saude@vda.pt

9 a 13 de março de 2015

SAÚDE

LEGISLAÇÃO

NACIONAL

Portaria n.º 70/2015 - Diário da República n.º 48/2015, Série I de 2015-03-10

Ministérios das Finanças e da Saúde

Fixa o valor das ajudas de custo e de transporte a atribuir ao pessoal médico nas situações de mobilidade a tempo parcial, nos casos em que a realização do período normal de trabalho seja em dois ou mais serviços ou estabelecimentos de saúde, que distem entre si mais de 60 km

REGULAÇÃO

PRESIDÊNCIA CONSELHO DE MINISTROS

Resolução n.º 16/2015 - Diário da República n.º 47/2015, Série II de 2015-03-09

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia um vogal executivo do conselho de administração do Hospital Professor Doutor Fernando Fonseca, E.P.E.

MINISTÉRIO DA SAÚDE

Despacho n.º 2510/2015 - Diário da República n.º 48/2015, Série II de 2015-03-1066693636

Ministérios da Justiça e da Saúde - Gabinetes da Ministra da Justiça e do Secretário de Estado da Saúde

Nomeia membro da Comissão de Avaliação de Medicamentos o Dr. Nuno Miguel Martinho Jones Oliveira Gonçalves

INFARMED

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

SPMS

Lista de Entrada em Vigor CPAs 10/03/2015

Consulta Pública – Acordo Quadro de Telemedicina n.º 02|2015|SPMS

Envolver os interessados no processo de preparação do acordo quadro;

Estimular a participação dos stakeholders na preparação do procedimento, esperando

sugestões tanto de fornecedores como das instituições de saúde relativos à proposta para o desenvolvimento do modelo concetual e formação do acordo quadro;

Identificar os principais constrangimentos e procurar as melhores soluções para que o projetado Acordo Quadro sirva as instituições nacionais de saúde e facilite os processos de aquisição de serviços de telemedicina.

Concurso 2015 / 8 - antissséticos, desinfetantes e outros

Programa de Concurso

Caderno de Encargos

Consulta Pública - Acordo Quadro para Fornecimento de Suturas Cirúrgicas

Concurso 2015 / 48 - Medicamentos do Aparelho Geniturinário

Programa de Concurso

Caderno de Encargos

Norma nº 002/2015 de 06/03/2015 - Triagem de Manchester e Referenciação Interna Imediata

DGS

Commission Staff Working Document - Country Report Portugal 2015

Including an In-Depth Review on the prevention and correction of macroeconomic imbalances

COMISSÃO EUROPEIA

Human Medicines | Scientific guideline: Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues, adopted

Human Medicines | Regulatory and procedural guideline: Packaging 'blue-box' requirements and additional information on labelling/package leaflet for products authorised via national, mutual recognition, decentralised or centralised procedures

Human Medicines | Explanatory note on pharmacovigilance fees payable to the European Medicines Agency

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

Human Medicines | Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for similar biological medicinal product applications (updated)

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

Human Medicines | Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for generic / hybrid applications (track changes)

EMA

Human Medicines | Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for generic / hybrid applications (updated)

Human Medicines | Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for similar biological medicinal product applications (track changes) (updated)

Human Medicines | Regulatory and procedural guideline: European Medicines Agency / PDCO standard paediatric investigation plan for allergen products for specific immunotherapy, adopted (updated)

Human Medicines | Q&A on generic and hybrid application - Generic / hybrid applications: questions 23 to 34 (updated)

Human Medicines | Q&A on generic and hybrid application - Presubmission guidance: questions and answers (updated)

Human Medicines | Q&A on generic and hybrid application - Similar-biological-medicine applications: questions and answers (updated)

Human Medicines | Q&A on generic and hybrid application - Generic / hybrid applications: questions 35 to 43 (updated)

Human Medicines | Q&A on generic and hybrid application - Presubmission guidance: questions 31 to 41 (updated)

Human Medicines | Q&A on generic and hybrid application - Generic / hybrid applications: questions and answers (updated)

Human Medicines | Q&A on generic and hybrid application – Q&A 31-44: Similar biological product applications (updated)

Human Medicines | Scientific guideline: Guideline on core core summary of product characteristics (SmPC) and package leaflet for (99Mo/99mTc) generator,

Human Medicines | List of Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)

Human Medicines | Regulatory and procedural guideline: Recommended submission dates for centralised (initial and extension applications) and maximum-residue-limit procedures – 1st phase (120-day assessment) (updated)

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

HMA

Information on applications referred in accordance with Article 30 of Directive 2001/83/EC | Article 30 Tracking table

Questions & Answers | Variations

PSURs | Guidance Requirements on Submissions for Periodic safety update reports (PSUR) to National Competent Authorities (NCAs) for products authorised via National Procedures, MRP and DCP (NAPs)

Procedure Guidance | Position paper on the use of the Quick Response (QR) codes to provide information about the medicinal product

Procedure Guidance | CMDh Best Practice Guidance on collaboration between Member States in relation to serious GMP non-compliance issues (February 2015)

EFPIA

EFPIA Supports New Wellcome Trust Statement

EFPIA is adding its voice to that of the scientific community to call for a halt to the Stop Vivisection Initiative, which advocates the abolition of this most advanced animal protection legislation, and the prohibition of animals testing and in essential biomedical research.

Our legislation in Europe ensures that scientific justification, ethical review and authorisation are mandatory. Far from being selective, it protects all animals, from the octopus through to mice, dogs and primates.

IMI Provides Successful Platform To Fight Epidemics

Mutation-capable viruses such as Ebola recognise no borders and can only be properly opposed by a committed coalition of borderless union of researchers, health authorities, official agencies, international organisations, biotechnology companies, and pharmaceutical and vaccine manufacturers. Speaking at a recent press briefing hosted by the French research-based pharmaceutical agency, LEEM, Magda Chlebus, Director Science Policy at the European Federation of Pharmaceutical Industries and Associations (EFPIA) stressed that the highly successful Innovative Medicines Initiative offers precisely this kind of platform.

EFPIA Welcomes UK Move to Speed Patient Access to Innovative Drugs

EFPIA welcomes the planned review into plans to give NHS patients quicker access to innovative medicines and medical technology, announced on 11th March by the UK's Department of Health and Office for Life Sciences.

Speeding up the assessment of the safety and efficacy of innovative medicines by adapting systems and better exploiting the UK's integrated healthcare system is crucial to increasing and accelerating patient access to these products.

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

Timor-Leste
Timor Plaza
Rua Presidente Nicolau Lobato, Unidade 433
Comoro, Dili | Timor-Leste
timorleste@vda.pt