

SAÚDE

EM DESTAQUE

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



20 a 24. de fevereiro de 2023

LEGISLAÇÃO

NACIONAL

[Portaria n.º 51/2023](#)

Saúde

Atualiza o programa de formação especializada em cirurgia maxilofacial, constante do anexo à presente portaria, da qual faz parte integrante

[Portaria n.º 52/2023](#)

Saúde

Atualiza o programa de formação especializada em pediatria, constante do anexo à presente portaria, da qual faz parte integrante

EUROPEIA

[Decisão de Execução \(UE\) 2023/396 da Comissão, de 20 de fevereiro de 2023, que estabelece a equivalência, a fim de facilitar o exercício do direito de livre circulação na União, dos certificados COVID-19 emitidos pela Região Administrativa Especial de Hong Kong aos certificados emitidos em conformidade com o Regulamento \(UE\) 2021/953 do Parlamento Europeu e do Conselho](#)

[Regulamento Delegado \(UE\) 2023/361 da Comissão, de 28 de novembro de 2022, que complementa o Regulamento \(UE\) 2016/429 do Parlamento Europeu e do Conselho no que diz respeito às regras de utilização de determinados medicamentos veterinários para efeitos de prevenção e controlo de certas doenças listadas](#)

REGULAÇÃO

NACIONAL

[Deliberação \(extrato\) n.º 188/2023](#)

Saúde – Administração Regional de Saúde de Lisboa e Vale do Tejo, I. P.
Atualizados os elementos que constituem o Grupo Regional Estratégico para a Vacinação contra a COVID-19 da Administração Regional de Saúde de Lisboa e Vale do Tejo, I. P.

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.

[Notícias](#)

[Infarmed Newsletter, Nº 219](#)

DGS

[Newsletter](#)

[Newsletter DGS n.º 207 de 2023-02-20](#)

SPMS

[Submissão de propostas \(Saúde\)](#)

[Medicamentos do aparelho cardiovascular](#)

HMA

[NEW - 21-22 February CMDh Agenda](#)

EMA

Corporate | [Management Board meeting: 14-15 December 2022](#), European Medicines Agency, Amsterdam, the Netherlands, from 14/12/2022 to 15/12/2022 (updated)

Corporate | [Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products \(MSSG\)](#), Online, 09:30 - 12:00 Amsterdam time (CEST), from 23/02/2023 to 23/02/2023 (updated)

Human Regulatory | Withdrawn application: [Ilaris](#), canakinumab, Date of withdrawal: 26/10/2022, Post-authorisation (updated)

Medicinal Products for Human Use | [List of medicines under additional monitoring](#) (updated)

Medicinal Products for Human Use | Medicines under additional monitoring: [List of medicinal products under additional monitoring](#) (updated)

Medicinal Products for Human Use | Medicines under additional monitoring: [List of medicinal products under additional monitoring](#) (updated)

Medicinal Products for Human Use | Periodic safety update single assessment: [Piracetam: List of nationally authorised medicinal products - PSUSA/00002429/202204](#)

Other: [Languages on this website](#) (updated)

Medicinal Products for Human Use | Other: [Origio - Procedural steps and scientific information after initial consultation](#) (updated)

REGULAÇÃO

INFARMED

[Comunicado de Imprensa - CHESSMEN, lançamento oficial](#)

[Diretora Científica do EATRIS Portugal recebe Menção Honrosa](#)

[Agenda](#)

[EATRIS Summer School | De 17 a 20 de abril de 2023 | Inscrições abertas](#)

DGS

[Newsletter](#)

[Newsletter DGS n.º 206 de 2023-02-13](#)

SPMS

[Publicações](#)

[Estimativas Época Gripal 2023/2024](#)

EMA

Medicinal Products for Veterinary Use | [Chemistry of active substances for veterinary medicinal products - Scientific guideline \(updated\)](#)

Committees | Regulatory and procedural guideline: [Rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee \(PRAC\) \(updated\)](#)

Regulatory | Template or form: [Innovation Task Force \(ITF\) briefing meeting request form \(updated\)](#)

Medicinal Products for Human Use | [Adjuvants in vaccines for human use - Scientific guideline \(updated\)](#)

Medicinal Products for Human Use | [ICH guideline M13A on bioequivalence for immediate-release solid oral dosage forms ICH Guideline M13A on bioequivalence for immediate-release solid oral dosage forms - Scientific guideline \(updated\)](#)

Medicinal Products for Human Use | News and press releases: [Human medicines: highlights of 2022](#)

Medicinal Products for Veterinary Use | News and press releases: [Veterinary medicines: highlights of 2022](#)

Medicinal Products for Human Use | Template or form: [Day 80 assessment report - Overview and D120 LOQ template with guidance - Rev. 02.23 \(updated\)](#)

Events | [Clinical Trials Information System \(CTIS\) bitesize talk: Annual safety report \(ASR\), Online, 16:30 - 18:00 Amsterdam time \(CET\) \(Updated\), from 15/12/2022 to 15/12/2022 \(updated\)](#)

Events | [Product Management Service \(PMS\) Webinar on Data Migration, Online, 14:00 - 15:30 Amsterdam time \(CEST\), from 23/02/2023 to 23/02/2023 \(updated\)](#)

Committees | Other: [Mandate, objectives and rules of procedure of the Scientific Advice Working Party \(SAWP\) \(updated\)](#)

Events | [EIC / EMA Info Day: Regulatory support for the development of innovative medicines and technologies, Online, 09:00 - 12:30 Amsterdam time \(CET\), from 31/01/2023 to 31/01/2023 \(updated\)](#)

[CHMP opinions on consultation procedures](#)(updated)

Events | [Clinical Trials Information System \(CTIS\) Webinar – 9 months on and going forward](#), Online, 13:30 – 17:30 Amsterdam time (CET), from 16/11/2022 to 16/11/2022 (updated)

Medicinal Products for Human Use | Periodic safety update single assessment: [Glimepiride : List of nationally authorised medicinal products – PSUSA/00001534/202206](#)

[Nitrosamines Safety Operational Expert Group](#)

Events | [Quarterly system demo – Q1 2023](#), Online, 09:00 – 13:00 Amsterdam time (CET), from 22/03/2023 to 22/03/2023

Other: [Release Notes 1.6.16](#) (updated)

Other: [CTIS Training materials – Latest updates](#) (updated)

Other: [CooperSurgical Inc ART Media – Procedural steps and scientific information after initial consultation](#) (updated)

Medicinal Products for Human Use | Herbal medicinal product: [Vaccinii macrocarpi fructus, Vaccinii macrocarpi fructus, F: Assessment finalised](#) (updated)

Human Regulatory | Regulatory and procedural guideline: [List of centrally authorised products requiring a notification of a change for update of annexes](#) (updated)

EMA

Medicinal Products for Human Use | Direct healthcare professional communication (DHPC): [Xalkori \(crizotinib\): Vision disorders, including risk of severe visual loss, need for monitoring in paediatric patients](#), Active substance: crizotinib, DHPC type: Adverse event, Last updated: 21/02/2023

Medicinal Products for Human Use | Direct healthcare professional communication (DHPC): [Spikevax bivalent Original/Omicron BA.1, pre-filled syringe – Labelling deviation](#), Active substance: 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), DHPC type: Adverse event, Last updated: 21/02/2023

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, 35, Authorised (updated)

Medicinal Products for Veterinary Use | Referral: [Procaine benzylpenicillin](#), Article 82, Under evaluation, 18/02/2022, 20/02/2023 (updated)

Medicinal Products for Human Use | Herbal medicinal product: [Agrimoniae herba, Agrimoniae herba, F: Assessment finalised](#) (updated)

Regulatory | Other: [Considerations for research / project teams seeking competent authority participation in externally funded regulatory science and public health research projects related to medicinal products](#)

Medicinal Products for Human and Veterinary Use | [Innovation in medicines](#) (updated)

**COMISSÃO
EUROPEIA**

[Recording and presentations – Webinar: Towards a comprehensive approach to mental health – Strengthening the link between mental health and environment \(22 February 2023\)](#)

[SCHEER – Minutes of the Working Group meeting on protection of Animals of 27 January 2023](#)

[SCHEER – Minutes of the WG on Draft Environmental Quality Standards for the Water Framework Directive Priority Substances & groundwater quality standards 10 February 2023](#)

[Video recording – HPP webinar: Standards of Care: HIV, VH, and TB \(16 February 2023\)](#)

Contactos



saude@vda.pt

Esta informação é de distribuição reservada, destinando-se exclusivamente aos clientes Vieira de Almeida, e não deve ser entendida como qualquer forma de publicidade, pelo que se encontra vedada a sua cópia ou circulação. A informação proporcionada e as opiniões expressas são de carácter geral, não substituindo o recurso a aconselhamento jurídico adequado para a resolução de casos concretos.