

LEGISLAÇÃO

[Resolução do Conselho de Ministros n.º 81/2020 - Diário da República n.º 190/2020, Série I de 2020-09-29](#)

Presidência do Conselho de Ministros

NACIONAL

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

[Decreto-Lei n.º 78-A/2020 - Diário da República n.º 190/2020, 1º Suplemento, Série I de 2020-09-29](#)

Presidência do Conselho de Ministros

Altera as medidas excecionais e temporárias relativas à pandemia da doença COVID-19

REGULAÇÃO

[Despacho n.º 9277/2020 - Diário da República n.º 190/2020, Série II de 2020-09-29](#)

MINISTÉRIO DA SAÚDE

Saúde - Gabinete da Secretária de Estado Adjunta e da Saúde

Subdelegação de competências da Secretária de Estado Adjunta e da Saúde no conselho diretivo do INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

[Atualização da informação relativa à gestão da disponibilidade do medicamento](#)

INFARMED

[Nota Informativa para profissionais de saúde e doentes - Novo tratamento para a COVID-19: EMA recomenda a utilização de dexametasona nos doentes com COVID-19 que requerem terapia com oxigénio](#)

[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.

ERS [Alerta de Supervisão n.º 13/2020 – Dever de informação aos utentes sobre continuidade de prestação de cuidados de saúde, em casos suspeitos ou diagnosticados de infeção epidemiológica por COVID-19](#)

[Orientação Conjunta DGS/SPMS/ANAC/Turismo de Portugal nº 001/2020 de 02/10/2020](#)

Operacionalização do Cartão de Localização de Passageiro (Passenger Locator Card – PLC)

[Manual de tuberculose e micobactérias não tuberculosas - Recomendações](#)

DGS [Norma nº 018/2020 de 27/09/2020](#) - Programa Nacional de Vacinação 2020

[Norma nº 016/2020 de 25/09/2020](#) - Vacinação contra a gripe. Época 2020/2021.

[Norma nº 017/2020 de 25/09/2020](#) - Implementação da Nutrição Entérica e Parentérica no Ambulatório e Domicílio em Idade Adulta

SPMS [Lista de Entrada em Vigor dos novos CPA \(29/09/2020\)](#)

Medicinal Products for Human Use | [Submitting annual reports on medicine development](#) (updated)

Medicinal Products for Human Use | Other: [Procedural advice for post-orphan medicinal product designation activities: Guidance for sponsors](#) (updated)

Medicinal Products for Human Use | News and press releases: [EMA reminds physicians to use Tecentriq with nab-paclitaxel for treating breast cancer](#)

EMA **Medicinal Products for Human Use** | [COVID-19 vaccines: key facts](#)

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

Medicinal Products for Human Use | News and press releases: [EMA starts first rolling review of a COVID-19 vaccine in the EU](#)

Medicinal Products for Human Use | PRAC recommendation on signal: [PRAC recommendations on signals adopted at the 11-14 May 2020 PRAC meeting](#) (updated)

Medicinal Products for Human Use | Scientific guideline: [Draft ICH guideline Q3D \(R2\) on elemental impurities - Step 2b](#) (updated)

Medicinal Products for Human and Veterinary Use | Regulatory and procedural guideline: [Dates of 2021 Scientific Advice Working Party \(SAWP\) meetings and deadlines for submission of scientific advice, protocol assistance, qualification of biomarkers and parallel consultation \(EMA / EUnetHTA\) requests](#) (updated)

Medicinal Products for Human Use | [Annex III - List of intravenous iron-containing medicinal products in the European Union](#) (updated)

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

Medicinal Products for Human Use | Annex to CHMP highlights: [Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 17 September 2020](#) (new)

Medicinal Products for Human Use | Report: [List of products granted eligibility to PRIME](#) (updated)

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

Medicinal Products for Human Use | [COVID-19: What's new \(updated\)](#)

[Agenda - Workshop on the General Data Protection Regulation \(GDPR\) and secondary use of data for medicines and public health purposes](#) (updated)

Medicinal Products for Human Use | [Agenda - PRAC draft agenda of meeting 28 September - 1 October 2020](#) (new)

Medicinal Products for Human Use | Report: [Medicinal products for human use: monthly figures - August 2020](#) (new)

Medicinal Products for Human Use | Minutes: [Minutes of the CAT meeting 15-17 July 2020](#) (new)

Medicinal Products for Human Use | Committee meeting report: [Monthly report on application procedures, guidelines and related documents for veterinary medicines: July 2020](#) (new)

Medicinal Products for Human Use | Agenda: [Agenda - EMA 25th anniversary symposium: New approaches in patient-focused cancer drug development](#) (updated)

Medicinal Products for Human Use | [Orphans: Regulatory and procedural guidance and forms](#) (updated)

Other: [Quick interactive guide to IRIS registration process](#) (updated)

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

Medicinal Products for Human Use | PRAC recommendation on signal: [PRAC recommendations on signals adopted at the 31 August-3 September 2020 PRAC meeting](#) (new)

Medicinal Products for Human Use | PRAC recommendation on signal: [New product information wording: extracts from PRAC recommendations on signals adopted at the 31 August-3 September 2020 PRAC](#) (new)

Medicinal Products for Human Use | Other: [Important medical event terms list version \(MedDRA version 23.1\)](#) (updated)

CMDh

[NEW - PSUFU summary assessment report for standardised allergen extract from birch \(Betula verrucosa\);](#)

[NEW - Art. 46 assessment reports for Vaxigrip Tetra \(quadrivalent influenza virus vaccine \(inactivated, split\)\); Wilate \(and associated names\) \(human von Willebrand factor, human coagulation factor VIII\); Foster NEXThaler \(and associated names\) \(beclometasone dipropionate, formoterol fumarate dihydrate\); Temesta/Tavor/Ativan \(lorazepam\);](#)

[NEW - 2020 January - June Statistics for New Applications \(MRP/DCP\), Variations, Referrals and Paediatric Worksharing procedures;](#)

[NEW - Timetables 2021 for requests to CMDh for a recommendation on classification of an unforeseen variation - Article 5;](#)

[NEW - Overview of timetables 2021 - CMDh 60-day procedures for MRP/DCP applications;](#)

[UPDATE - Best Practice Guide for the Decentralised and Mutual Recognition Procedures;](#)

[UPDATE - Best Practice Guide on the Assessment Report for Mutual Recognition and Decentralised Procedures;](#)

[UPDATE - MSs Recommendations on Extension Applications in Mutual Recognition and Decentralised Procedures;](#)

[UPDATE - 'Blue-box' requirements;](#)

HMA

[UPDATE - CMDh practical guidance for Marketing Authorisation Holders of nationally authorised products \(incl. MRP/DCP\) in relation to the Art. 5\(3\) Referral on Nitrosamines;](#)

[UPDATE - Procedural Advice on Repeat Use;](#)

[UPDATE - Decentralised Procedure Members States' Standard Operating Procedure;](#)

[Summary report - 35th Health Security Committee on COVID-19 outbreak](#)

COMISSÃO EUROPEIA

[Minutes - 3rd Drafting group meeting on organisation of health and social care following the COVID-19 pandemic \(16 September 2020\)](#)
