VIEIRA DE ALMEIDA

SAÚDE

EM DESTAQUE

VdA EXPERTISE

11 a 15 de outubro de 2021

LEGISLAÇÃO

NACIONAL	Declaração de Retificação n.º 33/2021 **Presidência do Conselho de Ministros - Secretaria-Geral** Retifica o Decreto-Lei n.º 78-A/2021, de 29 de setembro, que altera as medidas excecionais e temporárias relativas à pandemia da doença COVID-19
EUROPEIA	Retificação do Regulamento (UE) 2021/1099 da Comissão, de 5 de julho de 2021, que altera os anexos II e III do Regulamento (CE) n.o 1223/2009 do Parlamento Europeu e do Conselho relativo aos produtos cosméticos (JO L 238 de 6.7.2021) Alterações aprovadas pelo Parlamento Europeu, em 13 de novembro de 2020, sobre a proposta de regulamento do Parlamento Europeu e do Conselho relativo à criação de um programa de ação da União no domínio da saúde para o período 2021-2027 e que revoga o Regulamento (UE) n.o 282/2014 («Programa UE pela Saúde») (COM(2020)0405 – C9-0152/2020 – 2020/0102(COD))

REGULAÇÃO

ECONOMIA E TRANSIÇÃO DIGITAL, FINANÇAS E SAÚDE

Regulamento n.º 915/2021
Ordem dos Médicos
Proposta de Regulamento Constituição das Equipas Médicas nos Serviços de Urgência

Despacho n.º 10049/2021
Saúde - Gabinete do Secretário de Estado da Saúde
Aprova o modelo de guia de tratamento de receita médica hospitalar desmaterializada

Despacho n.º 9936/2021
Administração Interna e Saúde - Gabinetes da Secretária de Estado da Administração Interna e do Secretário de Estado Adjunto e da Saúde
Determina os subsídios a atribuir pelo Instituto Nacional de Emergência Médica, I. P., para os postos de emergência médica (PEM) e postos reserva (PR)

Despacho n.º 9860/2021
Saúde - Gabinete da Ministra
Designa para o cargo de diretor executivo do Agrupamento de Centros de Saúde do Pinhal Interior Norte, pelo período de três anos, o licenciado Victor Hugo Ferreira Bernardo

INFARMED

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.**

EMA inicia avaliação de medicamento para a COVID-19

Circular Informativa Conjunta 013/2021/INFARMED/ACSS/SPMS | Normas técnicas e especificações e requisitos técnicos dos sistemas informáticos de prescrição e dispensa de medicamentos a utentes em regime de ambulatório hospitalar pelos serviços farmacêuticos hospitalares do SNS

Infarmed Newsletter n.º 194

Comissão Europeia convida representantes da sociedade civil para participarem no Conselho de Administração e em Comités da EMA

Circular Informativa 110/CD/100.20.200 | Atualização da lista de medicamentos cuja exportação é temporariamente suspensa

Presidente do Infarmed eleito Presidente da Heads of Agencies Group (HAG)

DGS

Norma nº 019/2020 de 26/10/2020 atualizada a 13/10/2021 | COVID-19: Estratégia Nacional de Testes para SARS-CoV-2

Orientação nº 038/2020 de 17/12/2020 atualizada a 12/10/2021 | COVID-19: Acompanhantes e Visitas nas Unidades Hospitalares

Norma nº 021/2020 de 23/12/2020 atualizada a 10/10/2021 | Campanha de Vacinação contra a COVID-19: Vacina COMIRNATY®

Norma nº 002/2021 de 30/01/2021 atualizada a 08/10/2021 | Campanha de Vacinação Contra a COVID-19

REGULAÇÃO

EMA

Medicinal Products for Human Use | News and press releases: First-in-class medicine to treat aggressive form of breast cancer

Medicinal Products for Human Use | News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 11-14 October 2021

Medicinal Products for Human Use | Regulatory and procedural guideline: Qualification opinion on IMI PREFER

Medicinal Products for Human Use | Regulatory and procedural guideline: HMPC rules of procedure (updated)

Medicinal Products for Human Use | Report: Medicinal products for human use: monthly figures - September 2021

Medicinal Products for Human Use | Regulatory and procedural guideline: ICH guideline E8 (R1) on general considerations for clinical studies

Medicinal Products for Human Use | Other: Records of data processing activity for Clinical data publication website

Medicinal Products for Human Use | News and press releases: EMA starts rolling review of Evusheld (tixagevimab and cilgavimab)

Medicinal Products for Human Use | Other: Tailored Scientific advice to support step-by-step development of new biosimilars (updated)

Medicinal Products for Human Use | Report: Tailored Scientific Advice for biosimilar development: report on the experience from the pilot (2017-2020)

Medicinal Products for Human Use | Other: Principles for Sponsor organisation modelling for CTIS

Medicinal Products for Human Use | Regulatory and procedural guideline: COMP rules of procedure (updated)

Medicinal Products for Human Use | Other: CHMP rules of procedure (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: CAT rules of procedure (updated)

Medicinal Products for Human Use | News and press releases: EMA ends rolling review of CVnCoV COVID-19 vaccine following withdrawal by CureVac AG

Medicinal Products for Human Use | Other: Article 57 product data (updated)

Medicinal Products for Human Use | Agenda: Agenda - PDCO agenda of the 12-15 October 2021 meeting

Medicinal Products for Human Use | Other: Letter of support for International Niemann-Pick Disease Registry (INPDR)

Medicinal Products for Human Use | Agenda: Agenda - CHMP agenda of the 11-14 October 2021 meeting

EMA

Medicinal Products for Human Use | Other: Step-by-step guide : Assess an annual safety report – CTIS Training Programme – Module 20

Medicinal Products for Human Use | Other: Instructor's guide: Assess an annual safety report – CTIS Training Programme – Module 20

Medicinal Products for Human Use | Other: FAQs: Assess an annual safety report – CTIS Training Programme – Module 20

Medicinal Products for Human Use | Other: Crossword puzzle: How to assess an annual safety report – CTIS Training Programme – Module 20

Medicinal Products for Human Use | News and press releases: EMA receives application for marketing authorisation for Ronapreve (casirivimab / imdevimab) for treatment and prevention of COVID-19

Medicinal Products for Human Use | Other: Clinical Trial Information System (CTIS) – Sponsor user personas (updated)

Medicinal Products for Human Use | Agenda: Agenda – PDCO agenda of the 22–25 June 2021 meeting (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: Member states contact points for translations review (updated)

Medicinal Products for Human Use | Agenda: Agenda – CAT agenda of the 6–8 October 2021 meeting

Medicinal Products for Human Use | Template or form: Plasma master file timetable: 60-day – Period 2021-2024 (updated)

Medicinal Products for Human Use | Template or form: Plasma master file timetable: 30-day – Period 2021-2024 (updated)

Medicinal Products for Human Use | Template or form: Plasma master file timetable: 90-day – Period 2021-2024 (updated)

Medicinal Products for Human Use | Other: European Union Clinical Trials Information System CTIS: Go-live planning – Summary of key areas in preparation of the operation of CTIS

Medicinal Products for Human Use | News and press releases: Highlights of Management Board – October 2021 meeting

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: CVMP rules of procedure (updated)

Medicinal Products for Veterinary Use | Minutes: Minutes of the CVMP meeting of 7-9 September 2021

Medicinal Products for Veterinary Use | News and press releases: Meeting highlights from the Committee for Medicinal Products for Veterinary Use (CVMP) 5-7 October 2021

Medicinal Products for Veterinary Use | Agenda: Agenda - Info day for micro, small and medium-sized enterprises (SMEs): EMA support for SMEs under the new Veterinary Medicinal Products Regulation (updated)

Report: Final programming document 2021-2023 (updated)

Other: Decision of the Management Board on amending budget No. 01, amending appropriations in budget 2021

EMA	Report: Outcome of written procedures finalised during the period from 26 May 2021 to 13 September 2021 Report: European Medicines Agency mid-year report 2021 (January-June 2021) Other: Revised rules of procedure of the Management Board (updated)
HMA	NEW – 12-14 October CMDh Agenda
COMISSÃO EUROPEIA	EU Health Policy Platform webinar – EU4Health 2021 work programme Information Session second wave of calls for action grants (28 October 2021, 9:45-13:30 CET)) Second wave of the EU4Health calls for project grants now published Independent Expert Panel on effective ways of investing in health publishes opinion on supporting the mental health of the health workforce and other essential workers COM(2021)627 – Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices Commission proposes a progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation Questions and Answers on the progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation Version 4.1 (September 2021) – Clinical Trials Regulation (EU)No 536/2014 Draft Questions & Answers Full report – Hearing on European solidarity in public health emergencies (16 September 2021) 2021 EU Health Award – The Frequently Asked Question document has been updated Minutes – 9th Plenary meeting of the Expert Panel (22 September 2021) Calls for expression of interest: Representatives of Patients' Associations and Clinicians: Call for expressions of interest is open for the EMA Committee for Advanced Therapies; Civil Society representatives: Call for expressions of interest is open for the EMA Management Board; Civil Society representatives: Call for expressions of interest is open for the EMA Pharmacovigilance Risk Assessment Committee SCCS – Request for a scientific advice on the safety of Homosalate as a UV-filter in cosmetic products SCCS – Request for a scientific Opinion on Butylparaben Minutes – Meeting of the Subgroup on Cancer (8 July 2021) Consultation outcome – Cross-border healthcare: Evaluation of patients' rights Flash report and presentations – Meeting of the Subgroup on Cancer (23 September 2021)

Contactos

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