saude@vda.pt

30 de março a 2 de abril de 2015

SAÚDE

REGULAÇÃO

CONSELHO DE MINISTROS

Resolução n.º 20/2015 - Diário da República n.º 63/2015, Série II de 2015-03-31

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia os membros do conselho de administração do Centro Hospitalar do Baixo Vouga, E. P. E.

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

SPMS

Consulta Pública - **Acordo Quadro de Auditoria e Certificação de SI na Saúde**

Concurso 2015 / 41 - Medicamentos antivíricos e antifúngicos

— Programa de Concurso

— Caderno de Encargos

CEIC

Aviso - Entrada em vigor da Portaria nº 63/2015

Alerta-se para a entrada em vigor da Portaria nº 63/2015, de 5 de março, que fixa as taxas que são devidas pelos atos prestados no âmbito da Lei n.º 21/2014, de 16 de abril, com novas regras, no próximo dia 20 de Abril de 2015.

Mais se recorda da necessidade de todos os processos entregues à CEIC a partir deste dia, inclusivé, serem entregues com o comprovativo de pagamento da taxa em vigor, sem o qual serão devolvidos na receção.

COMISSÃO EUROPEIA

Relatório Da Comissão Ao Parlamento Europeu E Ao Conselho relativo ao exercício da delegação conferida à Comissão nos termos da Diretiva 2001/83/CE do Parlamento Europeu e do Conselho, de 6 de novembro de 2001, que estabelece um código comunitário relativo aos medicamentos para uso humano e nos termos do Regulamento (CE) n.º 726/2004 do Parlamento Europeu e do Conselho, de 31 de março de 2004, que estabelece procedimentos comunitários de autorização e de fiscalização de medicamentos para uso humano e veterinário e que institui uma Agência Europeia de Medicamentos

74th meeting of the Pharmaceutical Committee, 17 March 2015

— The background documents and the presentations

Eudralex Volume 4

— Annex 15 - A new version of Annex 15 has been published. This version will become operational on 1 October 2015.

— New guidelines published:

- The guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use have been published. A risk assessment as set out in these guidelines should be carried out for excipients for authorised medicinal products for human use by 21 March 2016
- The guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use have also been published and come into operation on 21 September 2015.

Notice to applicant, Eudralex Volume 2C

The revision 14.1 of the Guideline on the packaging information of medicinal products for human use authorised by the Union is published

EMA

Human Medicines | Plasma-master-file certifications (updated)

Human Medicines | List of Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)

Human Medicines | Concept paper on clinical investigation of medicinal products for the treatment of Axial Spondyloarthritis

The concept of spondyloarthritis (SpA) includes ankylosing spondylitis (AS), psoriatic arthritis, arthritis/spondylitis with inflammatory bowel disease, reactive arthritis, as well as undifferentiated SpA. All of these can present with a predominantly peripheral or axial subtype.

Human Medicines | Notification of discontinuation of a paediatric development which is covered by an agreed paediatric-investigation-plan decision (updated)

Human Medicines | Submission deadlines for 2015-2016 for submitting a request for modification to an agreed paediatric investigation plan (updated)

Human Medicines | Submission deadlines for 2015-2016 for submitting a request for compliance check (updated)

Human Medicines | Submission deadlines for 2015 and 2016 for paediatric investigation plan applications, applications for waivers and answers to request for modification plan of the application (updated)

Human Medicines | Scientific guideline: Draft guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease

Since the publication of the CPMP guidance on clinical investigation of medicinal products for the treatment of venous thromboembolic disease [CPMP/EWP/563/98] in 2000 [2], there has been intense research in this field. An update of the mentioned guideline is considered necessary to adapt its content to current scientific knowledge and to harmonise it with the content of new or revised EMA guidelines related to clinical investigation with antithrombotics.

Human Medicines | Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures - Revised implementing rules to the Fee Regulation as of 1 April 2015

Human Medicines | Explanatory note on fees payable to the European Medicines Agency

Human Medicines | Scientific guideline: Guideline on clinical investigation of medicinal products for the treatment of multiple sclerosis

The present document is a general guidance on the development for medicinal products for the treatment of Multiple Sclerosis (MS) and should be read in conjunction with other EMA and ICH guidelines, which may apply to these conditions and patient populations.

Human Medicines | Scientific guideline: Draft Questions and answers on 'Guideline on the environmental risk assessment of medicinal products for human use'

Human Medicines | Scientific guideline: Draft concept paper on the need for revision of the guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials

This concept paper addresses the need to update and revise the CHMP/QWP/185401/2004 final guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials. This guideline was originally adopted on 23rd March 2006 and came into operation on 1st October 2006.

VeterinaryMedicines | Quality of medicines questions and answers: Part 1

These questions and answers address a number of questions that have been brought to the attention of the Joint Committee for Medicinal Products for Human Use / Committee for Medicinal Products for Veterinary Use Quality Working Party (QWP) by marketing-authorisation holders (MAHs) or European Economic Area (EEA) competent authorities, on matters related to the quality of medicines. They have been developed and are maintained by the QWP.

Veterinary Medicines | Quality of medicines questions and answers: Part 2

These questions and answers address a number of questions that have been brought to the attention of the Joint Committee for Medicinal Products for Human Use / Committee for Medicinal Products for Veterinary Use Quality Working Party (QWP) by marketing-authorisation holders (MAHs) or European Economic Area (EEA) competent authorities, on matters related to the quality of medicines. They have been developed and are maintained by the QWP.

Human Medicines | Elemental impurities in marketed products. **Recommendations for implementation**

Human Medicines | Scientific guideline: Final guideline on adjustment for baseline covariates in clinical trials

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’. It also cautions against adjusting for ‘covariates measured after randomisation because they may be affected by the treatments’.

— Overview of comments received on 'Guideline on adjustment for baseline covariates'

Human Medicines | Scientific guideline: Final reflection paper on the data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product

The present document reflects the current thinking of the CHMP. The principles spelled out in this reflection paper will be reviewed in light of the experience gained with regulatory submissions and contribution from stakeholders.

This reflection paper replaces the "Reflection paper on non-clinical studies for generic nanoparticle iron medicinal product applications" (EMA/CHMP/SWP/100094/2011).

— Overview of comments received on Reflection paper on the data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product

Human Medicines | Scientific guideline: Guideline on clinical investigation of medicinal products for the treatment of systemic lupus erythematosus and lupus nephritis

This document is intended to provide guidance on the clinical investigation of medicinal products for the chronic treatment of systemic lupus erythematosus (SLE), a complex autoimmune disease that can affect multiple organs.

Overview of external comments received on the 'Guideline on clinical investigation of medicinal products for the treatment of systemic lupus erythematosus, and lupus nephritis'

Variation Procedure | Chapter 4: CMDh BPG for the processing of Type IB Minor Variations (Notifications) in the Mutual Recognition Procedure

HMA

Q&A | Variations

Q&A | Pharmacovigilance Legislation

Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research

WHO

This report, with a focus on sustainable access to new medicines, reviews policies that affect medicines throughout their lifecycle (from research and development to disinvestment), examining the current evidence base across Europe. While many European countries have not traditionally required active priority-setting for access to medicines, appraising new medicines using pharmacoeconomics is increasingly seen as critical in order to improve efficiency in spending while maintaining an appropriate balance between access and cost–effectiveness. The study features findings from 27 countries and explores different ways that health authorities in European countries are dealing with high spending on new medicines, including methods such as restrictive treatment guidelines, target levels for use of generics, and limitations on the use of particularly expensive drugs.

— **Press Release:** New WHO report shows that transparency and cooperation help to reduce high prices for new medicines

As the number of new medicines introduced in Europe rises, governments are finding it increasingly difficult to afford them, according to a comprehensive study released today by the WHO Regional Office for Europe. The study illustrates the challenges for national health systems, with specific examples, and shows that few countries in the WHO European Region have mechanisms in place to evaluate the cost–effectiveness of new drugs; this hampers the value-assessment and decision-making processes

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