VIEIRA DE ALMEIDA & Associados Sociedade de Advogados, RL

EM DESTAQUE

SAÚDE

1 e 5 de julho de 2013

saude@vda.pt

SAÚDE

REGULAÇÃO

Despacho n.º 8487-C/2013. D.R. n.º 123, 3.º Suplemento, Série II de 2013-06-28 **Ministérios da Economia e do Emprego e da Saúde - Gabinetes dos Secretários de Estado do Empreendedorismo, Competitividade e Inovação e da Saúde** Aprova os preços de referência unitários dos grupos homogéneos de medicamentos, para vigorar no trimestre civil que se inicia em 1 de julho de 2013	MINISTÉRIO DA SAÚDE
Relatório de Análise do Mercado de Medicamentos no âmbito do Serviço Nacional de Saúde, em Meio Hospitalar (CHNM) - maio **Relatório de Análise do Mercado de Medicamentos, em Ambulatório** - maio **Circular Informativa N.º 152/CD/8.1.7. Data: 28/06/2013 -** Medicamentos contendo derivados da ergotamina - restrição da utilização **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
Aviso CPA **2012/36 - Dispositivos Medicos Diversos** - No dia 05/07/2013 entram em vigor os novos contratos públicos de aprovisionamento, os quais já se encontram disponíveis no catálogo	SPMS
Estudo relativo ao novo regime jurídico das taxas moderadoras - a ERS procedeu ao estudo das principais alterações introduzidas, e, nesse âmbito, à análise do processo de implementação do novo regime jurídico e dos impactos no perfil dos utentes isentos, no acesso a cuidados de saúde primários e hospitalares do SNS e no financiamento global do SNS.	ERS
Notice to applicants, update of variations application forms (human and veterinary) The Notice to applicants, volumes 2 and 6 have been updated with the publication of the updated application form for the submission of variations. The new form reflects the changes in the Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use	COMISSÃO EUROPEIA

and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures.

> Volume 2C : Human medicinal products - Regulatory Guidelines
> Volume 6C : Veterinary medicinal products - Regulatory Guidelines

The electronic version of the new variation application forms will be made available by the European Medicines Agency at http://esubmission.emea.europa.eu/eaf/index.html

Update of application form for renewal of marketing authorisation (human and veterinary)

The Notice to applicants, volumes 2C and 6C Regulatory guidelines have been updated with the publication of the updated application form for renewal of marketing authorisation.

The update consists in adding Croatia within the form.

> Volume 2C : Human medicinal products - Regulatory Guidelines
> Volume 6C : Veterinary medicinal products - Regulatory Guidelines

In addition, the updated version of the CMDh Best Practice Guide on the processing of renewals in the MRP/DCP from April 2013, which is already available on CMDh website, is published under volume 2C.

Decisão da Comissão, de 28 de junho de 2013, que nomeia os membros e os suplentes do Comité das Terapias Avançadas a fim de representarem os clínicos e as associações de doentes

HMA

Q&A - PSURs (Transitional arrangements for nationally authorised products) [Tracked]

CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008 (June 2013)

Q&A - Pharmacovigilance Legislation

Worksharing on Article 45 - List of the active substances included in the work-sharing procedure

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

Contact Points - HMA provided a List to assist pharmaceutical companies in identifying a contact point for requests for variation grouping numbers in each Member State.

EMA

Human Medicines | List of medicinal products under additional monitoring

Human Medicines | Scientific guideline: Draft concept paper on the need for revision of the note for guidance on manufacture of the finished dosage form

This concept paper addresses the need to update and revise the CPMP/QWP/486/95 note for guidance on manufacture of the finished dosage form (1). This guideline was originally adopted in September 1995 and came into operation in 1st April 1996. Since then, the references to directives and format of dossier has been changed, new guidance (i.e. ICH Q8(2), Q9(3), Q10(4)) has been developed. Also the manufacture of finished dosage form has spread worldwide and terms like holding time and bulk product are now important part of the description of manufacturing process.

Human Medicines | Regulatory and procedural guideline: Dossier requirements for centrally authorised products

Human Medicines | Scientific guideline: Draft concept paper on the need for revision of the note for guidance on manufacture of the finished dosage form (Consultation end date 31/12/2013)

This concept paper addresses the need to update and revise the CPMP/QWP/486/95 note for guidance on manufacture of the finished dosage form (1).

Human Medicines | Regulatory and procedural guideline: Dossier requirements for centrally authorised products

Human Medicines | Regulatory and procedural guideline: Initial notices for parallel distribution – June 2013

Human Medicines | Notification of a change for parallel distribution of a centrally authorized medicinal product (updated).

Human Medicines | Application form for European Medicines Agency certificates of medicinal products (updated).

Human Medicines | Notification of annual update to the parallel distribution of a centrally authorized medicinal product (updated).

Human Medicines | Scientific guideline: Draft note for guidance on clinical investigation of medicinal products for treatment of asthma, (deadline for comments – December 31, 2013).

Human Medicines | Regulatory and procedural guideline: Practical guidance on the extension of Commission decision annexes in the new accession country language (updated).

Human Medicines | Scientific guideline: Draft guideline on adjustment for baseline covariates (Consultation end date 31/12/2013)

The note for guidance on statistical principles for clinical trials (ICH E9) briefly addresses the problem of adjustment for covariates. It advises experimenters 'to identify the covariates expected to have an important influence on the primary outcome' and to specify 'how to account for them in the analysis in order to improve precision and to compensate for any lack of balance between groups'.

Human Medicines | **Scientific guideline:** Draft concept paper on the need for a reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development (Consultation end date 30/09/2013)

The reflection paper (RP) should provide an overview of statistical principles with a potential of useful application in the context of the comparison of quality attributes as mentioned above. For situations where a meaningful set of CQAs can be identified, the RP should give an overview of what statistical methods for the comparison are available, and which of those might be preferred under which circumstances (e.g. number of batches available).

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