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SAÚDE

REGULAÇÃO

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia um vogal executivo do conselho de administração do Centro Hospitalar do Médio Tejo, E. P. E.

CONSELHO DE
MINISTROS

[Resolução n.º 29/2014 - Diário da República n.º 197/2014, Série II de 2014-10-13](#)

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia um vogal executivo do conselho de administração do Centro Hospitalar de Lisboa Norte, E. P. E.

[Despacho n.º 12674/2014 - Diário da República n.º 200/2014, Série II de 2014-10-16](#)

Ministérios da Administração Interna e da Saúde - Gabinetes dos Secretários de Estado Adjunto do Ministro da Administração Interna e da Saúde

O pagamento das comparticipações do Estado na compra de medicamentos dispensados a beneficiários, dos sistemas de assistência na doença da Guarda Nacional Republicana (GNR) e da Polícia de Segurança Pública (PSP), é encargo do SNS, em 2014

MINISTÉRIO DA
SAÚDE

[Despacho n.º 12573/2014 - Diário da República n.º 198/2014, Série II de 2014-10-14](#)

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Estabelece disposições no âmbito da Serviços Partilhados do Ministério da Saúde, EPE (SPMS, EPE), referentes aos Contratos Públicos de Aprovisionamento (CPA) que determinam as condições de fornecimento de medicamentos do foro oncológico II

[Despacho n.º 12528/2014 - Diário da República n.º 197/2014, Série II de 2014-10-13](#)

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Estabelece disposições no âmbito da Serviços Partilhados do Ministério da Saúde, EPE (SPMS, EPE), referentes aos Contratos Públicos de Aprovisionamento (CPA) que determinam as condições de fornecimento de Medicamentos do Aparelho Cardiovascular

[Despacho n.º 12529/2014 - Diário da República n.º 197/2014, Série II de 2014-10-13](#)

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Estabelece disposições no âmbito da Serviços Partilhados do Ministério da Saúde, EPE (SPMS, EPE), referentes aos Contratos Públicos de Aprovisionamento (CPA) que determinam as condições de fornecimento de medicamentos do sistema nervoso cerebrospinal, exceto: anestésicos, relaxantes musculares, analgésicos, antipiréticos, antidepressores e antipsicóticos

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Estabelece disposições no âmbito da Serviços Partilhados do Ministério da Saúde, EPE (SPMS, EPE), referentes aos Contratos Públicos de Aprovisionamento (CPA) que determinam as condições de fornecimento de medicamentos do aparelho digestivo

Nota - [Compromisso do INFARMED I.P. em dar resposta prioritária a pedidos de realização de ensaios clínicos de fase I e a estudos de BD/BE](#)

INFARMED

Atento o interesse para a atividade nacional e as características específicas destes estudos, o INFARMED I.P. assumiu o compromisso de dar **resposta prioritária** a ensaios clínicos de fase I e a estudos de **BD/BE** (biodisponibilidade/bioequivalência) relativamente a outros tipos de ensaios

Esclarecimento - [Notícia do jornal Diário de Notícias de 10-10-2014 - "Faltam 255 medicamentos nos hospitais e nas farmácias"](#)

[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

[Esclarecimento sobre a apólice de seguro](#)

CEIC

É entendimento jurídico, que as apólices de seguro não carecem de alteração decorrente da entrada em vigor da nova Lei n.º 21/2014, de 16 de abril. Ou seja, as apólices contratadas ao abrigo da Lei n.º 46/2004, de 19 de agosto, mantêm-se na íntegra, pelo que permanecem válidas na sua plenitude, sem necessidade de qualquer alteração ou modificação.

Assim para as submissões de novos ensaios clínicos, a apólice de seguro terá de figurar a lei 21/2014. Caso contrário, o processo não será considerado válido.

Para submissões de alterações substanciais de ensaios clínicos cuja apólice de seguro tenha sido contratualizada em data anterior à publicação da lei é aceitável que os certificados emitidos ainda façam referência à lei 46/2014

Perguntas frequentes sobre publicidade relativa a serviços de saúde

ERS

A ERS considera oportuno disponibilizar informação, em formato de [perguntas e respostas frequentes](#), sobre publicidade relativa a serviços de saúde

[Council conclusions on measures in support of investment in Europe](#)

CONSELHO
EUROPEU

[Proposal for a regulation of the European Parliament and of the Council amending Regulation \(EC\) No 726/2004](#) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

COMISSÃO
EUROPEIA

[Proposal for a Regulation](#) of the European Parliament and of the Council on veterinary medicinal products

[Commission staff working document](#) - Impact assessment

[Commission staff working document](#) - Executive summary of the impact assessment

[The Economic Adjustment Programme for Portugal. 2011-2014](#)

Report [The Economic Adjustment Programme for Portugal. 2011-2014](#)

[Summary for non-specialists](#)

This report by the European Commission services assesses the overall implementation of the Economic Adjustment Programme for Portugal and sets out future policy challenges for the Portuguese economy.

This report provides a general overview and assessment of the Portuguese economy under its 2011-2014 EU/IMF adjustment programme and the remaining challenges ahead.

Overall, despite challenging circumstances, Portugal's implementation of its programme over the last three years has succeeded in improving public finances, stabilising the financial sector, and setting the economy onto a path towards recovery.

(V. pág. 44 – 47 e 77 e seguintes)

Consulta Pública - [A modern framework for standardisation involving intellectual property rights](#)

Topic and objective: The objective of this consultation is to gather information and views on the interplay between standardisation and intellectual property rights (IPR) such as patents.

[Driving Health and Growth in Europe: European Pharmaceutical Trade Body EFPIA Sparks Discussion with #HealthyEU Conference](#)

EFPIA

EFPIA is pleased to announce today the successful conclusion of its first #HealthyEU Conference: Health Driving Growth in Europe. The aim of the event was to advance the conversation for boosting health and economic growth for Europe.

Transparency in Pharmaceuticals” – [SFEE Disclosure Code](#)

EFPIA Member Association SFEE (The Hellenic Association of Pharmaceutical Companies) last week introduced a new code of industry self-regulation, in line with the EFPIA Disclosure Code. Through the new Disclosure Code, which was formally adopted by the General Assembly of SFEE, member pharmaceutical companies, based in Greece or abroad, commit themselves to disclose all the details of their interactions with Healthcare Professionals (CRPs) and the Healthcare Organisations (HCOs).

Human Medicines | Scientific guideline: Draft - [Concept paper on the need for revision of the points to consider on the clinical investigation of new medicinal products for the treatment of acute coronary syndrome](#)

EMA

An update of the Committee for Medicinal Products for Human Use points to consider on new medicinal products for the treatment of acute coronary syndrome is foreseen. This document covers a number of points that are proposed to be addressed in the update.

Human Medicines | Regulatory and procedural guideline: [European Medicines Agency guidance for applicants seeking scientific advice and protocol assistance](#) (updated)

This guidance document addresses a number of questions that users of the Scientific Advice or Protocol Assistance procedures may have.

It provides an overview of the procedure to obtain Scientific Advice or Protocol Assistance and gives guidance to companies in preparing their request. This guidance document also explains the scope and nature of Scientific Advice and Protocol Assistance. It will enable companies to submit requests which are in conformity with Scientific Advice Working Party (SAWP) requirements and which can be validated and evaluated quickly and efficiently.

Human Medicines | Regulatory and procedural guideline: [Initial notices for parallel distribution – September 2014](#)

Human Medicines | Regulatory and procedural guideline: [Dossier requirements for centrally authorised products](#) (updated)

Human Medicines | Report: [Applications for new human medicines under evaluation by the CHMP: October 2014](#)

Human Medicines | Scientific guideline: [Reflection paper on the requirements for selection and justification of starting materials for the manufacture of chemical active substances](#)

This reflection paper aims to clarify some of the expectations of EU competent authorities arising from the guidance found in ICH Q11 (Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)¹ regarding the information to be submitted in marketing authorisation dossiers to justify the selection of starting materials.

Human Medicines | Regulatory and procedural guideline: [Draft functional specifications for the European Union portal and European Union database to be audited](#)

The Clinical Trials Regulation has opened a new era for the conduct of clinical trials in the European Union (EU). One of the main features of the Regulation is the creation of the EU portal and the EU database for clinical trials, which are intended to simplify and harmonise the submission, assessment and reporting of clinical trials. This Regulation gives the Agency the responsibility to prepare, in collaboration with the Member States and the European Commission, the functional specifications for these systems. The application of the Regulation will take place after an audit of the EU portal and the EU database has shown these systems are fully functional. This audit will be based on the functional specifications outlined in this document

CMDH

HMA

[Advice from CMDh](#) [[Track version](#)]

[Update - Q&As On Requests For Advice From CMDH](#)

This Question and answers section gives advice on regulatory issues in connection with the Mutual Recognition and Decentralised 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](#)

[Overview of timetables 2015](#)

This document was produced by the CMDh as a guidance to inform Applicants of the possible timetables for the applications referred to the CMDh, in accordance with Article 29(1) of Directive 2001/83/EC, as amended and Article 13 of Regulation (EC) No 1234/2008.

Decentralised Procedures

[Recommendations on submission dates for Applicants of the DCP](#)

Mutual Recognition Procedure

[Recommendations on submission dates for Applications of the Mutual Recognition Procedure](#)

Validation Procedure

[Procedural advice: Automatic validation of MR/Repeat-use/DC Procedures](#)

[CMDh Best Practice Guide on the compilation of the dossier for New Applications submitted in Mutual Recognition and Decentralised Procedures](#)

[CMDh Best Practice Guide for the Public Assessment Report and Summary Public Assessment Report in MRP/DCP](#)

Information on applications referred in accordance with Article 30(2) of Directive 2001/83/EC - [Tracking table](#)

National Competent Authorities

[Information on national timeslot booking systems and recommendations for requests to act as RMS](#)

The Heads of Medicines Agencies' Task Force on Resources in DCP in cooperation with CMDh has developed a common request form to be used when asking a National Competent Authority (NCA) to act as Reference Member State in a decentralised procedure. The Heads of Medicines Agencies has agreed to publish the request form on the CMDh website as well as on all national competent authorities websites

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