

SAÚDE

EM DESTAQUE

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



23 a 26 de maio de 2022

LEGISLAÇÃO

NACIONAL

[Aviso n.º 52/2022](#)

Negócios Estrangeiros

Entrada em vigor do Acordo de Cooperação entre a República Portuguesa e a República Democrática e Popular da Argélia no Domínio da Saúde, assinado em Lisboa em 3 de outubro de 2018

[Decreto Legislativo Regional n.º 11/2022/A](#)

Região Autónoma Dos Açores - Assembleia Legislativa

Primeira alteração ao [Decreto Legislativo Regional n.º 16/2015/A](#) de 17 de junho - Cria o Complemento Especial para o Doente Oncológico - CEDO

[Portaria n.º 151-B/2022](#)

Saúde

Regime excecional e temporário de comparticipação de testes rápidos de antigénio (TRAg) de uso profissional

REGULAÇÃO

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](#)

[Registo simplificado de medicamentos Alergénios](#)

Foi publicado o novo Regulamento dos medicamentos alérgenos destinados a um doente específico através da Deliberação n.º 035/CD/2022, de 14 de abril, que visa simplificar o processo de registo e comercialização deste tipo de produtos.

[Notícias](#)

[Testes rápidos de Antígeno voltam a ser comparticipados](#)

[Comunicado de Imprensa - Sexta doação de medicamentos à Ucrânia](#)

DGS

[Orientações e Circulares Informativas](#)

[Orientação nº 009/2020 de 11/03/2020 atualizada a 23/05/2022](#) | COVID-19: Procedimentos para Estruturas Residenciais para Idosos (ERPI) e para Unidades de Cuidados Continuados Integrados (várias tipologias).

[Orientação nº 016/2020 de 23/03/2020 atualizada a 23/05/2022](#) | COVID-19: Serviços prisionais e tutelares

[Documentos e Publicações](#)

[Programa Nacional de Saúde Ocupacional | Relatório Final do PNSOC: Extensão 2018/2020](#)

[Newsletter](#)

[Newsletter DGS n.º 172 de 2022-05-24](#)

HMA

[NEW - 20-21 April CMDh Minutes](#)

EMA

Events | [DARWIN EU Advisory Board meeting: 16 February 2022, Online, from 16/02/2022 to 16/02/2022 \(updated\)](#)

Events | [Clinical Trials Information System \(CTIS\) bitesize talk: Modifications, Online, 16:30 - 18:00 Amsterdam time \(CEST\), from 31/05/2022 to 31/05/2022 \(updated\)](#)

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 \(updated\)](#)

Medicinal Products for Veterinary Use | Other: [Antimicrobial use data reporting per animal categories \(numerator\) - Manual for reporting the data to EMA](#)

Events | [Digital application dataset integration \(DADI\) and Product Management Service \(PMS\) webinar - Variations form for human medicinal products - What will happen at go-live, Online, 10:00 - 12:00 Amsterdam time \(CEST\), from 16/05/2022 to 16/05/2022 \(updated\)](#)

Medicinal Products for Human Use | News and press releases: [Hydroxyethyl-starch solutions for infusion recommended for suspension from the market \(updated\)](#)

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 \(updated\)](#)

Miscellaneous | Other: [EMA medical terms simplifier \(updated\)](#)

Medicinal Products for Human Use | Template or form: [Step 2 - Nitrosamine detected response template \(updated\)](#)

Events | [Third Nitrosamine Implementation Oversight Group \(NIOG\) - meeting with pharmaceutical industry, Online, from 04/05/2022 to 04/05/2022 \(updated\)](#)

Big Data | Other: [Membership list - HMA / EMA joint Big Data Steering Group \(updated\)](#)

Pharmacovigilance | Other: [List of European Union reference dates and frequency of submission of periodic safety update reports \(PSURs\) \(updated\)](#)

Clinical Trial Information System | Other: [FAQs: Supervise a Clinical Trial and a Clinical Trial: Inspection records - CTIS Training Programme - Module 16 \(updated\)](#)

Events | [EMA and European Infrastructure for Translational Research \(EATRIS\) webinar on Scientific Advice for Advanced Therapy Medicinal Products \(ATMPs\): what and when to ask, Online, 13.00 - 14.00 Amsterdam time \(CEST\), from 10/06/2022 to 10/06/2022](#)

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

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

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 | Report: [Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 16-19 May 2022](#)

Clinical Trials | Newsletter: [Clinical Trials Highlights - May 2022](#)

Medicinal Products for Veterinary Use | Other: [Example files – production release version 1.6.4 May 2022 – Veterinary Medicinal Products Regulation: Union Product Database](#)

Medicinal Products for Veterinary Use | Other: [Release notes – production release version 1.6.4 May 2022 – Veterinary Medicinal Products Regulation: Union Product Database](#)

Medicinal Products for Human Use | [Evaluation of anticancer medicinal products in man\(updated\)](#)

Events | [Ad-hoc meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products \(MSSG\)](#), Online, 10:00 – 11:00 Amsterdam time (CEST), from 25/05/2022 to 25/05/2022

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

Corporate | Procurement: [Ex ante publicity of a negotiated procedure: EMA-2022-06-ST - Provision of external meeting and conference facilities](#)

Corporate | [Information management\(updated\)](#)

Medicinal Products for Human Use | [COVID-19 treatments: research and development\(updated\)](#)

Medicinal Products for Human Use | [COVID-19 vaccines: research and development\(updated\)](#)

EMA

Holidays | News and press releases: [EMA business hours over Ascension Day holidays, 26 and 27 May](#)

Medicinal Products for Human Use | [Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements\(updated\)](#)

Medicinal Products for Human Use | [Evaluation of medicinal products indicated for treatment of bacterial infections\(updated\)](#)

Medicinal Products for Human Use | News and press releases: [EMA guidance supports development of new antibiotics](#)

Medicinal Products for Human Use | [Antimicrobial resistance in human medicine\(updated\)](#)

Medicinal Products for Human Use | Other: [Contact details of national competent authorities for requests of translation exemptions falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages\(updated\)](#)

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 Human Use | [Pre-authorisation guidance under the Veterinary Medicinal Products Regulation \(Regulation \(EU\) 2019/6\)\(updated\)](#)

Medicinal Products for Veterinary Use | [European Medicines Agency veterinary medicines info day 2022](#), Online, from 12/05/2022 to 13/05/2022(updated)

Medicinal Products for Human Use | Other: [Article 57 product data\(updated\)](#)

EMA

Medicinal Products for Veterinary Use | Regulatory and procedural guideline: [EU Implementation Guide \(IG\) on veterinary medicines product data – Chapter 2: Format for the electronic submission of veterinary medicinal product information \(updated\)](#)

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 | News and press releases: [First therapy to treat rare genetic nervous system disorder AADC deficiency](#)

Medicinal Products for Human Use | News and press releases: [First treatment for children with Progeria or progeroid like syndromes \(rare premature aging syndromes\)](#)

Medicinal Products for Human Use | News and press releases: [First therapy to treat two types of Niemann-Pick disease, a rare genetic metabolic disorder](#)

Medicinal Products for Human Use | News and press releases: [Synchron Research Service: suspension of medicines over flawed studies](#)

Medicinal Products for Human Use | News and press releases: [Meeting highlights from the Committee for Medicinal Products for Human Use \(CHMP\) 16-19 May 2022](#)

**COMISSÃO
EUROPEIA**

[Questions and Answers: Stronger rules for placing medical tests on the market](#)

[Public health: Stronger rules for placing medical tests on the market](#)

[MDCG 2022-10 – Q&A on the interface between Regulation \(EU\) 536/2014 on clinical trials for medicinal products for human use \(CTR\) and Regulation \(EU\) 2017/746](#)

[Notice to Stakeholders: Status of the EU-Switzerland Mutual Recognition Agreement \(MRA\) for in vitro diagnostic medical devices](#)

[MDCG 2022-9 – Summary of safety and performance template](#)

[Webinar: Healthier Together – EU Non-communicable diseases initiative \(22 June 2022, 15.00 – 16.40 CET\)](#)

[MDCG 2022-8 – Regulation \(EU\) 2017/746 – application of IVDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2022](#)

[MDCG 2022-7 – Q&A on the Unique Device Identification system under Regulation \(EU\) 2017/745 and Regulation \(EU\) 2017/746](#)

Contactos



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