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1 a 5 de junho de 2015

SAÚDE

LEGISLAÇÃO

NACIONAL

Decreto-Lei n.º 97/2015 - Diário da República n.º 105/2015, Série I de 2015-06-01

Ministério da Saúde

Procede à criação **do Sistema Nacional de Avaliação de Tecnologias de Saúde**

Decreto-Lei n.º 99/2015 - Diário da República n.º 106/2015, Série I de 2015-06-02

Ministério das Finanças

Procede à terceira alteração ao Decreto-Lei n.º 127/2012, de 21 de junho, que contempla as normas legais disciplinadoras dos procedimentos necessários à aplicação da **Lei dos Compromissos e dos Pagamentos em Atraso**, aprovada pela Lei n.º 8/2012, de 21 de fevereiro

REGULAÇÃO

MINISTÉRIO DA SAÚDE

Despacho n.º 6214/2015 - Diário da República n.º 109/2015, Série II de 2015-06-05

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Determina que a SPMS - Serviços Partilhados do Ministério da Saúde divulga, em site próprio, todas as características dos produtos abrangidos por contratos públicos de aprovisionamento, que estabelecem as condições de fornecimento de medicamentos anti-infecciosos: Exceto antivíricos e antifúngicos

Despacho n.º 6215/2015 - Diário da República n.º 109/2015, Série II de 2015-06-05

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Determina que a SPMS - Serviços Partilhados do Ministério da Saúde divulga, em site próprio, todas as características dos produtos abrangidos por contratos públicos de aprovisionamento, que estabelecem as condições de fornecimento de medicação antialérgica, medicamentos usados no tratamento de intoxicações; vitaminas e sais minerais e grupo 20.9 - outros Produtos

Despacho n.º 6216/2015 - Diário da República n.º 109/2015, Série II de 2015-06-05

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Determina que a SPMS-Serviços Partilhados do Ministério da Saúde divulga, em site próprio, todas as características dos produtos abrangidos por contratos públicos de aprovisionamento, que estabelecem as condições de fornecimento de fornecimento de

meios de diagnóstico - medicina nuclear Portaria n.º 332/2015 - Diário da República n.º 107/2015, Série II de 2015-06-03

Ministérios das Finanças e da Saúde - Gabinetes dos Secretários de Estado Adjunto e do Orçamento e da Saúde

Autoriza o Centro Hospitalar do Médio Ave, EPE a assumir um encargo até ao montante máximo de 218.360,00 EUR (duzentos e dezoito mil trezentos e sessenta euros), com IVA incluído à taxa legal em vigor, referente à aquisição de gases medicinais

Despacho n.º 5786/2015 - Diário da República n.º 105/2015, Série II de 2015-06-01

Ministério da Saúde - Gabinete do Secretário de Estado Adjunto do Ministro da Saúde

Inclui a vacina Prevenar 13 no Programa Nacional de Vacinação (PNV) e aprova o esquema de vacinação universal recomendado do PNV 2015. Revoga o Despacho n.º 11961/2014, de 17 de setembro, publicado no Diário da República, 2.ª série, n.º 186, de 26 de setembro de 2014

MINISTÉRIO DAS FINANÇAS E DA SAÚDE

Portaria n.º 328/2015 - Diário da República n.º 106/2015, Série II de 2015-06-02

Ministérios das Finanças e da Saúde - Gabinetes dos Secretários de Estado Adjunto e do Orçamento e da Saúde

Autoriza a Unidade Local de Saúde do Alto Minho, E. P. E., a assumir um encargo plurianual até ao montante máximo de EUR 98.550,00 (noventa e oito mil, quinhentos e cinquenta euros), a que acresce o IVA à taxa legal em vigor, relativo ao aluguer de equipamento para a ventilação não invasiva

Portaria n.º 320/2015 - Diário da República n.º 105/2015, Série II de 2015-06-01

Ministérios das Finanças e da Saúde - Gabinetes dos Secretários de Estado Adjunto e do Orçamento e da Saúde

Autoriza o Hospital Professor Doutor Fernando Fonseca, E. P. E., a assumir um encargo plurianual até ao montante máximo de EUR 3.212.191, 68 (três milhões duzentos e doze mil cento e noventa e um euros e sessenta e oito cêntimos), a que acresce o IVA à taxa legal em vigor, relativo à aquisição de reagentes para testes de química clínica e imunoquímica.

CONSELHO DE MINISTROS

Resolução n.º 33/2015 - Diário da República n.º 105/2015, Série II de 2015-06-01

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia um vogal executivo do conselho diretivo da Administração Central do Sistema de Saúde, I.P.

Resolução n.º 33/2015 - Diário da República n.º 105/2015, Série II de 2015-06-01

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia um vogal executivo do conselho diretivo da Administração Central do Sistema de Saúde, I.P.

INFARMED

Despacho n.º 6088/2015 - Diário da República n.º 108/2015, Série II de 2015-06-04

Ministério da Saúde - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Designação da licenciada Marta Isabel Raposo Marques Marcelino para exercer, em comissão de serviço, o cargo de Diretor da Unidade de Introdução no Mercado do INFARMED, I.P.

Lançamento do Portal FIS - Fundo para a Investigação em Saúde

O Portal para submissão de candidaturas ao Fundo para a Investigação em Saúde já está disponível no site do Infarmed em Fundo para Investigação em Saúde juntamente com o respetivo "Guia para elaboração e submissão de propostas de projetos - Preenchimento da candidatura".

Publicação para efeitos do artigo 15º-A do Decreto -Lei n.º 176/2006, de 30 de Agosto - pedidos de autorização de introdução no mercado de medicamentos genéricos

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Lista de Entrada em Vigor dos CPAs - 03-06-2015

SPMS

Electronic Application Forms (eAF)

The use of the electronic Application Forms (eAF) is mandatory for Centralised procedure from 1 July 2015. The eAFs must be used for all Human and Veterinary applications : authorisations, variations and renewals.

COMISSÃO EUROPEIA

Annual report on benefits and infringements under the Paediatric Regulation

On an annual basis the European Medicines Agency reports on companies and products that have benefitted from the rewards and incentives provided by the Paediatric Regulation No 1901/2006 as well as on companies that have failed to comply with any of the obligations in that Regulation. This report is published by the Commission in accordance with Article 50(1) of the Regulation

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Human Medicines | Scientific guideline: Reflection paper on microbiological aspects of herbal medicinal products and traditional herbal medicinal products

In this reflection paper consideration is given as to how suitable microbial quality of herbal substances, herbal preparations, and HMPs can be achieved by preventative measures, manufacturing processes and by applying decontamination processes. The aim of the reflection paper is to provide an overview of the critical aspects to be taken into account to ensure suitable microbial quality. The focus is on current regulatory aspects, but aspects of GACP and GMP are discussed as well

Human Medicines | Scientific guideline: Draft guideline on clinical investigation of medicinal products other than non-steroidal anti-inflammatory drugs (NSAIDs) for treatment of rheumatoid arthritis

This document is intended to provide guidance on the clinical evaluation of medicinal products other than non-steroidal anti-inflammatory drugs (NSAIDs) in the treatment of rheumatoid arthritis (RA). RA is a chronic systemic inflammatory disease of synovial joints and other organ systems. If left untreated, it causes joint destruction, deformity and functional impairment.

Human Medicines | Scientific guideline: Draft guideline on clinical investigation of medicinal products other than non-steroidal anti-inflammatory drugs (NSAIDs) for treatment of rheumatoid arthritis

This document is intended to provide guidance on the clinical evaluation of medicinal products other than non-steroidal anti-inflammatory drugs (NSAIDs) in the treatment of rheumatoid arthritis (RA). RA is a chronic systemic inflammatory disease of synovial joints and other organ systems. If left untreated, it causes joint

Human Medicines | Regulatory and procedural guideline: Recommendations for the implementation of the exemptions to the labelling and package-leaflet obligations in the centralised procedure (updated)

Human Medicines | Regulatory and procedural guideline: Labelling-exemption requests under Article 63 of Directive 2001/83/EC examined by the Quality Review of Documents group (updated)

Human Medicines | Scientific guideline: Draft guideline on epidemiological data on

EMA

blood transmissible infections

This guideline outlines the scientific data requirements for epidemiological data on blood transmissible infections to be included in applications for Plasma Master File certification submitted to the European Medicines Agency (EMA). It is a new revision of the CHMP/EMA Plasma Master File epidemiology guideline (EMEA/CPMP/BWP/125/04) which came into operation in July 2005

Human Medicines | Scientific guideline: Draft guideline on the clinical investigation of recombinant and 4 human plasma-derived factor VIII products

This guideline describes the information to be documented when an application for a marketing authorisation for recombinant or human plasma-derived factor VIII products is made for use in treatment and prevention of bleeding in patients with haemophilia A. The guidance covers clinical investigations to be conducted pre- and post-marketing authorisation. Guidance is also provided for authorised products where a significant change in the manufacturing process has been made.

Human Medicines | Scientific guideline: new Guideline on clinical investigation of recombinant and human plasma-derived factor IX products

This guideline describes the information to be documented when an application for a marketing authorisation for recombinant or human plasma-derived factor IX products is made for use in treatment and prevention of bleeding in patients with haemophilia B. The guideline covers clinical investigations to be conducted pre- and post-marketing authorisation. Guidance is also provided for authorised products where a significant change in the manufacturing process has been made.

Human Medicines | Scientific guideline:Draft guideline on core summary of product characteristics for human plasma derived and recombinant coagulation factor VIII products

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

Human Medicines | Scientific guideline: Draft guideline on the clinical investigation of recombinant and 4 human plasma-derived factor VIII products

This guideline describes the information to be documented when an application for a marketing authorisation for recombinant or human plasma-derived factor IX products is made for use in treatment and prevention of bleeding in patients with haemophilia B. The guideline covers clinical investigations to be conducted pre- and post-marketing authorisation. Guidance is also provided for authorised products where a significant change in the manufacturing process has been made.

Human Medicines | Scientific guideline: n**ewGuideline** on clinical investigation of recombinant and human plasma-derived factor IX products, adopted

This guideline describes the information to be documented when an application for a marketing authorisation for recombinant or human plasma-derived factor IX products is made for use in treatment and prevention of bleeding in patients with haemophilia B. The guideline covers clinical investigations to be conducted pre- and post-marketing authorisation. Guidance is also provided for authorised products where a significant change in the manufacturing process has been made.

Human Medicines | Scientific guideline: D**raft guideline** on core summary of product characteristics for human plasma derived and recombinant coagulation factor VIII products

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Human Medicines | Scientific guideline: Concept paper on the revision of the guideline on quality of herbal medicinal products/traditional herbal medicinal products

A simplified registration procedure was established for traditional herbal medicinal products (THMPs) for human use with Directive 2004/24/EC of the European Parliament and of the Council. Herbal medicinal products (HMPs) contain exclusively as active ingredients one or more herbal substances or herbal preparations or combinations thereof.

Human Medicines | Scientific guideline: Concept paper on the revision of the guideline on specifications: Test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products

A simplified registration procedure was established for traditional herbal medicinal products (THMPs) for human use with Directive 2004/24/EC of the European Parliament and of the Council. Herbal medicinal products (HMPs) contain exclusively as active ingredients one or more herbal substances or herbal preparations or combinations thereof.

Human Medicines | Scientific guideline: Draft guideline on epidemiological data on blood transmissible infections

This guideline outlines the scientific data requirements for epidemiological data on blood transmissible infections to be included in applications for Plasma Master File certification submitted to the EMA. It is a new revision of the CHMP/EMA Plasma Master File epidemiology guideline (EMEA/CPMP/BWP/125/04) which came into operation in July 2005.

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

This guidance document addresses a number of questions which users of the centralised procedure may have. It provides an overview of the European Medicines Agency's position on issues, which are typically addressed during the course of pre-submission meetings.

Human Medicines | Presubmission guidance: questions 1 to 11 (updated)

Human Medicines | Presubmission guidance: questions 45 to 56 (updated)

Human Medicines | Presubmission guidance: questions 57 to 66 (updated)

Human Medicines | Good-manufacturing-practice and good-distribution-practice compliance (updated)

Human Medicines | Draft Concept paper on new guidance for importers of medicinal products

In recent years, the manufacture of medicinal products for the European Union (EU) market increasingly occurs outside of the EU. While this trend is particularly noted for the manufacture of active substances, it is also evident that a similar trend applies to medicinal product manufacture.

Human Medicines | Scientific guideline: Guideline adventitious agent safety of urine-derived medicinal products, adopted

This guideline considers various aspects of virus safety of urine-derived medicinal products. Incorporation of effective steps for virus inactivation/removal is considered a key measure towards virus safety and guidance on validation of process steps for virus inactivation/removal is provided

This guideline replaces the document on Biological Products derived from human Urine (CPMP/118/95).

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