SÍNTESE SEMANAL SAÚDE

Saude@vda.pt

17 e 21 de junho de 2019

LEGISLAÇÃO

COMUNITÁRIA	Lista dos **acordos bilaterais de investimento** referida no artigo 4.o, n.o 1, do Regulamento (UE) n.o 1219/2012 do Parlamento Europeu e do Conselho que estabelece disposições transitórias para os acordos bilaterais de investimento entre os Estados-Membros e os países terceiros

REGULAÇÃO

MINISTÉRIO DA SAÚDE	Portaria n.º 384/2019 - Diário da República n.º 114/2019, Série II de 2019-06-17 **Saúde - Gabinete do Secretário de Estado Adjunto e da Saúde** Procede ao reescalonamento dos encargos plurianuais autorizados pela Portaria n.º 161/2017, de 23 de junho (aquisição de dispositivos médicos para o bloco de urologia do Hospital do Espírito Santo de Évora) Aviso n.º 31/2019/M - Diário da República n.º 115/2019, Série II de 2019-06-18 **Região Autónoma da Madeira - Secretaria Regional da Saúde - Instituto de Administração da Saúde, IP-RAM** Autoriza a sociedade «HPM - Hospital Particular da Madeira, S. A.», a adquirir diretamente substâncias estupefacientes, psicotrópicas e seus preparados, para uso exclusivo dos doentes internados no seu estabelecimento «HPM - Hospital Particular da Madeira»
INFARMED	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	Lista de Entrada em Vigor dos **novos CPA** (17-06-2019)
EMA	**Patients' and Consumers**' Working Party (updated) **Healthcare Professionals**' Working Party (updated) **Medicinal Products for Veterinary Use |** News and press releases: Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 18-20 June 2019 **Medicinal Products for Human Use |** Report - European Medicines Agency stakeholder interaction on the development of **medicinal products for chronic non-infectious liver diseases** (PBC, PSC, NASH) **Medicinal Products for Veterinary Use |** Agenda: Agenda - **CVMP agenda** of the 18-20 June 2019 meeting

Medicinal Products for Human Use | Scientific guideline: Draft qualification opinion of **Multiple sclerosis clinical outcome assessment** (MSCOA)

Medicinal Products for Human Use | Scientific guideline: Draft qualification opinion of **clinically interpretable treatment effect** measures based on recurrent event endpoints that allow for efficient statistical analyses

Medicinal Products for Human Use | Minutes: **CHMP ORGAM minutes** for the meeting on 18 February 2019

Medicinal Products for Human Use | Minutes: **CHMP ORGAM minutes** for the meeting on 21 January 2019

Medicinal Products for Veterinary Use | Type-IA variations: questions and answers (updated)

Medicinal Products for Veterinary Use | Q&A: **Grouping of variations** (updated)

Medicinal Products for Veterinary Use | Veterinary **post-authorisation** Q&A: Introduction (updated)

Medicinal Products for Veterinary Use | Q&A: **Worksharing of variations** (updated)

Medicinal Products for Veterinary Use | Q&A: T**ype II variations** (updated)

Medicinal Products for Veterinary Use | Q&A: **Type II variations vs Extension applications** (updated)

Medicinal Products for Veterinary Use | Q&A: **Extension applications** (updated)

Medicinal Products for Veterinary Use | Q&A: **Mock-ups** (updated)

Medicinal Products for Veterinary Use | Q&A: **Transparency** (updated)

Medicinal Products for Veterinary Use | Q&A: Application of the so-called **'sunset clause'** to centrally authorised veterinary medicinal products (updated)

Medicinal Products for Veterinary Use | Q&A: Other (updated)

Medicinal products for Human Use | Regulatory and procedural guideline: **Recommendations for the implementation of the exemptions to the labelling and package-leaflet obligations** in the centralised procedure (updated)

Medicinal products for Human Use | Agenda: Agenda - COMP agenda of the 18-20 June 2019 meeting

EMA activities, other than the highest priority activities (category 1 activities), that will continue in 2019 - Annex 1 (updated)

United Kingdom's **withdrawal from the European Union** ('Brexit') (updated)

Brexit-related guidance for companies (updated)

	Medicinal products for Human Use | Clinical Trial Regulation (updated) **News and press releases:** Highlights of Management Board meeting: June 2019 Management Board meeting: 12-13 June 2019
HMA	CMDh CMDh Q&As on the implementation of the outcome of the Art. 31 referral on angiotensin-II-receptor antagonists (sartans) containing a tetrazole group