VIEIRA DE ALMEIDA

SAÚDE

EM DESTAQUE

16 a 20 de outubro de 2023

REGULAÇÃO

NACIONAL	Despacho n.º 10735/2023 Saúde – Gabinete do Ministro Autoriza o Centro Hospitalar Universitário de Santo António, E. P. E., a criar um Banco de Córneas de Cultura, de acordo com as disposições legais e regulamentares aplicáveis
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. Infarmed Newsletter, Nº 234, 17.outubro.2023
DGS	Rita Sá Machado nomeada Diretora-Geral da Saúde Relatório N.º 2 da Vacinação Sazonal 2023/2024
SPMS	Procedimentos em Submissão de Propostas (Saúde) Informação de Detalhe do Procedimento 2023 / 494 – Medicamentos para a Hepatite C crónica
HMA	Recommendations on submission dates in 2024 for Applications of the DCP Recommendations on submission dates in 2024 for Applications of the MRP Report from the meeting held on 10-11 October 2023 12-13 September 2023 CMDh minutes

EMA

- Human Medicines

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

- Human Regulatory

DNA and host cell protein impurities, routine testing versus validation studies – Scientific guideline (updated)

Public health threats (updated)

COVID-19 guidance: research and development (updated)

Procedures for monograph and list entry establishment (updated)

Opinions and letters of support on the qualification of novel methodologies for medicine development (updated)

Risk management plans (RMP) in post-authorisation phase: questions and answers (updated)

Buying medicines online (updated)

- Veterinary Regulatory

Stability testing for applications for variations to a marketing authorisation for veterinary medicinal products – Scientific guideline

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) (updated)

Overview of comments: Overview of comments received on 'Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy'

Calculation of dose factor to be submitted to the Union Product Database (UPD) – Scientific guideline

Scientific guideline: Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (updated)

- Human and Veterinary Regulatory

Scientific guideline: Draft guideline on the development and manufacture of Synthetic Peptides

- Committees

HMPC: overview of assessment work – priority list (updated)

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 October 2023

- Corporate

Report: European Medicines Agency mid-year report 2023 (January-June 2023)

- Events

EMA multi-stakeholder workshop on qualification of novel methodologies [Updated with presentation]

COMISSÃO EUROPEIA	Flash report - Meeting of the Sub-group on the EU NCD Initiative (18 October 2023) Advice on SARS-CoV-2 neutralising antibodies on request from the Medical Device Coordination Group MDCG 2023-4 - Medical Device Software (MDSW) – Hardware combinations Guidance on MDSW intended to work in combination with hardware or hardware components

Contactos

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