LEGISLAÇÃO

NACIONAL

Decretos n° 3-C/2021 – Diário da República n° 15/2021, 1º Suplemento, Série I de 2021-01-22

Presidência do Conselho de Ministros

ALTERA a regulação da situação de emergência decretada pelo Presidente da República

Decretos n° 3-B/2021 – Diário da República n° 12/2021, 1º Suplemento, Série I de 2021-01-19

Presidência do Conselho de Ministros

ALTERA a regulação da situação de emergência decretada pelo Presidente da República

COMUNITÁRIA

Recomendação do Conselho, relativa a um quadro comum para a utilização e a validação dos testes rápidos de deteção de antígenos para a COVID-19 e o reconhecimento mútuo dos resultados dos testes na UE

REGULAÇÃO

TRABALHO, SOLIDARIEDADE E SEGURANÇA SOCIAL

Circular Informativa n.º 005/CD/100.20.200.de 19/01/2021 – Disponibilidade de Imunoglobulina Humana Normal

Atualização da lista de grupos homogéneos e preços de referência

Circular Informativa n.º 03/CD/100.20.200.de 13/01/2021

Deliberação n.º 04/CD/2021

ERS

Alerta de supervisão nº 1/2021

Acesso de utentes beneficiários do SNS à realização de endoscopia, no âmbito da situação atual de pandemia SARS-CoV-2 e de infeção epidemiológica por COVID-19

DGS

Orientação nº 001/2021 de 20/01/2021

COVID-19: Vigilância e investigação epidemiológica

SPMS

Lista de Entrada em Vigor 19.01.2021

EMA

Report: European Medicines Agency’s interaction with industry stakeholders – Biennial report 2018-19 (new)

Medicinal Products for Veterinary Use | Implementation of the new Veterinary Medicines Regulation (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database (new)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database – Chapter 1: Registration and data access requirements for the User Interface (UI) and Application Programming Interface (API) (new)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: EU Implementation Guide (IG) on veterinary medicines product data – Chapter 2: Format for the electronic submission of veterinary medicinal product information (new)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database – Chapter 3: Process for the initial submission and maintenance of veterinary medicinal products information (new)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database – Chapter 4: Process and format for the submission of legacy data on veterinary medicinal products (new)
Medicinal Products for Veterinary Use | Regulatory and procedural guideline: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database – Chapter 5: Technical specifications

Agenda – Fourth EMA-Medicines for Europe bilateral meeting (new)

European Medicines Agency and Medicines for Europe fourth bilateral meeting, Virtual meeting, from 26/01/2021 to 26/01/2021

Medicinal Products for Human Use | Report: Human medicines highlights 2020 (new)

Medicinal Products for Human Use | News and press releases: Human medicines highlights of 2020

Medicinal Products for Veterinary Use | News and press releases: Veterinary medicines highlights of 2020

Medicinal Products for Veterinary Use | Report: Veterinary medicines highlights 2020 (new)

Medicinal Products for Human Use | News and press releases: Extra dose from vials of Comirnaty COVID-19 vaccine (updated)

Medicinal Products for Human Use | Other: Timetable: Annual renewal application of conditional marketing authorisation (updated)

Medicinal Products for Human Use | Other: Timetable: Annual renewal application of conditional marketing authorisation – ATMP (updated)

Medicinal Products for Human Use | Other: Timetable: Marketing authorisation renewal application – ATMP (updated)

Medicinal Products for Human Use | Other: Timetable: Annual reassessment – ATMP (updated)

Medicinal Products for Human Use | Other: Timetable: Marketing authorisation renewal application (updated)

Medicinal Products for Human Use | Other: Timetable: Annual reassessment (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes | (updated)

SME and academia Clinical Trials Information System (CTIS) two-part training webinar: Day 1, Virtual event, from 22/02/2021 to 22/02/2021

SME and academia Clinical Trials Information System (CTIS) two-part training webinar: Day 2, Virtual event, from 04/03/2021 to 04/03/2021

Newsletter: News bulletin for small and medium-sized enterprises – Issue 51 | (new)

Medicinal Products for Human Use | Agenda – CAT agenda of the 20-22 January 2021 meeting | (new)

Medicinal Products for Human Use | Agenda – CVMP agenda of the 19-21 January 2021 meeting | (new)

Medicinal Products for Human Use | News and press releases: Global regulators highlight key role of healthcare professionals in fostering confidence in COVID-19 vaccines

Medicinal Products for Human Use | COVID-19: latest updates | (updated)

Medicinal Products for Human Use | Agenda – COMP agenda of the 19-21 January 2021 meeting | (new)

Medicinal Products for Veterinary Use | Committee meeting report: Monthly report on application procedures, guidelines and related documents for veterinary medicines: November 2020 | (new)

Medicinal Products for Veterinary Use | Committee for Medicinal Products for Veterinary Use (CVMP): 3-5 November 2020, Virtual meeting, from 03/11/2020 to 05/11/2020 | (updated)

Medicinal Products for Human Use | Fifth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines, Virtual meeting, from 03/12/2020 to 03/12/2020 | (updated)

Medicinal Products for Human Use | Other: CHMP meeting dates 2019, 2020 and 2021 | (updated)

Medicinal Products for Human Use | Committee meeting report: COMP meeting report on the review of applications for orphan designation: September 2020 | (updated)
OMS

Statement to the 148th Executive Board by the Chair of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response

COMISSÃO EUROPEIA

Consulta Pública:

Blood, tissues and cells for medical treatments & therapies – revised EU rules

U health preparedness: Recommendations for a common EU approach regarding isolation for COVID-19 patients and quarantine for contacts and travellers
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