SRS ADVOGADOS
NEWS LETTER
LIFE SCIENCES

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Temas

LIFE SCIENCES

DESTAQUES

LEGISLAÇÃO PORTUGUESA

I. DIÁRIO DA REPÚBLICA

SPMS

Anúncio de procedimento n.º 4181/2016 - Diário da República n.º 130/2016, Série II de 2016-07-08 - SPMS - Serviços Partilhados do Ministério da Saúde, E. P. E. - Celebração de Acordo Quadro para a prestação de serviços de consultoria, desenvolvimento e manutenção de software

Concursos

Anúncio de procedimento n.º 4043/2016 - Diário da República n.º 126/2016, Série II de 2016-07-04 - Administração Regional de Saúde do Norte, I. P. - Aquisição de Material de Consumo Clinico.

Anúncio de procedimento n.º 4044/2016 - Diário da República n.º 126/2016, Série II de 2016-07-04 - Administração Regional de Saúde do Norte, I. P. - Aquisição de Material Consumo Clinico.

Anúncio de procedimento n.º 4086/2016 - Diário da República n.º 127/2016, Série II de 2016-07-05 - Centro Hospitalar Tondela-Viseu, E. P. E. - 22/01880/2016- Diverso material clinico para ORL

Anúncio de procedimento n.º 4093/2016 - Diário da República n.º 127/2016, Série II de 2016-07-05 - Hospital da Senhora da Oliveira Guimarães, E. P. E. - Fornecimento de Material para Medicina de Reprodução.

Anúncio de procedimento n.º 4095/2016 - Diário da República n.º 128/2016, Série II de 2016-07-06 - Instituto Nacional de Saúde Doutor Ricardo Jorge, I. P. - CP 40-2016 - Aquisição de material de colheitas

Anúncio de procedimento n.º 4113/2016 - Diário da República n.º 128/2016, Série II de 2016-07-06 - Centro Hospitalar de Leiria, E. P. E. - 1010A16 - Reagentes para Point of Care Tests e Imunoquímica.

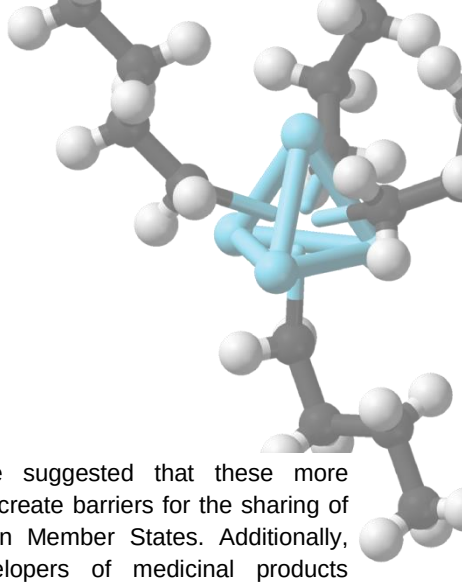
Anúncio de procedimento n.º 4115/2016 - Diário da República n.º 128/2016, Série II de 2016-07-06 - Centro Hospitalar de Lisboa Central, E. P. E. - 1-2.0106/16 - Concurso Público Tendente ao Fornecimento de Cateteres de Diagnóstico e Cateteres Guia.

Anúncio de procedimento n.º 4118/2016 - Diário da República n.º 128/2016, Série II de 2016-07-06 - Centro Hospitalar de Lisboa Central, E. P. E. - Aquisição de um Sistema para Quantificação Não-Invasiva da Fibrose e Esteatose Hepática destinado ao Serviço de Gastroenterologia do Centro Hospitalar de Lisboa Central, E.P.E. (CHLC) - Hospital dos Capuchos.

Anúncio de procedimento n.º 4153/2016 - Diário da República n.º 129/2016, Série II de 2016-07-07 - Instituto Português do Sangue e da Transplantação, I. P. - Concurso Público Internacional nº 1-1009/16 - Aquisição de Reagentes para os Laboratórios de Imunohematologia do IPST, IP, durante o ano 2016.

Anúncio de procedimento n.º 4155/2016 - Diário da República n.º 129/2016, Série II de 2016-07-07 - Centro Hospitalar e Universitário de Coimbra, E. P. E. - 2 Aparelhos de anestesia com monitorização para o Bloco Operatório do Serviço de Urgência dos HUC.

Anúncio de procedimento n.º 4171/2016 - Diário da República n.º 129/2016, Série II de 2016-07-07 - Santa Casa da Misericórdia de Lisboa - 002CP/2016/CMRA - Aquisição de material de ortoprotesia - próteses e



membros inferiores para o Centro de Medicina de Reabilitação do Alcoitão da Santa Casa da Misericórdia de Lisboa.

Anúncio de procedimento n.º 4182/2016 - Diário da República n.º 130/2016, Série II de 2016-07-08 - SPMS - Serviços Partilhados do Ministério da Saúde, E. P. E. - Medicamentos anestésicos e relaxantes musculares.

II. INFARMED

- **Caducidade das comparticipações**

Publicação da lista definitiva de medicamentos para os quais foi decidida a caducidade da comparticipação por não comercialização no período de Maio de 2016

LEGISLAÇÃO UNIÃO EUROPEIA

I. JORNAL OFICIAL DA UNIÃO EUROPEIA

Retificação da Comunicação da Comissão no âmbito da execução da Directiva 98/79/CE do Parlamento Europeu e do Conselho relativa aos dispositivos médicos de diagnóstico *in vitro* (Publicação dos títulos e das referências das normas harmonizadas ao abrigo da legislação de harmonização da União) (JO C 173 de 13.5.2016).

II. EUROPEAN COMMISSION

- **Mapping of More Stringent Tissues and Cells Donor Testing Requirements - Mapping Exercise 2015**

Directive 2004/23/EC defines the mandatory tests that must be performed on tissues and cells donors each time they donate. The legal basis of this legislation allows Member States to adopt more stringent measures on a national basis. Implementation surveys have indicated that many Member States have done this, in some cases in response to local epidemiological risks and in some other cases because they consider that a higher level of safety can be ensured with these more stringent provisions. The more stringent measures are either adopted in national legislation and/or they are defined by national standards organisations to be taken into consideration by authorities in their regular inspections.

Many stakeholders have suggested that these more stringent measures might create barriers for the sharing of tissues and cells between Member States. Additionally, manufacturers and developers of medicinal products derived from tissues and cells (e.g. advanced therapy medicinal products) comment that more stringent measures create a complex and unclear situation that makes distribution of these substances between Member States very challenging.
To address this issue, the Member State competent authorities and the European Commission, DG SANTE agreed to map the more stringent donor testing measures and to make the results of this mapping publicly available. The objective is not to evaluate or comment on the requirements in place at a national level but to provide greater clarity and transparency on this topic.

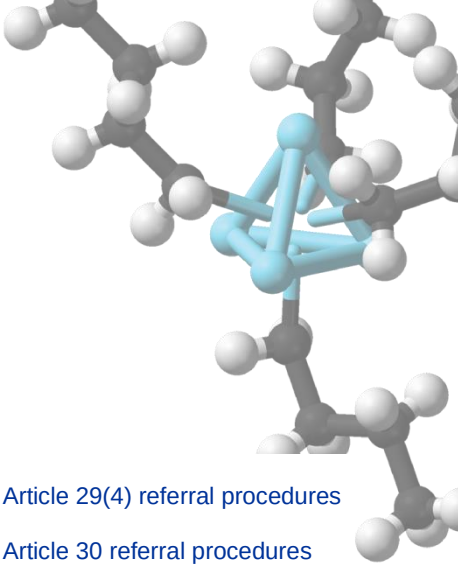
III. EUROPEAN MEDICINES AGENCY

- **Infringement procedure against Roche – EMA update**

The EMA has concluded its second inquiry within the framework of its infringement procedure against Roche. The infringement procedure was started by EMA on 23 October 2012 at the request of the European Commission in the framework of Commission Regulation (EC) No 658/2007, the so-called Penalties Regulation. The aim of the inquiry was to investigate allegations that Roche failed to comply with its pharmacovigilance obligations in relation to 19 of its centrally authorised products. Upon transmission of the investigation report, the procedure continued at European Commission level. However, in July 2015 the European Commission returned the file to EMA for a new period of inquiry and for further examination of certain points of fact. The Agency has now concluded its second inquiry and sent, on 1 July 2016, the final updated report to the European Commission summarising its findings in light of the inquiries carried out in accordance with the Penalties Regulation. For more information: Infringement procedure against Roche – EMA update

- **Draft guideline on the clinical evaluation of direct acting antivirals for the treatment of chronic hepatitis**

This draft guideline replaces the CHMP's Guideline on the clinical evaluation of direct acting antiviral agents intended for treatment of chronic hepatitis C



(EMEA/CHMP/EWP/30039/2008). There have been considerable developments in the field of hepatitis C virus (HCV) therapy since the adoption of EMEA/CHMP/EWP/30039/2008. Since 2013 direct acting antivirals (DAAs) have been approved for the treatment of chronic HCV infections within interferon-free combination regimens. Therefore this revision of the prior guidance concerns the development of DAA-only regimens.

Download document: Draft guideline on the clinical evaluation of direct acting antivirals for the treatment of chronic hepatitis
Reference number: EMEA/CHMP/EWP/30039/2008 Rev. 1
Consultation end date: 31/12/2016

Updates

PDCO monthly report of opinions on paediatric investigation plans and other activities 22-24 June 2016

List of nationally authorized medicinal products:
Diclofenac (systemic formulations) PSUSA/00001048/201509
Glycopyrronium bromide (all indications except for chronic obstructive pulmonary disease) PSUSA/00001556/201509
Glycopyrronium / neostigmine PSUSA/00001557/201509
Iodine (131i) iobenguane PSUSA/00001764/201505

Scientific guidelines (Adopted):
Guideline on clinical investigation of medicinal products in the treatment of lipid disorders

Guideline on clinical evaluation of medicinal products used in weight management
Guideline on clinical investigation of medicinal products in the treatment of hypertension

Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38

Report: Applications for new human medicines under evaluation by the CHMP: July 2016

European medicines agency Standard operating procedure: Standard operating procedure for micro, small and medium-sized enterprises (SME) conditional fee exemptions

Regulatory and procedural guidelines:
Questions and answers on Article 13 referral procedures

Questions and answers on Article 20 non-pharmacovigilance procedures

Questions and answers on Article 29(4) referral procedures

Questions and answers on Article 30 referral procedures

Questions and answers on Article 31 non-pharmacovigilance referrals

IV. HEADS OF MEDICINES AGENCIES

Co-Ordination Group For Mutual Recognition And Decentralised Procedures – Human

List of active substances included in the work-sharing procedures

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

LEGISLAÇÃO INTERNACIONAL

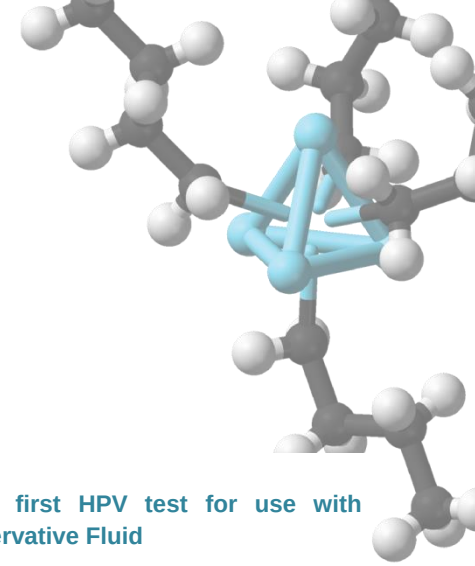
I. U.S. FOOD AND DRUG ADMINISTRATION

FDA approves first absorbable stent for coronary artery disease

The U.S. FDA approved the first fully absorbable stent to treat coronary artery disease. The Absorb GT1 Bioresorbable Vascular Scaffold System (BVS), which releases the drug everolimus to limit the growth of scar tissue, is gradually absorbed by the body in approximately three years. The Absorb GT1 BVS is manufactured by Abbott Vascular in Santa Clara, California.

FDA advances Precision Medicine Initiative by issuing draft guidances on next generation sequencing-based tests

In support of the President's Precision Medicine Initiative, the U.S. FDA issued two draft guidances that, when finalized, will provide a flexible and streamlined approach to the oversight of tests that detect medically important differences in a person's genomic makeup. The powerful new technology, known as next generation sequencing (NGS), can scan a person's DNA to detect genomic variations that may determine whether a person has or is at risk of disease or may help to inform treatment decisions.



While current regulatory approaches are appropriate for conventional diagnostics that measure a limited number of substances associated with a disease or condition, such as blood glucose or cholesterol levels, the new sequencing technologies can examine millions of DNA variants at a time, and thus require a flexible approach to oversight that is adapted to the novel nature of these tests.

The first draft guidance, titled "Use of Standards in FDA's Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases" provides recommendations for designing, developing and validating NGS-based tests for rare hereditary diseases, and addresses the potential for using FDA-recognized standards to demonstrate analytical validity, which is how well a test predicts the presence or absence of a particular genomic change.

The second draft guidance, titled "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics" describes an approach wherein test developers may rely on clinical evidence from FDA-recognized public genome databases to support clinical claims for their tests and provide assurance of accurate clinical interpretation of genomic test results – an easier path for marketing clearance or approval.

FDA approves first HPV test for use with SurePath Preservative Fluid

The U.S. FDA approved the Roche cobas HPV Test as the first test for Human Papilloma Virus (HPV) that can be used with cervical cells obtained for a Pap test and collected in SurePath Preservative Fluid. The FDA approves HPV tests to be used with specific collection fluid, which store and preserve cervical cell samples for testing in the laboratory. Until today, the FDA had not approved any HPV tests to be used with SurePath Preservative Fluid, one of two approved liquid collection fluids commonly used for Pap tests. The Roche cobas HPV Test is manufactured by Roche Molecular Systems, Inc., a part of the Roche Group, headquartered in Basel, Switzerland. SurePath Preservative Fluid is manufactured by Becton Dickinson and Company, located in Franklin Lakes, New Jersey.

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