VIEIRA DE ALMEIDA

SAÚDE

EM DESTAQUE

VdA EXPERTISE

13 a 17 de junho de 2022

LEGISLAÇÃO

NACIONAL	Resolução do Conselho de Ministros n.º 49/2022 Presidência do Conselho de Ministros Autoriza a realização da despesa pelas administrações regionais de saúde com a aquisição de vacinas contra a gripe
EUROPEIA	Decisão Conselho, de 13 de junho de 2022, relativa à nomeação de quatro membros do Conselho de Administração da Agência Europeia de Medicamentos Regulamento de Execução (UE) 2022/925 da Comissão, de 14 de junho de 2022, que altera o anexo do Regulamento de Execução (UE) 2018/1882 no que diz respeito às doenças listadas de animais aquáticos e à lista de espécies e grupos de espécies que apresentam um risco considerável para a propagação dessas doenças listadas

REGULAÇÃO

ECONOMIA E TRANSIÇÃO DIGITAL, FINANÇAS E SAÚDE

Despacho n.º 7566/2022
Saúde – Gabinete da Ministra
Constitui os grupos técnicos para a elaboração das propostas de revisão das Redes de Referenciação Hospitalar de cardiologia, cirurgia geral, cirurgia plástica, reconstrutiva e estética, hematologia clínica, medicina nuclear, oncologia médica, pneumologia, psiquiatria e saúde mental, radioncologia e reumatologia

Aviso n.º 12052/2022
Ordem dos Psicólogos Portugueses
Regulamento que define o ato do psicólogo

Deliberação n.º 689/2022
Saúde – Administração Regional de Saúde do Norte, I. P.
Nomeação da responsável regional do Plano das Demências, Dr.ª Maria Cristina de Castro Brito Ramos Paz de Amorim

Deliberação n.º 690/2022
Saúde – Administração Regional de Saúde do Norte, I. P.
Designação dos membros da Comissão Regional de Saúde para as Demências na Administração Regional de Saúde do Norte

Deliberação n.º 691/2022
Saúde – Administração Regional de Saúde do Norte, I. P.
Delegação de competências do conselho diretivo nos diretores executivos, no âmbito da Administração Regional de Saúde do Norte, I. P.

Deliberação n.º 692/2022
Saúde – Administração Regional de Saúde do Norte, I. P.
Delegação de competências em cada um dos membros do conselho diretivo da Administração Regional de Saúde do Norte, I. P.

Despacho n.º 7478/2022
Saúde – Administração Regional de Saúde do Norte, I. P.
Delegação de competências do presidente nos restantes membros do conselho diretivo da Administração Regional de Saúde do Norte

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 064/CD/100.20.200 de 14/06/2022 | Sistema de Preços de Referência – 3.º trimestre de 2022

Deliberação 054/CD/2022 de 08/06/2022 | Sistema de Preços de Referência – 3.º trimestre de 2022

Circular Informativa 061/CD/100.20.200 de 09/06/2022 | Aposição de Etiquetas em Produtos Cosméticos

Notícias

Infarmed Newsletter N.º 206

Início da avaliação da vacina Comirnaty COVID-19 adaptada

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INFARMED	Relatório de Farmacovigilância: monitorização da segurança das vacinas contra a COVID-19 em Portugal (dados recebidos até 31 de maio de 2022) Quadro regulamentar para dispositivos médicos e dispositivos médicos de diagnóstico in vitro – Implementação dos Regulamentos (UE) 2017/745 (MDR) e 2017/746 (IVDR) Eventos Manhãs Informativas "Farmacovigilância" – Inscrições abertas | 28.06.2022 | Sessão híbrida Inscrições até ao dia 24 de junho através do formulário. Programa
SPMS	Lista de Entrada em Vigor dos novos CPA_14-06-2022

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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, 25, Authorised (updated)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): Vaxzevria (previously COVID-19 Vaccine AstraZeneca), ChAdOx1-SARS-COV-2, COVID-19 virus infection, 29/01/2021, 21, Authorised (updated)

Human medicines European public assessment report (EPAR): Nuvaxovid, SARS-CoV-2 recombinant spike protein, COVID-19 virus infection, 20/12/2021, 2, Authorised (updated)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): Spikevax (previously COVID-19 Vaccine Moderna), CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) 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, 06/01/2021, 23, Authorised (updated)

Medicinal Products for Human Use | COVID-19 vaccine safety update: COVID-19 vaccines - Safety update: 17 June 2022

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

Data Management | Other: Article 57 product data (updated)

Corporate | Agenda: Agenda for the 116th meeting of the Management Board

Events | Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system , Online, 09:00 - 18:00 Amsterdam time (CEST), from 22/06/2022 to 24/06/2022 (updated)

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

Corporate | Minutes: Minutes of the 115th meeting of the Management Board: 16-17 March 2022

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)

Events | Clinical Trials Information System (CTIS) webinar: Six months of CTIS and looking forward , Online, 09:30-13:30 Amsterdam time (CEST), from 01/07/2021 to 01/07/2021

Events | Organisation Management System (OMS) Trouble Shooting Session for CTIS users , Online, 14:00 - 15:00 Amsterdam time (CEST), from 30/06/2022 to 30/06/2022

Medicinal Products for Veterinary Use | Other: Validation checklist for initial marketing authorisation applications - biologicals other than immunologicals (applicable to submissions under Regulation (EU) 2019/6)

Events | Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system , Online, 09:00 - 13:30 Amsterdam time (CET), from 30/11/2022 to 02/12/2022

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Events | Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system , Online, 14:00 – 18:00 Amsterdam time (CEST), from 05/10/2022 to 07/10/2022

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

Corporate | Template or form: Declaration on the qualification of an enterprise as a micro, small or medium-sized enterprise (SME) (updated)

Corporate | Template or form: Guidance for usage of application form related to Article 16 of the Staff Regulations (updated)

Medicinal Products for Human Use | Agenda: Agenda – CAT agenda of the 15-17 June 2022 meeting

Events | Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course on using the EudraVigilance system , Online, from 12/09/2022 to 16/09/2022

Events | Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course on using the EudraVigilance system , Online, from 10/10/2022 to 14/10/2022

Events | Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course on using the EudraVigilance system , Online, from 24/10/2022 to 28/10/2022

Events | Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course on using the EudraVigilance system , Online, from 21/11/2022 to 25/11/2022

Events | Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course on using the EudraVigilance system , Online, from 05/12/2022 to 09/12/2022

Medicinal Products for Human Use | Other: Dates of 2023 Scientific Advice Working Party (SAWP) meetings and submission deadlines scientific advice, protocol assistance, qualification of biomarkers and EMA/EUnetHTA parallel consultation requests

Medicinal Products for Veterinary Use | Agenda: Agenda – CVMP agenda of the 14-16 June 2022 meeting

Big Data | Big Data Steering Group and industry stakeholders meeting , Online, from 30/05/2022 to 30/05/2022

Events | First industry standing group (ISG) meeting , Online, from 21/06/2022 to 21/06/2022

Medicinal Products for Human Use | EPAR – Steps taken after authorisation when a cutoff date has been used: Evra : EPAR – Steps taken after authorisation when a cutoff date has been used (updated)

Medicinal Products for Human Use | EPAR – Procedural steps taken before authorisation: Evra : EPAR – Procedural steps taken before authorisation (updated)

Big Data | News and press releases: Big Data strategy for veterinary medicines in the EU

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Big Data | Big data (updated)

Data Elemetns Guideline | Other: Standard term lists mapping from Data Elements Guideline (DEG) standard to VICH standard (updated)

Medicinal Products for Human Use | Innovation in medicines (updated)

Medicinal Products for Human Use | Report: Faecal microbiota transplantation EU-IN Horizon Scanning Report

Medicinal Products for Human Use | Minutes: Minutes of the COMP meeting on 15-17 March 2022

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)

Pharmacovigilance | Other: EVVet3 EVWeb Production – Release notes (Release 1.3)

Pharmacovigilance | News and press releases: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7-10 June 2022

Medicinal Products for Human Use | News and press releases: EMA recommends withdrawal of marketing authorisation for amfepramone medicines

Pharmacovigilance | Pharmacovigilance (veterinary medicines) (updated)

Medicinal Products for Veterinary Use | Other: Recommended due dates (non-CAPs) for submission of the annual statement: July 2022 to December 2022

Medicinal Products for Veterinary Use | Other: Recommended due dates for centrally authorised products (CAPs) for the submission of the annual statements for the period: July 2022 to December 2022 (updated)

Corporate | News and press releases: EMA publishes annual report 2021

Corporate | Annual reports and work programmes (updated)

SME | Report: Small and medium-sized enterprise (SME) Office annual report 2021

Events | Clinical Trials Information System (CTIS) bitesize talk: Deferral rules and Public website , Online, 14:30 - 16:00 Amsterdam time (CET), from 20/07/2022 to 20/07/2022

Events | Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) , Online, 10:00 - 11:30 Amsterdam time (CEST), from 11/05/2022 to 11/05/2022 (updated)

Medicinal Products for Human Use | Minutes: Minutes - Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

Medicinal Products for Human Use | Agenda: Agenda - COMP agenda of the 14-16 June 2022 meeting

Medicinal Products for Human Use | Regulatory and procedural guideline: Compilation of quality review of documents (QRD) on stylistic matters in product information (updated)

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Medicinal Products for Human Use | Report: Medicinal products for human use: monthly figures - May 2022

Medicinal Products for Human Use | Submitting annual reports on medicine development (updated)

Medicinal Products for Human Use | Changing the name or address of a sponsor (updated)

Medicinal Products for Human Use | Template or form: QRD Appendix II - Medical Dictionary for Regulatory Activities terminology to be used in section 4.8 'undesirable effects' of the summary of product characteristics (updated)

Medicinal Products for Human Use | Orphans: Regulatory and procedural guidance and forms (updated)

Medicinal Products for Human Use | Other: Procedural advice for post-orphan medicinal product designation activities: Guidance for sponsors (updated)

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

Medicinal Products for Human Use | Transferring an orphan designation (updated)

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 | Regulatory and procedural guideline: Checklist for sponsors applying for the transfer of Orphan Medicinal Product (OMP) designation (updated)

COMISSÃO EUROPEIA

Draft Opinion - Managing antimicrobial resistance across the health system

Stakeholder meeting - Monkeypox, information meeting and exchange of activities (17 June 2022, 12.15-14.00 CET)

Registration open - 2023 EU4Health Stakeholders' Event (8 July 2022)

HERA secures vaccines for EU Member states in response to the monkeypox outbreaks

Agenda - 12th Plenary meeting of the Expert Panel (2019-2022) (23 June 2022)

Minutes - 4th drafting group meeting on facing the impact of post-COVID-19 condition on health systems (13 May 2022)

Minutes - Meeting of the Coalition for Vaccination (20 May 2022)

MDCG 2022-11 - MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements

General Guidelines - Guidelines on the electronic exchange of health data under Cross-Border Directive 2011/24/EU

ePrescription and eDispensation of Authorised Medicinal Products - Guidelines on the electronic exchange of health data under Cross-Border Directive 2011/24/EU

EMA

Information Management | Regulatory and procedural guideline: Article 57 user interface (UI) installation guide: Installation of Article 57 UI components and initial set up (updated)

Information Management | Other: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual (updated)

Events | Committee for Herbal Medicinal Products (HMPC): 16-18 May 2022, Online, from 16/05/2022 to 18/05/2022 (updated)

Events | Paediatric Committee (PDCO): 22-25 March 2022, Virtual meeting, from 22/03/2022 to 25/03/2022 (updated)

Clinical Trials Information System | Other: Quick guide - Introduction: How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 (updated)

Clinical Trials Information System | Other: Quick guide - Part I : How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 (updated)

Clinical Trials Information System | Other: Quick guide - Part II : How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 (updated)

Clinical Trials Information System | Other: Quick guide - Decision: How to evaluate an Initial Clinical Trial Application: Assessment and Decision - CTIS Training Programme - Module 08 (updated)

Clinical Trials Information System | Other: Quick guide - Introduction: CTIS for SMEs and Academia - CTIS Training Programme - Module 19 (updated)

Medicinal Products for Human Use | Clinical trials in human medicines (updated)

COMISSÃO EUROPEIA

SCCS - Minutes of the Working Group meeting on Cosmetic Ingredients of 31 May - 1 June 2022

Minutes - 6th drafting group meeting on managing AMR across the health system (16 May 2022)

Invitation and agenda - Hearing on Managing antimicrobial resistance across the health system

Agenda and registration - Webinar: Healthier Together – EU Non-communicable diseases initiative (22 June 2022)

Presentation - Stakeholder webinar: Healthier Together – EU NCD Initiative (3 June 2022)

COMISSÃO EUROPEIA

15th update – Common list of COVID-19 rapid antigen tests

EU Digital COVID Certificate: Commission welcomes political agreement on one year extension

European Commission and United States sign cooperation arrangement on preparedness and response to public health threats

SCCS - Minutes of the Working Group meeting on Cosmetic Ingredients of 31 May - 1 June 2022

Contactos

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