

# Life Sciences

O boletim eletrônico **Life Sciences no Brasil** traz informações sobre recente legislação na área de Saúde, Agricultura, Inovação, Biotecnologia e Biodiversidade.

A publicação é preparada mensalmente, em português e inglês, pelo grupo de Life Sciences de Pinheiro Neto Advogados.

#### PERIODICIDADE

Mensal

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#### CONTATO

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#### HUMAN HEALTH

- **SUS**
- Pharmaceuticals
- Others

#### ANIMAL HEALTH AND PLANT PRODUCTS

- Animal Health And Plant Products

#### HEALTH CARE SERVICES AND PROFESSIONALS

- Healthcare Professionals



(FOTO: PEXELS).

#### SUS

### Joint Ordinance SAS No. 6 of March 23, 2018, published on March 1, 2018

Approves the Clinical Protocol and Therapeutic Guidelines on Infantile Hemangioma.

### Joint Ordinance SAS No. 7 of February 23, 2018, published on March 1, 2018

Approves the Clinical Protocol and Therapeutic Guidelines on Iron Overload.

### Bill Draft No. 111 of 2018, published on March 8, 2018

Establishes that Public and Private Hospitals holding a partnership with SUS shall provide patients or their family members with copies of documents signed by them, as well as of the expenses paid by SUS, and

makes other provisions.

### Ordinance SCITIE No. 11 of March 13, 2018

Makes public the decision of including in SUS elbasvir combined with grazoprevir for the treatment of chronic hepatitis C virus genotypes 1 and 4 infections in adult patients.

### Ordinance SCITIE No. 12 of March 13, 2018

Makes public the decision of approving the inclusion in SUS of ledipasvir combined with sofosbuvir for the treatment of chronic hepatitis C virus genotypes 1 in adult patients.

## Ordinance SCITIE No. 13 of March 13, 2018

Makes public the decision of updating the Clinical Protocol and Therapeutic Guidelines on chronic hepatitis C and coinfections, in the ambit of SUS.

## Ordinance MS No. 559 of March 9, 2018, published on March 14, 2018

Amends the Consolidation Ordinance GM/MS No. 5 of September 28, 2017 to create the Action Plan for Clinical Research in Brazil.

## Joint Ordinance SAS No. 8 of March 15, 2018

Approves the Clinical Protocol and Therapeutic Guidelines on Diabetes Mellitus Type 1.

## Ordinance MS No. 702 of March 21, 2018

Amends the Consolidation Ordinance GM/MS No. 2 of September 28, 2017 to include new practices in the National Police on Integrative and Supplementary Healthcare Practices - PNPIC.

## Ordinance SCITIE No. 15 of March 28, 2018

Makes public the decision of including in SUS the endoscopic implantation of self-expanding metal esophageal prosthesis for the treatment of dysphagia of advanced and obstructive esophageal tumors. ■

### PHARMACEUTICALS

## Communiqué CMED No. 2 of March 6, 2018

Discloses the Inter-Sector Relative Price Adjustment Factor (Factor Y) for 2018, relating to the adjustment of pharmaceutical prices.

## Communiqué CMED No. 3 of March 9, 2018, published on March 14, 2018

Discloses, in ANVISA's website, the list of new presentations of pharmaceuticals, recognized by the Technical Executive Committee as similar to those included in the list of Resolution No. 5 of October 9, 2003, which are also exempted from the criteria of adjustment or establishment of Factory Price dealt with in article 6, IV of Law No. 10,742 of October 6, 2003.

## Ordinance ANVISA No. 369 of March 19, 2018

Approves the Internal Rules of the Committee for Monitoring the Implementation of the Experimental Phase of the National Pharmaceutical Control System - CAIFE/SNCM. ■



(FOTO: PEXELS).

### OTHERS

## Resolution RDC ANVISA No. 220 of March 9, 2018, published on March 14, 2018

Amends Resolution RDC No. 61 of February 03, 2016, which approves and enacts ANVISA Internal Rules.

## Executive Branch Decree No. 9,307 of March 15, 2018

Amends Decree No. 9,245 of December 20, 2017 that institutes the National Policy on Technological Innovation in Healthcare.

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## Resolution RDC ANVISA No. 210 of January 19, 2018, rectified and republished on March 20, 2018

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

## Resolution RDC ANVISA No. 221 of March 28, 2018

Deals with the criteria and procedures for toxicological reevaluation of active ingredients of agrochemicals, in the ambit of ANVISA.

## Resolution RDC ANVISA No. 222 of March 28, 2018

Good Practices on Healthcare Waste Management.■



(FOTO: DEPOSITPHOTOS).



(FOTO: ADOBE STOCK).

### ANIMAL HEALTH AND PLANT PRODUCTS

## Ordinance MAPA No. 249 of February 22, 2018, published on March 5, 2018

Approves the Code of Ethical Conduct for MAPA Officials.

## Ordinance MAPA No. 266 of February 28, 2018, published on March 7, 2018

Defines the coverage area of Services in connection with the Monitoring and Inspection of Products of Animal Origin.

## Normative Ruling MAPA No. 14 of February 8, 2018, published on March 9, 2018

Establishes the supplementation of identity and quality standards of wines as well as of grape and wine products.

## Normative Ruling MAPA No. 15 of March 9, 2018, published on March 15, 2018

Creates the National System of Agriculture and Cattle Breeding Emergencies - SINEAGRO, comprised of bodies, activities, standards and procedures, operating on a permanent and coordinated basis in relation to the preparation for and response to agriculture and cattle breeding emergencies.■

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(FOTO: PEXELS).

## HEALTHCARE PROFESSIONALS

### Bill Draft of São Paulo State No. 117 of 2018, published on March 8, 2018

Establishes that healthcare professionals and employees that work in the healthcare segment present periodical vaccination certificates, in the ambit of São Paulo.

### Ordinance CFF No. 23 of March 9, 2018

Deals with the accreditation for the supplementary training course in accordance with article 8 of Resolution CFF No. 654 of February 22, 2018 (Deals with the requirements necessary for the pharmacist to provide vaccination services, and makes other provisions).

### Resolution COFFITO No. 488 of October 20, 2017, rectified and republished on March 14, 2018

Regulates the use of Integrative and Supplementary Healthcare Practices by the occupational therapist, and makes other provisions.

### Resolution CFE No. 571 of March 21, 2018, published on March 28, 2018

Establishes that the Occupational Health Nurse is authorized to complete, issue and sign the Biological Monitoring Report, set forth in the Welfare Occupational Report.

### Resolution CFE No. 297 of March 23, 2018, published on of March 29, 2018

Deals with rules for the creation and operation of the Nursing Ethics Committees on Nursing Service Institutions.■

## GLOSSARY

**ANVISA** – National Public Health Agency

**CFE** – Federal Council of Nursing

**CFF** – Federal Council of Pharmacy

**CMED** – Drugs Market Regulation Chamber

**COFFITO** - Federal Council of Physiotherapy and Occupational Therapy

**MAPA** – Ministry of Agriculture, Livestock and Supply

**MS** – Ministry of Health

**SAS** – Health Support Office

**SCTIE** – Secretariat of Science, Technology and Strategic Input of the Ministry of Health

**SUS** – Integrated Health System