

Life Sciences

Life Sciences in Brazil is an electronic newsletter with information on recent legislation in the areas of Agriculture, Health Care, Innovation, Biotechnology and Biodiversity.

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PUBLICATION FREQUENCY

Monthly

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(PHOTO: ADOBE STOCK).

SUS

Ordinance MS No. 4,073 of December 29, 2017, published on January 5, 2018

Amends Ordinance No. 3,502/GM/MS of December 19, 2017, which institutes, in the scope of SUS, the strategy to strengthen healthcare actions of children suspected or confirmed for Congenital Syndrome associated with Zika virus infection and other syndromes caused by syphilis, toxoplasmosis, rubella, cytomegalovirus and herpes virus.

Ordinance SCTIE No. 65 of January 15, 2018

Makes public the decision of including in SUS secukinumab for the treatment of active ankylosing spondylitis, as per the Clinical Protocol and Therapeutic Guidelines of the Ministry of Health.

Ordinance MS No. 106 of January 15, 2018

Amends Ordinance GM/MS No. 6 of September 28, 2017, which consolidates the rules on financing and transfer of federal funds to the healthcare actions and services of SUS.

Joint Ordinance SAS No. 1 of January 10, 2018, published on January 16, 2018

Approves the Clinical Protocol and Therapeutic Guidelines of Primary Nephrotic Syndrome in Children and Adolescents.

Joint Ordinance SAS No. 2 of January 10, 2018, published on January 16, 2018

Approves the Clinical Protocol and Therapeutic Guidelines of Diabetes Insipidus.

Joint Ordinance SAS No. 3 of January 15, 2018, published on January 17, 2018

Approves the Clinical Protocol and Therapeutic Guidelines of the Stomach Adenocarcinoma.

Ordinance SCTIE No. 2 of January 17, 2018

Makes public the decision of incorporating in SUS tafamidis meglumine for adult patients with symptomatic polyneuropathy at an early stage, not submitted to liver transplantation, upon price negotiation and Clinical Protocol and Therapeutic Guidelines of the Ministry of Health.

Ordinance MS No. 159 of January 19, 2018

Changes attributes and includes procedures of chemotherapy of acute lymphocytic leukemia/ acute lymphoblastic leukemia in the List of Procedures, Drugs, Ortheses and Prostheses and Special Materials of SUS.

Ordinance MS No. 163 of January 19, 2018

Extends the time period of the implementation of the strategy for expanding the access to Elective Surgical Procedures, in the scope of SUS.

Ordinance SAS No. 103 of January 23, 2018

Repeals Ordinance SAS/MS No. 1,253 of November 12, 2013, which changes the List of Procedures, Drugs, Ortheses and Prostheses and Special Materials of SUS.

Ordinance SCTIE No. 3 of January 24, 2018

Makes public the decision of including in SUS secukinumab for the treatment of psoriatic arthritis in adult patients with inadequate response to synthetic or biological disease-modifying drugs of anti-TNF class.

Ordinance SCTIE No. 8 of January 24, 2018

Makes public the decision of expanding the indication of the allogeneic hematopoietic stem cell transplantation procedure, to include the treatment of the mucopolysaccharidosis type I, according to the List of Procedures, Drugs, Ortheses and Prostheses and Special Materials, in the ambit of SUS.

Ordinance SCTIE No. 9 of January 24, 2018

Makes public the decision of expanding the indication of the allogeneic stem cell-hematopoietic transplantation procedure, to include the treatment of the mucopolysaccharidosis type II, according to the List of Procedures, Drugs, Ortheses and Prostheses and Special Materials, in the ambit of SUS.

Ordinance SCTIE No. 10 of January 24, 2018

Makes public the decision of including enoxaparin sodium 40 mg/0.4 mL for the treatment of pregnant women with thrombophilia, in the ambit of SUS.

OTHERS

Resolution RDC ANVISA No. 207 of January 3, 2018

Provides for the organization of healthcare actions, performed by the Federal Government, States, the Federal District and Municipalities, relating to the Permit for Operation, Licensing, Registration, Certificate of Good Practices, Monitoring, Inspection and Standardization, in the ambit of the National Public Health Control System (SNVS).

Resolution MS No. 34 of December 14, 2017, published on January 8, 2018

Changes the information model of the Minimum Healthcare Data Set (MDS).



RDC ANVISA No. 208. (PHOTO: ADOBE STOCK).

Resolution RDC ANVISA No. 208 of January 8, 2018

Provides for streamlining of procedures for the importation of goods and products subject to Sanitary Surveillance.

Ordinance ANVISA No. 35 of January 11, 2018

Creates the policy on granting of sponsorships through Anvisa.

São Paulo State Law No. 16,657 of January 12, 2018

Creates, on a permanent basis, in the Healthcare Office of the State of São Paulo, the “Central Unit for Regulating the Offer of Healthcare Services – CROSS-U”, and makes other provisions.

RDC ANVISA No. 211 of January 22, 2018

Provides for the validity of the registration of medical devices.

RDC ANVISA No. 212 of January 22, 2018

Amends Resolution RDC No. 250 of October 20, 2004, which provides for procedures related to the revalidation of registration of products, and makes other provisions.



RDC ANVISA No. 211. (PHOTO: ADOBE STOCK).

RDC ANVISA No. 213 of January 23, 2018

Provides for the sale and marketing of tobacco smoking products.

Ordinance CVS No. 1 of January 2, 2018, published on January 25, 2018

Deals with, in the scope of the State System of Health Surveillance (Sevisa), the licensing of healthcare establishments and of sources of ionizing radiation, and makes other related provisions. ■

ANIMAL HEALTH AND PLANT PRODUCTS

Normative Ruling MAPA No. 2 of January 8, 2018, published on January 12, 2018

Subjects to official control procedures, the exports of products and by-products of animal origin, and they may be monitored and re-inspected by the units of the International Agricultural Surveillance System, ports, airports, border units and special customs offices, in accordance with this Normative Ruling.

Ordinance MAPA No. 11 of January 8, 2018, published on January 12, 2018

Repeals Ordinance No. 158 of August 24, 2016 (Exempts animal origin products - those packed in export containers, sealed in the Federal Inspection Service (SIF) of the respective manufacturing establishment or warehouse and accompanied by an International Healthcare Certificate – from the monitoring procedures carried out by the Agricultural and Livestock Surveillance System and Agricultural and Livestock Unit.

Ordinance MAPA No. 14 of January 3, 2018, published on January 12, 2018

Publishes the minimum prices for the 2018-crop extractive products.

Normative Ruling MAPA No. 7 of January 18, 2018

VOIDS Normative Ruling No. 1 of January 8, 2018, published in the Official Gazette of the Federal Executive (DOU) of January 8, 2018, Section 1, Page 1 (Amends article 1 of Normative Ruling MAPA No. 5 of February 14, 2017 (Establishes the requirements for assessing the equivalence of the Unified Agricultural and Stockbreeding Healthcare System - SUASA relating to the building, facilities and equipment of the small agribusiness of animal origin products)).

Normative Ruling MAPA No. 8 of January 18, 2018

VOIDS a Normative Ruling No. 3 of January 18, 2018, published in the Official Gazette of the Federal Executive (DOU) of January 18, 2018, Section 1, Page 1 (Repeals Normative Ruling No. 14 of April 6, 2010 (Establishes the rules for monitoring the transit of plants and parts thereof, except in vitro material, hosts of the red palm mite (*Raoiella indica*))).

Normative Ruling MAPA No. 9 of January 18, 2018

AMENDS article 1 of Normative Ruling MAPA No. 5 of February 14, 2017 (Establishes the requirements for assessing the equivalence of the Unified Agricultural and Stockbreeding Healthcare System - SUASA relating to the building, facilities and equipment of the small agribusiness of animal origin products)).

Normative Ruling MAPA No. 10 of January 18, 2018

REPEALS Normative Ruling No. 14 of April 6, 2010 (Establishes the rules for monitoring the transit of plants and parts thereof, except in vitro material, hosts of the red palm mite (*Raoiella indica*)).

Normative Ruling MAPA No. 11 of January 18, 2018, published on January 22, 2018

APPROVES the Technical Regulation on the Production, Quality Control, Marketing and Use of Vaccines against foot-and-mouth disease.

Normative Ruling MAPA No. 5 of January 8, 2018, published on January 26, 2018

APPROVES the Central Bank of Animal Identification Data for supply and control of the distribution of animal official identification codes to public and private bodies and entities throughout the Brazilian territory. ■

- SUS
- Others

- Animal Health And
Plant Products

- **Healthcare Professionals**



HEALTHCARE PROFESSIONALS

Resolution CFM No. 2,171 of October 30, 2017, published on January 8, 2018

Regulates the Committees on Review of Death, making them mandatory in hospitals and in Emergency Care Units (UPAs). ■

GLOSSARY

ANVISA – National Health Surveillance Agency

CFM – Federal Council of Medicine

CVS – Public Health Control Center

MAPA – Ministry of Agriculture, Livestock and Supply

MS – Ministry of Health

SAS – Health Support Office

SCTIE – Office of Science, Technology and Strategic Inputs of the Ministry of Health

SUS – Integrated Health System

RESOLUTION CFM No. 2.711 – REGULATES THE COMMITTEES ON REVIEW OF DEATH. (PHOTO: ADOBE STOCK).