

SAÚDE

EM DESTAQUE

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



3 a 7 de maio de 2021

LEGISLAÇÃO

NACIONAL

[Resolução do Conselho de Ministros n.º 45-C/2021](#)
Presidência Do Conselho De Ministros
Declara a situação de calamidade, no âmbito da pandemia da doença COVID-19

COMUNITÁRIA

[Acordo de Comércio e Cooperação entre a União Europeia e a Comunidade Europeia da Energia Atómica, por um lado, e o Reino Unido da Grã-Bretanha e da Irlanda do Norte, por outro](#)

REGULAÇÃO

INFARMED

[Atualização da lista de grupos homogéneos e preços de referência](#)

- [Circular Informativa N.º 57/CD/100.20.200, de 06/05/2021](#)
- [Deliberação N.º 55/CD/2021.](#)

[Circular Informativa n.º 054/CD/100.20.200 de 03/05/2021](#) – Reporte de número de auto-testes SARS-CoV-2 distribuídos e dispensados

[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.

DGS

[Norma n.º 002/2021 de 30/01/2021 atualizada a 04/05/2021](#)
Campanha de Vacinação Contra a COVID-19

EMA

Medicinal Products for Human Use | Referrals document: [Regdanvimab for the treatment of COVID-19 \(Celltrion\) - COVID-19 - Article-5\(3\) procedure: Assessment report](#)

Medicinal Products for Human Use | News and press releases: [Confidentiality arrangement between EU and Brazilian regulatory authorities](#)

Medicinal Products for Human Use | Other: [Working arrangement between EMA, Directorate-General Health and Food Safety \(DG SANTE\) and the Brazilian Health Regulatory Agency \(ANVISA\) for the exchange of non-public information on medical/medicinal products](#)

Medicinal Products for Human Use | [Substance and product data management services](#) (updated)

Medicinal Products for Human Use | [CHMP: Working parties and other groups](#) (updated)

[Agenda - Data Standardisation Strategy stakeholder workshop](#)

[Joint HMA/EMA workshop on artificial intelligence in medicines regulation](#) , Virtual event, from 19/04/2021 to 20/04/2021 - Presentations

Other: [Handling times for requests for EMA certificates through standard procedure](#) (updated)

Medicinal Products for Human Use | [Minutes of the CAT meeting 17-19 February 2021](#)

Medicinal Products for Human Use | Committee meeting report: [CAT monthly report of application procedures, guidelines and related documents on advanced therapies: March 2021](#)

Medicinal Products for Human Use | Committee meeting report: [CAT monthly report of application procedures, guidelines and related documents on advanced therapies: April 2021](#)

Medicinal Products for Human Use | [Minutes - PDCO minutes of the 23-26 February 2021](#)

Regulatory and procedural guideline: [Member states contact points for translations review](#) (updated)

Medicinal Products for Human Use | News and press releases: [EMA starts rolling review of COVID-19 Vaccine \(Vero Cell\) Inactivated](#)

Medicinal Products for Human Use | [COVID-19 vaccines: under evaluation](#) (updated)

Medicinal Products for Human Use | [COVID-19 vaccines](#) (updated)

Medicinal Products for Human Use | [Minutes of the COMP meeting 16-18 March 2021](#)

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

Medicinal Products for Human Use | News and press releases: [EMA starts rolling review of COVID-19 Vaccine \(Vero Cell\) Inactivated](#)

Medicinal Products for Veterinary Use | [Minutes of the CVMP meeting of 16-18 March 2021](#)

EMA

Medicinal Products for Human Use | [Nullification ICSRs received by EudraVigilance](#) (updated)

Medicinal Products for Human Use | [Agenda – PRAC draft agenda of meeting 3-6 May 2021](#)

Medicinal Products for Human Use | [Minutes of the COMP meeting 16-18 February 2021](#)

Medicinal Products for Human Use | Regulatory and procedural guideline: [Information note on the format and validity features of electronic certificates for medicines issued by the European Medicines Agency](#) (updated)

Medicinal Products for Human Use | [Agenda – HMPC agenda of the 3-5 May 2021 meeting](#)

Medicinal Products for Human Use | Other: [Updated handling times for requests for EMA certificates through standard procedure](#) (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: [European Medicines Agency certificates of medicinal products – instructions on how to fill in the application form](#) (updated)

Medicinal Products for Human Use | Other: [Information package for certificates of medicinal products issued by the European Medicines Agency](#) (updated)

Medicinal Products for Human Use | Other: [Notification on authenticity of European Medicines Agency certificates](#) (updated)

Medicinal Products for Human Use | [Minutes of the CHMP meeting 22-25 February 2021](#)

Medicinal Products for Human Use | News and press releases: [EMA starts evaluating use of COVID-19 vaccine Comirnaty in young people aged 12 to 15](#)

Medicinal Products for Human Use | [PRAC recommendations on safety signals](#) (updated)

HMA

[_CMDh annotated QRD template for MRP/DCP](#)

[UPDATE – Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP](#)

**COMISSÃO
EUROPEIA**

[Coronavirus: Commission proposes EU Strategy for the development and availability of therapeutics](#)

[Registration open – Hearing on “Supporting mental health of health workforce and other essential workers” \(8 June 2021\)](#)

[Commission launches online consultation on patients’ rights in cross-border healthcare](#)

[Updated document – Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional](#)

[Factsheet for Manufacturers of Implantable Medical Devices](#)

[European Health Union: Commission publishes open public consultation on the European Health Data Space](#)

[Minutes – AMR One Health Network \(25 March 2021\)](#)

Contactos



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