VIEIRA DE ALMEIDA

HEALTH

EM DESTAQUE

VdA EXPERTISE

1 a 5 de fevereiro de 2021

LEGISLAÇÃO

NACIONAL

Decreto-Lei n.º 10-A/2021 - Diário da República n.º 22/2021, 2º Suplemento, Série I de 2021-02-02

Presidência do Conselho de Ministros
Estabelece mecanismos excecionais de gestão de profissionais de saúde para realização de atividade assistencial, no âmbito da pandemia da doença COVID-19

Lei n.º 4-B/2021 - Diário da República n.º 21/2021, 1º Suplemento, Série I de 2021-02-01

Assembleia da República
Estabelece um regime de suspensão de prazos processuais e procedimentais decorrente das medidas adotadas no âmbito da pandemia da doença COVID-19, alterando a Lei n.º 1-A/2020, de 19 de março

REGULAÇÃO

DEFESA NACIONAL, ADMINISTRAÇÃO INTERNA, FINANÇAS E SAÚDE

Despacho n.º 1448-A/2021 - Diário da República n.º 24/2021, 2º Suplemento, Série II de 2021-02-04

Defesa Nacional, Administração Interna e Saúde - Gabinetes dos Ministros da Defesa Nacional e da Administração Interna e da Ministra da Saúde
Designação de novo coordenador da task force para a elaboração do «Plano de vacinação contra a COVID-19 em Portugal»

Despacho n.º 1460/2021 - Diário da República n.º 25/2021, Série II de 2021-02-05

Finanças e Saúde - Gabinetes da Secretária de Estado do Orçamento e do Secretário de Estado da Saúde
Autoriza o Centro Hospitalar de Entre o Douro e Vouga a assumir um encargo plurianual até ao montante de (euro) 618 498,32, a que acresce IVA, referente à aquisição de gases medicinais

INFARMED

Revisão Anual de Preços para o ano 2021 de medicamentos genéricos (mercados ambulatório e hospitalar)

Publicação para efeitos do artigo 15º-A do Decreto-Lei n.º 176/2006, de 30 de Agosto - pedidos de autorização de introdução no mercado de medicamentos genéricos.

DGS

Despacho nº 004/2021 de 02/02/2021

Designação da Dra. Rita Sá Machado como Consultora da Direção-Geral da Saúde

Norma nº 002/2020 de 16/03/2020 atualizada a 04/02/2021

COVID-19: Procedimentos post mortem

Orientação nº 002/2021 de 03/02/2021

COVID-19: Procedimentos para estruturas de acolhimento e abrigo de pessoas com necessidade de proteção

Norma nº 002/2021 de 30/01/2021

Campanha de Vacinação Contra a COVID-19 – Fase 1

EMA

Medicinal Products for Human Use | COVID-19 vaccines: key facts (updated)

Medicinal Products for Human Use | COVID-19 vaccines: development, evaluation, approval and monitoring (updated)

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

Medicinal Products for Human Use | Treatments and vaccines for COVID-19: medicines under evaluation (updated)

Medicinal Products for Human Use | News and press releases: EMA reviewing data on monoclonal antibody use for COVID-19

Medicinal Products for Human Use | Annex to CHMP highlights: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 25-29 January 2021 (new)

Medicinal Products for Human Use | Other: Timetable: Accelerated assessment request for initial marketing authorisations - ATMP (new)

Other: Questions and Answers on the pilot project 'OPEN' (new)

Medicinal Products for Veterinary Use | EMA's governance during COVID-19 pandemic (updated)

Medicinal Products for Veterinary Use | News and press releases: EMA COVID-19 assessments 'OPEN' to non-EU regulators

Medicinal Products for Veterinary Use | News and press releases: EMA starts rolling review of Novavax's COVID-19 vaccine (NVX-CoV2373)

Medicinal Products for Veterinary Use | Minutes of the CAT meeting 4-6 November 2020 (new)

Other: List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)

Report: Final programming document 2021-2023 (new)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: Guideline on good pharmacovigilance practices (GVP): Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 3) (new)

Medicinal Products for Human Use | Regulatory and procedural guideline: Guideline on good pharmacovigilance practices (GVP): Module XVI Addendum II – Methods for effectiveness evaluation (new)

Medicinal Products for Human Use | Regulatory and procedural guideline: Guidelines on good pharmacovigilance practices (GVP): Introductory cover note, last updated with revision 3 of Module XVI on risk minimisation measures and its Addendum II on methods for their effectiveness evaluation for public consultation (new)

Medicinal Products for Human Use | Human medicines highlights – February 2021 (new)

Medicinal Products for Human Use | Minutes of the COMP meeting 3-5 November 2020 (new)

Medicinal Products for Human Use | Committee meeting report: COMP meeting report on the review of applications for orphan designation: January 2021 (new)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Dossier requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency (EMA) and to members of the Committee for Medicinal Products for Veterinary use (CVMP) (updated)

Medicinal Products for Human Use | Scientific guideline: Draft toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications (new)

Template or form: Public declaration of interests and confidentiality undertaking of European Medicines Agency scientific committees' members and experts – prefilled sample form (version 4) (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Union Product Database (UPD) Access Policy – Veterinary Medicinal Products – Policy no 0082 (updated)

Medicinal Products for Veterinary Use | Overview of comments received on 'CVMP strategy on antimicrobials 2021–2025' (new)

Medicinal Products for Veterinary Use | Scientific guideline: CVMP strategy on antimicrobials 2021–2025 (new)

Medicinal Products for Human Use | News and press releases: EMA starts rolling review of REGN-COV2 antibody combination (casirivimab / imdevimab)

Medicinal Products for Human Use | Minutes of the HMPC 16–18 November 2020 meeting (new)

Medicinal Products for Human Use | Committee meeting report: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 11-13 January 2021 (new)

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

Medicinal Products for Human Use | Clinical Trial Regulation (updated)

Big data (updated)

Medicinal Products for Human Use | News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 25-29 January 2021 (updated)

HMA

CMDh
Report from the meeting held on 26-27 January 2021

December 2020 CMDh Minutes

COMISSÃO EUROPEIA

Agenda - 6th Plenary meeting of the Expert Panel (2019-2022) (10 February 2021)

Expert Panel on Effective Ways of Investing in Health - Request for an opinion: European solidarity in public health emergencies

Expert Panel on Effective Ways of Investing in Health - Request for an opinion: Supporting the mental health of health workforce and other essential workers

Remarks by Vice-President Schinas at the press conference on Europe's Beating Cancer Plan

Speech by President von der Leyen to the European Society for Paediatric Oncology

Remarks by Commissioner Stella Kyriakides at the press conference on Europe's Beating Cancer Plan

Europe's Beating Cancer Plan: A new EU approach to prevention, treatment and care

Commission statement on the vaccine export authorisation scheme

Contactos

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