saude@vda.pt

29 de abril a 3 de maio de 2013

SAÚDE

REGULAÇÃO

Documento de Estratégia Orçamental 2013-2017	GOVERNO
Resolução n.º 11/2013. D.R. n.º 83, Série II de 2013-04-30 **Presidência do Conselho de Ministros - Conselho de Ministros** Nomeia o conselho de administração do Hospital Santa Maria Maior, E. P. E.	CONSELHO DE MINISTROS
Publicação para efeitos do artigo 15º-A do Decreto -Lei n.º 176/2006, de 30 de Agosto - pedidos de autorização de introdução, ou registo, no mercado de medicamentos genéricos	INFARMED
Concurso 2013 / 18 - Medicamentos de consumo geral - grupo 4: sangue (caderno de encargos) Data limite da apresentação das informações para o Catálogo – 03/06/2013	SPMS
Lista das entidades do sector empresarial do Estado da área da Saúde que se encontram em incumprimento nos termos dos n.ºs 5 e 6 do art.º 7.º do DL 127/2012, de 21 de junho Reporte de março/2013	DGO
Eudralex Volume 10 : Clinical Trials - Chapter III: Quality of the Investigational Medicinal Product - Template for the qualified person's declaration equivalence to EU GMP for Investigational Medicinal Products manufactured in third countries	COMISSÃO EUROPEIA
Human Medicines | Draft guideline on similar biological medicinal products (end of consultation 31/10/2013) This Guideline outlines the general principles to be applied for similar biological medicinal products (also known as biosimilars) as referred to in Section 4, Part II, Annex I to Directive 2001/83/EC, as amended, where it is stated that 'the general principles to	EMA

be applied [for similar biological medicinal products] are addressed in a guideline taking into account the characteristics of the concerned biological medicinal product published by the Agency'.

Human Medicines | Scientific guideline: Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure

The objective of the guideline is to provide applicants/Marketing Authorisation Holders (MAHs) guidance on the criteria applied by CVMP when reviewing the acceptability of the proposed names for medicinal products processed through the centralised procedure.

It provides details on the procedure for checking the acceptability of the proposed names.

Human Medicines | Questions and answers: Paediatric-investigation-plan guidance (updated)

Human Medicines | Documents from advisory groups on clinical-trial data

Human Medicines | Scientific guideline: Procedural advice on the submission of variations for annual update of human influenza inactivated vaccines applications in the centralised procedure - Rev. 2,

This document describes the specific procedure, timelines and data requirements for the adoption of an opinion of such change(s) by the CHMP.

Human Medicines | Regulatory and procedural guideline: Procedure for orphan-medicinal-product designation: Guidance for sponsors

Human Medicines | Appendix V - Adverse-drug-reaction reporting details (updated)

List of details of the national reporting systems to communicate adverse reactions (side effects) for use in section 4.8 "Undesirable effects" of SmPC and section 4 "Possible side effects" of package leaflet.

LISBOA
Av. Duarte Pacheco, 26
1070-110 Lisboa Portugal
lisboa@vda.pt

PORTO
Av. da Boavista, 3433 - 8º
4100-138 Porto Portugal
porto@vda.pt