SÍNTESE SEMANAL SAÚDE

Saude@vda.pt

29 de julho a 2 de agosto de 2019

REGULAÇÃO

MINISTÉRIO DAS FINANÇAS E DA SAÚDE	Despacho n.º 6741/2019 - Diário da República n.º 143/2019, Série II de 2019-07-29 **Saúde - Gabinete do Secretário de Estado Adjunto e da Saúde** Estabelece disposições sobre a cedência de dados estatísticos de produção e consumos, por todas as entidades integradas no âmbito do Ministério da Saúde. Revoga o Despacho n.º 4354-A/2017, de 17 de maio, publicado no Diário da República, 2.ª série, n.º 97, de 19 de maio
ASSEMBLEIA DA REPÚBLICA	Resolução da Assembleia da República n.º 124/2019 - Diário da República n.º 143/2019, Série I de 2019-07-29 **Assembleia da República** Recomenda ao Governo que desenvolva ações de sensibilização visando a entrega, nas farmácias, dos resíduos das embalagens e restos de medicamentos
INFARMED	**Ensaios clínicos**: Europa reforça a importância da publicação de resultados 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	**Boletim Informativo** Nº 40 – julho de 2019 Manual **Submissão Faturas** (relacionadas com processos de compra, alvo de Agregação Centralizada, desenvolvidos pela SPMS, E.P.E., para as Instituições do Serviço Nacional de Saúde (SNS))
ACSS	**Circular Informativa** n.º 13/2019 - Decreto-Lei n.º 25/2015, de 6 de fevereiro - **Pagamento de suplementos remuneratórios**
CNECV	**Parecer N.º 105/CNECV/2019** sobre **tratamento compulsivo e direitos das pessoas com doença mental**
HMA	CMDh End of pilot for splitting of MRP/DCPs (July 2019) [Tracked] Templates for ASMF procedures CMDh Guidance on the Informal Work-Sharing procedure for follow-up for PSUSA for NAPs (PSUFU) (July 2019) [Track version]

Lead Member State PSUR Follow-Up assessment report (July 2019)

Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedures

Minutes from May 2019 CMDh meeting with Interested Parties

June 2019 CMDh Minutes

EMA

Medicinal Products for Human Use | Medicine for use outside EU: Tritanrix HB: Public statement on the withdrawal of the scientific opinion under Article 58

Medicinal Products for Human Use | New Organization First User QPPV/RP or Change of EU QPPV/RP (updated)

Medicinal Products for Human and Veterinary Use | European Union (EU) International Organisation for Standardization (ISO) for identification of medical products (IDMP)/Substance, Product, Organisation and Referential (SPOR) data Task Force meeting , European Medicines Agency, Amsterdam, the Netherlands, from 24/05/2019 to 24/05/2019

Medicinal Products for Human Use | Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 22-25 July 2019

Medicinal Products for Human Use | Medicines under additional monitoring: Annex VII - List of Targocid and associated names (teicoplanin-containing medicinal products in the EU) (updated)

Medicinal Products for Human Use | Medicines under additional monitoring: Annex VII - List of Targocid and associated names (teicoplanin-containing medicinal products in the EU) (updated)

Medicinal Products for Human Use | Report: Workshop with stakeholders on support to quality development in early access approaches (i.e. PRIME, Breakthrough Therapies)

Medicinal Products for Human Use | News and press releases: Supporting medicine developers in generating quality data packages in early access approaches (PRIME and breakthrough therapies): workshop report published

Medicinal Products for Human Use | News and press releases: Names of liposomal medicines to be changed to avoid medication errors

Medicinal Products for Human Use | COMP meeting report on the review of applications for orphan designation: July 2019

Medicinal Products for Human Use | List of medicinal products under additional monitoring (updated)

Medicinal Products for Human Use | List of European Union reference dates and

frequency of submission of periodic safety update reports(updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: EudraVigilance release notes v.1.20 (updated)

Medicinal Products for Veterinary Use | Monthly report on application procedures, guidelines and related documents for veterinary medicines: May 2019

Medicinal Products for Human Use | Pre-authorisation guidance (updated)

Medicinal Products for Veterinary Use | European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) web based sales and and animal population data collection protocol (updated)

Medicinal Products for Veterinary Use | Template or form: European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) web based data collection form (updated)

Medicinal Products for Veterinary Use | Substances considered as not falling within the scope of Regulation (EC) No. 470/20091, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (updated)

Medicinal Products for Human Use | Scientific guideline: Fingolimod capsules 0.25 and 0.5 mg product-specific bioequivalence guidance (updated)

Medicinal Products for Human Use | Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 July 2019

Medicinal Products for Human Use | Updated restrictions for Gilenya: multiple sclerosis medicine not to be used in pregnancy

Medicinal Products for Human Use | First 'histology-independent' treatment for solid tumours with a specific gene mutation

Medicinal Products for Human Use | Scientific advice and protocol assistance adopted during the CHMP meeting 22-25 July 2019