saude@vda.pt

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SAÚDE

REGULAÇÃO

HMA

EMA/CMDh explanatory notes on Variation Application Form - Human medicinal products only

Questions & Answers | Variations

Core SmPC/PL | Hormone Replacement Therapy - Core Package Leaflet

PSUR Work Sharing and Synchronisation Project | List of substances under PSUR Work Sharing scheme and other substances contained in Nationally Authorised Products with DLP synchronised-Excel

MINISTÉRIO DAS FINANÇAS E DA SAÚDE

Despacho n.º 15013/2014 - Diário da República n.º 239/2014, Série II de 2014-12-1163528731

Ministérios das Finanças e da Saúde - Gabinetes da Secretária de Estado do Tesouro e do Secretário de Estado da Saúde

Aumento de capital dos hospitais, EPE em espécie (conversão dívidas em capital)

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

ACSS

Circular Normativa n.º28 de 25/11/2014 - Lei n.º 8/2012, de 21 de fevereiro - **aprova as regras aplicáveis aos montantes a considerar nos fundos disponíveis, à assunção de compromissos e aos pagamentos em atraso das entidades públicas do SNS.**

Circular Normativa n.º27 de 30/09/2014 - C**uidados de Saúde Transfronteiriços** - Linhas de orientação para a adoção de medidas de restrição o acesso a cuidados de saúde no SNS - artº 7 da Lei n.º 51/2014, de 25 de agosto.

SPMS

Concurso 2014 / 22 - seringas, agulhas e contentores

- Programa de Concurso
- Caderno de Encargos

Listas das entidades (Administração Central, Administração Regional, Sector Empresarial do Estado da área da Saúde, Municípios, Segurança Social), 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. Lista das entidades do sector empresarial do Estado da área da Saúde (reporte de outubro/2014)	DGO
Projeto de conclusões do Conselho sobre a vacinação enquanto instrumento eficaz no domínio da saúde pública **Conclusões do Conselho sobre a segurança dos pacientes e a qualidade dos cuidados de saúde**, incluindo a prevenção e o controlo de infeções associadas aos cuidados de saúde e à resistência antimicrobiana **Conclusões do Conselho sobre a inovação em benefício dos doentes**	CONSELHO EUROPEU
Jobs, Growth and Investment - Investment Plan (Junker's Plan) Report of the Task Force on investment in the EU Project List - Part 1 Project List - Part 2 (Portugal – página 68) Project List - Part 3 **Common approach for definition of reportable serious adverse events and reactions** as laid down in the Directive 2002/98/EC1 (**the blood directive**) and Commission Directive 2005/61/EC2 version 5 (2014)	COMISSÃO EUROPEIA
Human Medicines | Scientific guideline: Guideline on the use of phthalates as excipients in human medicinal products The European Commission has decided to revise the "Guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00)" and a concept paper on the need for such revision has been published in 2012 (EMA/CHMP/SWP/888239/2011). Phthalates used in medicinal products is one of the priority among excipients under revision. This guideline covers the phthalates most commonly used as excipients in medicinal products authorised in the EU. The recommendations provided in this document apply to new and existing marketed medicinal products. **Human Medicines | Report: Applications for new human medicines under evaluation by the CHMP: December 2014** This document lists information on applications for centralised marketing authorisation for human medicines that the European Medicines Agency has received for evaluation. It includes the international non-proprietary names (INN) and therapeutic areas for all new innovative medicines under evaluation by the Committee for Medicinal Products for Human Use (CHMP). For generic and biosimilar medicines, it includes the INN (active moiety only, with no information on salt, ester or derivative) and therapeutic area.	EMA

Human Medicines | Report: Medicinal products for human use: Monthly figures - November 2014

This document provides current information related to the volume and evaluation of marketing authorisation and post-authorisation applications for medicinal products for human use received by the European Medicines Agency.

Human Medicines | Regulatory and procedural guideline: Compilation of Community procedures on inspections and exchange of information (updated)

Human Medicines | Regulatory and procedural guideline: Initial notices for parallel distribution – November 2014

Human Medicines | Classification and analysis of the good clinical practice (GCP) inspection findings of GCP inspections conducted at the request of CHMP

The information included in this report refers to the inspections carried out on behalf of the Agency from January 2000 to December 2012.

Report: Workshop report - Benefit-risk communication to medicines users: How can regulators best meet the information needs of patients and healthcare professionals?

Human Medicines | Press Release: GVK Biosciences review: some Member States suspend marketing authorisations for concerned medicines

Update on review of studies performed at GVK Biosciences site in Hyderabad, India

Some Member States have decided to suspend the marketing authorisations of medicines that have been authorised on the basis of studies conducted at the GVK Biosciences site in Hyderabad, India.

The European Medicines Agency (EMA) is currently reviewing findings of non-compliance with good clinical practice at this site and determining their impact on medicines authorised on the basis of studies performed at the site. These suspensions taken at national level are precautionary measures until the review is finalised.

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