saude@vda.pt

**19 a 23 de agosto de 2013**

# SAÚDE

## REGULAÇÃO

Aviso n.º 10478/2013. D.R. n.º 162, Série II de 2013-08-23

**Ministério das Finanças - Direção-Geral do Tesouro e Finanças**

Taxa supletiva de juros moratórios relativamente a créditos de que sejam titulares empresas comerciais, singulares ou coletivas, em vigor no 2.º semestre de 2013

MINISTÉRIO DAS FINANÇAS

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

INFARMED

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Circular Normativa nº. 27 de 14/08/2013 - **Registo de Dispositivos Médicos nos termos do Despacho 15371/2012 de 26 de novembro** (Hospitais EPE, SPA, Unidades Locais de Saúde, PPP e H Prelada)

> Folha de Codificação DM - 2013

ACSS

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**Aviso - 2013/50 – medicamentos** - No dia 23/08/2013 entraram em vigor os novos contratos públicos de aprovisionamento, os quais já se encontram disponíveis no catálogo

**Aviso CP 2013/18 - medicamentos grupo 4 – sang** - No dia 23/08/2013 entraram em vigor os novos contratos públicos de aprovisionamento, os quais já se encontram disponíveis no catálogo

SPMS

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**EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organisations**

Adopted by the EFPIA Statutory General Assembly of 24 June 2013, and requiring implementation in national codes by 31 December 2013 - Final Edited Version Following General Assembly Approval

Healthcare professionals and healthcare organisations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. Healthcare professionals and healthcare

EFPIA

organisations should be fairly compensated for the legitimate expertise and services they provide to the industry.

EMA

**Human Medicines | Scientific guideline:** International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline M8 on eCTD – questions and answers,

**Human Medicines | Regulatory and procedural guideline:** Guidance on format of the risk-management plan in the European Union for generics (updated)

This guidance covers the Parts and modules of the RMP which may be required for applications concerning generics in the EU.

**Human Medicines | Regulatory and procedural guideline:** Guidance on format of the risk-management plan in the European Union part II: Module SII - Non-clinical part of the safety specification (updated)

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices: Risk Management Systems. This module should present a summary of the important non-clinical safety findings.

**Human Medicines | Regulatory and procedural guideline:** Guidance on format of the risk-management plan in the European Union part II: Module SIV - Populations not studied in clinical trials

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices: Risk Management Systems. This module should discuss the limitations of the clinical trial population in relation to predicting the safety of the medicinal product(s) in the market place.

**Human Medicines | Regulatory and procedural guideline:** Guidance on format of the risk-management plan in the European Union part II: Module SVIII - Summary of the safety concerns (updated)

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices: Risk Management Systems.

**Human Medicines | Regulatory and procedural guideline:** Guidance on format of the risk-management plan in the European Union part VI: Summary of activities in the risk-management plan by product (updated)

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices: Risk Management Systems. A separate RMP Part VI should be provided for each product in the RMP.

**Human Medicines | Regulatory and procedural guideline:** Guidance on format of the risk-management plan in the European Union – in integrated format (updated)

**Human Medicines | Points to consider** for assessors, inspectors and EMA inspection coordinators on the identification of triggers for the selection of applications for “routine” and/or “for cause” inspections, their investigation and scope of such inspections

This document provides a non-exhaustive overview of the potential pre-defined factors that can be used for the selection of marketing authorisation applications (MAAs) to be part of a programme of routine inspections and non-exhaustive overview of potential triggers that can be detected at the different stages of the assessment process and that can help the assessor to decide on the need for “for cause” inspections and be used to prepare an inspection .

This document does not cover triggers specific for inspection of bioequivalence trials

**Human Medicines | Regulatory and procedural guideline:** Good-clinical-practice-inspection guidance on triggers for inspections of bioequivalence trials

The following checklist is designed to be used by assessors when reviewing bioequivalence studies. Missing documentation should first be solved through questions to the applicant. If triggers are identified after the completion of the checklist which have a major impact on the quality of the data and may result in a potential serious risk to public health, the assessor is advised to have further discussions with their GCP Inspectorate.

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**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