

SAÚDE

EM DESTAQUE

V d A E X P E R T I S E



10 a 14. de outubro de 2022

LEGISLAÇÃO

EUROPEIA

[Decisão de Execução \(UE\) 2022/1948 da Comissão, de 13 de outubro de 2022, que estabelece a equivalência, a fim de facilitar o exercício do direito de livre circulação na União, dos certificados COVID-19 emitidos pela República Federativa do Brasil aos certificados emitidos em conformidade com o Regulamento \(UE\) 2021/953 do Parlamento Europeu e do Conselho](#)

[Decisão de Execução \(UE\) 2022/1949 da Comissão, de 13 de outubro de 2022, que estabelece a equivalência, a fim de facilitar o exercício do direito de livre circulação na União, dos certificados COVID-19 emitidos pela Nova Zelândia no que diz respeito às Ilhas Cook, a Niue e a Toquelau aos certificados emitidos em conformidade com o Regulamento \(UE\) 2021/953 do Parlamento Europeu e do Conselho](#)

[Decisão n.º 165/2022 do Comité Misto do EEE, de 10 de junho de 2022, que altera o anexo I \(Questões veterinárias e fitossanitárias\) do Acordo EEE \[2022/1865\]](#)

[Decisão n.º 166/2022 do Comité Misto do EEE, de 10 de junho de 2022, que altera o anexo I \(Questões veterinárias e fitossanitárias\) do Acordo EEE \[2022/1866\]](#)

[Decisão do Comité Misto do EEE n.º 167/2022, de 10 de junho de 2022, que altera o anexo I \(Questões veterinárias e fitossanitárias\) do Acordo EEE \[2022/1867\]](#)

REGULAÇÃO

ECONOMIA E TRANSIÇÃO DIGITAL, FINANÇAS E SAÚDE

[Despacho n.º 12062/2022](#)

Finanças e Saúde – Gabinetes do Ministro da Saúde e do Secretário de Estado do Tesouro

Delegação de competências no conselho diretivo da Administração Regional de Saúde de Lisboa e Vale do Tejo, I. P., no âmbito do procedimento relativo à formação do contrato relativo à gestão e prestação de cuidados de saúde no Hospital de Cascais

[Regulamento n.º 951/2022](#)

Ordem dos Médicos

Alteração ao Regulamento n.º 628/2016, de 6 de julho – Regulamento Geral dos Colégios de Especialidades e de Competências e das Secções de Subespecialidades

[Despacho n.º 11921/2022](#)

Finanças e Saúde – Gabinetes do Ministro da Saúde e do Secretário de Estado do Tesouro

Designa os membros para exercerem funções no conselho de administração do Instituto Português de Oncologia do Porto Francisco Gentil, E. P. E., no mandato 2022-2024

[Despacho n.º 11942/2022](#)

Agricultura e Alimentação – Direção-Geral de Alimentação e Veterinária

Prorroga o prazo estabelecido no Despacho n.º 1280/2022, de 31 janeiro, para a adaptação às regras de fornecimento ao utilizador final de medicamentos veterinários não sujeitos a receita médico-veterinária

[Deliberação \(extrato\) n.º 1069/2022](#)

Saúde – Administração Regional de Saúde de Lisboa e Vale do Tejo, I. P.

Designação do Dr. Rodrigo Hugo Farinha Henriques Marques para o cargo de vogal do conselho clínico e de saúde do Agrupamento de Centros de Saúde Oeste Sul

[Deliberação \(extrato\) n.º 1070/2022](#)

Saúde – Administração Regional de Saúde de Lisboa e Vale do Tejo, I. P.

Designação dos profissionais que integram o conselho clínico e de saúde do Agrupamento de Centros de Saúde Oeste Norte

[Deliberação n.º 1071/2022](#)

Saúde – Instituto Nacional de Emergência Médica, I. P.

Altera o Regulamento de Características de Identificação das Ambulâncias

[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](#)

INFARMED

[Circular Informativa 122/CD/100.20.200 de 11/10/2022](#) | Sistema de Preços de Referência – Aditamento de novos grupos homogéneos

[Notícias](#)

[EMA lança uma consulta pública sobre o guia de boas práticas para a utilização do catálogo de meta-dados do mundo real](#)

DGS

[Newsletter](#)

[Newsletter DGS n.º 191 de 2022-10-13](#)

SPMS

[Lista de Entrada em Vigor 12 10 2022](#)

HMA

[NEW - 11-13 October CMDh Agenda](#)

EMA

Medicinal Products for Human Use | Other: [Notification on arrangements for requesting EMA certificates through urgent and standard procedure for December 2022](#)

Clinical Trials Information System | Other: [Instructor's guide: How to create, submit and withdraw a Clinical Trial Application - CTIS Training Programme - Module 10 \(updated\)](#)

Medicinal Products for Veterinary Use | Scientific guideline: [Reflection paper on criteria for determining that an active substance is essential when considered in the context of Article 37\(2\)\(j\) of Regulation \(EU\) 2019/6](#)

Medicinal Products for Veterinary Use | Overview of comments: [Overview of comments received on 'Reflection paper on criteria for determining that an active substance is essential when considered in the context of Article 37\(2\)\(j\) of Regulation 2019/6'](#)

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 \(updated\)](#)

Medicinal Products for Human Use | [Opinions and letters of support on the qualification of novel methodologies for medicine development \(updated\)](#)

Medicinal Products for Human Use | Report: [Medicinal products for human use: monthly figures - September 2022](#)

Medicinal Products for Human Use | Report: [Applications for new human medicines under evaluation by the CHMP: October 2022](#)

Events | [Webinar on the draft Data Quality Framework for EU medicines regulation , Online, 15:00 - 16:00 Amsterdam time \(CEST\), from 18/10/2022 to 18/10/2022 \(updated\)](#)

Corporate | Minutes: [Minutes of the 116th meeting of the Management Board: 15-16 June 2022](#)

Publications | Newsletter: [Human medicines highlights - September 2022](#)

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, 24, Authorised \(updated\)](#)

EMA

Stakeholders | Report: [Pilot on early dialogue with patient organisations for orphan marketing authorisation applications: Outcome Report](#)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [Nuvaxovid, SARS-CoV-2 recombinant spike protein, COVID-19 virus infection, 20/12/2021, 5, Authorised \(updated\)](#)

DADI | [DADI PDF electronic application forms \(eAF\) training webinar, Online, 11:00 - 12:30 Amsterdam time \(CEST\), from 02/09/2022 to 02/09/2022 \(updated\)](#)

DADI | [DADI PDF electronic application forms \(eAF\) training webinar, Online, 11:00 - 12:30 Amsterdam time \(CEST\), from 26/07/2022 to 26/07/2022 \(updated\)](#)

Medicinal Products for Human Use | Paediatric Committee (PDCO): [11-14 October 2022, Virtual meeting, from 11/10/2022 to 14/10/2022 \(updated\)](#)

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

Medicinal Products for Human Use | Referrals document: [Nitrosamines EMEA-H-A5\(3\)-1490 - Questions and answers for marketing authorisation holders / applicants on the CHMP Opinion for the Article 5\(3\) of Regulation \(EC\) No 726/2004 referral on nitrosamine impurities in human medicinal products \(updated\)](#)

IRIS | [IRIS for Good Pharmacovigilance practice \(GVP\) inspections training session for industry users, Online, 10:00 - 11:30 Amsterdam time \(CEST\), from 07/09/2022 to 07/09/2022 \(updated\)](#)

EUnetHTA 21 | Minutes: [Minutes of the European Medicines Agency/European Network for Health Technology Assessment meeting - June 2022](#)

Quality Assurance | Other: [European Medicines Agency practical guidance on the application form for centralised type IA and IB variations \(updated\)](#)

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, 31, Authorised \(updated\)](#)

| [EMA Account Management training webinar, Online, 10:30 - 12:30 Amsterdam time \(CEST\), from 03/10/2022 to 03/10/2022 \(updated\)](#)

IRIS | Other: [IRIS guide for applicants - How to create and submit scientific applications, for industry and individual applicants \(updated\)](#)

Medicinal Products for Human Use | [Q&A: Good clinical practice \(GCP\) \(updated\)](#)

Data Quality | Regulatory and procedural guideline: [Data Quality Framework for EU medicines regulation](#)

Medicinal Products for Human Use | Agenda: [CHMP agenda of the 10-13 October 2022 meeting](#)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [Jcovden \(previously COVID-19 Vaccine Janssen\), adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein \(Ad26.COV2-S\), COVID-19 virus infection, 11/03/2021, 23, Authorised \(updated\)](#)

Corporate | Other: [Highlights of the fifth EMA - Medicines for Europe bilateral meeting](#)

Shortages and Safety of Medicinal Products | [Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products \(MSSG\)](#), Online, 08:30 – 10:30 Amsterdam time (CEST), from 05/10/2022 to 05/10/2022 (updated)

Events | [Pharmacovigilance Risk Assessment Committee \(PRAC\): 29 November–2 December 2021, European Medicines Agency, Amsterdam, the Netherlands, from 29/11/2021 to 02/12/2021 \(updated\)](#)

Pharmacovigilance | [PRAC: Agendas, minutes and highlights \(updated\)](#)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [COVID-19 Vaccine \(inactivated, adjuvanted\) Valneva, SARS-CoV-2 virus \(inactivated\) Wuhan strain hCoV-19 / Italy / INMI1-isl / 2020, COVID-19 virus infection, 24/06/2022, 3, Authorised \(updated\)](#)

Clinical Trials Information System | [Clinical Trials Information System \(CTIS\) bitesize talk: Notifications – Part 1](#), Online, 14:30 – 16:00 Amsterdam time (CEST), from 28/09/2022 to 28/09/2022 (updated)

Partners & Networks | Work programme: [2022–2025 Work plan for the Patients’ and Consumers’ Working Party \(PCWP\) and the Healthcare Professionals’ Working Party \(HCPWP\) \(updated\)](#)

Partners & Networks | [Meeting of the CTTI/FDA Patient Engagement Collaborative \(PEC\) and EMA Patients and Consumers Working Party \(PCWP\)](#), Online, from 15/07/2022 to 15/07/2022 (updated)

IRIS | Regulatory and procedural guideline: [IRIS guide for parallel distribution applicants \(updated\)](#)

Committees | [Methodology Working Party](#)

Committees | [3Rs Working Party](#)

Committees | [Non-clinical Working Party](#)

Pharmacovigilance | News and press releases: [Regulatory information – adjusted fees for pharmacovigilance applications from 3 October 2022](#)

Pharmacovigilance | Other: [Explanatory note on pharmacovigilance fees payable to EMA \(as of 3 October 2022\) \(updated\)](#)

Medicinal Products for Human Use | News and press releases: [New recommendations for terlipressin-containing medicines in the treatment of hepatorenal syndrome](#)

Pharmacovigilance | News and press releases: [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 26–29 September 2022](#)

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

Medicinal Products for Veterinary Use | Other: [Release notes – production release version 1.6.10 October 2022 – Veterinary Medicinal Products Regulation: Union Product Database](#)

Medicinal Products for Human Use | [Plasma master file certificates \(updated\)](#)

Medicinal Products for Human Use | Scientific guideline: [ICH: S 1 B 9R1: Testing for carcinogenicity of pharmaceuticals – Step 5](#)

Medicinal Products for Human Use | Scientific guideline: [ICH: Q 5 A \(R2\): Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin – Step 2b](#)

EMA

REGULAÇÃO

Medicinal Products for Human and Veterinary Use | Other: [Terms of reference of the HMA/EMA task force on availability of authorised medicines for human and veterinary use \(updated\)](#)

Medicinal Products for Human and Veterinary Use | Work programme: [Work programme until 2025 of the HMA/EMA task force on availability of authorised medicines for human and veterinary use \(updated\)](#)

Corporate | Other: [Composition of the HMA/EMA task force on availability of authorised medicines for human and veterinary use](#)

EMA

Corporate | News and press releases: [EMA Management Board: highlights of October 2022 meeting](#)

Stakeholders | Other: [Assessment of patient, consumer and healthcare professional organisations' compliance with EMA eligibility criteria \(updated\)](#)

Corporate | Other: [Members of the Coordinating group of European network of paediatric research at the European Medicines Agency \(Enpr-EMA\) \(updated\)](#)

Medicinal Products for Veterinary Use | News and press releases: [Meeting highlights from the Committee for Veterinary Medicinal Products \(CVMP\) 4-6 October 2022](#)

Pharmacovigilance | [PRAC: Agendas, minutes and highlights \(updated\)](#)

[Joint EU-US press release on strengthened cooperation in the area of health](#)

[SCCS - Minutes of the Working Group meeting on Cosmetic Ingredients of 3-4 October 2022](#)

[Recommendations for a common EU approach regarding vaccination policies for monkeypox outbreak response](#)

[Joint Statement by Commissioner Stella Kyriakides, WHO Regional Director for Europe Dr Hans Henri P. Kluge and Director of the ECDC Dr Andrea Ammon: working together towards COVID-19 and seasonal influenza vaccinations for this winter](#)

COMISSÃO EUROPEIA

[Draft Opinion on "Facing the impact of the post-COVID-19 condition on health systems"](#)

[Agenda - 100th meeting of the Pharmaceutical Committee \(21 October 2022\)](#)

[Updated agenda - HPP Webinar on EU4Health 2022 Work Programme - Information session: Second Wave of Open Calls for Action Grants \(19 October, 14.00-17.00 CET\)](#)

[Updated agenda - Hearing on Facing the impact of post-COVID-19 condition on health systems \(18 October 2022\)](#)

[2022 Thematic Networks - Pitch webinar: get to know the leaders and their initiatives \(17 October 2022, 11-12.30 CET\)](#)

Contactos



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