Regulatory Sanitary Framework in Coping with Covid-19 in Brazil

Marco Regulatório Sanitário no Enfrentamento do Covid-19 no Brasil

Marco Normativo Sanitario para Enfrentar el Covid-19 en Brasil

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RESUMO

Introdução. A atuação da Vigilância Sanitária na prevenção, promoção e proteção da saúde estão voltadas para as ações que interferem nos fatores de risco relacionados ao processo saúde-doença. **Objetivo.** Descrever sobre o marco regulatório sanitário brasileiro diante do enfrentamento da Covid-19 no Brasil. **Método**. Trata-se de estudo exploratório no tocante ao propósito, desenvolvido por meio de pesquisa documental. **Resultados**. Foi possível identificar que os esforços da Anvisa vão além de tentar conter a disseminação do coronavírus, tendo suas ações voltadas nos mais diversos setores da saúde, como medicamentos e equipamentos para a saúde; imunobiológicos; serviços de diagnóstico; e barreira sanitária. **Conclusão**. A Anvisa exerce papel primordial no combate e enfrentamento a Covid-19.

Descritores: Infecção por Coronavírus; Agência Nacional de Vigilância Sanitária; Sistema Único de Saúde.

ABSTRACT

Introduction. The role of Health Surveillance in the prevention, promotion and protection of health is focused on actions that interfere with risk factors related to the health-disease process. **Objective.** Describe the Brazilian health regulatory framework in the face of the Covid-19 confrontation in Brazil**. Method.** This is an exploratory study with regard to the purpose, developed through documentary research. **Results.** It is possible to identify that Anvisa's efforts go beyond trying to contain the spread of the coronavirus, with its actions focused on the most diverse health sectors, such as medicines and health equipment; immunobiologicals; diagnostic services; and sanitary barrier. **Conclusion.** Anvisa plays a major role in combating and confronting Covid-19.

Descriptors: Coronavírus Infections; Brazilian Health Surveillance Agency; Unified Health System.

RESUMEN

Introducción. El papel de la Vigilancia en Salud en la prevención, promoción y protección de la salud se centra en acciones que interfieran con los factores de riesgo relacionados con el proceso salud-enfermedad. **Objetivo.** Describir el marco regulatorio de salud brasileño ante el enfrentamiento Covid-19 en Brasil. **Método.** Se trata de un estudio exploratorio con respecto al propósito, desarrollado a través de la investigación documental. **Resultados.** Es posible identificar que los esfuerzos de Anvisa van más allá de tratar de contener la propagación del coronavirus, con sus acciones enfocadas en los más diversos sectores de la salud, como medicamentos y equipos de salud; inmunobiológicos; servicios de diagnóstico; y barrera sanitaria. **Conclusión.** Anvisa juega un papel importante en la lucha y el enfrentamiento al Covid-19.

Descriptores: Infección por coronavirus; Agencia Nacional de Vigilancia Sanitaria; Sistema de Salud Unificado.

REVISÃO

Introduction

In Brazil, health surveillance was relevant after the promulgation of the Federal Constitution of Brazil, and after 1990 surveillance actions became more expressive with the implementation of the Unified Health System (SUS) – the Regulatory Agency was created. Created by Law 9782, the National Health Surveillance Agency (Anvisa) emerged with the institutional role of promoting the health of the population and the sanitary control of the production and sale of products and services.[1]

Law 8080/90 states that sanitary surveillance is a set of actions capable of eliminating, reducing or preventing health risks and intervening in sanitary problems arising from the environment, the production and circulation of goods and the provision of services in the interest of health , covering: I - the control of consumer goods that, directly or indirectly, are related to health, including all stages and processes, from production to consumption; II - the control of the provision of services that are directly or indirectly related to health.[2]

The role of Health Surveillance in the prevention, promotion and protection of health are aimed at actions that interfere with risk factors related to the health-disease process, with prevention actions aimed at preventing the emergence of specific diseases, with a reduction in its incidence and prevalence in the population. In health promotion, the actions are aimed at training and raising awareness in an educational way, in order to intervene in improving health and consequently in the quality of life. Health protection actions concentrate a large part of health surveillance actions, based on the structural concept of risk, as the possibility of occurrence of events with damage to health.[3]

In this sense, since December 2019, the world has been concerned about Covid-19 - Coronavirus (Sars-CoV-2) - which has spread with high levels of contamination throughout the world, being declared a pandemic in March 2020 by the World Health Organization (WHO). The first cases were registered by the Wuhan Municipal Health and Sanitation Commission, China, which identified 27 cases of severe pneumonia of unknown etiology. In January 2020, Chinese authorities identified the virus of the Coronaviridae family, thus called the new Coronavirus or Coronaviridae family, called Covid-19.[4] In Brazil, data from the Ministry of Health indicate that the first case was identified on February 26, 2020. On March 17, 2020, the first death was registered. Until March 23, 2021, 12,130,019 cases and 298,676 confirmed deaths had been recorded, with a mortality rate of 2.5%.[5]

With the worsening of Covid-19, Anvisa played an important role in society, as the pandemic strongly encompasses health issues, and these have an essential role in combating and controlling the new coronavirus. Sanitary measures encompass a wide range of actions, namely: standards for the production and distribution of drugs to combat the coronavirus; control of the manufacture, import and sale of medical equipment and devices necessary for the treatment of the disease; health control at ports, airports and borders; manufacture and distribution of sanitizers – such as alcohol gel; technical criteria for examination and screening of coronaviruses using blood, cells, tissues and organs; guidelines on clinical trials and the experimental use of options for

coping with the disease; measures relating to the continuity of vaccination services during the pandemic; actions to prevent contamination of the elderly in long-stay institutions; among others.[5]

However, the objective of this text is to describe the Brazilian sanitary regulatory framework in the face of Covid-19.

Method

This is an exploratory study in terms of purpose, developed through documentary research, which provided a comprehensive approach to the main regulatory standards for sanitary surveillance in Brazil, in confronting the Covid-19.

The survey was carried out on April 8, 2021 by consulting the Anvisa website http://antigo.Anvisa.gov.br/legislacao#/. Two searches were made, one with the descriptor "Covid" and the other with "coronavirus infection" and the type of legal acts selected in the two searches were: "Resolution of the Collegiate Board of Directors – RDC"; "Resolution – RES"; "Resolution – RE"; "Normative Instruction – IN" and "Joint Normative Instruction – INC". Revoked and expired acts were excluded, resulting in a final sample of twenty-seven documents. Data analysis was based on the thematic organization of regulatory standards for the discussion.

This research followed the provisions of Resolution 510/2016 of the National Research Ethics Commission, as it used information from public domain or access.

Results e Discussion

After searching with the descriptor "Covid", seventeen documents were identified, and of these, six were excluded because they were revoked acts (with eleven rules included). After conducting the research with the descriptor "coronavirus infection", 23 documents were found, of which one was a revoked act; three expired acts – which lost their validity; and three appeared repeated in the search made by the descriptor "Covid", and were excluded from the sample (with sixteen current norms remaining).

For a better discussion of the measures adopted by Anvisa in the fight against Covid-19, the rules were separated by thematic areas arranged in tables. Thus, it forms a sample of 27 norms organized into thematic categories, namely: I) Medicines and equipment for health; II) Immunobiologicals; III) Diagnostic services and IV) Sanitary barrier.

Table 1- Standards for medicines and health equipment.

Resolution	Objective
RDC No. 485, OF MARCH 26, 2021.[6]	Changes RDC No. 352/20, which provides for the prior authorization for the purpose of exporting raw material, semi-finished product, bulk product or finished pharmaceutical product intended to combat COVID-19.
RDC No. 352, OF MARCH 20, 200.[7] Effective with amendment	Provides for the prior authorization for export of chloroquine and hydroxychloroquine, azithromycin intended to combat Covid-19.
RDC No. 425, OF SEPTEMBER 24, 2020.[8]	Changes RDC No. 357/20, which temporarily extends the maximum quantities of drugs subject to special control allowed in Prescription Notifications and Special Control Prescriptions and allows, due to the Public Health Emergency of International Importance related to the new Coronavirus.
RDC No. 419, OF SEPTEMBER 1, 200.[9]	Amend RDC No. 346/20, which defines the extraordinary and temporary criteria and procedures for the certification of good manufacturing practices for the purposes of registration and post-registration changes of active pharmaceutical ingredient, medicine and health products due to the emergency of Coronavirus International Public Health.
RDC No. 415 OF AUGUST 26, 2020.[10]	Defines new extraordinary criteria and procedures for handling registration petitions and post-registration changes of medicines and biologicals due to the international public health emergency arising from the new Coronavirus.
RDC No. 405, OF JULY 22, 2020.[11] Effective with change	Establishes the control measures for drugs that contain substances alone or in association, due to the Public Health Emergency of International Importance related to the new Coronavirus.
RDC No. 402, OF JULY 21, 2020.[12] Effective with change	Establishes the temporary opening of entry and exit points for substances subject to special control, due to the Public Health Emergency of International Importance related to the new Coronavirus.
RDC No. 400, OF JULY 21, 2020.[13]	Defines the extraordinary and temporary criteria and procedures for the application of exceptionalities to specific labeling requirements and drug inserts, due to the international public health emergency arising from the new Coronavirus.
RDC No. 392 OF MAY 26, 2020.[14] Effective with change	Defines the extraordinary and temporary criteria and procedures for the application of exceptionalities to specific requirements of the Good Manufacturing and Importing Practices of Medicines and Pharmaceutical Ingredients, due to the international public health emergency resulting from the new Coronavirus.
RDC No. 387, OF MAY 26, 2020.[15]	Alters Annex I of the Collegiate Board Resolution - RDC No. 357/20, which temporarily extends the maximum quantities of drugs subject to special control allowed in Special Control Prescription and Prescription Notifications and temporarily allows remote delivery defined by a public program and the home delivery of drugs subject to special control, due to the Public Health Emergency of International Importance related to the new Coronavirus.
RDC No. 357, OF MARCH 24, 2020.[16]	It temporarily extends the maximum quantities of drugs subject to special control allowed in Prescription Notifications and Special Control Prescriptions and allows remote delivery defined by a

Effective with amendment	specific public program and home delivery of drugs subject to special control, due to the Emergency of Public Health of International Importance related to the new Coronavirus.
RDC No. 346, OF MARCH 12, 2020.[17]	Defines the extraordinary and temporary criteria and procedures for the certification of good manufacturing practices for the purposes of registration and post-registration changes of active pharmaceutical ingredient, medicine and health products due to the international public health emergency of the new Coronavirus.
RDC No. 484, OF MARCH 19, 2021.[18]	Provides for temporary and extraordinary procedures for the authorization, on an emergency basis, of anesthetics, sedatives, neuromuscular blockers and other hospital drugs used to maintain the lives of patients in the face of a public health emergency of national importance resulting from the outbreak of the new coronavirus.
RDC No. 378, OF APRIL 28, 2020 [19]	Provides, in an extraordinary and temporary way, on the requirements for the import, marketing and donation of pulmonary ventilators, vital signs monitors, infusion pumps, used oximetry equipment and capnographs, indispensable in intensive care units, due to the emergency of international public health related to COVID-19.

With regard to sanitary standards that encompass Anvisa's actions in the areas of medicines and health equipment, it is observed that in 2020 RDC were published that provide for temporary and extraordinary procedures for manufacturing, registration and post-registration change active pharmaceutical ingredient, medicine, health products and equipment. In addition, it establishes control measures for drugs subject to special control during the duration of the pandemic by the new coronavirus (SARS-CoV-2).

RDC No. 419/209 amends Resolution of RDC No. 346/2017, in order to modify its validity, which will automatically terminate when the Ministry of Health configures that there is no longer an emergency situation in public health. The last resolution mentioned deals with the temporary criteria and procedures for certification of good manufacturing practices, registration and post-registration alteration of pharmaceutical inputs, medicines and health products.

RDC No. 357/2016 temporarily expands the maximum quantities of drugs subject to special control allowed, which remains in force, but with two new changes - one through RDC No. 387/20 15 that excludes the maximum allowed amounts of base drugs thalidomide and lenalidomide for women of childbearing age or of childbearing potential, who must meet the provisions previously provided; and the other change is given by RDC No. 425/208, which changes in terms of its validity, which will automatically end when the Ministry of Health establishes that there is no longer an emergency situation in public health.

On March 26, 2021, Anvisa enacted RDC No. 4856, which amended RDC No. 352/207, which deals with the export of medicinal oxygen (O2), Covid-19 vaccines and drugs used in Covid-19 treatment. In addition, it provides that bulk products or finished products (ready for sale) will temporarily require prior authorization from Anvisa. Corroborating, RDC No. 484/2118, provides for extraordinary procedures for authorization of the

manufacture of drugs used in the treatment and maintenance of life of patients with Covid-19.

Table 2 presents the sanitary norms aimed at immunobiologicals. Note that in November 2020, Anvisa publishes Normative Instruction No. 7720, which deals with differentiated procedures to allow the analysis of data for registration of vaccines in the Covid-19 combat, as they are generated and presented to the Agency.

Table 2- Standards for immunobiologicals

Resolução	Objetivo
NORMATIVE INSTRUCTION - IN No. 77, OF NOVEMBER 17, 2020.[20]	Provides for the continuous submission procedure of technical data for the registration of Covid-19 vaccines.
RDC No. 465, OF FEBRUARY 9, 2021.[21]	It establishes the exemption from registration and authorization for emergency use and the procedures for importing and monitoring Covid-19 vaccines acquired by the Ministry of Health, under the Covid-19 Global Access Instrument for Vaccines (Covax Facility).
RDC No. 475, OF MARCH 10, 2021.[22]	Establishes the procedures and requirements for submitting a request for temporary authorization for emergency use (AUE), on an experimental basis, of drugs and vaccines for Covid-19 to face a public health emergency of national importance.
RDC No. 476, OF MARCH 10, 2021 (*).[23]	Establishes the procedures and requirements for submitting an exceptional and temporary authorization request for the import and distribution of medicines and vaccines to Covid-19 to face the public health emergency of national importance resulting from the outbreak of the new coronavirus, pursuant to Law No. 14,124 /2021.

RDC No. 465/21[21] extraordinarily established the exemption from registration and authorization for emergency use, as well as the procedures for importing and monitoring Covid-19 vaccines acquired exclusively by the Ministry of Health, within the scope of the Covax Facility instrument, which is a international alliance managed by the World Health Organization that aims to help all nations have equal and fair access to immunization.

In relation to RDC No. 475/21[22], it aims to establish the procedures and requirements for submitting a request for temporary authorization for emergency use (AUE), on an experimental basis, of drugs and vaccines for Covid-19, while RDC No. 476/21[23] regulates the requirements for submitting an exceptional and temporary authorization request for the import and distribution of drugs and vaccines against Covid 19.

It should be noted that measures were adopted to ease the procedures for registration, authorization, import and distribution of medicines and vaccines for the duration of the pandemic. Table 3 describes the health standards related to diagnostic services.

Table 3- Standards aimed at diagnostic services.

Resolution	Objective
RDC No. 377 OF APRIL 28, 2020.[24]	It authorizes, on a temporary and exceptional basis, the use of "quick tests" (immunochromatographic tests) for COVID-19 in pharmacies, suspending the effects of § 2 of art. 69 and art. 70 of RDC No. 44/09.
RDC No. 426, OF SEPTEMBER 30, 2020.[25]	Changes RDC No. 364/20, which suspends the effects of Resolution of the Collegiate Board of Directors - RDC No. 302, of October 13, 2005, on a temporary and exceptional basis, for the official laboratories that will carry out the diagnosis of COVID-19.
RDC No. 364, OF APRIL 1, 2020.[26] Effective with change	Suspends the effects of Collegiate Board Resolution - RDC No. 302/05, on a temporary and exceptional basis, for the Federal Agricultural Defense Laboratories (LFDA) that will carry out analyzes for the diagnosis of COVID-19
RDC No. 366, OF APRIL 2, 2020[27]	Provides for the importation of products for in vitro diagnosis of Coronavirus during the public health emergency of international importance arising from the new Coronavirus.

Due to the pandemic related to the new coronavirus, RDC nº 364/2020[26] suspended the effects of RDC nº 302/2005[28] in relation to the Federal Agricultural Defense Laboratories (LFDA) that will carry out analyzes for the diagnosis of COVID-19. RDC No. 426/20[25] amended RDC No. 364/20[26] where it modifies its validity, which will automatically terminate when the Ministry of Health configures that there is no longer an emergency situation in public health of national importance.

RDC nº 366/20[27] established the activities of sanitary surveillance in relation to the importation of products for *in vitro* diagnosis of Coronavirus. This import must be through the Import Licensing modalities only to authorized companies.

Furthermore, since April 2020, RDC No. 377/20[24] has authorized pharmacies and drugstores to carry out rapid tests to diagnose the new coronavirus. Such tests must be performed by the responsible pharmacist, who must use devices regulated by the Regulatory Agency - the results must be recorded to ensure their traceability and informed to the competent health authority. Table 4 describes the standards for the sanitary barrier.

Table 4- Standards aimed at the sanitary barrier.

Resolution	Objective
RDC No. 384, OF MAY 12, 2020.[29]	Provides for the temporary inclusion of the procedure for issuing a health certificate by documentary analysis, regulated in RDC No. 72/09 to vessels during the COVID-19 pandemic period.
RDC No. 373, OF APRIL 16, 2020.[30]	Changes art. 29 of RDC No. 72/09, which provides for the Technical Regulation aimed at promoting health in sanitary control ports installed in the national territory, and vessels that pass through them during the Public Health Emergency of International Importance COVID-19.

RDC No. 479, OF MARCH 12, 2021.[32]	Provides for prohibitions on imports carried out by individuals for their own use by any import modalities during the new coronavirus pandemic.
RDC No. 477, OF MARCH 11, 2021.[33]	Changes RDC No. 456/20, which provides for the measures to be adopted at airports and aircraft due to the situation of Public Health Emergency of National Importance resulting from the outbreak of the new coronavirus.
RDC No. 456 OF DECEMBER 17, 2020.[34] Effective with amendment	Provides for the measures to be adopted at airports and aircraft due to the situation of Public Health Emergency of National Importance resulting from the outbreak of the new coronavirus.

As a strategy to fight Covid-19, since April 2020, sanitary barriers have been created in order to control the inflow and outflow of people, reducing the possibility of contagion and dissemination of the coronavirus. RDC No. 373/2030 amended RDC No. 72/200931 on the validity of the National Onboard Sanitary Control Certificate (CCSB) and the National Onboard Sanitary Control Exemption Certificate (CICSB) of a national and international vessel, which may be extended, once, in a period of 30 (thirty) days.

The RDC nº 477/2133 changed some measures to be adopted in airports and aircraft due to the coronavirus outbreak, which contemplated the RDC nº 456/20.34 Some changes involve the writing of articles, definitions, dispensing with the use of masks for people with autism spectrum disorder, with intellectual and sensory disabilities, and children under 3 years of age; among other measures.

In addition, RDC No. 479/2132 deals with products that will be prohibited from being imported by individuals during the duration of the coronavirus pandemic. Such products involve the classes of medicines, health products, food, sanitizers, cosmetics, personal care products and perfumes and brings other provisions.

Conclusion

Since the World Health Organization (WHO) declared a global pandemic situation caused by SARS-CoV-2, all the Organs in their most diverse attributions have mobilized to combat the spread of this virus.

It is possible to identify that Anvisa's efforts go beyond trying to contain the dissemination of the coronavirus, having its actions focused on the most diverse sectors of health, such as: medicines and health equipment; immunobiologicals; diagnostic services; and sanitary barrier.

It was observed that Anvisa, as a Regulatory Agency, has as its main functions the prevention, promotion and protection of health, and because its theme involves health issues, it plays a key role in combating and confronting Covid-19.

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References

1. Brasil. Presidência da República. Lei nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária e dá outras providências. Diário Oficial da União 1999; 27 jan.
2. Brasil. Presidência da República. Lei nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Diário Oficial da União 1990; 20 set.
3. Silva JAA, Costa EA, Lucchese G. SUS 30 anos: Vigilância Sanitária. Ciênc. saúde coletiva [Internet]. 2018 Jun [citado 2021 Maio 19]; 23(6):1953-1961. Disponível em: http://dx.doi.org/10.1590/1413-81232018236.04972018.
4. Timerman S, Guimarães HP, Rochitte CE, Polastri TF, Lopes MACQ. Corrente de sobrevivência à COVID-19. Arq. Bras. Cardiol. [Internet]. 2021 Feb [citado 2021 Maio 19]; 116(2):351-354. Disponível em: http://dx.doi.org/10.36660/abc.20201171.
5. Guerra S, Salinas NSC, Gomes LT. As agências reguladoras em resposta à crise da COVID-19. Rev. Adm. Pública. [Internet] 2020 [citado 2021 Maio 19]; 54(4):874-897. Disponível em: https://doi.org/10.1590/0034-761220200321.
6. Brasil. Agência Nacional de Vigilância Sanitária. RDC 485/21. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/2957335/RDC_485_2021_.pdf/1b3f5cd3-221c-48dc-9f78-866a259ed990. Acesso em: 20 Abr.2021.
7. Brasil. Agência Nacional de Vigilância Sanitária. RDC 352/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/2957335/%285%29RDC_352_2020_COMP.pdf/baa03651-b7ce-4300-952b-b9663edeaf68. Acesso em: 20 Abr.2021.
8. Brasil. Agência Nacional de Vigilância Sanitária. RDC 425/20/20. Disponível http://antigo.Anvisa.gov.br/documents/10181/5824703/RDC_425_2020_.pdf/e11b516d-7251-4c83-a27f-c8a1a95a9079. Acesso em: 20 Abr.2021.
9. Brasil. Agência Nacional de Vigilância Sanitária. RDC 419/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5809525/%281%29RDC_419_2020_.pdf/34b803de-618a-435a-adcf-6aa24ac680c9. Acesso em: 20 Abr.2021.
10. Brasil. Agência Nacional de Vigilância Sanitária. RDC 3415/20. Disponível em:
http://antigo.Anvisa.gov.br/documents/10181/6005608/RDC_415_2020_.pdf/ecaf98cb-4b5c-4f22-b632-7a7d70694303. Acesso em: 20 Abr.2021.
11. Brasil. Agência Nacional de Vigilância Sanitária. RDC 405/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5956497/%281%29RDC_405_2020_COMP.pdf/32673d71-222d-4af9-9fc6-f22c40a6e1b2. Acesso em: 20 Abr.2021.
12. Brasil. Agência Nacional de Vigilância Sanitária. RDC 402/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5963526/RDC_402_2020_COMP.pdf/b442f070-74c9-42be-ae29-5169e4f70e2b. Acesso em: 20 Abr.2021.
13. Brasil. Agência Nacional de Vigilância Sanitária. RDC 400/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5956475/RDC_400_2020_.pdf/60a135b1-144c-4647-94e7-7850536d2ebc. Acesso em: 20 Abr.2021.
14. Brasil. Agência Nacional de Vigilância Sanitária. RDC 392/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5893706/%281%29RDC_392_2020_COMP.pdf/d29d9365-c22f-4ff6-b77f-3722dfd50de8. Acesso em: 20 Abr.2021.

15. Brasil. Agência Nacional de Vigilância Sanitária. RDC 387/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5824703/RDC_387_2020_.pdf/9f213ba9-f23c-4d82-afb4-910b2dd9b398. Acesso em: 20 Abr.2021.
16. Brasil. Agência Nacional de Vigilância Sanitária. RDC 357/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5824703/%282%29RDC_357_2020_COMP.pdf/7a6265a8-87c2-4c79-b6ae-58b3857cd2d3. Acesso em: 20 Abr.2021.
17. Brasil. Agência Nacional de Vigilância Sanitária. RDC 346/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5809525/%282%29RDC_346_2020_COMP.pdf/4a81a956-909e-4fce-b47a-cc5f7b7a71d3. Acesso em: 20 Abr.2021.
18. Brasil. Agência Nacional de Vigilância Sanitária. RDC 484/21. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/6245834/RDC_484_2021_.pdf/442fc93e-8079-42d9-b45a-cef8ee0f70a1. Acesso em: 20 Abr.2021.
19. Brasil. Agência Nacional de Vigilância Sanitária. RDC 378/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5868576/RDC_378_2020_.pdf/76614d07-781b-4108-91ba-069ced2f1569. Acesso em: 20 Abr.2021
20. Brasil. Agência Nacional de Vigilância Sanitária. IN 77/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/6118549/IN_77_2020_.pdf/54b561e4-bfba-4f87-9fd6-c71862bf69dd. Acesso em: 20 Abr.2021.
21. Brasil. Agência Nacional de Vigilância Sanitária. RDC 465/21. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/6226224/%281%29RDC_465_2021_.pdf/16a0b13f-4cdd-4f97-9f45-a99c915c38b9. Acesso em: 20 Abr.2021.
22. Brasil. Agência Nacional de Vigilância Sanitária. RDC 475/21. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/6134216/RDC_475_2021_.pdf/a9edad40-f6de-4d2d-891b-be84e4ee4171. Acesso em: 20 Abr.2021.
23. Brasil. Agência Nacional de Vigilância Sanitária. RDC 476/2. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/6240597/RDC_476_2021_COMP.pdf/6c077803-fc71-4120-90a7-73c609156e76. Acesso em: 20 Abr.2021.
24. Brasil. Agência Nacional de Vigilância Sanitária. RDC 377/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5864561/%281%29RDC_377_2020_COMP.pdf/73324688-74c5-45f9-9010-87f0ad3c0091. Acesso em: 20 Abr.2021
25. Brasil. Agência Nacional de Vigilância Sanitária. RDC 426/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5835858/RDC_426_2020_.pdf/6b17480e-67f8-4f23-82cd-40c3debee011. Acesso em: 20 Abr.2021.
26. Brasil. Agência Nacional de Vigilância Sanitária. RDC 364/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5835858/%283%29RDC_364_2020_COMP.pdf/50a9314c-c694-49a1-8658-5e3bd0d2d830. Acesso em: 20 Abr.2021.
27. Brasil. Agência Nacional de Vigilância Sanitária. RDC 366/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/2957335/RDC_366_2020_.pdf/a8e4fb7f-d334-4c02-8141-92a7e80f973e. Acesso em: 20 Abr.2021.
28. Brasil. Agência Nacional de Vigilância Sanitária. RDC 302/2005. Disponível em: https://pncq.org.br/wp-content/uploads/2020/05/RDC-302-2005.pdf. Acesso em: 20 Abr.2021.
29. Brasil. Agência Nacional de Vigilância Sanitária. RDC 384/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5878758/RDC_384_2020_.pdf/8f5d632d-7bc3-4f4d-9884-96cb74a2b6e5. Acesso em: 20 Abr.2021.

30. Brasil. Agência Nacional de Vigilância Sanitária. RDC 373/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5853219/RDC_373_2020_.pdf/70beb41c-c829-4b2e-aaf0-bc68a613014b. Acesso em: 20 Abr.2021.
31. Brasil. Agência Nacional de Vigilância Sanitária. RDC 72/2009. Disponível em: http://bvsms.saude.gov.br/bvs/saudelegis/Anvisa/2009/res0072_29_12_2009.html. Acesso em: 20 Abr.2021.
32. Brasil. Agência Nacional de Vigilância Sanitária. RDC 479/21. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/2957335/RDC_479_2021_.pdf/e11d63c5-b224-4c3e-95c1-adf02c21c87a. Acesso em: 20 Abr.2021.
33. Brasil. Agência Nacional de Vigilância Sanitária. RDC 477/21. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5993637/%281%29RDC_477_2021_.pdf/692719a4-6a95-4974-bfb6-47dfa1c174f5. Acesso em: 20 Abr.2021.
34. Brasil. Agência Nacional de Vigilância Sanitária. RDC 456/20. Disponível em: http://antigo.Anvisa.gov.br/documents/10181/5993637/RDC_456_2020_COMP.pdf/d16fcb70-6850-4b8b-a868-8f43e5916ddb. Acesso em: 20 Abr.2021.

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