# SÍNTESE SEMANAL SAÚDE

Saude@vda.pt

**1 a 5 de julho de 2019**

## REGULAÇÃO

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| MINISTÉRIO DAS FINANÇAS E DA SAÚDE | Portaria n.º 416/2019 - Diário da República n.º 127/2019, Série II de 2019-07-05<br>**Finanças e Saúde - Gabinetes dos Secretários de Estado do Orçamento e Adjunto e da Saúde**<br>Estabelece limites quanto à autorização para a assunção de compromissos plurianuais relativos a contratos financiados maioritariamente por fundos europeus ou fundos internacionais |
| | Decreto do Representante da República para a Região Autónoma dos Açores n.º 2/2019 - Diário da República n.º 124/2019, Série I de 2019-07-02<br>**Gabinete do Representante da República para a Região Autónoma dos Açores**<br>Nomeia a Secretária Regional da Saúde |
| | Decreto do Representante da República para a Região Autónoma dos Açores n.º 1/2019 - Diário da República n.º 124/2019, Série I de 2019-07-02<br>**Gabinete do Representante da República para a Região Autónoma dos Açores**<br>Exonera o Secretário Regional da Saúde |
| INFARMED | **Circular Informativa Nº 111/CD/550.20.1**, de 01-07-2019 - **Lisados Bacterianos - Restrições da utilização**<br><br>Nova edição do **Boletim de Farmacovigilância**, Volume 23, n.º 5, maio de 2019<br><br>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** |
| ACSS | **Circular Normativa nº 10/2019 - Documentos e Registos Médicos a utilizar na recolha de informação clínica, codificação de diagnósticos adicionais e procedimentos de codificação obrigatória**. |
| SPMS | **Boletim Informativo** nº 39 – junho de 2019 |
| COMISSÃO EUROPEIA | Clinical trials: Call for all sponsors to **publish results in EU database** |

**Medicinal Products for Human Use |** Removing an orphan designation (updated)

**Medicinal Products for Human Use |** Post-orphan medicinal product designation procedures - **guidance to submit an application via IRIS online portal** (updated)

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

**Medicinal Products for Veterinary Use |** Work programme of the **HMA/EMA task force on availability of authorised medicines** for human and veterinary use (updated)

**Medicinal Products for Human and Veterinary Use |** Regulatory and procedural guideline: Good practice guidance for **communication to the public on medicines' availability issues**

**Medicinal Products for Human and Veterinary Use |** News and press releases: Medicine shortages: EU network takes steps to improve reporting and communication

**Medicinal Products for Human and Veterinary Use |** Regulatory and procedural guideline: **Guidance on detection and notification of shortages** of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)

**Medicinal Products for Human Use |** EudraVigilance training and support (updated)

**EMA**

**Medicinal Products for Human Use |** Report: Recommendations on **eligibility to PRIME scheme** - Adopted at the CHMP meeting of 24-27 June 2019

Other: Joint letter by the European Commission, EMA and HMA to stakeholders regarding the **requirements to provide results for authorised clinical trials** in EudraCT

**Medicinal Products for Human Use |** Clinical trials in human medicines (updated)

**Medicinal Products for Human Use |** Minutes: Minutes of the PRAC meeting 12-15 March 2019

**Medicinal Products for Human Use |** Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated)

**eXtended EudraVigilance** Medicinal Product Dictionary face-to-face **training course (Lisbon)** , INFARMED, Lisbon, Portugal, from 21/11/2019 to 22/11/2019

**Medicinal Products for Human and Veterinary Use |** Other: List of European Union **reference dates and frequency of submission** of periodic safety update reports(updated)

Public Statement: **Public statement** on Airexar Spiromax: Withdrawal of the marketing authorisation in the European Union

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

**Medicinal Products for Human Use |** Overview of comments: Overview of comments received during the public consultation on 'Concept paper on the need for revision of the guideline on the investigation of **medicinal products in the term and preterm neonate**' (EMA/PDCO/362462/2016) - Revision 1

**Medicinal Products for Human Use |** Scientific guideline: Concept paper on the need for revision of the guideline on the investigation of **medicinal products in the term and preterm neonate** - Revision 1

**Medicinal Products for Human Use |** Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: May 2019

**Medicinal Products for Human Use |** Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: April 2019