VIEIRA DE ALMEIDA

SAÚDE

EM DESTAQUE

VdA EXPERTISE

20 a 24 de junho de 2022

LEGISLAÇÃO

NACIONAL	Resolução da Assembleia Legislativa da Região Autónoma dos Açores n.º 25/2022/A **Região Autónoma dos Açores – Assembleia Legislativa** Revisão do regime da prestação do trabalho médico extraordinário nos serviços de urgência e de atendimento permanente das unidades de saúde de ilha com serviço de urgência Decreto Regulamentar Regional n.º 8/2022/A **Região Autónoma dos Açores – Presidência do Governo** Procede à primeira alteração do Decreto Regulamentar Regional n.º 1/2022/A, de 21 de janeiro, regime de atribuição de incentivos à fixação, aplicável ao pessoal médico, na Região Autónoma dos Açores Decreto Legislativo Regional n.º 13/2022/M **Região Autónoma da Madeira – Assembleia Legislativa** Regula as atividades de distribuição, venda e aplicação de produtos fitofarmacêuticos para uso profissional e de adjuvantes de produtos fitofarmacêuticos, define os procedimentos de monitorização da utilização dos produtos fitofarmacêuticos para uso profissional e estabelece o regime de inspeção obrigatória dos equipamentos de aplicação de produtos fitofarmacêuticos autorizados para uso profissional na Região Autónoma da Madeira
EUROPEIA	Regulamento de Execução (UE) 2022/944 da Comissão, de 17 de junho de 2022, que estabelece regras de aplicação do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho no que diz respeito às tarefas dos e aos critérios aplicáveis aos laboratórios de referência da União Europeia no domínio dos dispositivos médicos para diagnóstico in vitro Regulamento de Execução (UE) 2022/945 da Comissão, de 17 de junho de 2022, que estabelece regras de aplicação do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho relativas às taxas que podem ser cobradas pelos laboratórios de referência da União Europeia no domínio dos dispositivos médicos para diagnóstico in vitro

REGULAÇÃO

ECONOMIA E TRANSIÇÃO DIGITAL, FINANÇAS E SAÚDE

Deliberação n.º 738/2022
Centro Hospitalar Universitário de Lisboa Norte, E. P. E.
Delegação de competências do conselho de administração

Deliberação n.º 739/2022
Centro Hospitalar Universitário de Lisboa Norte, E. P. E.
Distribuição de áreas pelos membros do conselho de administração

Despacho n.º 7739-A/2022
Negócios Estrangeiros, Defesa Nacional, Administração Interna, Economia e Mar, Saúde e Infraestruturas e Habitação - Gabinetes do Ministro dos Negócios Estrangeiros, da Ministra da Defesa Nacional, dos Ministros da Administração Interna e da Economia e do Mar, da Ministra da Saúde e do Ministro das Infraestruturas e da Habitação
Suspensão das regras aplicáveis à entrada em território nacional, por via aérea, constantes no Despacho n.º 4829-A/2022, de 22 de abril, que integrem as delegações dos diversos países participantes na Segunda Conferência dos Oceanos das Nações Unidas

Despacho n.º 7739-B/2022
Negócios Estrangeiros, Administração Interna, Saúde e Infraestruturas e Habitação - Gabinetes dos Ministros dos Negócios Estrangeiros e da Administração Interna, da Ministra da Saúde e do Ministro das Infraestruturas e da Habitação
Reconhece a validade do certificado de vacinação da Austrália para efeitos de verificação e aceitação em território nacional e emissão de Certificado Digital COVID da UE

Despacho n.º 7702/2022
Saúde - Gabinete da Ministra
Designa como chefe do Gabinete da Ministra da Saúde o licenciado Miguel Leal de Faria

Despacho n.º 7619/2022
Saúde - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.
Subdelegação de competências do presidente do conselho diretivo, Dr. Rui Santos Ivo, no diretor da Unidade de Projetos Interinstitucionais e para o Sistema de Saúde (USS), Dr. Nuno Filipe Cabrita Vieira Simões

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.

Circulares e Deliberações

Circular Informativa N.º 067/CD/100.20.200 de 23/06/2022 | Lista de medicamentos utilizados por QUE

Circular Informativa N.º 069/CD/100.20.200 de 24/06/2022 | Reporte de consumos de AUE de benefício clínico bem reconhecido

Notícias

Boletim de Farmacovigilância, Volume 26, n.º4, abril de 2022

REGULAÇÃO

DGS	Informações Informação nº 003/2022 de 17/06/2022 | Comunicação, medidas preventivas e o envolvimento da comunidade no surto por vírus Monkeypox Newsletter Newsletter DGS n.º 176 de 2022-06-21
SPMS	Lista de Entrada em Vigor dos Novos CPA_23-06-2022
HMA	UPDATE - 'Blue-box' requirements UPDATE - National recommendations for requests to act as RMS NEW - 21-22 June CMDh Agenda

REGULAÇÃO

Data Processing | Other: Records of data processing activity relating to the switchboard recording system (public) (updated)

Medicinal Products for Veterinary Use | Data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats (updated)

Medicinal Products for Veterinary Use | Overview of comments: Overview of comments received on the 'Guideline on data requirements for veterinary medicinal products for the prevention of transmission of vector-borne diseases in dogs and cats' (EMA/CVMP/EWP/278031/2015)

Medicinal Products for Veterinary Use | EudraVigilance Veterinary (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (Excel) (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Non-current Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) low level terms (LLT) and codes (updated)

Medicinal Products for Veterinary Use | Other: Call for comments on the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) standard list for EudraVigilance Veterinary (EVVet) (updated)

EMA

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (updated)

Medicinal Products for Veterinary Use | Template or form: Template for submission of comments for the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) standard list for EudraVigilance Veterinary (EVVet) (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: List of changes to combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse reactions in animal and humans to veterinary medicinal products (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) dataload friendly file including deprecated terms (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Guidance notes on the use of Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) terminology for reporting suspected adverse reactions in animals and humans (updated)

Medicinal Products for Veterinary Use | Requirements for the production and control of immunological veterinary medicinal products (updated)

Medicinal Products for Veterinary Use | Other: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2022 (updated)

REGULAÇÃO

EMA

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)

Events | Clinical Trials Information System (CTIS) bitesize talk: Transitional trials and additional Member State concerned (MSC) application , Online, 14:00 - 15:30 Amsterdam time (CEST), from 23/06/2022 to 23/06/2022 (updated)

Medicinal Products for Human Use | News and press releases: EMA recommends authorisation of Nuvaxovid for adolescents aged 12 to 17

Medicinal Products for Human Use | Summary of opinion: COVID-19 Vaccine (inactivated, adjuvanted) Valneva, COVID-19 vaccine (inactivated, adjuvanted, adsorbed), 23/06/2022, Positive

Medicinal Products for Human Use | Summary of opinion: Nuvaxovid, COVID-19 Vaccine (recombinant, adjuvanted), 23/06/2022, Positive

Medicinal Products for Human Use | News and press releases: EMA recommends Valneva's COVID-19 vaccine for authorisation in the EU

Corporate | Report: Annual activity report 2021

Medicinal Products for Human Use | Regulatory and procedural guideline: Procedural guidance for variant strain(s) update to vaccines intended for protection against human coronavirus (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: Checklist for annual updates for parallel distribution: guidance for industry (updated)

Events | Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - June 2022 , Online, 14:00 - 18:00 Amsterdam time (CEST) , from 30/06/2022 to 01/07/2022 (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations (updated)

Events | European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting , Online, from 01/06/2022 to 02/06/2022 (updated)

Medicinal Products for Veterinary Use | Other: Release notes - production release version 1.6.5 June 2022 - Veterinary Medicinal Products Regulation: Union Product Database

Global Regulators Work | News and press releases: Global regulators work towards strengthening collaboration on observational research beyond COVID-19 pandemic

Medicinal Products for Human Use | Type-II variations: questions and answers (updated)

Medicinal Products for Human Use | Pre-authorisation guidance (updated)

REGULAÇÃO

EMA

Medicinal Products for Human Use | Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with track changes (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes (updated)

Medicinal Products for Human Use | Renewal and annual re-assessment of marketing authorisation (updated)

Medicinal Products for Human Use | Transfer of marketing authorisation: questions and answers (updated)

Medicinal Products for Human Use | Extensions of marketing authorisations: questions and answers (updated)

Events | Protection of personal data and commercially confidential information (CCI) for documents uploaded and published in the Clinical Trials Information System (CTIS): Workshop on draft guidance , Online, 10:00-17:00 Amsterdam time (CEST), from 14/07/2022 to 14/07/2022

Events | Union Product Database: webinar on variations not requiring assessment (VNRAs) for marketing authorisation holders , Online, 10:00 - 11:30 Amsterdam time (CEST), from 08/09/2022 to 08/09/2022

Events | Committee for Medicinal Products for Human Use (CHMP): 20-23 June 2022 , European Medicines Agency, Amsterdam, the Netherlands, from 20/06/2022 to 23/06/2022 (updated)

Medicinal Products for Human Use | Agenda: Agenda - CHMP agenda of the 20-23 June 2022 meeting

Events | Eighth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicine , Online, from 27/06/2022 to 27/06/2022 (updated)

Medicinal Products for Human Use | Other: European Medicines Agency's Data Protection Notice concerning the processing of patient and product traceability data for Zynteglo following the withdrawal of the marketing authorisation

Corporate | Management Board meeting: 15-16 June 2022 , European Medicines Agency, Amsterdam, the Netherlands, from 15/06/2022 to 16/06/2022 (updated)

Corporate | News and press releases: EMA Management Board: highlights of June 2022 meeting

Medicinal Products for Human Use | Availability of medicines (updated)

EMA

Clinical Trials Information System | Clinical Trials Information System: training and support (updated)

Events | Clinical Trials Information System (CTIS): Walk-in clinic , Online, 16:00 – 16:45 Amsterdam time (CEST), from 15/11/2022 to 15/11/2022 (updated)

Events | Clinical Trials Information System (CTIS): Walk-in clinic , Online, 15:00 – 15:45 Amsterdam time (CEST), from 12/12/2022 to 12/12/2022 (updated)

Events | Clinical Trials Information System (CTIS): Walk-in clinic , Online, 16:00 – 16:45 Amsterdam time (CEST), from 20/09/2022 to 20/09/2022 (updated)

Events | Clinical Trials Information System (CTIS): Walk-in clinic , Online, 15:00 – 15:45 Amsterdam time (CEST), from 05/10/2022 to 05/10/2022 (updated)

Events | Clinical Trials Information System (CTIS): Walk-in clinic , Online, 16:00 – 16:45 Amsterdam time (CEST), from 22/08/2022 to 22/08/2022 (updated)

Medicinal Products for Human Use | News and press releases: Start of rolling review for adapted Spikevax COVID-19 vaccine

Medicinal Products for Veterinary Use | News and press releases: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 14–15 June 2022

Medicinal Products for Human Use | Pre-authorisation guidance (updated)

COMISSÃO EUROPEIA

European Health Union: Political agreement on the Serious Cross-Border Threats to Health Regulation
Speech by President von der Leyen at the Vaccine Equity for Africa Ceremony, via video message
Webinar recording – Healthier Together – EU Non-communicable diseases initiative (22 June 2022)

SCHEER – Request for a scientific opinion in support of a targeted revision of Annexes III and IV of Directive 2010/63/EU on the protection of animals used for scientific

EU-Latin America and Caribbean Partnership: manufacturing vaccines, medicines and health technologies and strengthening health systems

Flash report – Hearing – Managing antimicrobial resistance across the health system

Video recording – Hearing on Managing antimicrobial resistance across the health system (20 June 2022)

Presentation of the opinion by the Expert Panel – Hearing on Managing antimicrobial resistance across the health system (20 June 2022)

Setting the scene for EU reference labs for high-risk diagnostics

Summary record – 99th meeting of the Pharmaceutical Committee (11 May 2022)

SCCS – Minutes of the Working Group meeting on Nanomaterials in Cosmetic Products of 9 June 2022

Contactos

saude@vda.pt