VIEIRA DE ALMEIDA

SAÚDE

EM DESTAQUE

VdA EXPERTISE

31 de janeiro a 4 de fevereiro de 2022

LEGISLAÇÃO

NACIONAL

Portaria n.º 85/2022
Administração Interna
Regulamentação do curso de formação de oficiais para o quadro de técnicos de enfermagem, diagnóstico e terapêutica

Portaria n.º 76/2022
Finanças, Saúde, Ambiente e Ação Climática E Agricultura
Fixa as taxas devidas pelos serviços prestados e os encargos associados relativos à disponibilização no mercado e à utilização de produtos biocidas

EUROPEIA

Retificação do Regulamento (UE) 2022/112 do Parlamento Europeu e do Conselho, de 25 de janeiro de 2022, que altera o Regulamento (UE) 2017/746 no que diz respeito às disposições transitórias aplicáveis a determinados dispositivos médicos para diagnóstico in vitro e à aplicação diferida das condições aplicáveis aos dispositivos fabricados e utilizados na própria instituição de saúde (JO L 19 de 28.1.2022)

Regulamento Delegado (UE) 2022/139 da Comissão, de 16 de novembro de 2021, que complementa o Regulamento (UE) 2016/429 do Parlamento Europeu e do Conselho no que se refere à gestão, armazenamento e substituição de reservas dos bancos de antigénios, vacinas e reagentes de diagnóstico da União e aos requisitos de bioproteção, biossegurança e biocontenção para o funcionamento desses bancos

Regulamento de Execução (UE) 2022/140 da Comissão, de 16 de novembro de 2021, que estabelece regras de execução do Regulamento (UE) 2016/429 do Parlamento Europeu e do Conselho no que se refere aos bancos de antigénios, vacinas e reagentes de diagnóstico da União

Regulamento (UE) 2022/135 da Comissão, de 31 de janeiro de 2022, que altera o Regulamento (CE) n.o 1223/2009 do Parlamento Europeu e do Conselho no que diz respeito à utilização de Methyl-N-methylanthranilate em produtos cosméticos

Regulamento (UE) 2022/123 do Parlamento Europeu e do Conselho, de 25 de janeiro de 2022, relativo ao reforço do papel da Agência Europeia de Medicamentos em matéria de preparação e gestão de crises no que diz respeito a medicamentos e dispositivos médicos

Resumo das decisões da União Europeia relativas às autorizações de introdução no mercado dos medicamentos de 1 a 31 de dezembro de 2021 [publicado nos termos do artigo 13.o ou do artigo 38.o do Regulamento (CE) n.o 726/2004 do Parlamento Europeu e do Conselho]

REGULAÇÃO

ECONOMIA E TRANSIÇÃO DIGITAL, FINANÇAS E SAÚDE

Despacho n.º 1451/2022
Saúde - Gabinete do Secretário de Estado Adjunto e da Saúde
Determina que a vacina contra a gripe sazonal é gratuita na época 2022/2023 para pessoas com idade igual ou superior a 65 anos, bem como para outros grupos alvo prioritários, definidos em norma anual da Direção-Geral da Saúde

Despacho n.º 1277/2022
Saúde - Gabinete da Ministra
Fixa a composição da comissão executiva do Plano Nacional da Saúde para as Demências e altera o Despacho n.º 12761/2021, de 21 de dezembro, publicado no Diário da República, 2.ª série, n.º 251, de 29 de dezembro de 2021

INFARMED

Medicamentos centralizados - Publicação para efeitos do artigo 15º-A do Decreto-Lei n.º 176/2006, de 30 de agosto, de medicamentos genéricos aprovados por procedimento centralizados (atualizada)

Notícias

Relatório de Farmacovigilância: Monitorização da segurança das vacinas contra a COVID 19 em Portugal (atualizado)

Disponíveis as apresentações das Manhãs Informativas "Implementação do Regulamento Europeu de Ensaios Clínicos"

Publicado regulamento que reforça mandato da EMA

Publicação de alteração ao Regulamento (UE) 2017/746 relativo aos dispositivos para diagnóstico in vitro

Novo Regulamento Europeu de Ensaios Clínicos entra em aplicação

Sessão de informação aos promotores no âmbito da ação conjunta do programa UE pela Saúde (EU4Health) para avaliação coordenada e acelerada de ensaios multinacionais COVID-19

Circulares e Deliberações

Circular Informativa 009/CD/100.20.200 | Vacinas COVID-19 - Condições de conservação – Atualização

Circular Informativa 006/CD/100.20.200 | Atualização das listas previstas no Regulamento sobre notificação prévia de transações de medicamentos para o exterior do país

Circular Informativa 007/CD/100.20.200 | Revisão Anual de Preços de Medicamentos Genéricos - 2022

Circular Informativa 005/CD/550.20.001 | Autoteste COVID-19 SARS-CoV-2 Antigen Test Kit (Colloidal Gold) do fabricante Genrui Biotech Inc.

DGS

Notícias

Newsletter DGS n.º 159 de 2022-01-31

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SPMS	Informação de Detalhe do Procedimento 2021 / 38 | Suturas Mecânicas para Laparoscopia Lista de Entrada em Vigor dos novos CPA (31/02/2022)
HMA	NEW – 2021 – Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedures UPDATE – Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP UPDATE – Practical guidance on the implementation of the Protocol on Ireland/Northern Ireland for medicinal products for human use approved via MRP/DCP UPDATE – Mandate of the Working Party on Pharmacovigilance Procedures Work Sharing UPDATE – Template for the End of Procedure NEW – Minutes for November 2021 CMDh meeting with IPs NEW – Report from the meeting held on 25-27 January 2022

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Medicinal Products for Human Use | Other: Instructor's guide: How to evaluate a CT application – CTIS Training Programme – Module 06 (updated)

Medicinal Products for Human Use | News and press releases: International regulators' recommendations on COVID-19 vaccines and the Omicron variant

Medicinal Products for Veterinary Use | Other: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database – Chapter 7: Submission of other post-authorisation data (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)

Medicinal Products for Veterinary Use | Committee meeting report: Monthly report on application procedures, guidelines and related documents for veterinary medicines: November 2021

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

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): COVID-19 Vaccine Janssen, adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad26.COV2-S), COVID-19 virus infection, 11/03/2021, 16, Authorised (updated)

Medicinal Products for Human Use | Other: Quick guide: How to search, view and download a Clinical Trial and a Clinical Trial Application (authority) – CTIS Training Programme – Module 15 (updated)

Medicinal Products for Human Use | Other: Instructor's guide: Supervise a CT: corrective measures – CTIS training programme – Module 14 (updated)

Medicinal Products for Human Use | Other: Step-by-step guide: Supervise a CT: corrective measures – CTIS training programme – Module 14 (updated)

Medicinal Products for Human Use | Other: FAQs: Supervise a CT: corrective measures – CTIS training programme – Module 14 (updated)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): Comirnaty, Single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2, COVID-19 virus infection, 21/12/2020, 19, Authorised (updated)

Medicinal Products for Human Use | Other: FAQs: How to search, view and download a Clinical Trial and a Clinical Trial Application (authority) – CTIS Training Programme – Module 15 (updated)

Medicinal Products for Human Use | Other: Instructor's guide: How to search, view and download a Clinical Trial and a Clinical Trial Application (authority) – CTIS Training Programme – Module 15 (updated)

Medicinal Products for Human Use | Other: Step-by-step guide: How to search, view and download a Clinical Trial and a Clinical Trial Application (authority) – CTIS Training Programme – Module 15 (updated)

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Medicinal Products for Human Use | Guidance on good manufacturing practice and good distribution practice: Questions and answers (updated)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): Comirnaty, Single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2, COVID-19 virus infection, 21/12/2020, 20, Authorised (updated)

Medicinal Products for Human Use | Other: HMPC: overview of assessment work – priority list (updated)

Medicinal Products for Human and Veterinary Use | Learnings initiative webinar for optimal use of big data for regulatory purpose , Online, 09:00 – 11:00 Amsterdam time (CET), 13:45 – 17:00 Amsterdam time (CET), from 30/11/2021 to 30/11/2021 (updated)

Medicinal Products for Human and Veterinary Use | Report: Meeting report – Learnings initiative webinar for optimal use of big data for regulatory purpose (updated)

Medicinal Products for Human Use | Other: EudraVigilance: Obtaining EDQM terms from SPOR

Medicinal Products for Human Use | Minutes: Minutes of the HMPC 22-24 November 2021 meeting

Medicinal Products for Human and Veterinary Use | Other: Mandatory use of ISO ICSR/ICH E2B(R3) and EDQM terminology for Dosage Forms (DF) and Routes of Administration (RoA)

Medicinal Products for Human Use | Clinical Trials Information System (CTIS) sponsor end user training programme – May 2022 , Online, 09:00 – 13:30 Amsterdam time (CET), from 10/05/2022 to 13/05/2022 (updated)

Medicinal Products for Human Use | Clinical Trials Information System (CTIS) sponsor end user training programme – June 2022 , Online, 14:00 – 18:30 Amsterdam time (CET), from 20/06/2022 to 23/06/2022 (updated)

Medicinal Products for Human Use | Clinical Trials Information System (CTIS) sponsor end user training programme – April 2022 , Online, 14:00 – 18:30 Amsterdam time (CET), from 05/04/2022 to 08/04/2022 (updated)

Medicinal Products for Human Use | Clinical Trials Information System (CTIS) sponsor end user training programme – March 2022 , Online, 09:00 – 13:30 Amsterdam time (CET), from 01/03/2022 to 04/03/2022 (updated)

Medicinal Products for Human Use | Clinical Trials Information System (CTIS) sponsor end user training programme – February 2022 , Online, 09:00 – 13:30 Amsterdam time (CET), from 15/02/2022 to 18/02/2022 (updated)

IT | Introducing DADI: webinar on the digital application dataset integration (DADI) network project to replace electronic application forms , Online, 10:30 – 12:00 Amsterdam time (CET), from 18/01/2022 to 18/01/2022 (updated)

Medicinal Products for Human Use | Report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: December 2021

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Medicinal Products for Human Use | Clinical Trials Information System (CTIS): online modular training programme (updated)

Medicinal Products for Human Use | Other: Roles and permissions matrix summary – Authority workspace – CTIS Training Programme – Module 07

Medicinal Products for Human Use | Other: Member states business processes and roles – CTIS Training Programme – Module 07

Medicinal Products for Human Use | Other: Roles and permissions matrix summary – Sponsors workspace – CTIS Training Programme – Module 07

Medicinal Products for Human Use | Other: Sponsors business processes and roles – CTIS Training Programme – Module 07

Medicinal Products for Human Use | Other: Notices and alerts per role – CTIS Training Programme – Module 07

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: The checking process of mock-ups and specimens of outer/immediate labelling and package leaflets in the centralised procedure for veterinary medicinal products (updated)

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: Mock-ups checklist – Guidance for checking mock-ups (updated)

Medicinal Products for Human Use | Seventh meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicine , Online, 13:00-17:00 Amsterdam time (CET), from 01/12/2021 to 01/12/2021 (updated)

Medicinal Products for Human Use | PRIME: priority medicines (updated)

Medicinal Products for Human Use | Report: List of products granted eligibility to PRIME (updated)

Medicinal Products for Human Use | Annex to CHMP highlights: Recommendations on eligibility to PRIME scheme – Adopted at the CHMP meeting of 24-27 January 2022

Medicinal Products for Human Use | Committee meeting report: PDCO monthly report of opinions on paediatric investigation plans and other activities 7-10 September 2021

Medicinal Products for Human Use | Other: List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)

Medicinal Products for Human and Veterinary Use | Other: Guide on access to unpublished documents (updated)

IT | Clinical Trials Information System (CTIS) bitesize talk: User access and role management , Online, 14:00 – 15:30 Amsterdam time (CET), from 24/02/2022 to 24/02/2022

IT | Clinical Trials Information System (CTIS) bitesize talk: Initial clinical trial application , from 23/03/2022 to 23/03/2022

IT | Introduction to Organisation Management Service (OMS) and Referentials Management Service (RMS) services and activities: Industry webinar , Online, 10:00 – 12:00 and 14:00 – 16:00 Amsterdam time (CEST), from 10/03/2022 to 10/03/2022

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IT | Webinar on requesting access to and using EMA's substance, product, organisation and referential (SPOR) application programming interface (API) , Online, 14:00 – 16:00 Amsterdam time (CEST), from 18/03/2022 to 18/03/2022

Medicinal Products for Human Use | Template or form: Template – Translations required with the submission of an application for transfer of orphan medicinal product designation (updated)

Medicinal Products for Human Use | Template or form: Template – Translations required with the submission of an application for orphan medicinal product designation (updated)

IT | Regulatory and procedural guideline: IRIS guide for applicants (updated)

Corporate | News and press releases: A stronger role for EMA

IT | Other: Step-by-step guide: User access management – CTIS Training Programme – Module 03

IT | Other: Quick guide: User access management – CTIS Training Programme – Module 03 (updated)

IT | Other: Instructor's guide: User access management – CTIS Training Programme – Module 03 (updated)

IT | Other: FAQs: User access management – CTIS Training Programme – Module 03 (updated)

Medicinal Products for Human Use | Seventh meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicine , Online, 13:00–17:00 Amsterdam time (CET), from 01/12/2021 to 01/12/2021 (updated)

Medicinal Products for Veterinary Use | Work programme: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Safety Working Party (SWP-V) 2022

Data Analytics | Learnings initiative webinar for optimal use of big data for regulatory purpose , Online, 09:00 – 11:00 Amsterdam time (CET), 13:45 – 17:00 Amsterdam time (CET), from 30/11/2021 to 30/11/2021 (updated)

Data Analytics | Report: Meeting report – Learnings initiative webinar for optimal use of big data for regulatory purpose

Medicinal Products for Human Use | Other: Sponsors' guide: Transition of trials from EudraCT to CTIS – CTIS Training Programme – Module 23

Medicinal Products for Human Use | Other: Member states' guide: Transition of trials from EudraCT to CTIS – CTIS Training Programme – Module 23

Medicinal Products for Human Use | Other: FAQs: Transition of trials from EudraCT to CTIS – CTIS Training Programme – Module 23

Medicinal Products for Veterinary Use | Quality, safety and efficacy of bacteriophages as veterinary medicines

Medicinal Products for Human Use | Development and data requirements of potency tests for cell-based therapy products and the relation to clinical efficacy

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Medicinal Products for Veterinary Use | European Medicines Agency veterinary medicines info day , Online, 10:00 - 16:30 Amsterdam time (CET), from 30/11/2021 to 30/11/2021 (updated)

Medicinal Products for Human Use | EMA regular press briefing on COVID-19 , Online, 14:00 - 14:30 Amsterdam time (CET), from 03/02/2022 to 03/02/2022

Medicinal Products for Veterinary Use | Work programme: Work plan for the Committee for Medicinal Products for Veterinary Use (CVMP) Pharmacovigilance Working Party (PhVWP-V) 2022 (updated)

Medicinal Products for Veterinary Use | Work programme: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Scientific Advice Working Party (SAWP-V) for 2022

Medicinal Products for Veterinary Use | Work programme: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Efficacy Working Party (EWP-V) 2022

Medicinal Products for Veterinary Use | Work programme: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Antimicrobials Working Party (AWP) 2022

Medicinal Products for Veterinary Use | Work programme: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Environmental Risk Assessment Working Party (ERAWP) 2022

Medicinal Products for Veterinary Use | Pre-authorisation guidance under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) (updated)

Medicinal Products for Veterinary Use | Work programme: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Immunologicals Working Party (IWP) 2022

Medicinal Products for Veterinary Use | Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances (updated)

Medicinal Products for Human Use | News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24-27 January 2022

Medicinal Products for Human Use | News and press releases: New gene therapy treatment for patients with relapsed or refractory large B-cell lymphoma

Medicinal Products for Human Use | Annex to CHMP highlights: Start of Union reviews adoped during the CHMP meeting of 24-27 January 2022

Medicinal Products for Human Use | Other: Floseal haemostatic matrix (Floseal VH S/D) - Procedural steps and scientific information after initial consultation (updated)

Medicinal Products for Human Use | News and press releases: COVID-19: EMA recommends conditional marketing authorisation for Paxlovid (updated)

Medicinal Products for Veterinary Use | Guideline on clinical trials with immunological veterinary medicinal products (updated)

Medicinal Products for Veterinary Use | Other: EVVET - EVWEB user manual

Medicinal Products for Veterinary Use | Other: EVVET - Procedures to be followed in case of prolonged system failure

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Medicinal Products for Veterinary Use | Other: EudraVigilance veterinary - Registration manual

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

Medicinal Products for Veterinary Use | Other: Annex to interim measures regarding notification of pharmacovigilance alerts by marketing authorisation holders under Regulation (EU) 2019/6: contact points

Medicinal Products for Veterinary Use | Other: EVVET – Data warehouse user manual

Medicinal Products for Veterinary Use | Other: Procedural note for interim measures regarding notification of pharmacovigilance alerts by marketing authorisation holders under Regulation (EU) 2019/6

Medicinal Products for Veterinary Use | Questions and answers on requirements for pre-clinical studies submitted in support of a marketing authorisation application for a veterinary medicinal product (updated)

Medicinal Products for Veterinary Use | News and press releases: New EU rules for safe and high-quality medicines for animals become effective

Medicinal Products for Human Use | Requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (updated)

Medicinal Products for Veterinary Use | Prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6

COMISSÃO EUROPEIA

SCCS - Final Opinion on Prostaglandins and prostaglandin-analogues used in cosmetic products

SCCS - Request for a scientific opinion on Salicylic acid

SCCS - Request for a scientific opinion on Benzyl Salicylate

SCCS - Request for a scientific opinion on Methylparaben

Agenda - Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases

Coronavirus: Commission proposes to extend the EU Digital COVID Certificate by one year

Europe's Beating Cancer Plan: New actions to increase access to cancer prevention, early detection, treatment and care

European Cancer Inequalities Registry: join the 08/02 webinar presenting this new initiative

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

Commission Implementing Regulation (EU) 2021/1248 on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6

REGULAÇÃO

COMISSÃO EUROPEIA	Commission Implementing Regulation (EU) 2021/1280 on good distribution practice for active substances used as starting materials in veterinary medicinal products New template - Compliance with applicable rules for biological samples Questions and Answers Document – Regulation (EU) 536/2014 – Version 5 (January 2022) Flash report - Meeting of the Subgroup Non-Communicable Diseases (28 January 2022)

Contactos

saude@vda.pt