VIEIRA DE ALMEIDA & Associados Sociedade de Advogados, RL

EM DESTAQUE

SAÚDE

De 10 a 14 setembro de 2012

saude@vda.pt

SAÚDE

REGULAÇÃO

MINISTÉRIO DA SÁUDE

Portaria n.º 276/2012. D.R. n.º 177, Série I de 2012-09-12

Ministérios das Finanças e da Saúde

Cria o Centro Hospitalar do Oeste (CHO), que integra o Centro Hospitalar de Torres Vedras e o Centro Hospitalar do Oeste Norte (CHON)

Portaria n.º 277/2012. D.R. n.º 177, Série I de 2012-09-12

Ministério da Saúde

Define o horário padrão de funcionamento das farmácias de oficina, regula o procedimento de aprovação e a duração, execução, divulgação e fiscalização das escalas de turnos, bem como o valor máximo a cobrar pelas farmácias de turno pela dispensa de medicamentos não prescritos em receita médica do próprio dia ou do dia anterior, e revoga a Portaria n.º 31-A/2011, de 11 de janeiro

INFARMED

Publicação para efeitos do artigo 15º-A do Decreto -Lei n.º 176/2006, de 30 de Agosto (novos pedidos de autorização de introdução, ou registo, no mercado de medicamentos genéricos

SPMS

Aviso CP 2012/5 - No dia 11/09/2012, No dia 11/09/2012 entram em vigor os novos CPA relativos a medicamentos anti-infeciosos: exceto antivíricos e antifúngicos

Aviso CP 2012/41 - No dia 11/09/2012 entram em vigor os novos CPA relativos a medicamentos anti-infeciosos:antivíricos e antifúngicos

Aviso CP 2012/22 - No dia 11/09/2012, entram em vigor os novos CPA relativos a seringas, agulhas e contentores

Aviso Fornecedores - O anexo I e II ao CCP, foram alterados a partir de 13 de agosto (anexo I e II ao Código dos Contratos Públicos - alterações do DL 149/2012 de 12/07)

FMI, BCE, CE

Statement by the EC, ECB, and IMF on the Fifth Review Mission to Portugal (versão portuguesa)

Statement by Vice President Rehn following the conclusion of the fifth review mission to Portugal

COMISSÃO EUROPEIA

Publication of chapter 1, chapter 7 and Annex 2 of the detailed guidelines of the good manufacturing practices:

- Chapter 1 on Pharmaceutical Quality System is amended in order to align with the concepts and terminology described in the ICH Q10 tripartite guideline on Pharmaceutical Quality System. The title of the chapter itself is also changed accordingly.
- Chapter 7 on Outsourced activities is revised in order to provide updated guidance on outsourced GMP regulated activities beyond the current scope of contract manufacture and analysis operations and in view of the ICH Q10

guideline on the Pharmaceutical Quality System The title of the Chapter has been changed to reflect this.

> Annex 2 on Manufacture of Biological active substances and Medicinal Products for Human Use is revised as a consequence of the restructuring of the GMP Guide, new manufacturing technology and concepts, the increased breadth of biological medicinal products to include several new product types such as transgenic derived products and the Advanced Therapy Medicinal Products, (ATMPs) together with associated new legislation.

(Deadline for coming into operation: 31 January 2013)

EAHP and EFPIA to work together on the future of medicines bar coding to the single unit

EFPIA

The European Association of Hospital Pharmacists (EAHP) and European Federation of Pharmaceutical and Industry Associations (EFPIA) have recently agreed to work towards a joint vision on the future of medicines bar coding to the single unit administered in hospitals.

EMA

Human Medicines | Scientific guideline: Draft Guideline on quality of transdermal patches (Consultation end date 15/03/2013)

This guideline together with the new Guideline on Quality of Oral Modified Release Products replaces the Note for Guidance on Modified Release products: A: Oral dosage Forms B: Transdermal Dosage Forms. Part I (Quality).

Human Medicines | Scientific guideline: Draft Guideline on quality of oral modified release products (Consultation end date 15/03/2013)

This guideline together with the Guideline on Quality of Transdermal Patches replaces Note for Guidance on Modified Release products: A: Oral dosage Forms B: Transdermal Dosage Forms. Part I (Quality).

Human Medicines | Regulatory and procedural guideline: Reporting requirements of individual case safety reports applicable to marketing-authorisation holders during the interim period (updated)

Explanatory note on fees payable to the European Medicines Agency (updated)

Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures (updated)

Human Medicines | Regulatory and procedural guideline: Reporting requirements of individual case safety reports applicable to marketing-authorisation holders during the interim arrangements (updated)

Human Medicines | Regulatory and procedural guideline: Procedure for orphan medicinal product designation - general principles (updated)

Human Medicines | Regulatory and procedural guideline: Initial notices for parallel distribution – August 2012

Mock-ups, Specimens and Samples for new applications

In accordance with Article 8 of Directive 2001/83/EC, a mock-up of the sales presentation of the medicinal product, together with the proposed package leaflet should be included with the application. In addition, Member States may require specimens of the sales presentation of the medicinal product to be submitted, in order to check compliance with the relevant articles in Title V of Directive 2001/83/EC.

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