saude@vda.pt

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SAÚDE

LEGISLAÇÃO

NACIONAL

Lei n.º 31/2013. D.R. n.º 90, Série I de 2013-05-10

Assembleia da República

Concede autorização legislativa ao Governo no âmbito da aprovação do regime jurídico aplicável às práticas individuais restritivas do comércio

Decreto-Lei n.º 62/2013. D.R. n.º 90, Série I de 2013-05-10

Ministério das Finanças

Estabelece medidas contra os atrasos no pagamento de transações comerciais, e transpõe a Diretiva n.º 2011/7/UE, do Parlamento Europeu e do Conselho, de 16 de fevereiro de 2011

REGULAÇÃO

MINISTÉRIO DA SAÚDE

Despacho n.º 6021/2013. D.R. n.º 89, Série II de 2013-05-09

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Estabelece disposições no âmbito dos Serviços Partilhados do Ministério da Saúde, EPE (SPMS, EPE) referentes aos Contratos Públicos de Aprovisionamento (CPA) para fornecimento de Medicamentos Analgésicos, Antipiréticos e Antidepressores

Despacho n.º 5967/2013. D.R. n.º 88, Série II de 2013-05-08

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Estabelece disposições no âmbito dos Serviços Partilhados do Ministério da Saúde, EPE (SPMS, EPE), referentes aos Contratos Públicos de Aprovisionamento com vista ao fornecimento de Medicamentos do Sistema Nervoso Cerebrospinal: exceto Anestésicos, Relaxantes Musculares, Analgésicos, Antipiréticos, Antidepressores e Antipsicóticos

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
Aviso - CP 2012/14 - ap. Digestivo- No dia 23/04/2013 entraram em vigor os novos contratos públicos de aprovisionamento, os quais já se encontram disponíveis no catálogo. **Concurso 2013 / 34 - Stents Coronários** (caderno de encargos) (Data Limite da Apresentação das Informações para o Catálogo 17/06/2013) **Detalhe do Concurso 2013 / 35 -** Aquisição de Equipamentos / consumíveis para Diálise peritoneal (caderno de encargos) (Data Limite da Apresentação das Informações para o Catálogo 14/06/2013) **Concurso 2013 / 48 -** Medicamentos de consumo geral: aparelho geniturinário (caderno de encargos) (Data Limite da Apresentação das Informações para o Catálogo 21/06/2013) **Concurso 2013 / 49 -** Medicamentos De Consumo Geral: Medicamentos Usados Nas Afeções Oculares E Otorrinolaringológicas (caderno de encargos) (Data Limite da Apresentação das Informações para o Catálogo 25/06/2013) **Concurso 2013 / 50 -** Med. consumo geral: medicação antialérgica; medicamentos usados no tratamento de intoxicações e grupo 20.9 - outro produtos (caderno de encargos) (Data Limite da Apresentação das Informações para o Catálogo 24/06/2013) **Nota** relativa ao Despacho 5456-B/2013 - A SPMS em articulação com o Infarmed encontram-se a produzir informação complementar sobre a matéria que melhor permita dilucidar o alcance e regras de aplicação do citado normativo, a veicular e difundir junto de todas as entidades e serviços do SNS, com a máxima brevidade. **Circular Informativa Conjunta SPMS/SG de 30 de abril de 2013** - Procedimentos de aquisição centralizada a desenvolver pela SPMS e pela SG no âmbito das suas atribuições enquanto Unidades Ministeriais de Compras (UMC).	SPMS
Steering Group (Platform on Ethics & Transparency) - **Outcome – April 2013** - **List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector**	COMISSÃO EUROPEIA
Human Medicines | Regulatory and procedural guideline: Procedural advice on appeal procedure for orphan medicinal product designation or review of orphan designation criteria at the time of marketing authorisation **Human Medicines | Regulatory and procedural guideline:** Procedure for orphan-medicinal-product designation: Guidance for sponsors **Human Medicines | Report:** Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in European Union Member	EMA

States

Human Medicines | Public Consultation: Draft guideline on similar biological medicinal products

Human Medicines | Scientific guideline: Draft reflection paper on the use of methyl- and propylparaben as excipients in human medicinal products for oral use

The European Commission has decided to revise the 'Guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00 Rev.1)'. A concept paper on the need for such revision has been published in 2012(EMA/CHMP/SWP/888239/2011). Parabens used in medicinal products is one of the priorities among excipients under revision.

Human Medicines | Scientific guideline: Draft guideline on the use of phthalates as excipients in human medicinal products

Literature data in animals show that certain phthalates are associated with effects on reproduction and development in relation to their hormonal (anti-androgenic) properties. Currently available human data on the impact of phthalate exposure are limited and therefore the clinical relevance of such findings remains to be established. The most commonly used phthalates in medicinal products licensed in the EU are: dibutyl phthalate (DBP), diethyl phthalate (DEP), polyvinyl acetate phthalate (PVAP), cellulose acetate phthalate (CAP), and hydroxypropyl methylcellulose acetate phthalate (HPMCP).

Human Medicines | Regulatory and procedural guideline: Procedural advice on publication of information on withdrawals of applications related to the marketing authorisation of human medicinal products

This paper describes the publication of information on the withdrawals of marketing authorisation applications for human medicinal products. It updates the information in a reflection paper adopted by the European Medicines Agency (EMA) in September 2006, taking into account recent changes in EMA communication practices for certain types of applications as well as new guidance on the identification of personal data and commercially confidential information in marketing authorisation applications.

Human Medicines | Regulatory and procedural guideline: Procedural advice on publication of information on negative opinions and refusals of marketing authorisation applications for human medicinal products

This paper describes the documents to be published following negative opinions and refusals of marketing authorisation applications for human medicinal products. This document updates information of the reflection paper on the publication of information on negative opinions and refusals of marketing authorisation applications for human medicinal products adopted by the European Medicines Agency (EMA) in September 2006.

Human Medicines | Regulatory and procedural guideline: Deadlines for submission of applications for orphan-medicinal-product designation to the European Medicines Agency 2013/2014

Q&A | Variations

HMA

Best Practice Guides (BPGs) for the Submission and Processing of Variations in the Mutual Recognition Procedure

(Please note: for purely national Marketing Authorisations these Best Practise Guides will apply from 4 August 2013)

- Chapter 1: CMDh BPG for the allocation of the mutual recognition variation number for Type I Notifications, Type II Variations, Grouping and Worksharing
- Chapter 2: Procedure for automatic validation of Mutual Recognition Procedures for Variations (February 2013)
- Chapter 3: CMDh BPG for the processing of Type IA Minor Variations (Notifications) in the Mutual Recognition Procedure (April 2013
- Chapter 4: CMDh BPG for the processing of Type IB Minor Variations (Notifications) in the Mutual Recognition Procedure (February 2013)
- Chapter 5: CMDh BPG for the handling of Type II Variations in the Mutual Recognition Procedure (February 2013)
- Chapter 6: CMDh BPG for the processing of Grouped Applications in the Mutual Recognition Procedure (February 2013)
- Chapter 7: CMDh BPG on Worksharing (April 2013)
- Chapter 8: CMDh BPG on CMDh Recommendations on Unforseen Variations (February 2013)
- Chapter 9: CMDh BPG on fast track procedure for annual update of Human Influenza Vaccines (April 2013)

Chapter 9: CMDh Best Practice Guide on fast track procedure for annual update of Human Influenza Vaccines

This Guidance has been introduced to facilitate the processing of the annual change in vaccine composition (annual change in vaccine composition (influenza A and B virus variants).

This guidance covers the fast track procedure for MRP/DCP products. However, the same rules apply for purely nationally authorised products, except the commenting and adoption procedure by the CMSs.

This document provides guidance on the procedural steps, dossier content and timelines.

Request to CMDh for a recommendation on the classification of an unforeseen variation under Article 5 | Template Request form for recommendation - Article 5 (April 2013)

Application for Marketing Authorisation | Best Practice Guide for the Decentralised and Mutual Recognition Procedures

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

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