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## LEGISLAÇÃO

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### COMUNITÁRIA

[Regulamento de Execução \(UE\) 2020/977 da Comissão, de 7 de julho de 2020, que derroga os Regulamentos \(CE\) n.º 889/2008 e \(CE\) n.º 1235/2008 no respeitante aos controlos da produção de produtos biológicos devido à pandemia de COVID-19](#) [med. veterinários]

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## REGULAÇÃO

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### SAÚDE

[Despacho n.º 7057/2020 - Diário da República n.º 133/2020, Série II de 2020-07-10](#)

#### **Saúde - Gabinete do Secretário de Estado da Saúde**

Cria a Comissão de Avaliação e Acompanhamento do Plano de Expansão da Capacidade Laboratorial Nacional para diagnóstico de SARS-CoV-2

[Despacho n.º 6971/2020 - Diário da República n.º 130/2020, Série II de 2020-07-07](#)

#### **Saúde - Gabinete da Secretária de Estado Adjunta e da Saúde**

Cria um Grupo de Trabalho para a Dispensa de Proximidade de Medicamentos

[Portaria n.º 483/2020 - Diário da República n.º 130/2020, Série II de 2020-07-07](#)

#### **Saúde - Gabinete da Secretária de Estado Adjunta e da Saúde**

Procede ao reescalonamento dos encargos plurianuais autorizados pela Portaria n.º 406/2019, publicada no Diário da República, 2.ª série, n.º 122, de 28 de junho de 2019

[Comunicado de Imprensa - Criado Grupo de Trabalho para a \*\*facilitação de dispensa de medicamentos hospitalares\*\*](#)

### INFARMED

[Comunicado de Imprensa - EMA finaliza parecer sobre \*\*presença de nitrosaminas em medicamentos\*\*](#)

[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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### DGS

[Norma nº 002/2020 de 16/03/2020 atualizada a 03/07/2020](#)

COVID-19: Procedimentos post mortem

[Orientação nº 030/2020 de 29/05/2020 atualizada a 03/07/2020](#)

COVID-19: Atividade Física e Desporto - Espaços de Prática de Exercício Físico e Desporto, e Competições Desportivas de Modalidades Individuais sem Contacto

AT	<a href="#">Ofício-circulado n.º 15775/2020, de 19/06</a> Importação /exportação de medicamentos de uso humano: Condicionalismos.
ERS	<a href="#">Alerta de Supervisão n.º 11/2020 - Gravidez e parto em contexto de epidemia SARS-CoV-2 e de infeção epidemiológica por COVID-19</a>
SPMS	<a href="#">Lista de Entrada em Vigor dos novos CPA (08-07-2020)</a> <b>Procedimentos</b> <a href="#">2020/80</a> - Ligaduras de compressão e dispositivos de imobilização
EMA	<p><b>Medicinal Products for Human Use</b>   Other: <a href="#">European Commission-DG Health and Food Safety and European Medicines Agency action plan on advanced therapy medicinal products (ATMPs)</a> (updated)</p> <p>News and press releases: <a href="#">Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 July 2020</a></p> <p><b>Medicinal Products for Veterinary Use</b>   <a href="#">Marketing authorisation</a> (updated)</p> <p><a href="#">Medicinal Products for Human Use   Q&amp;A: 21-40</a> (updated)</p> <p><b>Medicinal Products for Human Use</b>   <a href="#">Q&amp;A: 1-20</a> (updated)</p> <p><b>Medicinal Products for Human Use</b>   Other: <a href="#">Validation checklist for initial marketing authorisation applications – immunologicals (applicable to submissions under Art. 12(3) of Directive 2001/82)</a> (updated)</p> <p><b>Medicinal Products for Human Use</b>   Other: <a href="#">Validation checklist for initial marketing authorisation applications – pharmaceuticals (applicable to submissions under Art. 12(3) of Directive 2001/82)</a> (updated)</p> <p><b>Medicinal Products for Human Use</b>   <a href="#">COVID-19: What's new</a> (updated)</p> <p><b>Medicinal Products for Human Use</b>   News and press releases: <a href="#">International regulators align positions on phase 3 COVID-19 vaccine trials Article 5(3) opinions</a> (updated)</p> <p><b>Medicinal Products for Human Use</b>   <a href="#">Nitrosamine impurities</a> (updated)</p> <p><b>Medicinal Products for Human Use</b>   News and press releases: <a href="#">EMA finalises opinion on presence of nitrosamines in medicines</a></p> <p>Other: <a href="#">Article 57 product data</a> (updated)</p> <p><b>Medicinal Products for Veterinary Use</b>   <a href="#">Implementation of the new Veterinary Medicines Regulation</a> (updated)</p> <p><b>Medicinal Products for Veterinary Use</b>   Regulatory and procedural guideline: <a href="#">Advice on implementing measures under Article 95(8) of Regulation (EU) 2019/6 on veterinary</a></p>

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[medicinal products - Good distribution practices \(GDP\) for active substances used as starting materials in veterinary medicinal products](#) (new)

**Medicinal Products for Veterinary Use** | Regulatory and procedural guideline: [Advice on implementing measures under Article 99\(6\) of Regulation \(EU\) 2019/6 on veterinary medicinal products - Good distribution practices \(GDP\) for veterinary medicinal products](#) (new)

**Medicinal Products for Veterinary Use** | Regulatory and procedural guideline: [Advice on implementing measures under Article 57\(4\) of Regulation \(EU\) 2019/6 on veterinary medicinal products - Report on the format of the data to be collected on antimicrobial medicinal products used in animals](#) (new)

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 Veterinary Use** | Regulatory and procedural guideline: [Pharmacovigilance regulatory recommendations for centrally authorised veterinary medicinal products during 2020](#) (updated)  
[Classifications as minor-use-minor-species and limited-market](#) (updated)

**Medicinal Products for Human Use** | [Agenda - HMPC agenda of the 6-8 July 2020 meeting](#) (new)

**Medicinal Products for Veterinary Use** | Maximum Residue Limits - Opinion: [Opinion of the CVMP on the establishment of maximum residue limits: Ketoprofen](#) (new)

Regulatory and procedural guideline: [Rules of engagement for patients' organisations and their representatives in repurposing activities and impact on involvement in EMA activities](#) (new)

Other: [European medicines agencies network strategy to 2025: Protecting public health at a time of rapid change](#) (new)

News and press releases: [Launch of public consultation on joint network strategy to 2025](#)

**Medicinal Products for Human Use** | [Agenda - PRAC draft agenda of meeting 6-9 July 2020](#) (new)

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

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

Other: [List of signals discussed at PRAC since September 2012](#) (updated)

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

PRAC recommendation on signal: [New product information wording: extracts from PRAC recommendations on signals adopted at the 8-11 June 2020 PRAC](#) (new)

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**Medicinal Products for Human Use** | PRAC recommendation on signal: [PRAC recommendations on signals adopted at the 8-11 June 2020 PRAC meeting](#) (new)

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CMDh

[Cover letter for Variation Applications in the Mutual Recognition Procedure](#)

[Cover letter for new applications submitted through MRP/DCP](#)

[Requirements on submissions \(number and format\) for Variations and Renewals within MRP and National procedure](#)

[Art. 61.3 Procedure Notification form](#)

HMA

[Flow chart of the Decentralised Procedure](#)

[CMDh Best Practice Guide on Multilingual Packaging](#)

[Procedural guidance during COVID-19 pandemic](#)

[CMDh Best Practice Guide on the processing of renewals in the MRP/DCP](#)

[Hormone Replacement Therapy - Core Package Leaflet](#)

[Hormone Replacement Therapy - Core SmPC](#)

[Art 46. PAR - Silkis ointment \(calcitriol\)](#)

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[Minutes - 22nd meeting of the Expert Group on Health Systems Performance Assessment \(HSPA\) \(26 June 2020\)](#)

[State of play of Joint implementation Plan on actions considered necessary to ensure the sound functioning of the new framework for medical devices under the MDR](#)

COMISSÃO EUROPEIA

[Minutes - 3rd Drafting group meeting on organisation of health and social care following the COVID-19 pandemic \(10 June 2020\)](#)

[Minutes - 3rd Plenary meeting of the Expert Panel \(24 June 2020\)](#)

[Summary report - 26th Health Security Committee on COVID-19 outbreak](#)

[EUnetHTA's response to the COVID-19 pandemic](#)

[Statement on Organ Donation and Transplantation and the COVID-19 pandemic](#)

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