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May 2018



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# 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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(PHOTO: JOEL FILIPE, UNSPLASH).

**SUS**

## **São Paulo State Bill No. 332 of 2018**

Deals with the supply of inputs in the state public network in SUS.

## **Ordinance SAS No. 566 of May 9, 2018, published on May 17, 2018**

Excludes procedures from the List of Procedures, Drugs, Ortheses, Prosthesis and Special Materials of SUS.

## **Joint Ordinance MS No. 1,409 of May 18, 2018**

Amends the Joint Ordinance MPOG/MS/MCT/MDIC No. 128/2008 of May 29, 2008 (Establishes the Guidelines to the Public Procurement of Pharmaceuticals and Medications through SUS).

## **Ordinance SAS No. 643 of May 17, 2018, published on May 21, 2018**

Amends characteristics of the procedure of the List of Procedures, Drugs, Ortheses/Prosthesis and Special Materials of SUS. ■

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## PHARMACEUTICALS

### Rio de Janeiro State Law No. 7,959 of May 15, 2018

Authorizes the Executive Branch to extend the period of the report on request, evaluation and authorization of pharmaceuticals of the Pharmaceutical Assistance Specialized Component, in the Rio de Janeiro State. ■

## OTHERS

### Resolution RDC ANVISA No. 226 of April 30, 2018, published on May 2, 2018

Provides for the registration of smoking products derived from tobacco.

### Resolution CNE No. 229 of May 3, 2018

Amends Regulatory Code CNEN 3.01/002:2011 – Weighting Factors for Radiation Protection Quantities.

### Ordinance MS No. 1,363 of May 21, 2018

Provides for the access to the CMD Gestão, a restricted area of the portal of the Minimum Set of Data of the Healthcare Assistance (CMD).



(PHOTO: OLIA GOZHA, UNSPLASH).

### Ordinance CVS No. 5 of May 15, 2018

Provides for the Quality Management System in the scope of the Health Control Center, and makes other provisions.

### Resolution RDC ANVISA No. 227 of May 17, 2018, published on May 22, 2018

Provides for the update of the Annex I (Lists of Narcotic, Psychotropic, Precursor and other Controlled Substances) of Ordinance SVS/MS No. 344, of May 12, 1998.

### Normative Ruling No. 24 of May 17, 2018, published on May 22, 2018

Provides for the criteria for registration, change and re-evaluation relating to the analytical performance of self-testing instruments for glucose and its medical consumables.

### Resolution RDC ANVISA No. 228 of May 23, 2018

Provides for health risk management of activities related to the control and supervision in the importation of goods and products subject to health control, and makes other provisions.

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**SAÚDE ANIMAL E PRODUTOS VEGETAIS****Normative Ruling MAPA No. 18 of April 23, 2018, published on May 3, 2018**

Amends Normative Ruling No. 4 of January 10, 2001 (Approves the phytosanitary requirements for the importation of products from the United States of America).

**Technical Guidance CONCEA No. 12 of May 8, 2018, published on May 17, 2018**

Provides for the animal welfare parameters to restrict activities in connection with scientific research or teaching within the scope of the Brazilian Committee for Control of Experiments with Animals (CONCEA). ■

**HEALTHCARE SERVICES****São Paulo State Bill No. 292 of 2018**

Requires that public and private hospitals provide a decompression room, to be used by nurses, nursing technicians and nursing assistants. ■

**HEALTHCARE PROFESSIONALS****Resolution CFF No. 526 of April 27, 2018, published on May 2, 2018**

Provides for the technical and legal qualification of the speech therapist to perform assessment and rehabilitation of vestibular function and of the human body balance.

**Resolution CFP No. 9 of April 25, 2018, published on May 2, 2018**

Establishes guidelines for the Psychological Evaluation in the professional exercise of the psychologist, regulates the Evaluation System of Psychological Tests - SATEPSI and revokes Resolutions No. 002/2003, No. 006/2004 and No. 005/2012 and Technical Notes No. 01/2017 and 02/2017.

**Ordinance CFF No. 43 of April 27, 2018, published on May 3, 2018**

Revokes Ordinance/CFF No. 23 of March 9, 2018, published in the Official Gazette of the Federal Executive (DOU) of March 12, 2018, Section 1, page 105 (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 CFE No. 575 of May 11, 2018**

Establishes that the Regional Councils of Nursing can register nursing specialization certificate, including the nursing residency certificate, and makes other provisions.

**Resolution CFN No. 603 of April 22, 2018, published on May 17, 2018**

Provides for the registration, in the Regional Councils of Nutritionists (CRN), of certificates attesting to the technical capacity of legal entities, to prove the capacity to perform activities in connection with food and nutrition areas, and makes other provisions.

**Resolution CFN No. 605 of April 22, 2018, published on May 22, 2018**

Provides for areas of professional performance and the duties of the Technician in Nutrition and Dietetics (TND), and makes other provisions. ■

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## PUBLIC CONSULTATIONS

Before a regulation comes into force, MS, ANVISA or MAPA publishes the proposed regulation for “Public Consultation”. Comments and suggestions can be submitted by any interested party within a certain period of time as from the publication date of the

Public Consultation in the Official Gazette of the Federal Executive. During such period, the Public Consultations are available at [www.anvisa.gov.br](http://www.anvisa.gov.br) or [www.agricultura.gov.br](http://www.agricultura.gov.br), the ANVISA and MAPA websites, respectively.

*A regulation only comes into force after it is published as a “Resolution”, “Normative Ruling”, “Ordinance” or the like.*

Rule / Public Consultation (PC)	Subject	Publication Date	Term
ANVISA – PC No. 510 of April 30, 2018	Establishes a period for submission of comments and suggestions on the proposals of new compendiums of pharmaceutical specialties and active pharmaceutical input.	May 4, 2018	30 days
ANVISA – PC No. 528 of May 16, 2018	Establishes a period for submission of comments and suggestions on the text of the proposed Resolution RDC that provides for the migration from the registration regime to the notification regime for medical devices of class I risk.	May 22, 2018	60 days
CMED – PC No. 1 of May 11, 2018	Establishes a period for submission of comments and suggestions on the text of the proposed Resolution that governs the monitoring and release of the criteria for establishing or adjusting prices of over-the-counter drugs, phytotherapeutic drugs and injectable local anesthetics for dental use.	May 14, 2018	30 days
MAPA – PC No. 511 of May 4, 2018	Establishes a period for submission of comments and suggestions on the text of the proposed review of Joint Normative Ruling MAPA/ANVISA/IBAMA No. 25 of September 14, 2005, which establishes the procedures to be adopted at MAPA, ANVISA and IBAMA, for the purposes of the preliminary assessments and obtaining of the Temporary Special Registration - RET, for technical products, pre-mixes, agrochemicals and the like, earmarked for research and experimentation.	May 8, 2018	30 days
MAPA – Ordinance No. 62 of May 10, 2018	Invites the civil society to participate in the public consultation on the proposed Normative Ruling that approves the Technical Regulation on Humane Slaughter and Pre-Slaughter Handling.	May 18, 2018	30 days

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## 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

(PHOTO: JOEL FILIPE, UNSPLASH).