SRS ADVOGADOS
NEWS LETTER
LIFE SCIENCES

1 Julho | 2016

LIFE SCIENCES

DESTAQUES

LEGISLAÇÃO PORTUGUESA

I. DIÁRIO DA REPÚBLICA

Decreto-Lei n.º 32/2016 - Diário da República n.º 122/2016, Série I de 2016-06-2874811832
Clarifica as posições jurídicas detidas pelo SUCH, pelo Centro Hospitalar Lisboa Central, E. P. E., pelo Centro Hospitalar Lisboa Ocidental, E. P. E., e pelo Centro Hospitalar de Lisboa Norte, E. P. E., nos Agrupamentos Complementares de Empresas «Somos Compras», «Somos Contas» e «Somos Pessoas», procedendo à terceira alteração ao **Decreto-Lei n.º 19/2010**, de 22 de março

Decreto Legislativo Regional n.º 26/2016/M - Diário da República n.º 124/2016, Série I de 2016-06-3074842306
Região Autónoma da Madeira - Assembleia Legislativa
Estabelece o Plano Regional de Prevenção e Controlo de Doenças Transmitidas por Vetores e define o âmbito territorial, os objetivos gerais e específicos e a atribuição das competências

Portaria n.º 178-A/2016 - Diário da República n.º 125/2016, 1º Suplemento, Série I de 2016-07-0174842335
Determina a aplicação do Sistema de Classificação para Doentes (SCD-MFRA), para efeitos da requisição de cuidados de Medicina Física e de Reabilitação em Ambulatório (MFRA), em todos os pedidos efetuados pelos cuidados de saúde primários às instituições do Serviço Nacional de Saúde (SNS) e do setor convencionado, estabelecendo regras de faturação, preços e taxas moderadoras aplicáveis

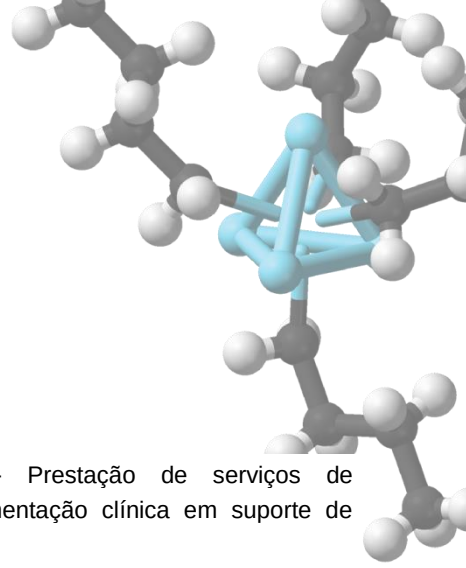
SPMS

Anúncio de procedimento n.º 3888/2016 - Diário da República n.º 121/2016, Série II de 2016-06-27
SPMS - Serviços Partilhados do Ministério da Saúde, E. P. E.
CP 2016/21 - Acordo quadro para fornecimento de Gazes Medicadas e Ligaduras de Gaze às Instituições e Serviços do Serviço Nacional de Saúde

Anúncio de procedimento n.º 3943/2016 - Diário da República n.º 123/2016, Série II de 2016-06-29
SPMS - Serviços Partilhados do Ministério da Saúde, E. P. E.
Ligaduras Medicadas, de Fixação e Proteção

Anúncio de procedimento n.º 3962/2016 - Diário da República n.º 124/2016, Série II de 2016-06-30
SPMS - Serviços Partilhados do Ministério da Saúde, E. P. E.
Serviços de manutenção corretiva, preventiva e evolutiva do sistema de informação BI-GDH

Concursos



Anúncio de procedimento n.º 3879/2016 - Diário da República n.º 121/2016, Série II de 2016-06-27
Administração Regional de Saúde do Algarve, I. P.
Concurso Público n.º 164/2016-Transporte e distribuição de materiais p/os ACES e outros serviços da ARS Algarve

Anúncio de procedimento n.º 3883/2016 - Diário da República n.º 121/2016, Série II de 2016-06-27
Centro Hospitalar de Lisboa Central, E. P. E.
1-2.0105/16 - Kit de tratamento de feridas

Anúncio de procedimento n.º 3901/2016 - Diário da República n.º 122/2016, Série II de 2016-06-28
Unidade Local de Saúde do Baixo Alentejo, E. P. E.
Aquisição de duodenoscópio

Anúncio de procedimento n.º 3935/2016 - Diário da República n.º 123/2016, Série II de 2016-06-29
Centro Hospitalar do Médio Ave, E. P. E.
Material para Cirurgia Oftalmológica

Anúncio de procedimento n.º 3952/2016 - Diário da República n.º 123/2016, Série II de 2016-06-29
Centro Hospitalar e Universitário de Coimbra, E. P. E.
Aquisição de um ecógrafo

Aviso de prorrogação de prazo n.º 625/2016 - Diário da República n.º 123/2016, Série II de 2016-06-29
Administração Central do Sistema de Saúde, I. P.
Contrato de aquisição de bens e serviços para a Gestão do Centro de Controlo e Monitorização do Serviço Nacional de Saúde

Anúncio de concurso urgente n.º 86/2016 - Diário da República n.º 124/2016, Série II de 2016-06-30
Centro Hospitalar de Entre o Douro e Vouga, E.P.E.
Concurso Publico Urgente N.º 02/00014.62/2016 - Aquisição de Exames de Medicina Nuclear

Anúncio de procedimento n.º 3968/2016 - Diário da República n.º 124/2016, Série II de 2016-06-30
Centro Hospitalar e Universitário de Coimbra, E. P. E.
CP n.º 010100192016 - Fornecimento de material para estomatologia

Anúncio de procedimento n.º 3996/2016 - Diário da República n.º 124/2016, Série II de 2016-06-30
Centro Hospitalar Lisboa Norte, E. P. E.
CP n.º 169A000009 - Prestação de serviços de microfilmagem de documentação clínica em suporte de papel

Anúncio de procedimento n.º 4004/2016 - Diário da República n.º 125/2016, Série II de 2016-07-01
Santa Casa da Misericórdia de Lisboa
16/CPS1008 - Aquisição de medicamentos diversificados para a Santa Casa da Misericórdia de Lisboa

Anúncio de procedimento n.º 4007/2016 - Diário da República n.º 125/2016, Série II de 2016-07-01
Hospital de Santa Maria Maior, E. P. E.
Aquisição de Material de Tratamento

II. INFARMED

Comunicado de Imprensa - Medicamentos biossimilares

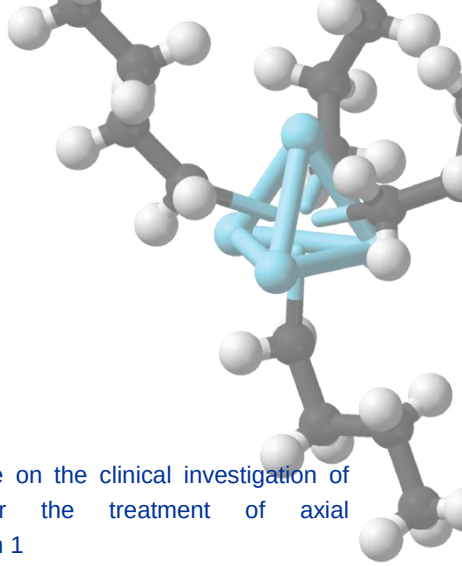
Circular Informativa N.º 099/CD/100.20.200 - Vacina BCG

LEGISLAÇÃO UNIÃO EUROPEIA

I. COMISSÃO EUROPEIA

- **Consultation on the draft Guidelines on Good Manufacturing Practice for Advanced Therapy Medicinal Products**

Objective of the consultation: Article 5 of *Regulation 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC* requires the Commission to draw up guidelines on good manufacturing practice specific to advanced therapy medicinal products.
A consultation on this topic was launched in 2015. On the basis of the comments received during the consultation, as well as input from consultation with the EMA and competent authorities in the Member States, the Commission services have developed draft Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products. With this consultation, the Directorate General for Health and Food Safety wants to give an additional opportunity for concerned stakeholders to express their views on the



GMP requirements that should apply to ATMPs. **Period of consultation:** 28 June to 26 September 2016

The consultation document: The consultation document can be downloaded here.

II. EUROPEAN MEDICINES AGENCY

Reflection paper on polycyclic aromatic hydrocarbons in herbal medicinal products/traditional herbal medicinal products

The purpose of this reflection paper is to promote discussion about the presence of polycyclic aromatic hydrocarbons in herbal substances, herbal preparations and herbal medicines and to invite all interested parties including suppliers and manufacturers of herbal substances/herbal preparations, manufacturers of HMPs/THMPs, pharmaceutical industry associations, health care professional groups, learned societies, consumers and patients' associations, governmental institutions as well as EU and EEA-EFTA Member States to submit any scientific data or documented information (new, published or unpublished) and comments relevant to the evaluation of this problem.

Document: Reflection paper on polycyclic aromatic hydrocarbons in herbal medicinal products/traditional herbal medicinal products
Reference number: EMA/HMPC/300551/2015
Consultation end date: 15/12/2016

Draft guideline on the clinical investigation of medicinal products for the treatment of axial spondyloarthritis - Revision 1

This document is a revision of the guideline on clinical investigation of medicinal products for the treatment of ankylosing spondylitis (CPMP/EWP/4891/03) which came into effect in May 2009. It should be considered as general guidance on the development of medicinal products for the treatment of axial spondyloarthritis and should be read in conjunction with other European and ICH guidelines which may apply to this disease area and patient population.

Document: Draft guideline on the clinical investigation of medicinal products for the treatment of axial spondyloarthritis - Revision 1
Reference number: CPMP/EWP/4891/03
Consultation end date: 31/12/2016

Updates

Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures adopted at the CHMP meeting of 20-23 June 2016

Guidelines and concept papers adopted during the CHMP meeting 20-23 June 2016

Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 20-23 June 2016

Explanatory note on pharmacovigilance fees payable to the European Medicines Agency

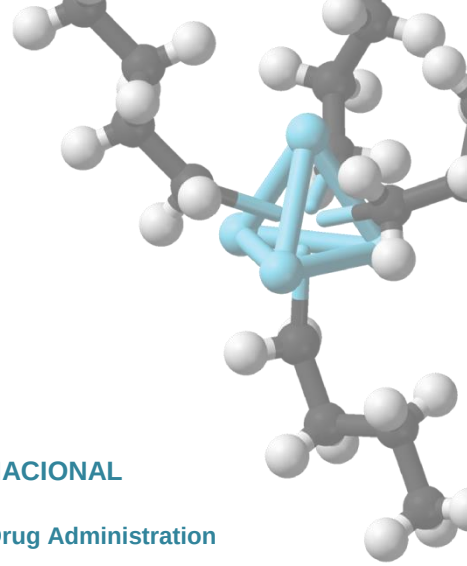
Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products

List of nationally authorized medicinal products:
Paraffin liquid PSUSA/00009251/201510
Azelastine / fluticasone PSUSA/00010067/201510
Acetylsalicylic acid / bisoprolol PSUSA/00010287/201511
Almagate PSUSA/00000097/201505
Diclofenac (topical formulations) PSUSA/00010342/201509

List of medicinal products under additional monitoring

Scientific guidelines:
List of changes to combined Veterinary Dictionary for Drug Related Affairs list of clinical terms for reporting suspected adverse reactions in animal and humans to veterinary medicinal products for 2016 (Adopted)

Guidance notes on the use of Veterinary Dictionary for Drug Related Affairs terminology for reporting suspected adverse reactions in animals and humans



Reflection paper on viral safety of plasma-derived medicinal products with respect to Hepatitis E virus (Adopted)

Guideline on user safety of topically administered veterinary medicinal products

Stem cell -based products for veterinary use: Specific questions on extraneous agents to be addressed by Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)

European medicines agency Standard operating procedure: Standard operating procedure for type IA variations (single and grouped) to centralised marketing authorisations (medicines for veterinary use)

III. HEADS OF MEDICINES AGENCIES

- **Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh)**

Examples for acceptable and not acceptable groupings for MRP/DCP products

Report from the meeting held on 20-22 June 2016

Template - Concerned Member State's Comments on Lead Member State's Preliminary assessment report

Art.46 public assessment reports for Avaxim 80U Pediatric (inactivated hepatitis A vaccine)

Q&As on Variations

Presentations from the May 2016 CMDh meetings with Interested Parties

LEGISLAÇÃO INTERNACIONAL

I. U.S. Food and Drug Administration

- **FDA approves Epclusa for treatment of chronic Hepatitis C virus infection**

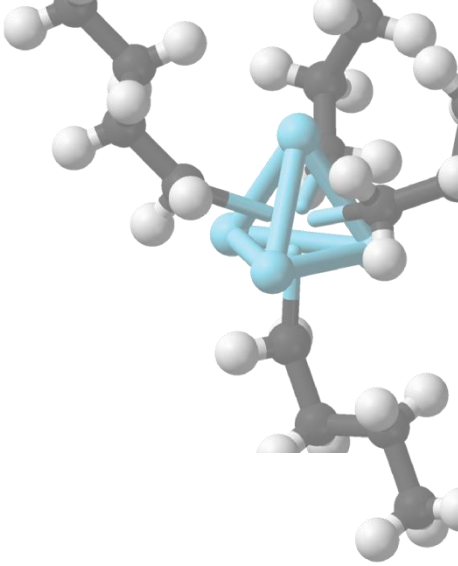
The U.S. FDA approved Epclusa to treat adult patients with chronic hepatitis C virus (HCV) both with and without cirrhosis (advanced liver disease). For patients with moderate to severe cirrhosis (decompensated cirrhosis), Epclusa is approved for use in combination with the drug ribavirin. Epclusa is a fixed-dose combination tablet containing sofosbuvir, a drug approved in 2013, and velpatasvir, a new drug, and is the first to treat all six major forms of HCV. Epclusa is manufactured and marketed by Gilead Sciences, Inc., of Foster City, California.

- **FDA approves implantable device that changes the shape of the cornea to correct near vision**

The U.S. FDA approved the Raindrop Near Vision Inlay, a device implanted in the cornea (the clear, front surface) of one eye to improve near vision in certain patients with presbyopia. It is the second FDA-approved implantable corneal device for correction of near vision in patients who have not had cataract surgery and the first implantable device that changes the shape of the cornea to achieve improved vision. The Raindrop Near Vision Inlay is manufactured by Revision Optics, Inc. of Lake Forest, California.

- **FDA clears first test to detect specific genetic markers for certain antibiotic-resistant bacteria directly from clinical specimens**

The U.S. FDA cleared for marketing the Xpert Carba-R Assay, an infection control aid that tests patient specimens to detect specific genetic markers associated with bacteria that are resistant to Carbapenem antibiotics. Carbapenem antibiotics are widely used in hospitals to treat severe infections. These resistant organisms are commonly referred to as Carbapenem-resistant Enterobacteriaceae, or CRE, and have been reported in almost all states within the U.S. The Xpert Carba-R Assay is manufactured by Cepheid, located in Sunnyvale, Calif.



II. OECD

OECD Health Statistics 2016

The online database OECD Health Statistics 2016 has been released.
The OECD Health Database offers a comprehensive source of comparable statistics on health and health systems across OECD countries. It is an essential tool to carry out comparative analyses and draw lessons from international comparisons of diverse health systems. Access to the 2016 online **database**.

OECD series to understand your country's health care system

The new OECD series aims to highlight the latest data in selected countries, to explain their health care systems and to provide key information in a clear and concise way, in just 2 pages. Each country snapshot highlights issues that are pertinent to that particular country, be it smoking, obesity, surgical interventions, consumption of antibiotics, physicians density, prevalence of mental disorders, etc., with the help of key statistics and are followed by brief policy recommendations.

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