saude@vda.pt

28 de abril a 2 de maio de 2014

SAÚDE

LEGISLAÇÃO

NACIONAL

Lei n.º 22/2014. D.R. n.º 81, Série I de 2014-04-28

Assembleia da República

Vigésima alteração ao Decreto-Lei n.º 15/93, de 22 de janeiro, que aprova o regime jurídico aplicável ao tráfico e consumo de estupefacientes e substâncias psicotrópicas, aditando a substância 5 (2-aminopropil)indole à tabela anexa II-A e a substância 4 metilanfetamina à tabela anexa II-B

REGULAÇÃO

GOVERNO

Estratégia Orçamental

- Documento de Estratégia Orçamental 2014-2018
- Documento de Estratégia Orçamental 2014-2018 - Anexos

Prazos Médios de Pagamento de Instituições Públicas

- Prazos médios de pagamento - Hospitais EPE
- Prazos médios de pagamento - Hospitais SPA

MINISTÉRIO DA SAÚDE

Despacho n.º 5635-A/2014. DR 81 SÉRIE II, 1º SUPLEMENTO de 2014-04-28
Ministério da Saúde - Gabinete do Secretário de Estado da Saúde
Determina a comparticipação pelo Escalão A dos medicamentos destinados a portadores de ictiose

INFARMED

Caducidade das comparticipações (abril de 2014) - lista definitiva

Ao abrigo do n.º 1 da Circular n.º106/CD, de 07-07-2010, publica-se a lista definitiva de medicamentos para os quais foi decidida a caducidade da comparticipação por não comercialização no período de abril de 2014, por deliberação do Conselho Diretivo do INFARMED, I.P. datada de 16-04-2014, no uso das suas competências.

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

Decisão de Execução do Conselho, de 23 de abril de 2014, que aprova a atualização do programa de ajustamento macroeconómico de Portugal

CONSELHO EUROPEU

EMA

Human Medicines | Scientific guideline: Draft guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues

This guideline lays down the non-clinical and clinical requirements for recombinant insulin-containing products, including human insulin and insulin analogues (both referred to as insulin), claiming to be similar to another one already authorised (the reference medicinal product).

Human Medicines | Scientific guideline: Draft guideline on non-clinical local tolerance testing of medicinal products

Local tolerance testing is intended to support human exposure to a medicinal product (both active substance and excipient) at contact sites of the body following clinical use.

Human Medicines | Regulatory and procedural guideline: Appendix IV - Terms for batch number and expiry date to be used on outer and / or inner labelling

Human Medicines | Questions and answers on quality of herbal medicinal products / traditional herbal medicinal products (updated)

Human Medicines | Register of deadlines to put a medicinal product on the market in accordance with Article 33 of the Paediatric Regulation (updated)

Human Medicines | Opinion template (annex I and II) (updated)

Human Medicines | Scientific guideline: Draft guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission

Guidance is provided on data requirements for process validation of biotechnology-derived proteins used as active substance in the manufacture of medicinal products. This guideline covers process evaluation and verification studies for the upstream and downstream process, in the context of a marketing authorisation application or a variation application if relevant.

Scientific guideline | Regulatory and procedural guideline: Draft European Union individual case safety report (ICSR) implementation guide

This guidance specifies the technical requirements and the process of transmission of Individual Case Safety Reports (ICSRs) and is applicable to all stakeholders, which are exchanging ICSRs electronically within the EEA.

Human Medicines | Report: 2013 annual report on EudraVigilance for the European Parliament, the Council and the Commission

Scientific guideline | Regulatory and procedural guideline: Compilation of Quality Review of Documents decisions on stylistic matters in product information (updated)

Human Medicines | Regulatory and procedural guideline: Compilation of Quality Review of Documents decisions on stylistic matters in product information (updated)

Scientific guideline | Scientific guideline: Draft - Guideline on the role of the pathological Complete Response as an endpoint in neoadjuvant breast cancer studies

COMISSÃO EUROPEIA

Explanatory note on the Joint Procurement Initiative

The EPSCO Council of 7 December 2010 approved the "Technical document on a mechanism for joint procurement of pandemic influenza vaccines and antivirals allowing MS, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry".

The need to create a mechanism for joint procurement was also expressed by the European Parliament in a resolution of 8 March 2011.

With this background the Commission took the necessary steps for the preparation of a mechanism for Joint Procurement of vaccines in the frame of a future pandemic.

EU Member States have participated in joint procurements previously, for example, common purchase procedures have been launched by several MS already in sectors such as defence and transport.

At EU level the first joint procurement involving all MS was organised by DG CLIMA, it is called "Joint Procurement Agreement of common auction platforms" and deals with the organisation of the auctioning of Co2 certificates in each MS.

Joint procurement at EU level needs to comply with EU procurement law, the EU Financial Regulation and the accompanying 'Rules of Application'. Using EU law as the framework for the joint procurement simplifies the choice of applicable law between MS and also enables the Commission to coordinate and facilitate the implementation of the joint procurement mechanism.

Responses to the public consultation on the Commission guideline on paediatric investigation plans

A public consultation took place from 9 October 2013 to 3 January 2014 on the Commission guideline on paediatric investigation plans.

Overall, the Commission received 26 responses. A summary of the comments as well as the replies are here.

The Economic Adjustment Programme for Portugal - Eleventh Review

The report assesses compliance with the terms and conditions set out in the Memorandum of Understanding as updated following the Tenth Review of the Portuguese Economic Adjustment Programme. The assessment is based on the findings of a joint European Commission (EC)/European Central Bank (ECB)/International Monetary Fund (IMF) staff mission to Lisbon between 20 February and 28 February 2014. The mission concluded that the programme implementation is broadly on track. The 2013 budget deficit was 4.9 percent of GDP, significantly below the Programme target of 5.5 percent of GDP. Most of the economic indicators point to a continued economic recovery and the authorities are committed to implement the required fiscal and structural reforms to recuperate sustainable growth. The Programme's financing envelope remains sufficient. Approval of the conclusions of this review will allow the disbursement of EUR 2.5 billion (EUR 1.6 billion by the EU and EUR 0.9 billion by the IMF), bringing the total amount disbursed to Portugal to EUR 77 billion representing roughly 97 percent of total available financial assistance.

- The Economic Adjustment Programme for Portugal - Eleventh Review
- Summary for non-specialists

Resumo das decisões da União Europeia relativas às autorizações de introdução no mercado dos medicamentos de 1 de março de 2014 a 31 de março de 2014*[Publicado nos termos do artigo 13.o ou do artigo 38.o do Regulamento (CE) n.o 726/2004 do Parlamento Europeu e do Conselho]*

Resumo das decisões da União Europeia relativas às autorizações de introdução no mercado dos medicamentos de 1 de março de 2014 a 31 de março de 2014*(Decisões adotadas nos termos do artigo 34.o da Directiva 2001/83/CE ou do artigo 38.o da Directiva 2001/82/CE)*

Substances considered as not falling within the scope of Regulation (EC) No. 470/20091, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

Public consultation on a draft Scientific Opinion on the essential composition of infant and follow-on formulae

EFSA

EFSA has launched an open consultation on the draft scientific opinion on the essential composition of infant and follow-on formulae. This document considers which nutrients/substances can be considered as essential constituents of infant and/or follow-on formula and proposes minimum and maximum contents for these nutrients/substances.

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