

SAÚDE

EM DESTAQUE

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



5 a 9 de abril de 2021

LEGISLAÇÃO

NACIONAL

[Decreto n.º 6/2021](#)

Presidência do Conselho de Ministros

Regulamenta o estado de emergência decretado pelo Presidente da República

REGULAÇÃO

INFARMED

[Circular Informativa N.º 043/CD/550.20.001 Data: 07/04/2021](#) - Vacina contra a COVID-19 da AstraZeneca: Conclusões do Comité de Avaliação de Risco em Farmacovigilância (PRAC)

[Nota Informativa: Ponto de situação sobre os autotestes COVID-19](#)

[Comunicado de Imprensa - Gestão da Disponibilidade de Medicamentos](#)

[Nova edição do Boletim de Farmacovigilância](#)

[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.

SPMS

[Lista de entrada em vigor dos novos CPA](#)

HMA

NEW - PSUR assessment reports for [doxylamine hydrogen succinate, pyridoxine hydrochloride](#) and [drospirenone](#)

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

[UPDATE - Q&A on the Paediatric Regulation](#)

[UPDATE - RMS validation checklist for human medicinal products in DCP](#)

EMA

Medicinal Products for Veterinary Use | [Webinar on reporting suspected side effects following administration of veterinary medicines](#), Virtual meeting, from 30/03/2021 to 30/03/2021 (updated)

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

Medicinal Products for Human Use | Report: [Hearing with the Association of the European Self-Medication Industry \(AESGP\) during the HMPC November 2020 meeting](#)

[Technical workshop on real-world metadata for regulatory purposes](#), Virtual meeting, from 12/04/2021 to 12/04/2021 (updated)

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

Other: [Mandate, objectives and rules of procedure of the Scientific Advice Working Party \(SAWP\)](#) (updated)

Medicinal Products for Human Use | News and press releases: [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 6–9 April 2021](#)

Medicinal Products for Human Use | News and press releases: [AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets](#)

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

Regulatory and procedural guideline: [EU E2B \(R3\) testing files \(EDQM revision\)](#) (new)

Regulatory and procedural guideline: [EU reference instances \(EDQM revision\)](#) (new)

Regulatory and procedural guideline: [European Union individual case safety report \(ICSR\) implementation guide](#) (updated)

Regulatory and procedural guideline: [EU Individual Case Safety Report \(ICSR\) implementation guide business rules spreadsheets](#) (updated)

Medicinal Products for Human Use | [Press briefing on the conclusion of the assessment of the Pharmacovigilance Risk Assessment Committee \(PRAC\) of Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\) and thromboembolic events](#), Virtual meeting, from 07/04/2021 to 07/04/2021

Medicinal Products for Veterinary Use | Other: [Mandate, objectives and rules of procedure for the CVMP Safety Working Party \(SWP-V\)](#) (updated)

Medicinal Products for Human Use | Agenda: [Agenda – PRAC draft agenda of meeting 6–9 April 2021](#)

Medicinal Products for Human Use | [Authenticity verification for electronic certificates](#)

Medicinal Products for Human Use | [Certification of medicinal products](#) (updated)

EMA

Medicinal Products for Human Use | Other: [CHMP meeting dates 2021, 2022, 2023 and 2024](#) (new)

Other: [Guide on access to unpublished documents](#) (updated)

Regulatory and procedural guideline: [Explanatory note on general fees payable to the European Medicines Agency as of 1 April 2021](#) (new)

[Technical workshop on real-world metadata for regulatory purposes](#), Virtual meeting, from 12/04/2021 to 12/04/2021 (updated)

Medicinal Products for Human Use | PRAC recommendation on signal: [PRAC recommendations on signals adopted at the 8-11 March 2021 PRAC meeting](#) (new)

Medicinal Products for Human Use | Other: [List of signals discussed at PRAC since September 2012](#) (updated)

Medicinal Products for Human Use | PRAC recommendation on signal: [New product information wording: extracts from PRAC recommendations on signals adopted at the 8-11 March 2021 PRAC](#) (new)

COMISSÃO EUROPEIA

[Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation \(EU\) 2017/746](#)

[Indicator on Infant Mortality \(ECHI 11\) and Health expectancy: Healthy Life Years \(ECHI 40\) updated with most recent Eurostat statistics](#)

[Updated - 2021 planned meetings of Medical Device Coordination Group \(MDCG\) and subgroups](#)

[Updated Implementation Rolling Plan - Regulation \(EU\) 2017/745 and Regulation \(EU\) 2017/746](#)

[Minutes - 2nd Drafting Group on European solidarity in public health emergencies \(3 March 2021\)](#)

[Minutes - 2nd Drafting Group on mental health of health workforce and other essential workers \(4 March 2021\)](#)

[Presentations - AMR One Health Network \(25 March 2021\)](#)

Contactos



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