SÍNTESE SEMANAL SAÚDE

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21 a 23 de dezembro de 2020

LEGISLAÇÃO

NACIONAL	Portaria n.º 297/2020 - Diário da República n.º 248/2020, Série I de 2020-12-23 **Saúde** Procede à manutenção, no ano de 2021, dos países de referência estabelecidos para o ano de 2020, para efeitos de autorização dos preços dos novos medicamentos, bem como para a revisão anual de preços dos medicamentos
COMUNITÁRIA	Comunicação da Comissão — Aplicação do acervo farmacêutico da União em mercados historicamente dependentes do fornecimento de medicamentos provenientes ou que transitam através da Grã-Bretanha após o termo do período de transição Resumo das decisões da Comissão Europeia relativas às autorizações de colocação no mercado para utilização e/ou às autorizações de utilização de substâncias enumeradas no anexo XIV do Regulamento (CE) n.o 1907/2006 do Parlamento Europeu e do Conselho relativo ao registo, avaliação, autorização e restrição dos produtos químicos (REACH), [Publicado nos termos do disposto no artigo 64.o, n.o 9, do Regulamento (CE) n.o 1907/2006] (1) Comunicação da Comissão sobre as taxas de juro em vigor aplicáveis na recuperação de auxílios estatais e as taxas de referência/atualização aplicáveis a partir de 1 de janeiro de 2021, [Publicado de acordo com o artigo 10.o do Regulamento (CE) n.o 794/2004 da Comissão, de 21 de abril de 2004(JO L 140 de 30.4.2004, p. 1)] Decisão de Execução (UE) 2020/2183 da Comissão, de 21 de dezembro de 2020, relativa a determinadas medidas de proteção respeitantes à notificação de infeção com SARS-CoV-2 em martas e outros animais da família Mustelidae e em cães-guaxinim [notificada com o número C(2020) 9531] Regulamento Delegado (UE) 2020/2154 da Comissão, de 14 de outubro de 2020, que complementa o Regulamento (UE) 2016/429 do Parlamento Europeu e do Conselho no que diz respeito aos requisitos de saúde animal, de certificação e de notificação aplicáveis à circulação na União de produtos de origem animal provenientes de animais terrestres

REGULAÇÃO

MINISTÉRIO DA SAÚDE	Despacho n.º 12400/2020 - Diário da República n.º 246/2020, Série II de 2020-12-21 **Saúde - Gabinete do Secretário de Estado da Saúde** Subdelegação de competências do Secretário de Estado da Saúde no conselho diretivo do INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.
INFARMED	Circular Informativa N.191CD10020200 22/12/2020 - Alterações e renovações com Portugal EME – publicação de RCM e FI no Infomed Comissão Europeia aprova vacina COVID-19 Nova área sobre vacinas COVID-19 Comunicado de Imprensa - EMA dá luz verde à primeira vacina COVID-19 na UE Colestiramina - Autorização de utilização de lotes rotulados em língua estrangeira Nova edição do Boletim de Farmacovigilância, Volume 24, n.º 11, novembro de 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.**
SPMS	Booking AQ/SAD _T4 Lista de Entrada em Vigor_21_12_2020
EMA	**Medicinal Products for Human Use |** News and press releases: Cyberattack on EMA - update 3 **Medicinal Products for Human Use |** Direct healthcare professional communication (DHPC): GLOBAL RECALL: Zerbaxa (ceftolozane / tazobactam) 1 g/0.5 g powder for concentrate for solution for infusion, Active substance: Ceftolozane, tazobactam, DHPC type: Quality defect, Last updated: 22/12/2020 **Medicinal Products for Human Use |** Supply shortage: Zerbaxa (ceftolozane / tazobactam) supply shortage (new) **Medicinal Products for Human Use |** Public stakeholder meeting on the approval and roll-out of COVID-19 vaccines in the EU , Virtual meeting, 13:00-15:15 CET, from 08/01/2021 to 08/01/2021 **Medicinal Products for Human Use |** News and press releases: EMA organises a second public meeting about the new COVID-19 vaccines **Medicinal Products for Human Use |** Other: CHMP rules of procedure (updated)

Medicinal Products for Human Use | Referral: Ranitidine-containing medicinal products , ranitidine , Article 31 referrals, European Commission final decision, 17/09/2020, 24/11/2020, 22/12/2020 (updated)

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

Medicinal Products for Veterinary Use | VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use (updated)

Medicinal Products for Veterinary Use | Scientific guideline: VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use (new)

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

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

Medicinal Products for Human Use | News and press releases: EMA recommends first COVID-19 vaccine for authorisation in the EU (updated)

Other: Timetable: Initial (full) marketing authorisation application (updated)

Other: Timetable: Extension application (updated)

Other: Timetable: Extension application - ATMP (updated)

Medicinal Products for Human Use | Periodic safety update single assessment: Trandolapril / verapamil : List of nationally authorised medicinal products - PSUSA/00003005/202003 (new)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): Anoro Ellipta (previously Anoro), umeclidinium bromide, vilanterol trifenatate,)

Medicinal Products for Human Use | Periodic safety update single assessment: Ascorbic acid / paracetamol / pheniramine maleate : List of nationally authorised medicinal products - PSUSA/00002368/202003 (new)

Medicinal Products for Human Use | Periodic safety update single assessment: Estradiol, estradiol /prednisolone : List of nationally authorised medicinal products - PSUSA/00010441/202004 (new)

Medicinal Products for Human Use | Periodic safety update single assessment: Lisdexamfetamine : CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00010289/202002 (new)

Medicinal Products for Human Use | Periodic safety update single assessment: Lisdexamfetamine : List of nationally authorised medicinal products - PSUSA/00010289/202002 (new)

Medicinal Products for Human Use | Human medicines European public assessment report (EPAR): Libmeldy, autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor
cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene, Leukodystrophy, Metachromatic,

Medicinal Products for Human Use | Orphan designation: Autologous CD34+ cells transfected with lentiviral vector containing the human arylsulfatase A cDNA for the: treatment of metachromatic leukodystrophy, 13/04/2007, Positive (updated)

Medicinal Products for Human Use | Paediatric investigation plans (updated)

Medicinal Products for Human Use | Orphan designation: Miransertib for the: Treatment of Proteus syndrome, 21/03/2018, Positive (updated)

Medicinal Products for Human Use | Orphan designation: Obeticholic acid for the: Treatment of primary sclerosing cholangitis, 16/03/2014, Positive (updated)

Medicinal Products for Human Use | Orphan designation: Ibutamoren mesilate for the: Treatment of growth hormone deficiency, 20/06/2017, Positive (updated)

Medicinal Products for Human Use | Orphan designation: Bardoxolone methyl for the: Treatment of Alport syndrome, 25/05/2018, Positive (updated)

Medicinal Products for Human Use | Summary of opinion: Comirnaty, COVID-19 mRNA vaccine (nucleoside-modified), 21/12/2020, Positive

Medicinal Products for Human Use | Press briefing on EU recommendation on first COVID-19 vaccine , Virtual meeting, from 21/12/2020 to 21/12/2020

Medicinal Products for Human Use | Conditional marketing authorisation (updated)

Medicinal Products for Human Use | Herbal medicinal product: Solani dulcamarae stipites, Solani dulcamarae stipites, F: Assessment finalised (updated)

Medicinal Products for Veterinary Use | Union Product Database: release notes (updated)

Medicinal Products for Human Use | Other: EMA's API general terms and conditions of use - Terms of use (new)

Medicinal Products for Veterinary Use | Other: European Medicines Agency/AnimalhealthEurope veterinary medicines info day 2021: first announcement - save this date in your diary! (new)

Medicinal Products for Veterinary Use |European Medicines Agency/AnimalhealthEurope veterinary medicines info day 2021 , Virtual meeting, from 25/03/2021 to 25/03/2021

Report: Stakeholder engagement report 2018-2019 (new)

	Medicinal Products for Human Use | News and press releases: EMA recommends first COVID-19 vaccine for authorisation in the EU Press briefing , Virtual meeting, from 21/12/2020 to 21/12/2020 **Medicinal Products for Veterinary Use |** Union Product Database: release notes (updated) Other: EMA's API general terms and conditions of use - Terms of use (new) **Medicinal Products for Veterinary Use |** Other: European Medicines Agency/AnimalhealthEurope veterinary medicines info day 2021: first announcement - save this date in your diary! (new) Report: Stakeholder engagement report 2018-2019 (new) **Medicinal Products for Human Use |** Template or form: Template - Orphan designation sponsor's name and/or address change notification letter (updated) **Medicinal Products for Human Use |** Other: Procedural advice for post-orphan medicinal product designation activities: Guidance for sponsors (updated) Management Board meeting: 16-17 December 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 16/12/2020 to 17/12/2020 (updated) **Medicinal Products for Human Use |** Report: Medicinal products for human use: monthly figures - November 2020 (new) **Medicinal Products for Human Use |** Medical devices (updated) Periodic safety update single assessment: Fluconazole: List of nationally authorised medicinal products - PSUSA/00001404/202003 (new) Periodic safety update single assessment: Fluconazole: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00001404/202003 (new)
HMA	List of safety concerns per approved Risk Management Plan (RMP) of active substances per product
COMISSÃO EUROPEIA	Summary report - Subgroup on Traceability and Security Features established by the Expert Group on Tobacco Policy (19 November 2020)Search for available translations of the preceding link••• European Commission authorises first safe and effective vaccine against COVID-19