SÍNTESE SEMANAL SAÚDE

Saude@vda.pt

16 a 20 de novembro de 2020

LEGISLAÇÃO

NACIONAL

Portaria n.º 270/2020 - Diário da República n.º 226/2020, Série I de 2020-11-19
Saúde
Regulamenta as matérias relativas à publicitação de procedimento concursal, prazos, forma de apresentação de candidatura, notificações e utilização de meios eletrónicos (profissionais de saúde)

Decreto Legislativo Regional n.º 15/2020/M - Diário da República n.º 223/2020, Série I de 2020-11-16
Região Autónoma da Madeira - Assembleia Legislativa
Procede à terceira alteração ao Decreto Legislativo Regional n.º 22/2008/M, de 23 de junho

Lei n.º 72/2020 - Diário da República n.º 223/2020, Série I de 2020-11-16
Assembleia da República
Estabelece um regime transitório de simplificação de procedimentos administrativos e altera o Código do Procedimento Administrativo

REGULAÇÃO

INFARMED

Circular informativa n.º 179/CD/100.20.200 de 19/11/2020 - Indisponibilidade de medicamentos contendo esomeprazol, 40 mg, pó para solução injetável ou para perfusão

Circular informativa N.º 175/CD/100.20.200 Data: 17/11/2020 - Rastreabilidade de stocks de medicamentos para COVID-19 - formato de reporte - atualização da lista de medicamentos (17/11/2020)

Comunicado de Imprensa - Dia Europeu do Antibiótico

Infarmed Newsletter N.º 180

Workshop virtual "How are vaccines developed, approved and produced?"

Circular Informativa Conjunta N.º 005/CD/100.20.200 - Data:13/11/2020 - COVID-19 – Operacionalização da utilização dos Testes Rápidos de Antigénio (TRAg)

Circular Informativa Conjunta DGS/INFARMED/INSA nº 004/CD/100.20.200 de 14/10/2020 - Diagnóstico COVID-19 - Testes de pesquisa de antigénio

	EMA inicia a avaliação dos dados disponíveis da vacina mRNA para COVID-19 do laboratório Moderna Biotech Spain, S.L 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 6/2020 (Atualização) - Acesso de cidadãos estrangeiros a cuidados de saúde no SNS, em especial, no âmbito da situação atual epidemia SARS-CoV-2 e de infeção epidemiológica por COVID-19
DGS	Despacho nº 012/2020 de 04/11/2020 Criação da Comissão Técnica de Vacinação contra COVID-19 Despacho nº 013/2020 de 09/11/2020 Nomeação do grupo de trabalho "Trace-COVID-19 – STAYAWAY COVID"
CEIC	Informação sobre submissão de estudos covid-19
CNPD	Orientações sobre o sentido e a execução das normas constantes no Decreto n.º 8/2020, de 8 de novembro, em matéria de tratamento de dados pessoais de saúde.
EMA	Report: List of products granted eligibility to PRIME (updated) Report: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 9-12 November 2020 (new) News and press releases: Call for independent scientific experts to join EMA's Pharmacovigilance Risk Assessment Committee (PRAC) - deadline extended (updated) **Medicinal Products for Human Use |** Pharmacovigilance Risk Assessment Committee (PRAC) (updated) **Medicinal Products for Human Use |** Template or form: Day 80 assessment report - Clinical template with guidance rev.02.20 (updated) **Medicinal Products for Human Use |** Report: Medicinal products for human use: monthly figures - October 2020 (new) **Medicinal Products for Human Use |** Minutes: Minutes of the PRAC meeting 11-14 May 2020 (new) Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated) **Medicinal Products for Human Use |** News and press releases: EMA organises public meeting on COVID-19 vaccines **Medicinal Products for Human Use |** Other: EMA considerations on COVID-19 vaccine approval (new) Multidisciplinary: vaccines (updated) **Medicinal Products for Human Use |** Treatments and vaccines for COVID-19 (updated)

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

Medicinal Products for Human Use | Guidance for medicine developers and other stakeholders on COVID-19 (updated)

Medicinal Products for Human Use | COVID-19 vaccines: key facts (updated

Transparency: exceptional measures for COVID-19 medicines (updated)

Medicinal Products for Human Use | COVID-19 vaccines: development, evaluation, approval and monitoring (updated)
Medical devices (updated)

Pharmacovigilance Inspectors Working Group (updated)

Medicinal Products for Veterinary Use | Other: List of acronyms and abbreviations used in CVMP agenda and minutes (updated)

Regulatory and procedural guideline: Remote pharmacovigilance inspections of MAHs during a crisis situation - Points to consider (updated)

15th industry stakeholder platform - operation of European Union (EU) pharmacovigilance , from 30/10/2020 to 30/10/2020 (updated)

Other: List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)

Medicinal Products for Human Use | News and press releases: EMA marks European Antibiotic Awareness Day

Medicinal Products for Human Use | Antimicrobial resistance (updated)

Medicinal Products for Human Use | Leaflet: Responsible use of antibiotics: what's your role? - Infocards

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

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

Medicinal Products for Human Use | News and press releases: EMA starts rolling review of mRNA COVID-19 vaccine by Moderna Biotech Spain, S.L.

Medicinal Products for Human Use | Paediatric Committee (PDCO): 10-13 November 2020 , Virtual meeting, from 10/11/2020 to 13/11/2020 (updated)

Medicinal Products for Human Use | Agenda - HMPC agenda of the 16-18 November 2020 meeting (new)

Regulatory and procedural guideline: IRIS guide for parallel distribution applicants (updated)

	Medicinal Products for Human Use | Agenda - PDCO agenda of the 10-13 November 2020 meeting (new) **Medicinal Products for Human Use |** PCWP/HCPWP meeting with all eligible organisations: COVID-19 pandemic update , Virtual meeting, from 16/11/2020 to 16/11/2020 (updated) **Medicinal Products for Human Use |** Agenda - PCWP/HCPWP meeting with all eligible organisations: COVID-19 pandemic update (updated) News and press releases: Emer Cooke takes office as head of EMA **Medicinal Products for Human Use |** Evaluation of anticancer medicinal products in man (updated) **Medicinal Products for Human Use |** Scientific guideline: Draft guideline on the evaluation of anticancer medicinal products in man - Revision 6 (new) **Medicinal Products for Human Use |** Other: Appendix 3 to the guideline on the clinical evaluation of anticancer medicinal products - Summary of Product Characteristics for an Anticancer medicinal product – mock-up of 4.8 (new)
HMA	UPDATE - Data requested for New Applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume 2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved Guidelines/Recommendation papers; NEW - Report from the meeting held on 10-11 November 2020 UPDATE - Requirements on submissions (number and format) for New MA Applications within MRP, DCP or National procedures; UPDATE - Requirements on submissions (number and format) for Variations and Renewals within MRP and National procedures;
COMISSÃO EUROPEIA	EU and South Korean research organisations sign an agreement to work together on the development of a COVID-19 treatment using Raloxifene Deadline for submission of applications prolonged until 4 December 2020 - Independent Scientific experts: Call for expressions of interest for the EMA PRAC Committee Meeting documents - 18th Meeting of the eHealth Network (12-13 November 2020) State of Health in the EU: The European Commission and the OECD release 'Health at a Glance: Europe 2020' Roadmap - Blood, tissues and cells for medical treatments & therapies – revised EU rules