quota is based on the criteria laid down in Annex II

This Resolution.

§ 2º The importer must request import quota by substance a úni ca time being subsequent dimensions requested as additional quotas for imports.

Art. 7° The following documents are required for import quota request: I - form of petition is completed, as appropriate;

II - technical justification of the request; and

III - estimation of the distribution and use of the substance or medication.

§ 1º All documentation must be filed by the Anvisa, duly signed by the legal representative and by the technical responsible of the importer.

§ 2º The form of petition that treats the paragraph I of this article must be populated with reliable data in relation to the declared in the balance sheets of psychoactive substances and other subject to special control (BSPO).

Art. 8 THE ADDITIONAL QUOTA OF IMPORTS can be requested whenever there is a lack of balance of quota, provided that they met the criteria and conditions set out in Annex II to this resolution.

Sole Paragraph. Will be rejected the request for additional dimension of importers who have not requested the corresponding import quota.

Art. 9 The following documents are required for the application of additional quota

Import:

I -form of petition, completed in that fit; II -technical justification of the request.

Sole Paragraph. The form of petition that treats the paragraph I of this article must be populated with reliable data in relation to the declared in the BSPO.

Art. 10. Set the dimension of import or additional quota of importation, the importer shall require the authorisation of imports (AI).

§ 1º The AI referred to in the *caput*of this Article may be requested at any time, provided that there is a balance of import quota or additional quota for imports.

§ 2º THE DIMENSION OF IMPORT OR ADDITIONAL QUOTA OF IMPORTS can be imported once or parceladamente.

§ 3º to the parceling of import quota or additional quota of imports, it is necessary to apply an AI for each shipment.

Art. 11. The import of the substances on the list D1, as well as medicines that contain it, is not subject to the fixing of dimension, and must be submitted, at the request of each AI statement containing reliable data handling of substances or drugs in 12 (twelve) months prior to the request, according to the model available at the Portal of the Anvisa.

Sole Paragraph. Will be adopted, for the evaluation of the data of movement mentioned in the *caput*of this article, the same criteria listed in Annex II to this resolution.

Art. 12. The import quota and the additional quota of importation must be ordered in quantity equivalent to the active substance.

Art. 13. The applications of AI, as well as the sending of the movement of plants and substances subject to special control regarding the annual BSPO, should be performed electronically through the NDS system.

Sole Paragraph. The rules relating to the use of the system NDS, for the sending of the BSPO

Anvisa, shall be laid down in specific Normative Instruction.

Art. 14. Users of the system NDS should, prior to its use, request registration in their own tool of the system, indicated at the Portal of the Anvisa.

§ 1º Each importer/exporter shall forward to the Agency letter, signed by a legal guardian, containing the list of authorized users to access the System NDS, including an indication of the appropriate profiles.

§ 2º Each user of the importer/exporter should make the request to register directly on the system NDS, which depend on the approval by Anvisa.

Art. 15. Only after the approval of the register, the importer/exporter will be able to carry out orders through the System NDS.

Art. 16. The AI should be peticionada through the electronic system for petitioning the Anvisa prior to completion of the request in the System NDS.

Art. 17. For the situations listed below, will obrigatóri the submission of the following documents, through the NDS system:

I - Import of samples for laboratory analysis: detailed technical justification, about the purpose of use, signed by the technician responsible;

II - Request for AI for substances in list D1, as well as the medications that contain: declaration mentioned in Art. 11 of this Resolution.

III - Manufacture of pilot batches not intended for marketing: detailed technical justification and statement from the importer, signed by the responsible technician, stating that the pilot batches to be produced will not be marketed.

Art. 18. The AI has a validity of 6 (six) months from the date of its issue, this being the final deadline for the shipment of cargo in the pool.

Art. 19. For the import of substances of lists (C1, C2, C3 and C5, as well as of medicines containing them, it is not necessary to request for quota import and AI.

Art. 20. Independent of the fixation of quota to import of substances and medicinal products subject to special control intended exclusively for the purpose of teaching, research, including clinical research, analysis or for the production, importation and distribution of analytical standards.

Sole Paragraph except that the *caput*of this Article the import of substances to be used in the manufacture of pilot batches intended for marketing.

Art. 21. The import of the substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and plants are subject to special control, as well as the medications that contain, intended solely for the purpose of teaching, research, analysis or for the production, importation and distribution of analytical standards, depends upon request, by means of the system NDS, for import authorization is intended solely for the purposes of teaching or research.

§ 1º When intended to units of forensic science officers, analytical reference laboratory, educational institution or research, including their support foundations, the import of the substances, plants and medicines  mentioned in the *caput*of this Article shall be requested by means of specific import authorisation.

§ 2º The requirements for granting the authorization of specific import are the same as those laid down for the granting of authorization that treats the *caput*of this article.

Art. 22. The AI that Art. 21 has a validity of 1 (one) year from the date of its issue, this being the final deadline for the shipment of cargo in the pool.

Art. 23. The validity of the AI mentioned in this section will be automatically extended for 2 (two) months, provided that the load has been shipped abroad within the term of validity of the authorisation.

Art. 24. Are subject to endorsement by the competent sanitary authority, by means of the system NDS, all imports of substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and plants are subject to special control, as well as the medications that contain it.

Art. 25. When required by the authority of the exporting country, the importer may request to Anvisa issuance of certificate of non-objection to import (CNI) of substances of lists (C1, C2, C3 and C5 and for those not subject to special control, as well as to the medicinal products containing them.

Sole Paragraph THE CNI is not bound to the exporter or the different chemical functions of the same substance, being possible to issue a single certificate for the realization of the imports that occur during the period of validity of the document.

Art. 26. The CNI request must be made by means of a petition form, completed in that fits.

Sole Paragraph. The documentation that comes the *caput*of this article must be filed by the Anvisa, duly signed by the legal representative and by the technical responsible of the importer.

Art. 27. The validity of the CNI is 3 (three) years.

Art. 28. The AI are issued in 3 (three) tracks, and CNI, in 2 (two) copies, with the following recipients:

I - first track: Anvisa;

II - second track: importer; and

III - traditionalism: the competent authority of the exporting country.

§ 1º The first track is retained in the Anvisa, being the importer responsible for sending the third track to the competent authority of the exporting country.

§ 2º if the competent authority of the exporting country requires the submission of original of the CNI, duplicate document may be requested, how many are the times required, throughout the period of its validity.

Art. 29. The import of the substances, plants and medicinal products subject to special control depends on registration of Import License (LI) in the Integrated System of Foreign Trade

- siscomex importation.

§ 1º the import of that treats *the caput*of this article requires prior authorization in favor of shipment of the Anvisa, submitting If, subsequently, the supervision by the health authority before its customs clearance.

§2 except that provided for in the *caput*of this Article the import of substances of lists (C1, C2, C3 and C5.

Art. 30. It is prohibited the customs transit regime for imports of goods and products based on substances of lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4 and plants s ujeitas the special control.

**Section III**

**Customs Clearance**

Art. 31. The importer must request the release of the health import to the health authority in the exercise at the border of Anvisa, in place of customs clearance of the product, by means of a petition for health surveillance and release, defined in the Resolution Board - RDC No 81 of 5 November 2008, and its updates.

Art. 32. For the exceptional cases in which there is a need for amendment of the quantitative or units of product, to a value less than the authorized, the importer shall require, next to Anvisa, authorization for the purpose of Customs Clearance (ADA).

Sole Paragraph THE ADA shall have the same validity of its AI.

Art. 33. The following documents are required for the peti tion of ADA: I - form of petition is completed, as appropriate;

II - technical justification of the request; and

III - a copy of the commercial invoice containing the amendment pled.

Art. 34. The ADA is issued in 2 (two) copies, with the following recipients: I - first track: Anvisa headquarters; and

II - second track: importer.

Art. 35. In cases in which the load contains quantitative or units  or divergent to those contained in the AI, and is authorized the sawing of cargo by the Federal Revenue of Brazil, quantitative or units previously authorized can be internalised.

Art. 36. In the impossibility of physical dismemberment of cargo containing quantity exceeding the authorized, exclusively due to the physical characteristics of the product, the authorization for

The acceptance of import will depend on evaluation of the technical authority of the Anvisa.

**Section IV**

**The return to the Pool**

Art. 37. When does not occur the effectuation of customs clearance of substances and plants subject to special control, as well as of medicines containing them, such products must be returned to the country of origin after verification by the Health Authority at the border of the Anvisa - the place where the load is.

§ 1º to realize the return provided for in the *caput*of this article, the importer must comply with the requirements set out in Section V of this Chapter, in that fits.

§ 2nd case is ascertained the impossibility of return, the customs may exceptionally be authorised, with the sole purpose of disposal, after authorisation of the competent technical area of the Anvisa.

**Section V**

**The Export**

Art. 38. To export the substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and the plants are subject to special control, as well as the medications that contain, the exporter shall require the authorisation of exports (PTB).

Art. 39. Applications for aex to Anvisa shall be carried out electronically, by means of the

NDS system.

Sole Paragraph. To use the System NDS, importers/exporters should request register, as set forth in Section II of this Resolution.

Art. 40. The PTB must be previously peticionada, through the system of electronic petitioning the Anvisa.

Art. 41. After the petitioning electronic, the importer/exporter should access the System

NDS to perform the request corresponding to the transaction number generated.

Art. 42. For the request of PTB, the exporter must fill all the mandatory information requested by the system NDS.

Sole Paragraph. The exporter must ceremonial at Anvisa the original document of AI or similar document issued by the competent authority of the importing country.

Art. 43. The aex shall have the same validity of AI or similar document issued by the competent authority of the importing country or, in the absence of these, it will be valid for 6 (s) months.

Art. 44. For the export of substances listed in Schedule C1, C2, C3 and C5, as well as the medications that contain it, is not necessary at the request of PTB.

Art. 45. When required by the authority of the importing country, the exporter may s prompt to Anvisa issuance of certificate of non-objection to Export (CNE) of substances of lists (C1, C2, C5 and for those not subject to special control, as well as to the medicinal products containing them.

Sole Paragraph The CNE is not bound to the exporter or the different chemical functions of the same substance, being possible to issue a single certificate for the realisation of exports that occur during the period of validity of the document.

Art. 46. At the request of the CNE shall be made by means of a petition form filled in that fits.

Sole Paragraph. The documentation that comes the *caput*of this article must be filed by the Anvisa, duly signed by the legal representative and by the technical responsible of the exporter.

Art. 47. The validity of the CNE is 3 (three) years.

Art. 48. The Anvisa shall deliver the aex in 3 (three) tracks and the CNE in 2 (two) copies, with the following recipients:

I - first track: Anvisa;

II - second track: exporter; and

III - traditionalism: the competent authority of the importing country.

§ 1º The first track is retained in the Anvisa, being the exporter is responsible for sending the third track to the competent authority of the importing country.

§ 2º if the competent authority of the importing country requires the submission of original of the CNE, duplicate document may be requested, how many are the times required, throughout the period of its validity.

Art. 49. To manufacture medicinal products and presentations not registered in Brazil, on the basis of substances subject to special control, the manufacturer must apply to the Anvisa Authorization to manufacture for the sole purpose of export (AFEX).

§ 1º The authorization mentioned in the *caput*of this article is not intended to certify or

Ensure the Good Manufacturing Practices (GMP) of the authorised product nor its safety and efficacy.

§ 2º Is prohibited the marketing of medicines that treat the *caput*of this article throughout the national territory.

Art. 50. The following documents are required for the request of the afex: I - form of petition is completed, as appropriate; and

II - a copy of the certificate of registration of the drug or similar document valid issued by the health authority of the importing country, which must appear on the presentations marketed and the proof that the manufacturer of the drug is the requestor of the afex.

Art. 51. The Afex is issued in 2 (two) copies, with the following recipients:

I - first track: Anvisa headquarters; and

II - second track: manufacturer/exporter.

Art. 52. The validity of the afex is 3 (three) years.

Art. 53. For export of samples of medicinal products subject to special control not registered in Brazil and in the importing country, the exporter must join to request authorization to export (AEX), by means of the system NDS, a statement signed by the responsible technician of the exporter, attesting that the samples of medicinal products are the sole purpose of analysis and that there will be marketed in the importing country.

Paragraph 1 of the declaration mentioned in the *caput*of this article shall contain: the name of the medication, the presentation, the country of destination and the quantity to be exported, which must be consistent with the purpose of exportation.

§ 2º For exports handled in the *caput*of this article, the exporter is exempt from petition AFEX request.

Art. 54. The data changes of the AEX and Certificate of No objection may be requested, by means of petitioning available at the Portal of the Anvisa.

Art. 55. It is prohibited the customs transit regime to the export of goods and products of substances contained in Lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4 and plants subject to special control.

**Chapter III**

**The special permit for Institution of Education and Research (AEP)**

Art. 56. To acquire and use the plants, substances and medicinal products subject to special c ontrole, with the sole purpose of teaching and research, the institutions must

Obtain special permission for Institution of Education and Research (AEP).

Art. 57. The legal responsible for institution must require AEP to lesson plans or research projects, upon petition accompanied by the following documents:

I - form of petition is completed, as appropriate;

II - copy of identification document journal and the CPF legal guardian by the institution; III - a document signed by the legal responsible for the institution, identifying the responsible

The control and custody of the substances or medicinal plants used, as well as the

Teachers and researchers;

IV - copy of identification document journal and the CPF of persons mentioned in subsection

(iii) of this Article;

V - synthesis of the course plans or projects of scientific and technical research, in order to demonstrate the compatibility of the request with the intended use; and

VI - the ratio of the substances, medicines or plants, expressed in quantitative limit equivalent to the active substance, and the quantities to be used.

Art. 58. The Anvisa shall deliver CEPOL in 3 (three) tracks, with the following recipients: I - first track: Anvisa;

II - second track: Solicitant and institution; and

III - traditionalism: supplier.

Sole Paragraph. The second and third tracks will be sent to the institution requester.

Art. 59. A CEPOL may contemplate all of lesson plans, training or research projects to be developed by the institution.

Art. 60. Any alteration of the data contained in the documents listed in sections II, III, IV, V and VI of art. 57 of this Resolution, including the insertion of new travel plans or projects of scientific and technical research, should be imediatament and informed to Anvisa, by means of a petition for amendment to the initial process of AEP.

Sole Paragraph. The amendment provided for in the *caput*of this article depends on prior authorisation from the

Anvisa.

Art. 61. The AEP is valid for 2 (two) years, and may be renewed, upon request of the applicant, if the study or lesson plan have not yet been finalised.

Sole Paragraph The renewal that treats the *caput*of this Article shall be requested by the legal responsible for the institution, upon petition instructed with doc umentos date laid down in Article 57 of this Resolution.

Art. 62. For the obtaining of AEP, with the aim of use of substances listed in

List C3 or medicine containing them, the institutions must follow, in addition to the provisions of this Chapter, the provisions set out in Resolutions Board - RDC No 11 of 22 March

2011, and RDC No. 191 of 11 December 2017, and its updates.

Art. 63. The legal responsible for institution which perform importation of plants, substances and medicinal products subject to special control must forward to Anvisa, annually, the BSPO (Annex XX of the SVS/MS Decree No 344 of 12 May 1998) concerning the movement of imported products contained in the AEP granted to your institution.

Art. 64. For import and export of substances, plants or medicinal products subject to special control, the teaching and research institutions must meet, in addition to the provisions of this Section, the other provisions of this Resolution.

**Chapter IV**

**The FINAL PROVISIONS**

Art. 65. Will only accept applications for AI and PTB carried out by means of the system NDS. Sole Paragraph. In the event of any operating system NDS, which causes

Unfeasibility of its use, other tools can be used in character

Exceptional, upon express authorization of the competent technical area and in order to be indicated at the Portal of the Anvisa.

Art. 66. The provisions of this Resolution also applies to inputs and veterinary medicines.

Art. 67. Non-compliance with the requirements of this Resolution shall constitute violation of sanitary ware, getting the violator subject to the penalties provided for in the Sanitary Legislation in force, without prejudice to the other sanctions of a civil nature or criminal sanctions.

Art. 68. Are repealed the Resolutions Board - RDC No 99, of 30 December 2008; RDC No. 11, 11 March 2013; DRC 201, 18 July 2002 and RDC No 62 of 11 February 2016; articles 7, 11, 12, 13, 14, 15, 16, 17, 18, 19, 21, 22 and 23 of the Ordinance SVS/MS No 344 of 12 May 1998; and Articles 8, 14, 15, 16, 17, 18, 19, 20, 21,

22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46,

47, 48 and 49 of the Ordinance SVS/MS no. 6/99, of 29 January 1999.

Art. 69. This Resolution shall enter into force thirty (30) days after the date of its publication.

**PRESIDENT AND CEO**

**Annex I**

**Locations authorized for entry and exit from national territory of substances in lists A1, A2, A3, B1, B2, D1, F1, F2, F3 and F4, and plants subject to control and special, as well as the medications that contain**

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

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

III - Port of Santos, Santos/SP; or

IV - São Paulo International Airport - Airport Governor Andre Franco Montoro, Guarulhos/SP.

**Annex II**

**Criteria for examination of applications for import quotas**

For the definition of the criteria of this Annex, were considered the proposiçõe s *guide to the forecast of substances subject to supervision international,*published by the International Joint supervision of narcotics - Incb, the organization of the United Nations - UN.

If the history of the use of substances subject to special control is stable, the estimates of consumption will be based on the average quantities consumed, according to the criteria listed in items 1.1 to 1.5.

If the history of the use of substances subject to special control is not es opment opposite the historical consumption, the criteria listed in items 2.1 to 2.3 shall be considered.

1.  **Stable use of the substance in the evaluation period, opposite the town of consumption**

1.1 For the calculation of the import quota / Additional import quota, will be used the average monthly consumption of 12 (twelve) months preceding the month of application.

The average monthly consumption will be designed for the 18 (eighteen) months subsequent to the period of reported consumption. This projection aims the adequation of regular demands of the importer and the needs of the country for the substance (  minimum security supply), as well as the steady growth in consumption during the period of

Exercise.

1.2 The value of consumption designed will be subtracted from the existing stock in the importer, in the month preceding the request (8 field of the form of Petition), as well as the import authorizations (AI) clearance pending until the date of the request. The calculation is carried out as described below:

|  |  |
| --- | --- |
| Calculation of import quota / Additional import quota | |
| A. Consumption\* of the period under evaluation |  |
| B. Average monthly consumption ("A" divided by 12 months) |  |
| C. Final stock (plus the remaining balance\*\*) |  |
| D. Estimate of consumption for 18 months ("B" times 18 months) |  |
| E. Dimension calculated ("D" - "C") |  |

*\* consumption, as shown in field 8 of the form of petition: Sale + Processing + Manufacture of non-Psychotropic + Manufacture of Psychotropic Drug Export ++ losses.*

*\*\*remaining balance: consider the quantitative not internalized for import authorisations issued, as well as the balance of the quota granted previously, still capable of being used*by the importer.

1.3 The space "Observations" (field 8 of the form of Petition) should be populated with information relating to losses and with the(s) No(s) of authorizations to import and export relating to field 8 drives as declared in the form of petition.

1.4 Once the import quota, all subsequent requests for quota will be requested as additional quota for imports. There is no time limit set for their request, provided that met all the criteria.

2.  **Use not stable of the substance in the evaluation period , the history of consumption:**

2.1 can be considered as stable use of the substance:

 First request for quota import or absence of consumption in 12 (twelve) months preceding the month of application. In this case may be uses the average of the amounts intended for importers who engaged in activities similar to those of the importer requester, in the previous year;

 Difficulties in international proceedings, due to the control of substance between the United -Part of the United Nations Organization;

 Reduction or intermittent consumption due to situations which prevent the regular use of existing stock or the sending of the substance by the exporter, as theft, accidents or disasters;

 Attending public bidding expired, whose amount will be added to the value resulting from the analysis of measurement;

 Special notes on the production/obtaining substance, especially when it comes to only manufacturers/EXTRACTORS in the world, or qualified for the production of certain medicine;

 Launch of new product registered, in 3 (three) years of use of the substance; and

Other situations, which are conditional on the assessment of the technical area of the Anvisa.

2.2 When considering the use not stable, it is up to the technical area of the Anvisa to evaluate the most appropriate criterion that will meet the needs of the country, as well as ensure the control of the substance.

2.3 For the purpose of calculating the additional quota of importation, shall not be considered to forecast of sale of product/substance.