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SAÚDE

LEGISLAÇÃO

Resolução da Assembleia da República n.º 48/2014. D.R. n.º 109, Série I de 2014-06-06 **Assembleia da República** Recomenda ao Governo que reforce o estudo das necessidades e devidas respostas no âmbito dos Cuidados Paliativos Pediátricos e que implemente as medidas necessárias à disponibilização efetiva desses cuidados no nosso País	NACIONAL
Decreto-Lei n.º 87-A/2014. D.R. n.º 104, 2.º Suplemento, Série I de 2014-05-30 **Ministério da Saúde** Procede à primeira alteração ao Decreto-Lei n.º 19/2014, de 5 de fevereiro, alargando o prazo de escoamento dos medicamentos	

REGULAÇÃO

Despacho n.º 7444/2014. D.R. n.º 109, Série II de 2014-06-06 **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 GASES MEDICINAIS E OUTROS	MINISTÉRIO DA SAÚDE
Despacho n.º 7279-A/2014. D.R. n.º 106, Suplemento, Série II de 2014-06-03 **Ministério da Saúde - Gabinete do Ministro** Determina a elaboração de um Relatório de Coordenação da Reforma Hospitalar	
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	INFARMED
Lista de entrada em vigor dos CPAs 02-06-2014	SPMS
Lei dos Compromissos e Pagamentos em Atraso Lista das entidades do sector empresarial do Estado da área da Saúde (reporte de abril/2014) que se encontram em incumprimento nos termos dos n.ºs 5 e 6 do art.º 7.º do Decreto-Lei n.º 127/2012, de 21 de junho	DGO
Report to the European Commission on companies and products that have benefited from any of the rewards and incentives in the Paediatric Regulation and on the companies that have failed to comply with any of the obligations in the Regulation	COMISSÃO EUROPEIA

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.

Medicines for Children - Responses to the public consultation on the Commission guideline on paediatric investigation plans

Public responses to the above-mentioned public consultation - summary of the responses

INFARMED. National Authority of Medicines and Health Products Parque da Saude, PT

One-year report on human medicines pharmacovigilance tasks of the European Medicines Agency

The report on the pharmacovigilance tasks of the European Medicines Agency that were completed the during the first year of application of the EU's new pharmacovigilance legislation is available here

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Parecer do Comité Económico e Social Europeu sobre o **Pacote relativo ao investimento na inovação**

COMITÉ ECONÓMICO E SOCIAL EUROPEU

Strategy Paper : Health & Growth - Working together for a healthy Europe

EFPIA

European healthcare systems are at a tipping point, driven by the increasing burden of providing world-class care for populations that are living longer – often with one or more chronic diseases – at a time when austerity measures are putting pressure on healthcare spending generally, and medicines expenditure in particular.

Human Medicines | Regulatory and procedural guideline: Draft detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency

EMA

Scientific and medical literature is an important source of information on suspected adverse reaction case reports (also referred to as individual case safety reports). Currently, for active substances included in more than one medicinal product for human use, literature cases are reported in adverse reaction case reports in a duplicative way by marketing-authorisation holders (MAHs) in the European Economic Area (EEA), which is based on their obligation to monitor scientific and medical literature as outlined in the Good Pharmacovigilance Practices (GVP) guideline, Module VI 'Management and reporting of adverse reactions to medicinal products'.

News | European Medicines Agency selects first two medicines to be included in its adaptive licensing pilot project

The European Medicines Agency has received 20 applications so far as part of its adaptive licensing pilot project. Following an in-depth review of nine of these applications, the Agency has selected the first two medicines to be included in the pilot. A further four applications are potential candidates for the pilot and may be considered at a later stage. The other three applications were not considered suitable for the pilot and the remaining eleven are currently being evaluated.

This is the first wave of medicine development programmes to be considered for this project and the Agency continues to accept applications from interested companies

Human Medicines | Scientific guideline: Guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations ,

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Human Medicines | Scientific guideline: Addendum to EMA/CHMP/CVMP/QWP/17760/2009 Rev 1: Defining the Scope of an NIRS Procedure

Human Medicines | Regulatory and procedural guideline: Guideline on the acceptability of names for human medicinal products processed through the centralised procedure, adopted

Human Medicines | Regulatory and procedural guideline: Guidance for the template for the qualified person's declaration concerning GMP compliance of active substance manufacture "The QP declaration template"

Human Medicines | Q&A: Type IA variations (updated)

Human Medicines | Scientific guideline: Final guideline on influenza vaccines – Quality module, adopted

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

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

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