

SAÚDE

EM DESTAQUE

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



na 14. de abril de 2022

LEGISLAÇÃO

NACIONAL

[Resolução do Conselho de Ministros n.º 41/2022](#)

Presidência Do Conselho De Ministros

Prorroga a declaração da situação de alerta, no âmbito da pandemia da doença COVID-19.

REGULAÇÃO

[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 033/CD/100.20.200](#) | Sistema de Preços de Referência – Aditamento de novos grupos homogéneos

[Notícias](#)

INFARMED

[NOTA INFORMATIVA – Recolha de lote da vacina Spikevax \(Vacina Moderna COVID-19\)](#)

[Infarmed distinguido nas comemorações do Dia Mundial da Saúde](#)

[Relatório de Farmacovigilância: monitorização da segurança das vacinas contra a COVID-19 em Portugal \(atualização\)](#)

[Eventos](#)

[Dia Internacional dos Ensaio Clínicos: Conferência "Investigação clínica em Portugal": inscrições abertas e programa já disponível](#) | 19.05.2022 | Porto | [Programa](#) | [Inscrições](#)

DGS

[Newsletter](#)

[Newsletter DGS n.º 169 de 2022-04-11](#)

SPMS

[Lista de Entrada em Vigor 11-04-2022 \(Novos CPA\)](#)

[Informação de Detalhe do Procedimento 2022 / 10 | Material de penso de efeito terapêutico](#)

REGULAÇÃO

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): [Regkirona, Regdanvimab, COVID-19 virus infection, 12/11/2021, 2, Authorised \(updated\)](#)

Medicinal Products for Human Use | Report: [HMPC meeting report on European Union herbal monographs, guidelines and other activities – 28–30 March 2022](#)

Medicinal Products for Human Use | Scientific guideline: [Points to consider on the impact of the war in Ukraine on methodological aspects of ongoing clinical trials](#)

Medicinal Products for Human Use | [Impact of the war in Ukraine on methodological aspects of ongoing clinical trials](#)

Medicinal Products for Human Use | [Clinical trials in human medicines \(updated\)](#)

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

Herbal medicinal products | Other: [Compilation of terms and definitions for Cannabis-derived medicinal products](#)

Medicinal Products for Human Use | Regulatory and procedural guideline: [Detailed guidance on ICSRs in the context of COVID-19 – Validity and coding of ICSRs \(updated\)](#)

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Medicinal Products for Human Use | [Scientific publications \(updated\)](#)

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

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 \(Ad26.COVS-2\), COVID-19 virus infection, 11/03/2021, 18, Authorised \(updated\)](#)

Medicinal Products for Human Use | COVID-19 vaccine safety update: [COVID-19 vaccines – Safety update: 13 April 2022](#)

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, 20, 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, 20, Authorised \(updated\)](#)

Medicinal Products for Human Use | [Frequently asked questions about parallel distribution \(updated\)](#)

REGULAÇÃO

Medicinal Products for Veterinary Use | Template or form: [Particulars to appear on the immediate package – combined label and package leaflet – with track-changes](#)

Medicinal Products for Veterinary Use | Template or form: [Particulars to appear on the immediate package – combined label and package leaflet \(updated\)](#)

PCWC and HCPWP | Minutes: [Meeting summary – European Medicines Agency \(EMA\) Patients' and Consumers' \(PCWP\) and Healthcare Professionals' \(HCPWP\) Working Parties joint meeting on 2-3 March 2022](#)

Medicinal Products for Human Use | Report: [PDCO meeting report of opinions on paediatric investigation plans and other activities 22-25 February 2022](#)

Medicinal Products for Human Use | [Parallel joint scientific consultation with regulators and health technology assessment bodies \(updated\)](#)

Partners & Networks | [Health technology assessment bodies \(updated\)](#)

Partners & Networks | Work programme: [European collaboration between regulators and health technology assessment bodies – Joint work plan \(2021-2023\) between EMA and European HTA bodies facilitated through EUnetHTA21](#)

Partners & Networks | News and press releases: [EMA and the EUnetHTA 21 consortium set priorities for their collaboration](#)

Medicinal Products for Veterinary Use | Other: [European Medicines Agency data protection notice concerning the Veterinary Info Day meeting on 12-13 May 2022](#)

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

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

Procurement | [Procurement \(updated\)](#)

Procurement | Procurement: [Ex ante publicity of a negotiated procedure – EMA/2022/09/IT – Transfer of registration of 21 public domain names from the current registrar and extension of their registration to 31/12/2024](#)

IT | Regulatory and procedural guideline: [IRIS guide for applicants – How to create and submit scientific applications, for industry and individual applicants \(updated\)](#)

Clinical Trial Information System | Newsletter: [CTIS newflash – 8 April 2022](#)

Medicinal Products for Human Use | Newsletter: [Human medicines highlights – April 2022](#)

Medicinal Products for Human Use | Agenda: [Agenda – Enpr-EMA Coordinating Group and networks meeting](#)

Medicinal Products for Human Use | Agenda: [Agenda – COMP agenda of the 11-13 April 2022 meeting](#)

Clinical Trial Information System | Other: [FAQs: How to create, submit and withdraw a Clinical Trial Application – CTIS Training Programme – Module 10 \(updated\)](#)

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Medicinal Products for Human Use | Agenda: [Agenda - CAT agenda of the 11-13 April 2022 meeting](#)

Medicinal Products for Veterinary Use | Agenda: [Agenda - CVMP agenda of the 11-13 April 2022 meeting](#)

Medicinal Products for Human Use | [Paediatric medicines: Overview\(updated\)](#)

Clinical Trial Information System | Other: [Draft guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System \(CTIS\)](#)

**COMISSÃO
EUROPEIA**

[Ukraine: Commission allocates €9 million for mental health assistance of Ukrainian refugees](#)

[Flash report - Meeting of the Subgroup on Cancer \(24 March 2022\)](#)

[Notice to Stakeholders EU-Turkey Customs Union Agreement in the field of medical devices](#)

[Questions and Answers Document – Regulation \(EU\) 536/2014 – Version 6 April 2022\)](#)

[Factsheet – Access to health care in EU countries for persons displaced from Ukraine](#)

[EU-UK relations: European Union ensures continued supply of medicines to Northern Ireland, as well as Cyprus, Ireland and Malta](#)

[HPP webinar - Healthier Together: EU NCD Initiative \(27 April 2022, 10.30-12.30 CET\)](#)

[The EUDAMED NBs & Certificates module updated technical documentation is available](#)

[The EUDAMED UDI/Devices module updated technical documentation is available](#)

[Flash report - Meeting of the Sub-group on the EU NCD Initiative \(8 April 2022\)](#)

[13th update - Common list of COVID-19 rapid antigen tests](#)

Contactos



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