saude@vda.pt

10 a 14 de dezembro de 2012

SAÚDE

LEGISLAÇÃO

INFARMED

Atualização - listagem de dispositivos médicos para diagnóstico in vitro, (anexo II lista A, para a detecção, confirmação e quantificação, em amostras humanas, de marcadores da infecção por HIV (HIV 1 e 2) – Testes Rápidos)

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

DGS

Orientação nº 025/2012 de 19/12/2012 - Sistema Nacional de Notificação de Incidentes e Eventos Adversos

Norma nº 017/2012 de 19/12/2012 - Taxonomia para notificação de incidentes e eventos adversos

SPMS

Concurso 2012 / 8 - Antisepticos, Desinfetantes E Outros (caderno de encargos)

COMISSÃO EUROPEIA

The Economic Adjustment Programme for Portugal. Sixth Review – Autumn 2012

Summary for non-specialists

Health Dialogue between the Russian Federation and the EU on medicinal products: publication of the report "Cooperation in the field of clinical trials"

EMA

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

Human Medicines | Regulatory and procedural guideline: Practical information on oral explanation for all referral procedures

Human Medicines | Scientific guideline: Draft guideline on clinical investigation of medicinal products in the treatment of lipid disorders

Human Medicines | Scientific guideline: Nonclinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues

Human Medicines | Regulatory and procedural guideline: ICH guideline E2C (R2) - Periodic benefit-risk evaluation report (PBRER) - Step 4

Human Medicines | Regulatory and procedural guideline: ICH guideline Q4B annex 14 to note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on bacterial endotoxins tests – general chapter - Step 4,

Human Medicines | Regulatory and procedural guideline: Draft ICH guideline S1 - Regulatory notice on changes to core guideline on rodent carcinogenicity testing of pharmaceuticals (Consultation end date 01/04/2013)

Human Medicines | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) M8 electronic common technical document - questions and answers: Step 5 (updated)

Human Medicines | Regulatory and procedural guideline: Draft ICH guideline S10 - Guidance on photosafety evaluation of pharmaceuticals - Step 3 (Consultation end date 01/06/2013)

Human Medicines | Regulatory and procedural guideline: Recommended submission dates for centralised and maximum-residue-limit procedures (new and extension applications) (updated)

Human Medicines | Regulatory and procedural guideline: Procedural advice on fee reductions for designated orphan medicinal products (updated)

- Executive decision on fee reductions for designated orphan medicinal products (updated)

Human Medicines | Regulatory and procedural guideline: Questions & answers on practical implementation of Urgent Union Procedure (Article 107i of Directive 2001/83/EC)

- Letter of representation - Explanatory note - Procedure under Article 107i of Directive 2001/83/EC

Human Medicines | Regulatory and procedural guideline: Practical information on oral explanation for all referral procedures

Template: Informed consent application letter (December 2012)

HMA

Template for Active Substance Master File (ASMF) Type IB Variation Assessment Report

Template for Active Substance Master File (ASMF) Assessment Report

Information on applications referred to the CMDh in accordance with Article 29(1) of Directive 2001/83/EC and Article 13 of Regulation (EC) No 1234/2008 - Tracking table

List of the active substances included in the work-sharing procedure

List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation

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