

# 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.

This monthly publication is prepared by the Life Sciences group of Pinheiro Neto Advogados in English and Portuguese.

**PUBLICATION FREQUENCY**

Monthly

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(PHOTO: ADOBE STOCK).

**SUS**

## **Joint Ordinance SAS No. 4 of January 23, 2018, published on February 1, 2018**

Approves the Clinical Protocol and Therapeutic Guidelines on Breast Carcinoma.

## **Law No. 16,835 of February 8, 2018**

Amends Law No. 15,199 of June 18, 2010, which provides for mandatory posting, in the places and conditions established thereby, of the list of drugs available in the municipal public healthcare chain, and makes other provisions.

## **Ordinance MS No. 298 of February 9, 2018, published on February 19, 2018**

Includes in the Technical Regulation of the National System of Transplants and makes compatible in the List of Procedures, Pharmaceuticals, Ortheses, Prostheses and Special Materials of SUS, the indication of related- and unrelated-donor myeloablative allogeneic transplantation of hematopoietic stem-cells for the treatment of mucopolysaccharidosis types I and II and extends the age range for indication of related-donor myeloablative allogeneic transplantation for the treatment of sickle cell disease.

## OTHERS

### Ordinance MS No. 235 of February 1, 2018

Amends Ordinance GM/MS No. 1,583 of July 19, 2012, which provides for, in the scope of the Ministry of Health and entities connected thereto, the enforcement of Law No. 12,527 of November 18, 2011, which deals with the Law on Access to Information, and of Decree No. 7,724, of May 16, 2012, which regulates it.

### Ordinance MS No. 248 of February 2, 2018

Amends Consolidation Ordinance GM/MS No. 4 of September 28, 2017, to provide for the biometric record of the newborn and his mother.

### Joint Normative Ruling ANVISA No. 2 of February 7, 2018

Establishes procedures for tracking the production chain of fresh vegetable products intended for human consumption, for monitoring and controlling agrochemical residues, throughout Brazil.

### Law No. 16,839 of February 8, 2018

Provides for inclusion of vaccination card in a computing system.

### Resolution RDC ANVISA No. 215 of February 8, 2018

Provides for the amendment of the vacatio legis of Resolution RDC 207 of January 3, 2018, which provides for the organization of healthcare actions, performed by the Federal Government, States, the Federal District and Municipalities, relating to the Permit for Operation, License, Registration, Certificate of Good Practices, Monitoring, Inspection and Regulation, in the ambit of the National Public Health Control System (SNVS).

### Resolution RDC ANVISA No. 216 of February 8, 2018

Amends Resolution RDC No. 11 of March 13, 2014, which provides for the Good Practices Requirements for Dialysis Services, and makes other provisions.

### Orders of the Head of ANVISA No. 19 on February 9, 2018

Proposed initiative on staying the effectiveness of articles 26 and 60 of RDC 11/2014, which provides for Good Practices Requirements for Dialysis Services, and makes other provisions.

### Ordinance SAS No. 5 of February 19, 2018

Approves the Clinical Protocol and Treatment Guidelines for Sickle Cell Disease.

### Ordinance MS No. 178 of February 5, 2018, published on February 21, 2018

Excludes procedures relating to the Hereditary Coagulopathies Program from the List of Procedures, Pharmaceuticals, Ortheses, Prostheses and Special Materials of SUS.

### Ordinance MS No. 352 of February 16, 2018, published on February 22, 2018

Establishes the procedure for centralized acquisition by the Ministry of Health of methotrexate 2.5 mg (per tablet) and 25 mg/ml injectable (per 2 ml ampoule), of the Pharmaceutical Care Specialized Component. ■

## **Ordinance MS No. 286 of February 8, 2018, published on February 19, 2018**

Creates the Committee on Reduction of Bureaucracy to subsidize the formulation and implementation of measures to reduce the bureaucracy of actions and procedures of the Ministry of Health.

## **Communiqué CMED No. 1 of February 7, 2018 (Rectification), published on February 20, 2018**

Discloses new presentations of pharmaceuticals deemed as similar to those included in the list of the Resolution No. 5 of October 9, 2003.

## **Resolution RDC ANVISA No. 214 of February 7, 2018, published on February 22, 2018**

Provides for the Good Practices on Human Cells for therapeutic use and clinical research, and makes other provisions.

## **Resolution RDC ANVISA No. 217 of February 20, 2018, published on February 27, 2018**

Amends Resolution RDC No. 39 of August 14, 2013 (Deals with the administrative procedures for issuance of Good Manufacturing Practices Certificate and Good Distribution and/or Storage Practices Certificate).

## **Resolution RE ANVISA No. 392 of February 20, 2018, published on February 27, 2018**

Recognizes the Medical Device Single Audit Program (Programa de Auditoria Única em Produtos para a Saúde - MDSAP), to subsidize actions on healthcare monitoring and inspection.

## **Resolution RDC ANVISA No. 218 of February 21, 2018, published on February 28, 2018**

Amends Resolution RDC No. 61 of February 3, 2016, which approves and enacts ANVISA Internal Rules.

## **Resolution RDC ANVISA No. 219 of February 27, 2018**

Provides for the guidelines for conditional approval of pharmaceutical post-registration change applications, and makes other provisions. ■



RESOLUTION ON ADMINISTRATIVE PROCEDURES FOR ISSUANCE OF GOOD MANUFACTURING PRACTICES CERTIFICATE AND GOOD DISTRIBUTION AND/OR STORAGE PRACTICES CERTIFICATE (RESOLUTION RDC ANVISA NO. 217 OF FEBRUARY 20, 2018). (PHOTO: ADOBE STOCK).





## ANIMAL HEALTH AND PLANT PRODUCTS

### Normative Act MAPA No. 1 of January 23, 2018, published on February 1, 2018

Changes items "a" and "b", I, article 1 of Normative Ruling No. 9 of May 12, 2016. Establishes the maximum limits of dioxin-like polychlorinated biphenyls (dl-PCBs) in products intended for animal feed.

### Resolution SAA No. 5 of February 2, 2018

Amends the provision of Resolution SAA No. 13 of March 3, 2017 (Creates the compulsory registration for establishments that manufacture, produce, process and pack in natura citrus fruits, in the State of São Paulo).

### Normative Ruling MAPA No. 4 of February 14, 2018

Exempts, in the ambit of SDA, the registration of byproducts not intended for human food obtained from animal sources or tissues and of establishments that manufacture or process them.

### Normative Ruling MAPA No. 3 of February 14, 2018, published on February 19, 2018.

Normative Ruling SDA/MAPA No. 30 of September 27, 1999 (Approves the Technical Regulation on the Establishment of Identity and Quality Standards of Diet and Low Calorie Beverages).

### Ordinance MAPA No. 200, of February 27, 2018

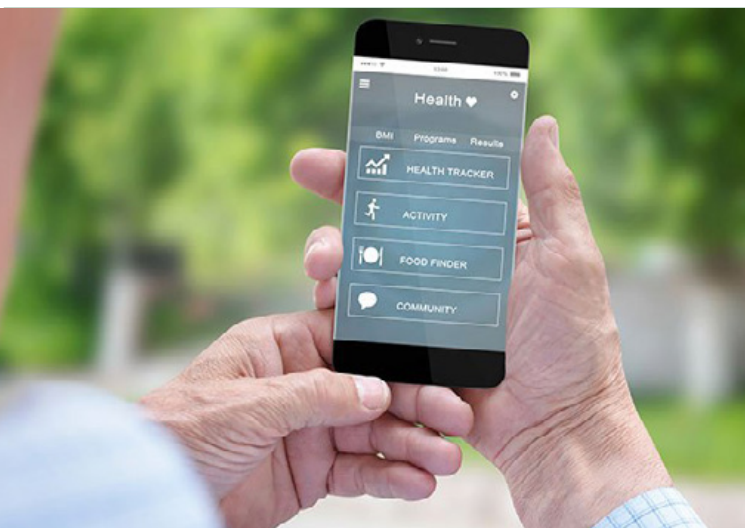
Establishes the basic guidelines of the National Plan for the Development of Fruit culture - PNDF/MAPA, with a view to stimulating the recognition of Brazilian fruit production. ■

RESOLUTION SAA Nº 5. (PHOTO: ADOBE STOCK).

- SUS
- Others

- Animal Health And  
Plant Products

- Healthcare Professionals



REGULATION OF APPLICATIONS THAT OFFER MEDICAL APPOINTMENT AT HOME. (PHOTO: ADOBE STOCK).

## HEALTHCARE PROFESSIONALS

### Resolution CFE No. 567 of January 29, 2018, published on February 6, 2018

Establishes rules for the performance of the Nursing Team in Care for patients with wounds.

### Resolution CFE No. 569 of February 19, 2018

Approves the Technical Regulation on the Performance of Nursing Professionals in Antineoplastic Chemotherapy.

### Resolution CFE No. 568 of February 9, 2018, published on February 20, 2018

Approves the Regulation of Nursing Offices and Nursing Clinics.

### Resolution CFM No. 2,174 of December 14, 2017, published on February 27, 2018

Provides for the anesthetic act practice and revokes Resolution CFM No. 1,802/2006.

### Resolution CFF No. 654 of February 22, 2018, published on February 27, 2018

Provides for the requirements necessary for the pharmacist to provide vaccination, and makes other provisions.

### Resolution CFF No. 655 of February 23, 2018, published on February 27, 2018

Provides for the rules and procedures of partnerships between the Federal Council of Pharmacy and the civil society organizations.

### Resolution CFM No. 2,178 of December 14, 2018, published on February 28, 2018

Regulates the operation of applications that offer medical appointment at home. ■

## GLOSSARY

**ANVISA** – National Health Surveillance Agency

**CFE** – Federal Board of Nursing

**CFF** – Federal Council of Pharmacy

**CFM** – Federal Council of Medicine

**CMED** - Medications Regulation Chamber

**MAPA** – Ministry of Agriculture, Cattle Breeding and Supply

**MS** – Ministry of Health

**SAA** – Agriculture and Supply Office

**SAS** – Health Support Office

**SDA** – Agricultural and Stockbreeding Defense Office

**SUS** – Integrated Health System