

## LEGISLAÇÃO

### NACIONAL

[Resolução do Conselho de Ministros n.º 96-B/2020 - Diário da República n.º 221/2020, 2º Suplemento, Série I de 2020-11-12](#)

**Presidência do Conselho de Ministros**

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

[Decreto n.º 8/2020 - Diário da República n.º 217-A/2020, Série I de 2020-11-08](#)

**Presidência do Conselho de Ministros**

Regulamenta a aplicação do estado de emergência decretado pelo Presidente da República

### COMUNITÁRIA

[Regulamento Delegado \(UE\) 2020/1677 da Comissão, de 31 de agosto de 2020, que altera o Regulamento \(CE\) n.º 1272/2008 do Parlamento Europeu e do Conselho, relativo à classificação, rotulagem e embalagem de substâncias e misturas, a fim de melhorar a viabilidade dos requisitos de informação relativos à resposta de emergência na área da saúde](#)

[Regulamento \(UE\) 2020/1682 da Comissão, de 12 de novembro de 2020, que altera o anexo III do Regulamento \(CE\) n.º 1223/2009 do Parlamento Europeu e do Conselho relativo aos produtos cosméticos](#)

[Regulamento \(UE\) 2020/1683 da Comissão, de 12 de novembro de 2020, que altera os anexos II e III do Regulamento \(CE\) n.º 1223/2009 do Parlamento Europeu e do Conselho relativo aos produtos cosméticos](#)

[Regulamento \(UE\) 2020/1684 da Comissão, de 12 de novembro de 2020, que altera o anexo VI do Regulamento \(CE\) n.º 1223/2009 do Parlamento Europeu e do Conselho relativo aos produtos cosméticos](#)

## REGULAÇÃO

### FINANÇAS E SAÚDE

[Despacho n.º 11005/2020 - Diário da República n.º 219/2020, Série II de 2020-11-10](#)

**Saúde - Gabinete da Ministra**

Subdelega na diretora-geral da Saúde a competência para a prática de todos os atos necessários à aquisição de vacinas contra a doença COVID-19

[Despacho n.º 10956/2020 - Diário da República n.º 218/2020, Série II de 2020-11-09](#)

**Saúde - Gabinete do Secretário de Estado Adjunto e da Saúde**

Designa, como adjunto do Gabinete do Secretário de Estado Adjunto e da Saúde, o mestre João Pedro Mendonça Vieira

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Atualização da lista de grupos homogêneos e preços de referência - 4.º trimestre de 2020

- [Circular Informativa N.º 173/CD/100.20.200, de 05/11/2020](#)
- [Deliberação N.º 86/CD/2020.](#)

INFARMED

[Infarmed Newsletter N.º 179](#)

[Consulte a nova infografia sobre o SIDM](#)

[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.**

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SPMS

[Entrada em vigor dos novos CPA – 12/11/20](#)

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DGS

[Norma nº 020/2020 de 09/11/2020](#)

COVID-19: Definição de Caso de COVID-19

[Norma nº 019/2020 de 26/10/2020 atualizada a 06/11/2020](#)

COVID-19 : Estratégia Nacional de Testes para SARS-CoV-2

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**Medicinal Products for Human Use | [Paediatric investigation plans: questions and answers](#)** (updated)

**Medicinal Products for Human Use | Report: [Applications for new human medicines under evaluation by the CHMP: November 2020](#)** (new)

**Medicinal Products for Human Use | Agenda: [Agenda - PCWP/HCPWP meeting with all eligible organisations: COVID-19 pandemic update](#)** (updated)

Other: [Guidance for submission and validation of electronic declaration of interests and electronic curriculum vitae](#) (updated)

EMA

Other: [Letter from the chairs of EMA's Management Board to Guido Rasi at the end of his term as EMA's Executive Director](#) (new)

**Medicinal Products for Human Use | [Pharmacovigilance: Overview](#)** (updated)

**Medicinal Products for Human Use | [Risk management plans](#)** (updated)

**Medicinal Products for Human Use | [COVID-19: latest updates](#)** (updated)

**Medicinal Products for Human Use | [Guidance for medicine developers and other stakeholders on COVID-19](#)** (updated)

**Medicinal Products for Human Use | [COVID-19 vaccines: development, evaluation, approval and monitoring](#)** (updated)

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**Medicinal Products for Human Use** | Other: [Pharmacovigilance plan of the EU Regulatory Network for COVID-19 vaccines](#) (new)

**Medicinal Products for Human Use** | Other: [Consideration on core requirements for RMPs of COVID-19 vaccines](#) (new)

**Medicinal Products for Human Use** | News and press releases: [EMA publishes safety monitoring plan and guidance on risk management planning for COVID-19 vaccines](#)

**Medicinal Products for Human Use** | News and press releases: [Meeting highlights from the Committee for Medicinal Products for Human Use \(CHMP\) 9-12 November 2020](#)

**Medicinal Products for Human Use** | News and press releases: [Nitrosamines: EMA aligns recommendations for sartans with those for other medicines](#)

**Medicinal Products for Human Use** | News and press releases: [Message from EMA's outgoing Executive Director, Guido Rasi](#)

**Medicinal Products for Human Use** | News and press releases: [Ulipristal acetate for uterine fibroids: EMA recommends restricting use](#)

**Medicinal Products for Human Use** | Annex to CHMP highlights: [Scientific advice and protocol assistance adopted during the CHMP meeting 9-12 November 2020](#) (new)

**Medicinal Products for Human Use** | [Report - Workshop on benefit-risk of medicines used during pregnancy and breastfeeding](#) (new)

[Fifth industry stakeholder platform on research and development support](#) , Virtual meeting, from 16/11/2020 to 16/11/2020

**Medicinal Products for Veterinary Use** | Minutes: [Minutes of the CVMP meeting of 6-7 October 2020](#) (new)

**Medicinal Products for Human Use** | Minutes: [Minutes of the COMP meeting 8-10 September 2020](#) (new)

**Medicinal Products for Human Use** | Committee meeting report: [COMP meeting report on the review of applications for orphan designation: November 2020](#) (new)

**Medicinal Products for Veterinary Use** | Regulatory and procedural guideline: [Draft concept paper on the reporting of antimicrobial sales and use in animals at the EU level](#) (new)

**Medicinal Products for Human Use** | Newsletter: [Human medicines highlights - November 2020](#) (new)

**Medicinal Products for Human Use** | Direct healthcare professional communication: [Gilenya \(fingolimod\): Updated recommendations to minimise the risk of drug-induced liver injury \(DILI\)](#) (new)

[Letter of support for Mobilise-D digital mobility outcomes as monitoring biomarkers](#) (new)

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[Opinions and letters of support on the qualification of novel methodologies for medicine development](#) (updated)

**Medicinal Products for Human Use** | Direct healthcare professional communication: [Gilenya \(fingolimod\): Updated recommendations to minimise the risk of drug-induced liver injury \(DILI\)](#) (new)

**Medicinal Products for Human Use** | Regulatory and procedural guideline: [Compilation of Quality Review of Documents decisions on stylistic matters in product information](#) (updated)

Other: [Detailed guide regarding the EudraVigilance data management activities by the European Medicines Agency](#) (updated)

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

[EMA roundtable with stakeholders on the 15-year anniversary of the SME Regulation](#) , Virtual meeting, from 27/11/2020 to 27/11/2020

**Medicinal Products for Human Use** | News and press releases: [Call for independent scientific experts to join EMA's Pharmacovigilance Risk Assessment Committee \(PRAC\)](#)

**Medicinal Products for Veterinary Use** | Other: [Veterinary Scientific Advice procedure - submission deadlines 2021](#) (new)

**Medicinal Products for Veterinary Use** | News and press releases: [Meeting highlights from the Committee for Medicinal Products for Veterinary Use \(CVMP\) 3-5 November 2020](#)

**Medicinal Products for Human Use** | [COVID-19: latest updates](#) (updated)

**Medicinal Products for Human Use** | News and press releases: [International regulators and WHO join forces to address COVID-19 challenges](#)

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CMDh  
[NEW - November CMDh Agenda](#)

HMA

[NEW - Art. 45 assessment report for pethidine hydrochloride](#)

[UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation](#)

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COMISSÃO EUROPEIA

[Press release - Building a European Health Union: Stronger crisis preparedness and response for Europe](#)

[Minutes - Meeting of the Subgroup on Proton Therapy Centres \(21 October 2020\)](#)