

## REGULAÇÃO

[Nova edição do Boletim de Farmacovigilância, Volume 24, n.º 8, agosto de 2020](#)

[Circular informativa N.º 164/CD/100.20.200](#) - Novo Sistema de Informação para Dispositivos Médicos (SIDM)

[Circular Informativa n.º 161/CD, de 16-10-2020](#) - Rastreabilidade de stocks de medicamentos para COVID-19 - formato de reporte - atualização da lista de medicamentos.

[Circular informativa n.º 162/CD/2020 de 19/10/2020](#) - Orientações da CNFT sobre a utilização da imunoglobulina humana normal

Atualização da lista de grupos homogéneos e preços de referência

- [Circular Informativa N.º 160/CD/100.20.200 Data:15/10/2020](#) - Sistema de Preços de Referência - 4º trimestre de 2020 (novembro)
- [Deliberação N.º 79/CD/2020](#).

[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.**

## INFARMED

## ERS

[Sistema de Gestão de Reclamações: Relatório do primeiro semestre de 2020](#)

## EMA

**Medicinal Products for human Use** | News and press releases: [Strengthening global collaboration on COVID-19 real-world evidence and observational studies](#)

**Medicinal Products for Human Use** | Regulatory and procedural guideline: [List of centrally authorised products requiring a notification of a change for update of annexes](#) (updated)

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**Medicinal Products for Human Use** | Regulatory and procedural guideline: [PRIME eligibility requests: 2021 deadlines for submission and timetable for assessment](#) (new)

**Medicinal Products for Human Use** | [Pharmaceutical development of medicines for use in the older population](#) (updated)

**Medicinal Products for Human Use** | Scientific guideline: [Reflection paper on the pharmaceutical development of medicines for use in the older population - First version](#) (new)

[PRIME: priority medicines](#) (updated)

**Medicinal Products for Human Use** | Annex to CHMP highlights: [Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 15 October 2020](#) (new)

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

**Medicinal Products for Veterinary Use** | Report: [Sales of veterinary antimicrobial agents in 31 European countries in 2018 - Trends from 2010 to 2018 Tenth ESVAC report](#) (new)

**Medicinal Products for Veterinary Use** | News and press releases: [10th ESVAC report shows continued decrease in sales of veterinary antibiotics](#)

**Medicinal Products for Human and Veterinary Use** | Leaflet: [Responsible use of antibiotics protects animals and people - 2011-2018 Sales of antibiotics for veterinary use are down - Infographic](#) (updated)

**Medicinal Products for Veterinary Use** | [Union Product Database: release notes](#)

**Medicinal Products for Veterinary Use** | Other: [Examples of bundles for create product functionality](#) (new)

**Medicinal Products for Veterinary Use** | Other: [UPD Production Release Notes](#) (new)

**Medicinal Products for Human and Veterinary Use** | Presentation: [Presentation PMS / ISO / IDMP / FHIR](#) (new)

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

**Medicinal Products for Human Use** | Other: [Contact details of national competent authorities for requests of translation exemption falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages](#) (updated)

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

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

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News and press releases: [EMA virtual conference: 25 years of advancing public and animal health](#)

**Medicinal Products for Veterinary Use** | [Veterinary pre-submission Q&A: 21-40](#) (updated)

**Medicinal Products for Human Use** | [Requesting scientific advice or protocol assistance from EMA](#) (updated)

Regulatory and procedural guideline: [European Medicines Agency guidance for applicants seeking scientific advice and protocol assistance](#) (updated)

**Medicinal Products for Veterinary Use** | Regulatory and procedural guideline: [European Medicines Agency guidance for companies requesting scientific advice \(veterinary\)](#) (updated)

**Medicinal Products for Veterinary Use** | Template or form: [Scientific advice request template](#) (updated)

Regulatory and procedural guideline: [Dates of 2020 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** | Regulatory and procedural guideline: [Qualification of novel methodologies for drug development: guidance to applicants](#) (updated)

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** | News and press releases: [First long-acting injectable antiretroviral therapy for HIV recommended for approval.](#)

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HMA

CMDh  
[September 2020 CMDh Minutes](#)

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COMISSÃO EUROPEIA

**Comissão Europeia**  
[EU Health Policy Platform webinar - Covid-19 health response package \(29 October 2020, 15.00–16.30 CET\)](#)  
[New web page with the basic information on the EUDAMED Actor registration module](#)

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[Presentation of the opinion by the Expert Panel - Hearing on the organisation of resilient health and social care following the COVID-19 pandemic \(20 October 2020\)](#)

[EU Health Policy Platform webinar - SEPEN and beyond: how can EU support to Member States' health workforce planning policies contribute to healthier societies? \(28 October 2020, 13.00 – 15.00 CET\)](#)

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

[Summary report - 37th Health Security Committee on COVID-19 outbreak](#)

[Updated presentation - Information on the applications for designation as a notified body under Regulations \(EU\) 2017/745 and 2017/746](#)

[Presentation of the opinion by the Expert Panel - Hearing on the organisation of resilient health and social care following the COVID-19 pandemic \(20 October 2020\)](#)

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