**28 de janeiro a 1 de fevereiro de 2013**

saude@vda.pt

# SAÚDE

## LEGISLAÇÃO

### NACIONAL

Portaria n.º 41/2013. D.R. n.º 23, Série I de 2013-02-01

**Ministérios das Finanças, da Saúde e da Solidariedade e da Segurança Social**

Fixa os preços dos cuidados de saúde e de apoio social prestado nas unidades de internamento e de ambulatório da Rede Nacional de Cuidados Continuados Integrados (RNCCI), a praticar no ano de 2012 e revoga a Portaria n.º 220/2011, de 1 de junho

## REGULAÇÃO

### CONSELHO DE MINISTROS

Declaração de retificação n.º 153/2013. D.R. n.º 23, Série II de 2013-02-01

**Presidência do Conselho de Ministros - Secretaria-Geral**

Retifica a Resolução n.º 1/2013, de 21 de janeiro, do Conselho de Ministros, que nomeia um vogal executivo para o conselho de administração da Unidade Local de Saúde de Matosinhos, E.P.E., publicada no Diário da República n.º 14, 2.ª Série, de 21 de Janeiro de 2013

### MINISTÉRIO DAS FINANÇAS E DA SAÚDE

Despacho n.º 1663/2013. D.R. n.º 20, Série II de 2013-01-29

**Ministérios das Finanças e da Saúde - Gabinetes dos Ministros de Estado e das Finanças e da Saúde**

Define, para 2013, o contingente de médicos aposentados que podem ser contratados pelos estabelecimentos e serviços do Serviço Nacional de Saúde

### INFARMED

**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

## SPMS

Despacho n.º 1966/2013. D.R. n.º 23, Série II de 2013-02-01

**Ministério da Saúde - Gabinete do Secretário de Estado da Saúde**

Estabelece disposições no âmbito dos Serviços Partilhados do Ministério da Saúde, E. P. E. (SPMS, E. P. E.), referente aos Contratos Públicos de Aprovisionamento (CPA), que estabelecem as condições de fornecimento de Medicamentos do Aparelho Respiratório

**CP 2012/20 – Contracetivos** - No dia 29/01/2013 entraram em vigor os novos contratos públicos de aprovisionamento, os quais já se encontram disponíveis no catálogo

## EFPIA

**Memorandum of Understanding –** Between **The European & Developing Countries Clinical Trials** and The European Federation of Pharmaceutical Industries and Associations (EFPIA), for Clinical Research Fellowships with the collaboration of European-based pharmaceutical companies

The objective of this fellowship scheme is to support EDCTP capacity-building efforts by hosting clinical researchers from sub-Saharan Africa within European operations of EFPIA corporate members, in order for them to acquire specific skills related to the design, conduct or analysis of clinical trials and to offer training opportunities in the broader field of clinical research, beyond what can be gained from academic study or usual employment.

**Joint Statement** - Healthcare Coalition on Data Protection calls for EU Data Protection Regulation to recognise the essential role of personal data in healthcare

## COMISSÃO EUROPEIA

**Decisão 2013/64/EU** - Decisão de Execução do Conselho, de 20 de dezembro de 2012, que altera a Decisão de Execução 2011/344/UE relativa à concessão de assistência financeira da União a Portugal

**Importation of active substances for medicinal products for human use**

- "questions and answers" document
- Amended template for "written confirmation

## PARLAMENTO EUROPEU

**Report on the proposal for a directive of the European Parliament and of the Council** relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems – 25.01.2013

Committee on the Environment, Public Health and Food Safety

Rapporteur: Antonyia Parvanova

## EMA

**Human Medicines |** Guideline on non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight heparins Consultation end date 31/07/2013

This guideline lays down the non-clinical and clinical requirements for low-molecular-weight-heparin (LMWH)-containing medicinal products claiming to be similar to another one already marketed. The non-clinical section addresses the pharmacotoxicological requirements and the clinical section the requirements for pharmacokinetic, pharmacodynamic, efficacy and safety studies as well as pharmacovigilance aspects

**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.I: Extended EudraVigilance product report message (XEVPRM) technical specifications

**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

**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

**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.I: Extended EudraVigilance product report message (XEVPRM) technical specifications

**Human Medicines |** Guidelines on good pharmacovigilance practices: Introductory cover note, last updated with finalisation of module XV

**Human Medicines |** **Points to consider** on good clinical practice inspection findings and the benefit-risk balance

The objective of this document is to assist inspectors and assessors in evaluating the consequences of inspection findings in relation to the benefit-risk balance. It should help inspectors in drafting the inspection reports and improve mutual understanding between inspectors and assessors in order to effectively aid clinical assessors, rapporteurs and ultimately the CHMP in their scientific evaluation of the benefit-risk balance. For this purpose, it is important to distinguish those findings that are likely to have an impact on the benefit-risk evaluation and those that are not. In this document, an attempt to rate inspection findings by their importance to the benefit-risk evaluation is made

**Human Medicines | Regulatory and procedural guideline:** Guidance for the format and content of the final study report of non-interventional post-authorisation safety studies

This document provides guidance for writing the final study report for non-interventional PASS in order to support the consistency of the information provided and facilitate its assessment. The guidance is based on Annex III(3) of Commission Implementing Regulation No 520/2012 with the additional instructions of Module VIII of the Good pharmacovigilance practices (GVP).

**Art.5 on Unforeseen Variations |** CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008

HMA

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

MADEIRA
Calçada de S. Lourenço, 3 - 2ºC
9000-061 Funchal Portugal
madeira@vda.pt