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22 e 26 de dezembro de 2014

SAÚDE

REGULAÇÃO

CENTRO HOSPITALAR DE VILA NOVA DE GAIA / ESPINHO, E. P. E.

Deliberação (extrato) n.º 2382/2014 - Diário da República n.º 249/2014, Série II de 2014-12-26 - Centro Hospitalar de Vila Nova de Gaia/Espinho, E. P. E., transição para o regime das 40 horas.

INFARMED

Circular Informativa n.º 250/CD/8.1.6 de 10/12/2014 - Sistema de Preços de Referência - 1.º trimestre 2015

A lista dos Grupos Homogéneos e dos preços de referência unitários a vigorar no 1.º trimestre de 2015 foi aprovada pela Deliberação n.º 149/CD/2014, de 10 de dezembro de 2014 do Conselho Diretivo1 e entra em vigor no dia 1 de janeiro de 2015. Foram criados 7 novos grupos homogéneos para as denominações comuns internacionais – celecoxib, nifedipina e etodolac resultantes da comercialização de novos medicamentos genéricos.

SPMS

Concurso 2015 / 70 - Sistemas Fechados de Colheita (Dispositivos Médicos)

- Programa de Concurso
- Caderno de Encargos

Concurso 2015 / 60 - Meios de diagnóstico - medicina nuclear

- Programa de Concurso
- Caderno de Encargos

Concurso 2014 / 30 - Gases medicinais considerados dispositivos médicos

- Programa de Concurso
- Caderno de Encargos
- Esclarecimentos
- Esclarecimentos2

COMISSÃO

Regulamento de Execução (UE) N.º 1390/2014 da Comissão de 19 de dezembro de 2014 que altera o anexo do Regulamento (UE) n.º 37/2010 no que se refere à

Human Medicines | Scientific guideline: **G**uideline on core Summary of Product Characteristics (SmPC) for human plasma derived and recombinant coagulation factor IX products

This guideline describes the information to be included in the Summary of Product Characteristics (SmPC) for human plasma derived and recombinant coagulation factor IX products, which are indicated for use in the treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency).

Human Medicines | Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with track changes (updated)

This guidance document addresses a number of questions which marketing authorisation holders (MAHs) may have on post-authorisation procedures. It provides an overview of the Agency's position on issues, which are typically addressed in discussions or meetings with MAHs in the post-authorisation phase.

Human Medicines | Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure (updated)

Human Medicines | Detailed guidance on the electronic submission of information on medicinal products for human use by marketing-authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance (updated)

Human Medicines | Scientific guideline: Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market

Human Medicines | Detailed guidance on the electronic submission of information on medicinal products for human use by marketing-authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance (updated)

Human Medicines | Regulatory and procedural guideline: Revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS) / limited market

Human Medicines | Scientific guideline: Compilation of individual product-specific guidance on demonstration of bioequivalence

The aim of publishing product-specific guidance on demonstration of bioequivalence is to enable a consistent approach to the assessment of applications based on bioequivalence data, particularly generic applications, across all submission routes, i.e. submitted centrally, via the decentralised procedure or mutually recognition procedure, or nationally.

Human Medicines | Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals

Human Medicines | Reflection paper on the use of heat treatment to inactivate retrovirus RD114 in live immunological veterinary medicinal products (IVMPs)

This guideline outlines the data requirements to be submitted by the marketing authorisation holder (MAH) to introduce a heat treatment to inactivate retroviruses in the active substance for the production of live viral vaccines for immunological veterinary medicinal products (IVMP) and to show the absence of negative impact of this treatment on the IVMP.

Human Medicines | Regulatory and procedural guideline: Substances considered as not falling within the scope of Regulation (EC) no 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

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