VIEIRA DE ALMEIDA

# SAÚDE

## EM DESTAQUE

VdA EXPERTISE

4 a 8 de abril de 2022

# LEGISLAÇÃO

## NACIONAL

Resolução do Conselho de Ministros n.º 39/2022
**Presidência do Conselho de Ministros**
Autoriza a reprogramação da despesa inerente à celebração do contrato de gestão e prestação de cuidados de saúde no Hospital de Cascais

Resolução do Conselho de Ministros n.º 37/2022
**Presidência do Conselho de Ministros**
Autoriza a realização da despesa associada aos procedimentos aquisitivos de medicamentos contra a COVID-19

## EUROPEIA

Parecer do Comité Económico e Social Europeu sobre a proposta de regulamento do Parlamento Europeu e do Conselho que altera o Regulamento (UE) 2017/746 no que diz respeito às disposições transitórias aplicáveis a determinados dispositivos médicos para diagnóstico in vitro e à aplicação diferida dos requisitos aplicáveis aos dispositivos internos [COM(2021) 627 final — 2021/0323 (COD)]

Regulamento Delegado (UE) 2022/524 da Comissão, de 27 de janeiro de 2022, que retifica o Regulamento Delegado (UE) 2021/577 no que diz respeito a determinadas referências a medicamentos veterinários

Decisão de Execução (UE) 2022/533 da Comissão, de 1 de abril 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 da Colômbia aos certificados emitidos em conformidade com o Regulamento (UE) 2021/953 do Parlamento Europeu e do Conselho

Decisão de Execução (UE) 2022/534 da Comissão, de 1 de abril 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 Malásia aos certificados emitidos em conformidade com o Regulamento (UE) 2021/953 do Parlamento Europeu e do Conselho

# REGULAÇÃO

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| **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.<br><br>Publicação para efeitos do artigo 15º-A do Decreto-Lei n.º 176/2006, de 30 de agosto medicamentos genéricos aprovados por procedimento centralizados.<br><br>Circulares e Deliberações<br><br>Circular Informativa 030/CD/100.20.200 \| Crise na Urânia – Acolhimento de refugiados – Integração em ensaios clínicos<br><br>Notícias<br><br>ECDC e EMA emitem parecer sobre quartas doses de vacinas de mRNA COVID-19<br><br>Infarmed Newsletter – Edição n.º 201 – 01.04.2022 |
| **DGS** | Documentos e Publicações<br><br>Guia de Consulta Rápida Sobre Prescrição de Exercício Físico em doentes oncológicos<br><br>Newsletter<br><br>Newsletter DGS n.º 168 de 2022-04-06<br><br>Newsletter DGS n.º 167 de 2022-04-04 |
| **SPMS** | Informação de Detalhe do Procedimento 2022 / 28 \| Suturas Cirúrgicas<br><br>Lista de Entrada em Vigor_04_04_2022 (Novos CPA) |

## REGULAÇÃO

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| **HMA** | UPDATE - CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008<br><br>UPDATE - Mandate for the Working Group on Active Substance Master File Procedures<br><br>UPDATE - The Worksharing Procedure for the Assessment of Active Substance Master File (ASMF)<br><br>UPDATE - Questions & Answers for the Active Substance Master File<br><br>NEW - Outcome of PSUSA follow-up via variation – Update of Gabapentn Product Information<br><br>UPDATE - CMDh procedural advice on changing the RMS<br><br>NEW - Art 45 assessment report for Ceftriaxone<br><br>NEW - Art 45 assessment report for Cinnarizine<br><br>NEW - Art 45 assessment report for Dalteparin<br><br>NEW - Art 45 assessment report for Eucalypti-aetheroleum<br><br>NEW - Art 45 assessment report for Fluticasone propionate<br><br>NEW - Art 45 assessment report for Octreotide<br><br>UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation |

# REGULAÇÃO

## EMA

**Medicinal Products for Human Use** | News and press releases: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 April 2022

**Medicinal Products for Human Use** | Report: Applications for new human medicines under evaluation by the CHMP: April 2022

**Clinical Trials Information System** | Other: Sponsors' guide: Transition of trials from EudraCT to CTIS – CTIS Training Programme – Module 23 (updated)

**Clinical Trials Information System** | Other: Member states' guide: Transition of trials from EudraCT to CTIS – CTIS Training Programme – Module 23 (updated)

**Clinical Trials Information System** | Other: FAQs: Transition of trials from EudraCT to CTIS – CTIS Training Programme – Module 23 (updated)

**Medicinal Products for Human Use** | Report: Annual report on the use of the special contribution for orphan medicinal products – 2021

**Clinical Trials Information System** | Clinical Trials Information System (CTIS) bitesize talk: Initial clinical trial application , Online, 14:00 – 15:30 Amsterdam time (CET), from 23/03/2022 to 23/03/2022 (updated)

**Medicinal Products for Human Use** | Regulatory and procedural guideline: Guidance on Irish language derogation ending on 1 January 2022 (updated)

**Active Substances Procedures** | Other: Mandate of the Working Group on Active Substance Master File Procedures (updated)

**Medicinal Products for Human Use** | News and press releases: ECDC and EMA issue advice on fourth doses of mRNA COVID-19 vaccines

**Medicinal Products for Human Use** | Template or form: PRIME eligibility request: applicant's justification template (updated)

**Events** | Data quality framework for medicines regulation , Online, 13:00 – 17:15 Amsterdam time (CEST), from 07/04/2022 to 07/04/2022 (updated)

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

**Regulatory Data Management** | Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) substances (updated)

**Regulatory Data Management** | Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) pharmaceutical dose forms (updated)

**Regulatory Data Management** | Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) organisations (updated)

**Medicinal Products for Human Use** | Good clinical practice (updated) – Guidance for applicants/MAHs involved in GMP and GCP inspections coordinated by EMA; IRIS guide for applicants

**Medicinal Products for Human Use** | Good manufacturing practice (updated)

**Medicinal Products for Human Use** | Other: Orphan medicines figures 2000-2021 (updated)

## REGULAÇÃO

### EMA

Events | Clinical Trials Information System (CTIS) bitesize talk: Requests for information, Online, 14:00 – 15:30 Amsterdam time (CET), from 28/04/2022 to 28/04/2022 (updated)

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

Events | Multistakeholder workshop on EMA's extended mandate, Online, from 01/04/2022 to 01/04/2022 (updated)

Medicinal Products for Human Use | Other: Nullification ICSRs received by EudraVigilance (updated)

Medicinal Products for Human Use | Other: Letter of support for the Global Platform Study of Novel Medicines in Paediatric and Adolescent Relapsed and Refractory B-cell Non-Hodgkin Lymphoma (Glo-BNHL platform)

Clinical Trials Information System | Newsletter: CTIS newsflash – 1 April 2022

Medicinal Products for Human Use | Report: PRIME: Analysis of the first 5 years' experience (updated)

Medicinal Products for Human Use | Minutes: PDCO meeting report of opinions on paediatric investigation plans and other activities 18-21 January 2022

Medicinal Products for Human Use | Agenda: Agenda – PRAC draft agenda of meeting 4-7 April 2022

Medicinal Products for Veterinary Use | Buying veterinary medicines online (updated)

Scientific Evidence | Regulatory and procedural guideline: European Medicines Agency guidance for applicants seeking scientific advice and protocol assistance (updated)

Clinical Trial Information System | Other: Member states business processes and roles – CTIS Training Programme – Module 07 (updated)

Clinical Trial Information System | Other: Sponsors business processes and roles – CTIS Training Programme – Module 07 (updated)

Clinical Trial Information System | Other: Roles and permissions matrix summary – Authority workspace – CTIS Training Programme – Module 07 (updated)

Clinical Trial Information System | Other: Roles and permissions matrix summary – Sponsors workspace – CTIS Training Programme – Module 07 (updated)

Medicinal Products for Human Use | Plasma master file certificates (updated)

Events | Clinical Trials Information System (CTIS): Walk-in clinic, Online, 16:00 – 17:00 Amsterdam time (CEST), from 04/04/2022 to 04/04/2022 (updated)

Medicinal Products for Human Use | Minutes: PDCO monthly report of opinions on paediatric investigation plans and other activities 14-17 December 2021

Medicinal Products for Human Use | Minutes: PDCO monthly report of opinions on paediatric investigation plans and other activities 9-12 November 2021

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| **EMA** | Medicinal Products for Human Use \| Other: List of signals discussed at PRAC since September 2012 (updated)<br><br>Medicinal Products for Human Use \| PRAC recommendation on signal: PRAC recommendations on signals adopted at the 7-10 March 2022 PRAC meeting<br><br>Medicinal Products for Human Use \| PRAC recommendation on signal: New product information wording: extracts from PRAC recommendations on signals adopted at the 7-10 March 2022 PRAC<br><br>Regulatory \| News and press releases: Regulatory information – 0.3% and 5.3% increase in general fees from 1 April 2022<br><br>Medicinal Products for Human Use \| COVID-19: latest updates (updated)<br><br>Regulatory \| Fees payable to the European Medicines Agency (updated)<br><br>Regulatory \| Regulatory and procedural guideline: Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the Regulatory \| European Medicines Agency and other measures - Revised implementing rules to the Fee Regulation as of 1 April 2022<br><br>Regulatory \| Regulatory and procedural guideline: Commission Regulation (EU) 2022/510 of 29 March 2022 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2022<br><br>Regulatory \| Other: Explanatory note on general fees payable to the European Medicines Agency as of 01 April 2022 |
| **CEIC** | Esclarecimentos CEIC sobre Impacto da Guerra na Ucrânia na Condução de Ensaios Clínicos |
| **COMISSÃO EUROPEIA** | Summary report and meeting documents - 20th Meeting of the eHealth Network (8 November 2021)<br><br>Deadline extended to 25 April 2022 - HADEA: Call for tenders to help EU countries monitor the performance of national vaccination programmes<br><br>EU Health Policy Platform Holds Annual Meeting<br><br>Minutes - 3rd drafting group meeting on managing AMR across the health system (8 March 2022)<br><br>Minutes - 2nd drafting group meeting on facing the impact of post-COVID-19 condition on health systems (11 March 2022)<br><br>Presentations - Meeting of the Subgroup on Cancer (24 March 2022)<br><br>Healthier Together Initiative: call for best practices on non-communicable diseases<br><br>EU non-communicable diseases (NCDs) initiative: Frequently asked questions<br><br>Update - Joint implementation and preparedness plan for Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) |

# Contactos

saude@vda.pt