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27 a 30 de abril de 2015

SAÚDE

REGULAÇÃO

MINISTÉRIO DAS FINANÇAS E DA SAÚDE

Despacho n.º 4180-A/2015 - Diário da República n.º 80/2015, 1º Suplemento, Série II de 2015-04-24

Ministérios das Finanças e da Saúde - Gabinetes da Secretária de Estado do Tesouro e do Secretário de Estado da Saúde

Autoriza o Instituto Português de Oncologia do Porto Francisco Gentil, E.P.E. a realizar um investimento relativo à aquisição de um acelerador linear que visa a melhoria da oferta pública na área dos tratamentos de radioterapia na região de saúde do Norte.

CONSELHO DE MINISTROS

Resolução n.º 25/2015 - Diário da República n.º 83/2015, Série II de 2015-04-29

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia o vogal executivo do conselho de administração do Centro Hospitalar de Trás-os-Montes e Alto Douro, E.P.E.

Resolução n.º 26/2015 - Diário da República n.º 83/2015, Série II de 2015-04-29

Presidência do Conselho de Ministros - Conselho de Ministros

Nomeia os membros do conselho de administração da Unidade Local de Saúde do Litoral Alentejano, 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

EMA

Human Medicines | Scientific guideline: Draft concept paper on the need to revise the "Guideline on the evaluation of anticancer medicinal products in man" in order to provide guidance on the reporting of safety data from clinical trials

The shift from conventional cytotoxic drugs to so called targeted drugs and immune modulators administered continuously and at maximum tolerated dose has changed the tolerability and toxicity profiles of anti-cancer drugs. Among medicinal products, however, anti-cancer drugs still stand out compared with other therapeutic areas.

Human Medicines | List of medicinal products under additional monitoring (updated)

Human Medicines | Regulatory and procedural guideline: Questions and answers on Article 20 pharmacovigilance procedures

This guidance document addresses a number of questions which stakeholders, in particular marketing authorisation holders (MAHs), may have on an Article 20 procedure resulting from the evaluation of data from pharmacovigilance activities. It provides an overview of the European Medicines Agency's (the Agency) practical and operational aspects with regards to the handling of Article 20 pharmacovigilance procedures.

Human Medicines | Regulatory and procedural guideline: Questions and answers on urgent Union procedures (Article 107i of Directive 2001/83/EC) (updated)

This guidance document addresses a number of questions which stakeholders, in particular marketing authorisation holders (MAHs), may have on an Urgent Union Procedure. It provides an overview of the European Medicines Agency's (the Agency) practical and operational aspects with regards to the handling of an Urgent Union Procedure.

Human Medicines | Regulatory and procedural guideline: Questions and answers on Article 31 pharmacovigilance referral (updated)

This guidance document addresses a number of questions which stakeholders, in particular the marketing authorisation holders (MAHs), may have on an Article 31 referral resulting from the evaluation of data from pharmacovigilance activities. It provides an overview of the European Medicines Agency's (the Agency) practical and operational aspects with regards to the handling of Article 31 pharmacovigilance referral procedures.

Human Medicines | Other post-authorisation activities: **questions and answers** (updated)

Human Medicines | Presubmission guidance: **questions 1 to 10** (updated)

Human Medicines | Regulatory and procedural guideline: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure (updated)

This guidance document addresses a number of questions which users of the centralised procedure may have. It provides an overview of the European Medicines Agency's position on issues, which are typically addressed during the course of pre-submission meetings.

Human Medicines | Regulatory and procedural guideline: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with track changes (updated)

Human Medicines | Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with track changes (updated)

This guidance document addresses a number of questions which marketing authorisation holders (MAHs) may have on post-authorisation procedures. It provides an overview of the Agency's position on issues, which are typically addressed in discussions or meetings with MAHs in the post-authorisation phase.

Human Medicines | Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure (updated)

This guidance document addresses a number of questions which marketing authorisation holders (MAHs) may have on post-authorisation procedures. It provides an overview of the Agency's position on issues, which are typically addressed in discussions or meetings with MAHs in the post-authorisation phase.

Human Medicines | Guidelines on good pharmacovigilance practices (GVP) - Introductory cover note, last updated with launch of public consultation of addendum I to module XVI on educational materials

Human Medicines | Guideline on good pharmacovigilance practices (GVP) - Module XVI Addendum I – Educational materials

Human Medicines | Reporting requirements of marketing authorisation holders in the EU regarding suspected adverse reactions occurring with medicinal products they donate outside the EU to public health programmes against neglected tropical diseases

Human Medicines | Scientific guideline: Draft guideline on the chemistry of active substances

This guideline replaces the 'Note for guidance on chemistry of new active substances' (CPMP/QWP/130/96, Rev 1) and 'Chemistry of active substances' (3AQ5a). It has been revised to cover new and existing active substances in one guideline.

Human Medicines | Scientific guideline: Draft reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances

This reflection paper is intended to reflect the current experience of the Quality Working Party (QWP), of the Committee for Medicinal Products for Human Use (CHMP) and the Co-ordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh) concerning the definition of a New Active Substance (NAS) in the context of preparation of dossiers and submissions of applications for Marketing Authorisation (MAA) in the Centralised Procedure (CP), the Mutual Recognition Procedure (MRP)/Decentralised Procedure (DCP) and purely national procedures for chemical medicinal products for human use.

HMA

Application for Marketing Authorisation | Template: Letter of access for informed consent applications

Renewals | Template - RMS End of Renewal Procedure

eSubmissions | Requirements on submissions (number and format) for New Applications within MRP, DCP or National procedures

Article 45 and previous Worksharing | List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation

Application for Marketing Authorisation | **Recommendations on Informed Consent Applications** in Mutual Recognition and Decentralised Procedures

This document was produced by the CMDh in order to facilitate and harmonise the regulatory issues for submission of informed consent applications in mutual recognition procedure and decentralised procedure.

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