SAÚDE

LEGISLAÇÃO

NACIONAL

Portaria n.º 96/2014. D.R. n.º 85, Série I de 2014-05-05

Ministério da Saúde

Regulamenta a organização e funcionamento do Registo Nacional do Testamento Vital (RENTEV)

REGULAÇÃO

GOVERNO

Um Estado Melhor

Guião com orientações para a reforma do Estado. Trata-se da versão final, após audição de partidos políticos, parceiros sociais e parceiros da economia social

Saúde: propostas de eficiência para garantir a universalidade do acesso (página 73 e seg.)

A área da Saúde constitui, compreensivelmente, uma das maiores preocupações dos portugueses e tem de ser, evidentemente, uma das áreas mais cuidadas pelo Estado.

A gestão do Programa de ajustamento

Saúde (página 76 e seguintes)

MINISTÉRIO DA SAÚDE

Despacho n.º 6045/2014. D.R. n.º 89, Série II de 2014-05-09

Ministério da Saúde - Gabinete do Secretário de Estado da Saúde

Estabelece disposições no âmbito da Serviços Partilhados do Ministério da Saúde, E. P. E. (SPMS, E. P. E.), referentes aos contratos públicos de aprovisionamento (CPA) que determinam as condições de fornecimento de medicamentos do aparelho respiratório

Deliberação (extrato) n.º 1037/2014. D.R. n.º 86, Série II de 2014-05-06

Ministério da Saúde - Centro Hospitalar Psiquiátrico de Lisboa

Regulamento Interno do Centro Hospitalar Psiquiátrico de Lisboa (CHPL)

Despacho n.º 5855/2014. D.R. n.º 85, Série II de 2014-05-05

Ministério da Saúde - Direção-Geral da Saúde

Determina a obrigatoriedade de utilização da aplicação informática de suporte ao

SINAVE para notificação de doenças transmissíveis e outros riscos em saúde pública

INFARMED

Deliberação n.º 051/CD/2014 - Atualização das tabelas com a classificação quanto à duração da terapêutica

Atualização das tabelas n.ºs 1 e 2 e as designações do anexo à Portaria n.º 1471/2004, de 21 de dezembro, nos termos que constam do anexo à Deliberação.

- Ver Anexo

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

SPMS

Concurso 2014 / 25 - material de incontinencia, proteção cutanea e alivio de pressao (caderno de encargos)

(Data Limite da Apresentação das Informações para o Catálogo | 16.06.2014)

Detalhe do Concurso 2014 / 55 - Medicamentos Diversos (Caderno de Encargos)

(Data Limite da Apresentação das Informações para o Catálogo | 17.06.2014)

Concurso 2014 / 18 - Medicamentos do Grupo 4: Sangue (Caderno de Encargos)

(Data Limite da Apresentação das Informações para o Catálogo | 18.06.2014)

DGO

Listas das entidades que se encontram em incumprimento nos termos dos n.ºs 5 e 6 do art.º 7.º do DL 127/2012 de 21 de junho: Lista das entidades do sector empresarial do Estado da área da Saúde (reporte de março/2014)

CONSELHO EUROPEU

Council ensures funding of strengthened monitoring of medicines

The Council today approved1 a draft regulation aimed at ensuring the funding of strengthened post-authorisation monitoring of medicines for human use ("pharmacovigilance") conducted at EU level. This follows a first-reading agreement reached with the European Parliament in February.

Eurogroup statement on Portugal - 5.05.2014

The Eurogroup welcomes the conclusion of the twelfth and final review mission by the Commission, the ECB and the IMF that Portugal's adjustment programme remains on track to be concluded and commends the Portuguese authorities for their successful implementation of the programme. The Eurogroup also commends the Portuguese people for their efforts and achievements under difficult circumstances. The success of Portugal's financial assistance programme also clearly illustrates our resolve to work together to ensure the cohesion and stability of the euro area.

COMISSÃO EUROPEIA

Relatório da Comissão Ao Parlamento Europeu, Ao Conselho, Ao Comité Económico E Social Europeu E Ao Comité Das Regiões segunda avaliação intercalar das empresas comuns de iniciativas tecnológicas conjuntas aeronáutica e transportes aéreos (clean sky), pilhas de combustível e hidrogénio e iniciativa **medicamentos inovadores**

— Main (Part 1) (páginas 8 e 9 e 14 and 16)

— Annex (Part 1)

Statement by the EC, ECB, and IMF on the Twelfth Review Mission to Portugal

Staff teams from the European Commission (EC), European Central Bank (ECB), and International Monetary Fund (IMF) visited Lisbon from 22 April to 2 May for the 12th and final review of Portugal's economic adjustment program. Discussion with the authorities also focused on the remaining challenges after the end of the program.

Consulta pública sobre a estratégia Europa 2020

A estratégia Europa 2020 é um plano de dez anos da União Europeia a favor do crescimento. Esta estratégia visa não só a saída da crise mas também a revisão do nosso modelo de crescimento e a criação das condições necessárias para obter um tipo diferente de crescimento: um crescimento mais inteligente, sustentável e inclusivo. A sua concretização será assegurada por cinco objetivos principais que a UE deverá atingir até ao fim da presente década e que dizem respeito aos seguintes domínios: emprego, educação, investigação e inovação, inclusão social e redução da pobreza e clima e energia.

A estratégia compreende também sete «iniciativas emblemáticas» que servem de enquadramento para atividades conjuntas da UE e das autoridades nacionais nas seguintes áreas: inovação, economia digital, emprego, política industrial, pobreza e eficiência na utilização dos recursos.

HMA

Position paper on the use of the Quick Response (QR) codes to provide information about the medicinal product

The possibility of using the QR code (abbreviated from Quick Response Code) as a way for providing information, in a broad sense, on medicinal products is currently being considered not only by the Pharmaceutical Companies but also the National Competent Authorities (NCAs).

QR codes and 2D barcodes in medicines' packaging have been proposed (1) to access web pages (either maintained by the industry or by NCAs) with information about the medicine, (2) to provide batch number and expiration date to visually handicapped, (3) for manufacturing processing and stock control or (4) as the safety features included in the falsified medicines legislation.

This paper only addresses the use of QR codes to access web pages with information about the medicinal products.

Q&A on Active Substance Master File

Template for Public AR for paediatric studies submitted in accordance with Article 45 of Regulation (EC) No 1901/2006

Harmonisation of SmPCs - Article 30 Referrals | Information on applications referred in accordance with Article 30(2) of Directive 2001/83/EC

EFPIA

EFPIA Welcomes Council Adoption of IMI2 Regulation as a Step Towards a More Innovative EU

(Brussels – 6 May): EFPIA welcomes the adoption of the IMI2 regulation by the European Council, another step towards the launch of the second Innovative Medicines Initiative. IMI2 will continue the success of the first IMI, a public-private partnership between the EU and EFPIA that aims to advance research and development, particularly in areas of unmet medical need.

IMI2 will further IMI's vision of service to public health needs, having looked to the World Health Organization's *Report on Priority Medicines for Europe and the World* in determining its Strategic Research Agenda (SRA). The SRA, an essential element of the evolution from IMI to IMI2, was determined with input from more than 80 organisations, including regulators, patients, academia and learned societies. The initial focus of IMI2 will be on fields such as neuro-degeneration, metabolic disorders, immune-mediated diseases,

infections and translational safety.

Joint Industry statement on EU-Japan FTA negotiations

European business organisations, signatories of this statement, are strong proponents of fostering the trade partnership and cooperation between the EU and Japan. We wish to reiterate the value of this relationship at a time when the progress of negotiations for a free trade agreement (FTA) is being reviewed by the Member States, and in view of the upcoming EU-Japan Summit.

We remain convinced that this FTA has the potential to deliver significant economic benefits and contribute to the development of both economies. An EU-Japan FTA is an opportunity to enlarge markets and improve regulatory coherence, and thereby expand trade and investment, economic growth and employment, and contribute to enhanced competitiveness and productivity of businesses in both economies and in the wider international context. Seamless, duty-free and barrier-free markets, built on high-standard rules and regulatory convergence between the EU and Japan would enable business to be conducted freely, and would enhance opportunities and incentives for further investment

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EMA

Human Medicines | Reporting requirements for marketing-authorisation holders (updated)

Human Medicines | Draft best practice guidance for pilot European Medicines Agency health technology assessment parallel scientific advice procedures

As the first step to market access, a new medicine requires a marketing authorisation from a medicines regulatory agency. The second step prior to enabling patient access to a new therapeutic option increasingly involves the assessment of its usefulness to the healthcare system that lies with a payer or healthcare-guidance organisation, and the Health Technology Assessment Bodies (HTABs) that advise them.

Human Medicines | Draft inventory of paediatric therapeutic needs - Ophthalmology

Based on Article 43 of the European Union Paediatric Regulation the Paediatric Committee at the European Medicines Agency (PDCO) is working to establish an inventory to identify the needs in the different therapeutic areas where there should be research and development of medicinal products for children. The inventory is based on the results of a survey of all paediatric uses of medicines in Europe and on the existing list of paediatric needs established by the former Paediatric Working Party

Human Medicines | Draft inventory of paediatric therapeutic needs - Neurology

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Veterinary Medicines | Public consultation regarding the request to the European Medicines Agency from the European Commission for scientific advice on the impact on public health and animal health of the use of antibiotics in animals

Human Medicines | Annex III - List of intravenous iron-containing medicinal products in the European Union (updated)

Human Medicines | Annex VI - List of flupirtine-containing medicinal products in the EU (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 | Draft concept paper on viral safety of plasma-derived medicinal products with respect to hepatitis E virus

Viral safety of plasma-derived medicinal products needs to be kept under review as viruses are identified that can be present in the plasma starting material. Initiating action with a workshop will provide an effective means of bringing together and discussing the currently available information on this topic. This will then allow further actions to be identified.

Human Medicines | Scientific guideline: Reflection paper on quality of essential oils as active substances in herbal medicinal products/traditional herbal medicinal products

This reflection paper applies to essential oils used as active substances in herbal medicinal products (HMPs) both for human and veterinary use and in traditional herbal medicinal products (THMPs) for human use.

The purpose of this reflection paper is to consider aspects related to the nature and the specific production processes of essential oils.

Human Medicines | Regulatory and procedural guideline: List of active substances subject to worksharing for signal management (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 | European Union reference dates and submission of periodic safety update reports (updated)

Human Medicines | Introductory cover note to the list of European Union reference dates and frequency of submission of periodic safety update reports (updated)

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

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