NEWSLETTER_LEGISLAÇÃO_LIFE SCIENCES N. 5/2016

Departamento de Life Sciences

I. DIÁRIO DA REPÚBLICA - LEGISLAÇÃO NACIONAL / REGULAÇÃO

Delegações

Deliberação n.º 122/2016 - Diário da República n.º 25/2016, Série II de 2016-02-05 - Saúde - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P. - Delegação de competências no Presidente do Conselho Diretivo do INFARMED, I. P.

Despacho n.º 1865/2016 - Diário da República n.º 25/2016, Série II de 2016-02-05 - Saúde - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P. -Subdelegação de competências na Diretora da Direção de Comprovação da Qualidade.

Despacho n.º 1866/2016 - Diário da República n.º 25/2016, Série II de 2016-02-05 - Saúde - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P. -Subdelegação de competências no Diretor da Unidade de Introdução no Mercado da Direção de Avaliação de Medicamentos.

Concursos

Anúncio de procedimento n.º 520/2016 - Diário da República n.º 21/2016, Série II de 2016-02-01
Centro Hospitalar de Leiria, E. P. E. - 1004A16 - Reagentes para hematologia.

Anúncio de procedimento n.º 522/2016 - Diário da República n.º 21/2016, Série II de 2016-02-01
Centro Hospitalar Lisboa Norte, E. P. E. - 169A000005 - Aquisição de serviços de manutenção às camas eléctricas do CHLN, EPE.

Anúncio de Procedimento n.º 532/2016 - Diário da República n.º 21/2016, Série II de 2016-02-01
Centro Hospitalar do Algarve, E. P. E. - Aquisição de drenos e sondas.

Anúncio de procedimento n.º 533/2016 - Diário da República n.º 21/2016, Série II de 2016-02-01
Centro Hospitalar do Algarve, E. P. E. - 21 555/2016 - Material de penso com efeito terapêutico.

Anúncio de procedimento n.º 542/2016 - Diário da República n.º 22/2016, Série II de 2016-02-02
Centro Hospitalar de Setúbal, E. P. E. - Reagentes para analisador multiparamétrico de imunoquimica - bioquimica - Ano 2016.

Anúncio de procedimento n.º 543/2016 - Diário da República n.º 22/2016, Série II de 2016-02-02
Centro Hospitalar de Setúbal, E. P. E. - Reagentes de imunologia - Tecnica de Quimioluminiscência - Ano 2016.

Anúncio de procedimento n.º 548/2016 - Diário da República n.º 22/2016, Série II de 2016-02-02
Centro Hospitalar Lisboa Norte, E. P. E. - 166A000005 - Aquisição de material genérico de serralharia p/ o ano de 2016.

Anúncio de procedimento n.º 564/2016 - Diário da República n.º 22/2016, Série II de 2016-02-02
Estado-Maior-General das Forças Armadas (EMGFA) - Aquisição de Reagentes de imunologia, com colocação de equipamentos.

Anúncio de procedimento n.º 572/2016 - Diário da República n.º 22/2016, Série II de 2016-02-02
Administração Regional de Saúde do Centro, I. P. – 16110207 - Aquisição de tiras p/ determinação de glicose no sangue.

Anúncio de procedimento n.º 606/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
SPMS - Serviços Partilhados do Ministério da Saúde, E. P. E. - Aquisição centralizada de três medicamentos derivados do plasma humano.

Anúncio de procedimento n.º 609/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
Centro Hospitalar de Trás-os-Montes e Alto Douro, E. P. E. - 214/2016 - Aquisição de próteses e stents para cirurgia vascular, para o CHTMAD, E.P.E.

Anúncio de procedimento n.º 613/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
Centro Hospitalar Barreiro Montijo, E. P. E. - 110028/2016 - Aquisição de reagentes para microbiologia, com colocação de equipamentos para o ano de 2016.

Anúncio de procedimento n.º 615/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
Centro Hospitalar do Tâmega e Sousa, E. P. E. - Material hemodinâmica – Cateteres.

Anúncio de procedimento n.º 620/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
Centro Hospitalar Vila Nova de Gaia - Espinho, E. P. E. - 2014016 - Aquisição de válvulas aórticas de introdução por via percutânea.

Anúncio de procedimento n.º 625/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
Centro Hospitalar de Lisboa Central, E. P. E. - 1-2.0082/16 - Dispositivo para encerramento do canal arterial para 2016.

Anúncio de procedimento n.º 626/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
Centro Hospitalar de Lisboa Central, E. P. E. -1-2.0083/16 - Sensores descartáveis de tecnologia oximax.

Anúncio de procedimento n.º 628/2016 - Diário da República n.º 24/2016, Série II de 2016-02-04
Centro Hospitalar do Algarve, E. P. E. - Aquisição de material diverso de bloco operatório.

Anúncio de procedimento n.º 631/2016 - Diário da República n.º 25/2016, Série II de 2016-02-05
Centro Hospitalar de Trás-os-Montes e Alto Douro, E. P. E. - 216/2016 - Aquisição de diverso material para cirurgia vascular, para o CHTMAD, E.P.E.

Anúncio de procedimento n.º 637/2016 - Diário da República n.º 25/2016, Série II de 2016-02-05
Centro Hospitalar de Trás-os-Montes e Alto Douro, E. P. E. - 130/2016 - aquisição de redes de reparação de hérnias..

II. INFARMED

Caducidade das comparticipações (Janeiro de 2016) - 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 Janeiro de 2016, por deliberação do Conselho Diretivo do INFARMED, I.P. datada de 18-01-16, no uso das suas competências.

Deliberações

Deliberação n.º 17/CD/2016 - Levantamento da suspensão da AIM do medicamento Esomeprazol Mylan, 40 mg, Cápsula gastrorresistente, com os números de registo: 5340674, 5340641, 5340658, 5340666, 5340542, 5340633, de que é titular a empresa Mylan, Lda..

Deliberação n.º 16/CD/2016 - Levantamento da suspensão da AIM do medicamento Esomeprazol Mylan, 20 mg, Cápsula gastrorresistente, com os números de registo: 5340567, 5340559, 5340609, 5340617, 5340625, 5340575, de que é titular a empresa Mylan, Lda..

Deliberação n.º 15/CD/2016 - Levantamento da suspensão da AIM do medicamento Esomeprazol Anova, 40 mg, Cápsula gastrorresistente, com os números de registo: 5340708, 5340757, 5340716, 5340732, 5340724, 5340740, de que é titular a empresa Laboratórios Anova - Produtos Farmacêuticos, Lda..

Deliberação n.º 14/CD/2016 - Levantamento da suspensão da AIM do medicamento Esomeprazol Anova, 20 mg, Cápsula gastrorresistente, com os números de registo: 5340468, 5340476, 5340526, 5340518, 5340534, 5340500, de que é titular a empresa Laboratórios Anova - Produtos Farmacêuticos, Lda..

III. JORNAL OFICIAL DA UNIÃO EUROPEIA

Tribunal de Justiça da União Europeia

Processo C-82/15 P: Acórdão do Tribunal de Justiça (Oitava Secção) de 3 de Dezembro de 2015 — PP Nature-Balance Lizenz GmbH/Comissão Europeia (Recurso de decisão do Tribunal Geral — Medicamentos para uso humano — Diretiva 2001/83/CE — Artigos 31.º e 116.º — Decisão da Comissão que impõe aos Estados-Membros a retirada e a alteração das autorizações nacionais de comercialização dos medicamentos para uso humano que contêm a substância ativa tolperisona).

IV. COMISSÃO EUROPEIA

On 2 February 2016, Vytenis Andriukaitis, European Commissioner for Health and Food Safety, answered an oral question in the EP on the criteria to identify endocrine disruptors

SCENIHR Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users was published in "Regulatory Toxicology and Pharmacology"

Quality Action, the EU co-funded three-year ‘Joint Action on Improving Quality in HIV Prevention’, held its concluding conference

V. HEADS OF MEDICINES AGENCIES

December 2015 CMDh Minutes

PSUR assessments for alprazolam, mefloquine, praziquantel and valaciclovir

Minutes of the CMDh meetings with Interested Parties in November 2015

Report from the meeting held on 25-27 January 2016

UPDATE

"Blue-box" requirements

CMDv GUI-25 Payment terms & addresses for national fees

CMDv GUI-31 Guidance for Marketing Authorisation Transfer – National Requirements

Summaries of Assessment Reports

i.	Alprazolam
ii.	Didanosine
iii.	Epirubicin
iv.	Felbamate
v.	Folinic acid / (di)sodium folinate / calcium folinate / calcium levofolinate
vi.	Gadopentetic acid dimeglumine
vii.	Imipenem/cilastatin
viii.	Labetalol
ix.	Macrogol 4000 and combinations
x.	Mefloquine
xi.	Mesalazine
xii.	Nedocromil
xiii.	Paracetamol for infusion
xiv.	Praziquantel
xv.	Quetiapine fumarate
xvi.	Ropinirole
xvii.	Strontium (89Sr) Chloride
xviii.	Tiagabine (hydrochloride)
xix.	Tixocortol, Tixocortol/chlorhexidine
xx.	Valaciclovir

VI. EUROPEAN MEDICINES AGENCY

How to facilitate development of cancer immunotherapies

A workshop on the challenges for the approval of immunotherapy medicines for cancer took place at the EMA. The workshop is organised jointly by EMA and the Cancer Drug Development Forum (CDDF).

Consultation on revised guideline on medicines to treat Alzheimer's disease

The EMA has released a revised guideline on medicines for the treatment of Alzheimer's disease and other types of dementias for a six-month public consultation. The revised guideline specifically addresses the: (i) impact of new diagnostic criteria for Alzheimer's disease, including early and even asymptomatic disease stages, on clinical trial design; (ii) choice of parameters to measure trial outcomes and the need for distinct assessment tools for the different disease stagesin Alzheimer's (different signs and symptoms, differences in changes over time, severity); (iii) potential use of biomarkers and their temporal relationship with the different phases of Alzheimer's disease at different stages of medicine development (mechanism of action, use as diagnostic test, enrichment of study populations, stratification of subgroups, safety and efficacy markers etc.); (iv) design of long-term efficacy and safety studies.
Comments received during the consultation will be taken into account in the finalisation of the guideline.

EMA fast-tracks treatment of multiple myeloma for approval in EU

The EMA has recommended granting a marketing authorization for Empliciti (elotuzumab) for the treatment of multiple myeloma. It is to be used in combination with lenalidomide and the anti-inflammatory medicine dexamethasone for the treatment of patients who have received at least one prior therapy. Empliciti is a monoclonal antibody that works by activating the body's immune system to attack and kill multiple myeloma cells.
The Committee for Medicinal Products for Human Use (CHMP) reviewed Empliciti under EMA's accelerated assessment programme. The opinion adopted by the CHMP at its January 2016 meeting is an intermediary step on Empliciti's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorization has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

First specific replacement therapy to treat rare bleeding disorder

The EMA has recommended granting a marketing authorization for Coagadex (human coagulation factor X) to treat factor X deficiency, a rare inherited bleeding disorder. Coagadex is indicated for the treatment and preventive management of bleeding episodes and the control of bleeding during surgical procedures in patients with hereditary factor X deficiency. The medicine's active substance is human coagulation factor X, a protein derived from

human plasma. Because factor X deficiency is rare, Coagadex was designated as an orphan medicine by the Committee for Orphan Medicinal Products (COMP).
The opinion adopted by the CHMP at its January 2016 meeting is an intermediary step on Coagadex's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorization has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 25-28 January 2016

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended six new medicines for marketing authorization at its January 2016 meeting.
The CHMP recommended granting a marketing authorisation, under accelerated assessment, for **Empliciti** (elotuzumab) for the treatment of multiple myeloma. Empliciti is to be used in combination with lenalidomide and dexamethasone for the treatment of patients who have received at least one prior therapy. Empliciti has an orphan designation. For more details, please refer to the press release in the grid below.
The Committee recommended granting a marketing authorization for **Coagadex** (factor X), for the treatment of factor X deficiency, a rare inherited bleeding disorder. Coagadex has an orphan designation and was reviewed under accelerated assessment. For more details, please refer to the press release in the grid below.
Uptravi (selexipag) was recommended by the Committee for the treatment of pulmonary arterial hypertension. Uptravi has an orphan designation.
Three generic medicines received a positive opinion from the Committee: **Amlodipine-Valsartan Mylan** (amlodipine/valsartan) for the treatment of essential hypertension,**Rasagiline Mylan** (rasagiline) for the treatment of idiopathic Parkinson's disease and **Zonisamide Mylan** (zonisamide) for the treatment of partial seizures, with or without secondary generalisation.
Two recommendations on extensions of therapeutic indications. The Committee recommended extensions of indication for **Revlimid** and **Revolade**.
Request for re-examination of CHMP recommendation. The applicant for **Dropcys** (mercaptamine hydrochloride) has requested a re-examination of the CHMP's negative opinion for this medicine adopted at the December 2015 meeting. Upon receipt of the grounds of the request for re-examination, the CHMPwill re-examine this opinion and issue a final opinion.

Draft guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias

Document	**Draft guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias**
Reference No.	EMA/CHMP/539931/2014
Status	draft: consultation open
First published	01/02/2016
Last updated	01/02/2016
Start date	01/02/2016
End date	31/07/2016
Email for submissions	cnswpsecretariat@ema.europa.eu

Summary - This guideline replaces 'Guideline on medicinal products for the treatment of Alzheimer's disease and other dementias' (CPMP/EWP/553/95 Rev. 1).

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): E18 on genomic sampling and management of genomic data - Step 3

Document	**International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): E18 on genomic sampling and management of genomic data - Step 3**
Reference No.	EMA/CHMP/ICH/11623/2016
Status	draft: consultation open
First published	01/02/2016

Last updated	01/02/2016
Start date	01/02/2016
End date	31/05/2016
Email for submissions	ich@ema.europa.eu

Summary - The main objective of this guideline is to provide harmonised principles of genomic sampling and management of genomic data in clinical studies. This guideline will facilitate the implementation of genomic studies by enabling a common understanding of critical parameters for the unbiased collection, storage and optimal use of genomic samples and data. Further objectives of this guideline are to increase awareness and provide considerations regarding subject privacy, data protection, informed consent and transparency of findings. This guideline is intended to foster interactions amongst stakeholders, including drug developers, investigators and regulators, and to encourage genomic research within clinical studies.

- **Draft guideline on core SmPC and Package Leaflet for gadopentetate dimeglumine**

Document	**Draft guideline on core SmPC and Package Leaflet for gadopentetate dimeglumine**
Reference No.	EMA/CHMP/39163/2016
Status	draft: consultation open
First published	01/02/2016
Last updated	01/02/2016
Start date	01/02/2016
End date	30/04/2016
Email for submissions	radiopharmaceuticalsDG@ema.europa.eu

Summary - This guideline describes the information to be included in the Summary of Products Characteristics (SmPC) and package leaflet for gadopentetate dimeglumine.

- **Draft guideline on core SmPC and Package Leaflet for nanocolloidal technetium (99mTc) albumin**

Document	**Draft guideline on core SmPC and Package Leaflet for nanocolloidal technetium (99mTc) albumin**
Reference No.	EMA/CHMP/39283/2016
Status	draft: consultation open
First published	01/02/2016
Last updated	01/02/2016
Start date	01/02/2016
End date	30/04/2016
Email for submissions	radiopharmaceuticalsDG@ema.europa.eu

Summary - This guideline describes the information to be included in the Summary of Products Characteristics (SmPC) and package leaflet for nanocolloidal technetium (99mTc) albumin.

- **Draft guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market**

Document	**Draft guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market**
Reference No.	EMA/CVMP/IWP/123243/2006 Rev.3
Status	draft: consultation open
First published	03/02/2016
Last updated	03/02/2016
Start date	03/02/2016
End date	31/07/2016
Email for submissions	vet-guidelines@ema.europa.eu

Summary - In order to stimulate the development of new veterinary medicines intended for minor uses or minor species (MUMS)/limited market the CVMP developed guidelines on data requirements for MUMS/limited market veterinary medicinal products for quality, safety and efficacy for pharmaceuticals and a guideline for immunologicals.

Draft guideline on safety and residue data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market

Document	**Draft guideline on safety and residue data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market**
Reference No.	EMA/CVMP/QWP/66781/2005 Rev.1
Status	draft: consultation open
First published	03/02/2016
Last updated	03/02/2016
Start date	03/02/2016
End date	31/07/2016
Email for submissions	vet-guidelines@ema.europa.eu

Summary - In order to stimulate the development of new veterinary medicines intended for minor uses or minor species (MUMS)/limited market the CVMP developed guidelines on data requirements for MUMS/limited market veterinary medicinal products for quality, safety and efficacy for pharmaceuticals and a guideline for immunologicals.

Draft guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market

Document	**Draft guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market**
Reference No.	EMA/CVMP/EWP/117899/2004 Rev.1
Status	draft: consultation open
First published	03/02/2016
Last updated	03/02/2016
Start date	03/02/2016
End date	31/07/2016
Email for submissions	vet-guidelines@ema.europa.eu

Summary - In order to stimulate the development of new veterinary medicines intended for minor uses or minor species (MUMS)/limited market the CVMP developed guidelines on data requirements for MUMS/limited market veterinary medicinal products for quality, safety and efficacy for pharmaceuticals and a guideline for immunologicals.

Concept paper for the revision on the guideline for the conduct of pharmacokinetic studies in target animal species

Document	**Concept paper for the revision on the guideline for the conduct of pharmacokinetic studies in target animal species**
Reference No.	EMA/CVMP/EWP/706701/2015
Status	draft: consultation open
First published	03/02/2016
Last updated	03/02/2016
Start date	03/02/2016
End date	30/04/2016
Email for submissions	vet-guidelines@ema.europa.eu

Summary - The guideline for the conduct of pharmacokinetic (PK) studies in target animal species was adopted in March 2000. Since its introduction, it has been referred to extensively in full application dossiers, but also in applications to vary existing marketing authorisations, e.g. addition of a new target species or route of administration.

Draft guideline on quality data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market

Document	**Draft guideline on quality data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market**
Reference No.	EMA/CVMP/QWP/128710/2004 Rev.1

Status	draft: consultation open
First published	03/02/2016
Last updated	03/02/2016
Start date	03/02/2016
End date	31/07/2016
Email for submissions	vet-guidelines@ema.europa.eu

Summary - In order to stimulate the development of new veterinary medicines intended for minor uses or minor species (MUMS)/limited market the CVMP developed guidelines on data requirements for MUMS/limited market veterinary medicinal products for quality, safety and efficacy for pharmaceuticals and a guideline for immunologicals.

VII. EFPIA

Vietnam Free Trade Agreement Will Boost Access to Medicines

EFPIA welcomes the publication of the EU-Vietnam Free Trade Agreement text, which provides a strong precedent for future FTAs in the region. EFPIA is furthermore grateful to the Commission for its work during three years of intense negotiations in securing this important agreement, which will provide concrete benefits both in terms of export opportunities for business, and more importantly, for patients.

We believe it offers pharmaceutical companies increased export opportunities, promotes a level playing field in Vietnam, supports significantly increased access to medicines for patients, and represents a boost for innovation and research.

To this end, we are particularly pleased to see the inclusion of a pharmaceutical annex, which includes arrangements for transparency and accountability as well as the inclusion of IP provisions, which will improve access to medicines, increase innovation and strengthen the Vietnamese health system. The Vietnamese government has, within the framework of the agreement, committed to a high level of protection of Intellectual Property Rights – including stronger enforcement provisions. EFPIA also welcomes strong provisions on public procurement, which will create a level playing field for foreign companies investing in Vietnam.

We look forward to studying the contents of the FTA more in detail, which we hope will serve as a vehicle to align Vietnamese regulatory standards and procurement provisions as well as improve patient access and increase innovation, creating a solid healthcare system in Vietnam for the benefit of patients.

EFPIA Director General Richard Bergström said: "This looks set to be the first of a new generation of bilateral trade agreements that raise IP standards at the same time as improving access to medicines."

VIII. Federal Drug Administration

Califf, FDA top officials call for sweeping review of agency opioids policies

In response to the opioid abuse epidemic, today Dr. Robert Califf, the FDA's Deputy Commissioner for Medical Products and Tobacco, along with other FDA leaders, called for a far-reaching action plan to reassess the agency's approach to opioid medications. The plan will focus on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief.

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