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LIFE SCIENCES

LEGISLATIVE HIGHLIGHTS

PORTUGUESE LEGISLATION

I. ASSEMBLY OF THE REPUBLIC

▶ Prevention and Control of Vector-Borne Diseases

[LAW No. 4/2016 – DIÁRIO DA REPÚBLICA No. 41/2016, SERIES I, 2016-02-29](#) – Assembly of the Republic – National Plan for the Prevention and Control of Vector-Borne Diseases.

▶ State Contribution – Reagents

[DECREE No. 35/2016 – DIÁRIO DA REPÚBLICA No. 42/2016, SERIES I, 2016-03-01 73727304](#) – Health - establishes the state contribution scheme for maximum prices of reagents (test strips) for the determination of blood sugar, ketone, and ketonuria, and of needles, syringes, lancets, and other medical devices for the purpose of self-monitoring of people with diabetes, to beneficiaries of the National Health Service and repeals Decree No. 222/2014, November 4.

▶ Public Administration – Hospitals

[ASSEMBLY OF THE REPUBLIC RESOLUTION – DIÁRIO DA REPÚBLICA No. 42/2016, SERIES I, 2016-03-01](#) – Assembly of the Republic - urges the Government to maintain management of the São José Hospital of Madeira and to make the necessary investment therein.

▶ SPMS

[NOTICE OF TERM EXTENSION No. 181/2016 – DIÁRIO DA REPÚBLICA No. 41/2016, SERIES II, 2016-02-29](#) – SPMS, E.P.E. – 2016/43 Framework agreement for the supply of material for packaging for sterilization to the Institutions and Services of the National Health Service.

[NOTICE OF TERM EXTENSION No. 183/2016 – DIÁRIO DA REPÚBLICA No. 42/2016, SERIES II, 2016-03-01](#) – SPMS, E.P.E. – 2016/112 Framework agreement for the Provision of Consultation Services in Health and Safety to the Institutions and Services of the National Health Service.

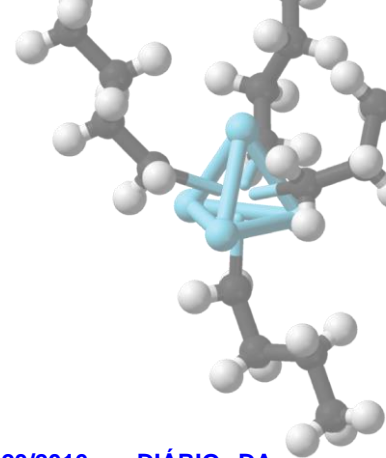
▶ Tenders

[PROCEDURE NOTICE No. 1194/2016 – DIÁRIO DA REPÚBLICA No. 41/2016, SERIES II, 2016-02-29](#) – North Lisbon Hospital Center, E.P.E. - 167A000004 – Acquisition of 40 infusion syringes.

[PROCEDURE NOTICE No. 1214/2016 – DIÁRIO DA REPÚBLICA No. 41/2016, SERIES II, 2016-02-29](#) – Leiria Hospital Center, E.P.E.- 1005A16 – Virology reagents.

[NOTICE OF TERM EXTENSION No. 178/2016 – DIÁRIO DA REPÚBLICA No. 41/2016, SERIES II, 2016-02-29](#) – Central Lisbon Hospital Center, E.P.E. – 1-2.0080/16 – Oximetry sensors compatible with masimo equipment.

[NOTICE OF TERM EXTENSION No. 179/2016 – DIÁRIO DA REPÚBLICA No. 41/2016, SERIES II, 2016-02-29](#) – Health Service of the Autonomous Region of Madeira,



E.P.E. – ICP20150031 – Reagents for automatic hematology for 2016.

[NOTICE OF URGENT TENDER No. 25/2016 – DIÁRIO DA REPÚBLICA No. 42/2016, SERIES II, 2016-03-01](#) – West Lisbon Hospital Center, E.P.E. – Acquisition of cochlear implants.

[PROCEDURE NOTICE No. 1255/2016 – DIÁRIO DA REPÚBLICA No. 43/2016, SERIES II, 2016-03-02](#) – West Lisbon Hospital Center, E.P.E. – CP200016 – Acquisition of orthopedic knee prostheses.

[PROCEDURE NOTICE No. 1263/2016 – DIÁRIO DA REPÚBLICA No. 43/2016, SERIES II, 2016-03-02](#) – Health Service of the Autonomous Region of Madeira, E.P.E. – CP20150009 – Gastroenterology equipment

[PROCEDURE NOTICE No. 1289/2016 – DIÁRIO DA REPÚBLICA No. 44/2016, SERIES II, 2016-03-03](#) – North Alentejo Local Health Unit, E.P.E. – Acquisition of medical urology equipment for the Urology Unit at the North Alentejo Local Health Unit, E.P.E.

[PROCEDURE NOTICE No. 1289/2016 – DIÁRIO DA REPÚBLICA No. 44/2016, SERIES II, 2016-03-03](#) – Francisco Gentil Portuguese Institute of Oncology of Coimbra, E.P.E. – Dressings for negative pressure therapy controlled by making equipment available.

[PROCEDURE NOTICE No. 1315/2016 – DIÁRIO DA REPÚBLICA No. 44/2016, SERIES II, 2016-03-03](#) – Barreiro Montijo Hospital Center, E.P.E. – Breast MRI exams and intervention for senology to CHBM E.P.E.

[NOTICE OF TERM EXTENSION No. 189/2016 – DIÁRIO DA REPÚBLICA No. 44/2016, SERIES II, 2016-03-03](#) – Health Service of the Autonomous Region of Madeira, E.P.E. – ICP20150014 – Miscellaneous osteosynthesis material for 2016.

[NOTICE OF TERM EXTENSION No. 191/2016 – DIÁRIO DA REPÚBLICA No. 44/2016, SERIES II, 2016-03-03](#) – Health Service of the Autonomous Region of Madeira, E.P.E. – NCP20150033 – Test strips for 2016.

[CORRECTION STATEMENT NOTICE No. 39/2016 – DIÁRIO DA REPÚBLICA No. 44/2016, SERIES II, 2016-03-03](#) – Health Service of the Autonomous Region of Madeira, E.P.E. – Acquisition of pain nueromodulation material – implantable systems.

[PROCEDURE NOTICE No. 1323/2016 – DIÁRIO DA REPÚBLICA No. 45/2016, SERIES II, 2016-03-04](#) – Cova da Beira Hospital Center, E.P.E. - Integrated Solution for the Anatomic Pathology Laboratory at the Cova da Beira Hospital Center.

II. MINISTRY OF HEALTH

▶ Commitment to Sustainability and Development of the National Health Service for the three year period 2016-2018.

The [Ministry of Health](#) and the representative associations of the pharmaceutical industry, distributors, pharmacies and the medical devices industry signed a commitment to the Sustainability and Development of the National Health Service for the three year period 2016-2018.

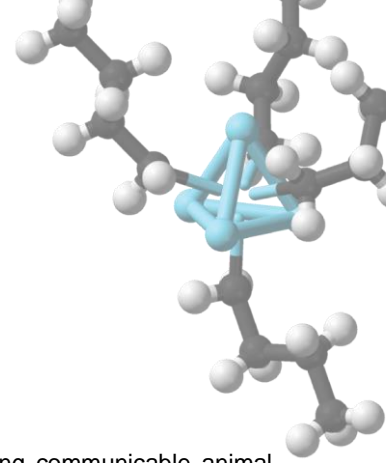
This commitment ensures that it will be possible to foresee the expense and stability of the sector agents, bringing together a wide range of agreements for the sustainability and the development of the National Health Service, meeting the needs of healthcare professionals and patients.

With this document, the Ministry of Health, APIFARMA (Portuguese Pharmaceutical Industry Association), APOGEN (Portuguese Association of Generic and Biogeneric Medicines), GROQUIFAR (Wholesalers of Chemical and Pharmaceutical Products Association), Norquifar (National Association of Importers/Wholesalers and Retailers of Chemical Products and Pharmaceuticals), ANF (National Pharmacy Association), AFO (Portuguese Pharmacies Association) and APORMED (Portuguese Association of Medical Devices Companies) strengthen their attitude of collaboration and convergence, based on a spirit of transparency, partnership and defending public interest.

III. INFARMED

▶ Drug for human use reimbursement assessment – Xarelto (rivaroxaban)

Rejection decision – The medicine Xarelto (rivaroxaban) for treatment of Acute Coronary Syndrome received a rejection decision on 30/12/2015 for a lack of added therapeutic



value. The evaluation report of the reimbursement for outpatients is available on the Evaluation Reports of Reimbursement Applications page.

IV. DIRECTOR GENERAL FOR HEALTH

▶ **Approved Work Program for 2016 of the 3rd Health Program 2014-2020**

Yesterday the [Work Program of the third Health Program 2014-2020](#) was approved. The highlights of this Work Program include 7 projects and over 25 procurement actions. All entities in the area of public health could benefit, including Hospitals, Universities, Companies, NGOs and National Authorities. Projects must involve at least 3 legal entity partners and must be innovative. To take advantage of the “exceptional utility” criterion, and receive a mark-up of co-financing of 80%, 60% of the total budget must finance staff and 30% of the budget has to be allocated to member states whose GDP is less than 90% of the European average.

▶ **Plan for the Prevention and Control of Mosquito-Borne Diseases**

The [Plan for the Prevention and Control of Mosquito-Borne Diseases](#), defines the areas of intervention relative to the capacity and mechanisms of preparation and responses to ensure the prevention and control of these diseases. It includes a set of mechanisms that guarantee entomological surveillance and early detection of populations of invasive mosquitoes. It focuses also on the early detection of mosquito-borne diseases and on the inter-sectorial response coordination required for the implementation of the appropriate measures. Communication also has a prominent place.

V. OFFICIAL JOURNAL OF THE EUROPEAN UNION

▶ **Third EU Action Program – Health**

Call for applications 2016 – Third EU Action Program in the field of health (2014-2020)

▶ **Animal Health Law**

Position (EU) No. 4/2016 of the Council at first reading with a view to the adoption of the Regulation of the European

Parliament and Council concerning communicable animal diseases and amending and repealing certain acts in the field of animal health (“Animal Health Law”) adopted by the Council on December 14, 2015.

Note of the Council’s reasons: Position (EU) No. 4/2016 of the Council at first reading with a view to the adoption of the Regulation of the European Parliament and Council concerning communicable animal diseases and amending and repealing certain acts in the field of animal health (“Animal Health Law”).

INTERNACIONAL LEGISLATION

I. OFFICIAL JOURNAL OF THE EUROPEAN UNION

▶ **Third EU Action Program – Health**

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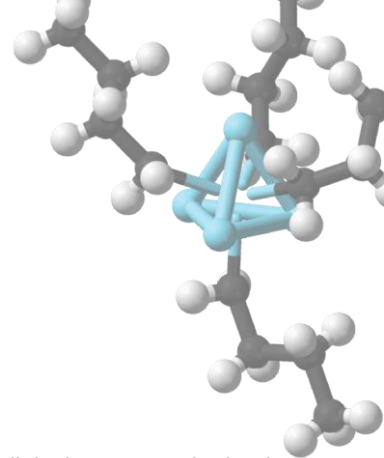
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I. COMISSÃO EUROPEIA

Summary minutes - Meeting of the Competent Authorities for Tissues and Cells (3-4 December 2015)

Kick-off meeting of the third HTA Joint Action: 3 March 2016

Interim guidance for healthcare providers - Technical document prepared by ECDC on 15 February 2016 and



endorsed by the HSC during the audio-conference of 24 February 2016

State of Play Investment Plan (January 2016)

EFSD project example in health: Midland Metropolitan Hospital

European Investment Project Portal (EIPP): call for input

Health Programme 2014-2020: Commission adopts Work Programme for 2016

Minutes of Working Group Meeting on Guidance on the structure and content of SCHEER of 17 February 2016

II. EUROPEAN MEDICINES AGENCY

▸ Guidance for the publication of clinical data

The [European Medicines Agency](#) has published [detailed guidance](#) for pharmaceutical companies on the requirements to comply with its policy on the publication of clinical data.

EMA's pioneering policy entered into force on 1 January 2015 and applies to clinical reports contained in all marketing-authorisation applications submitted on or after this date. The first reports are currently foreseen to be publicly available in September 2016.

The guidance consists of four chapters. The first is an overarching introduction with information on the scope and definitions used throughout the text. The second chapter details procedural aspects on the submission of clinical reports including the concrete processes. The third chapter gives guidance to companies on how to anonymise clinical reports for the purpose of publication. EMA recognises that a number of methods are available to make sure the data is presented in a form that does not allow re-identifying individuals who have participated in clinical trials. Therefore the guidance does not single out one specific anonymisation method yet gives recommendations to companies on how to best balance data utility for researchers with a minimal risk of re-identification.

Companies will need to provide a report explaining their approach to the anonymisation of the data, which will be reviewed and published by EMA. The fourth chapter focuses on the identification and redaction of commercially

confidential information (CCI) in clinical reports submitted to EMA for the purpose of publication. The guidance makes clear that the vast majority of the information contained in clinical reports is not considered CCI. However, in the limited circumstances in which clinical reports might contain CCI, companies will need to submit to EMA for review a table justifying why such data has been redacted. The guidance clarifies which type of data EMA would typically refuse as being CCI and how the redaction of such data will be handled.

▸ Novel veterinary medicines – how to make use of stem cells and monoclonal antibodies

The [European Medicines Agency](#) is seeking feedback from its stakeholders on possible issues encountered when developing new veterinary medicines based on stem cells or monoclonal antibodies. Stakeholders are invited to comment on two problem statements that discuss questions around the development of veterinary medicines using these new technologies by 15 May 2016. Comments should be sent by this date to vet-guidelines@ema.europa.eu using the template provided.

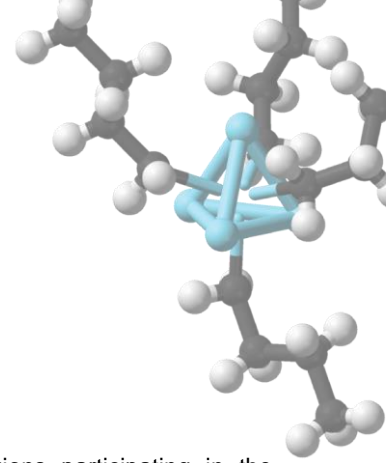
▸ Improving patient safety through more proactive risk management

The [European Medicines Agency](#) has published today a revision of [module V of the good pharmacovigilance practices \(GVP\) on risk management systems](#) for public consultation until 31 May 2016.

Risk management is a major component of the safety monitoring of medicines. Risk management entails putting in place measures to minimise potential risks and to fill knowledge gaps for medicines (e.g. through post-authorisation data). The goal is to ensure that throughout its lifespan the benefits of a particular medicine exceed the risks by the greatest achievable margin. Marketing authorisation holders are required to present the proposed activities in a risk management plan (RMP) that needs to be approved by the regulators before a medicine can be authorised.

▸ EMA confirms recommendations to minimise ketoacidosis risk with SGLT2 inhibitors for diabetes

The [European Medicines Agency](#) has confirmed recommendations to minimise the risk of diabetic ketoacidosis in patients taking SGLT2 inhibitors (a class of type 2 diabetes medicines).



▶ **EMA confirms recommendations to minimise risk of brain infection PML with Tysabri**

The [European Medicines Agency](#) has completed its review of the known risk of progressive multifocal leukoencephalopathy (PML) with the multiple sclerosis medicine Tysabri (natalizumab), and has confirmed initial recommendations aimed at minimising this risk.

▶ **Draft VICH GL55: Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use**

[Draft VICH GL55: Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use](#)

Summary: Submission of batch safety test data from target or laboratory animals is a requirement for batch release of veterinary vaccines in most regions participating in the VICH.

▶ **Draft reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances**

[Draft reflection paper on the authorisation of veterinary medicinal products containing \(potential\) persistent, bioaccumulative and toxic \(PBT\) or very persistent and very bioaccumulative \(vPvB\) substances](#)

Summary: Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances are associated with specific concerns because of their persistence, their ability to accumulate in the environment and in living organisms and their toxicity.

▶ **Draft VICH GL50: Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use**

[Draft VICH GL50: Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use](#)

Summary: Submission of batch safety test data from target or laboratory animals is a requirement for batch release of

veterinary vaccines in most regions participating in the VICH.

▶ **Draft guideline on the conduct of efficacy studies for intramammary products for use in cattle**

[Draft guideline on the conduct of efficacy studies for intramammary products for use in cattle](#)

Summary: This revised guideline is intended to provide guidance on the conduct of efficacy studies and their evaluation for veterinary medicinal products that are administered via the teat canal to cattle. It therefore addresses the treatment of clinical and subclinical mastitis during the lactation period, the treatment of subclinical mastitis at drying off, and the prevention of new intramammary infections during the dry period.

▶ **Guideline on good pharmacovigilance practices (GVP) 3 - Module V – Risk management systems (Rev 2)**

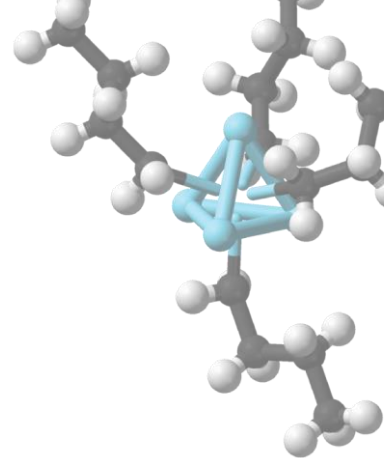
[Guideline on good pharmacovigilance practices \(GVP\) 3 - Module V – Risk management systems \(Rev 2\)](#)

Summary: Good pharmacovigilance practices (GVP) module V, released in 2012, advises developers of medicines, marketing authorisation holders and regulators on the design of effective risk management systems and plans. This first major revision clarifies the activities a risk management plan should focus on during the life cycle of a product. This will help to ensure that a risk-proportionate planning of activities directs resources to areas where the need for additional information and risk minimisation is greatest.

▶ **Draft guidance on format of the risk management plan (RMP) in the EU – in integrated format**

[Draft guidance on format of the risk management plan \(RMP\) in the EU – in integrated format](#)

Summary: The European Medicines Agency is consulting stakeholders on an amended risk management plan (RMP) template, to be used by medicine developers. The revision of the template is based on the principles described in the updated good pharmacovigilance practices (GVP) module V in the view of getting a focussed risk management



system and simplifying the way information is submitted to the regulators.

- ▶ **Draft stem cell-based products for veterinary use: specific questions on sterility to be addressed by ADVENT**

[Draft stem cell-based products for veterinary use: specific questions on sterility to be addressed by ADVENT](#)

Summary: Cell-based medicinal products (CBMP) are heterogeneous with regard to the origin and type of cells and to the complexity of the product. Cells may be - renewing stem cells, more committed progenitor cells or terminally differentiated cells exerting a specific defined physiological function.

- ▶ **Draft monoclonal antibodies for veterinary use: specific questions to be addressed by ADVENT**

[Draft monoclonal antibodies for veterinary use: specific questions to be addressed by ADVENT](#)

Summary: Monoclonal antibodies (mAbs) are immunoglobulins (Ig) with a defined specificity derived from a single clone of cells. Their biological activities are characterised by a specific binding characteristic to an antigen and may be dependent on immune effector function such as antibody-dependent cellular cytotoxicity and complement-dependent cytotoxicity.

- ▶ **Updates**

Scientific guideline: [Draft guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder](#)

[List of Union reference dates and frequency of submission of periodic safety update reports \(PSURs\)](#)

[Minutes of the COMP meeting 19-21 January 2016](#)

[Minutes - PDCO minutes of the 27-29 January 2016 meeting](#)

[Orphan medicines figures 2000-2015](#)

Scientific guideline (Adopted): [Questions and answers: Positions on specific questions addressed to the Pharmacokinetics Working Party](#)

[Background to clinical data publication policy](#)

[Justification table templates](#)

[Minutes of the PRAC meeting 11-14 January 2016](#)

[PRAC periodic-safety-update-report assessment report template CAP and NAP](#)

[PRAC periodic-safety-update-report assessment report template CAP only](#)

[PRAC periodic-safety-update-report assessment report template NAP only](#)

[CAT monthly report of application procedures, guidelines and related documents on advanced therapies: February 2016 meeting](#)

Regulatory and procedural guideline (Adopted): [Draft International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use \(ICH\) guideline S1 - Regulatory notice on changes to core guideline on rodent carcinogenicity testing of pharmaceuticals](#)

[Plasma-master-file certifications](#)

Scientific guideline: [Guideline on epidemiological data on blood transmissible infections \(Rev.1\), adopted](#)

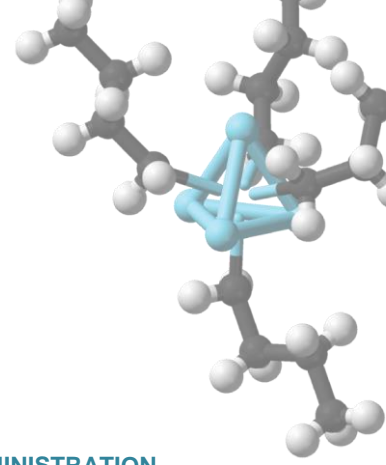
[Overview of comments received on Draft Revision of the Guideline on epidemiological data on blood transmissible infections \(EMA/CHMP/BWP/548524/2008\)](#)

[Appendices to Guideline on epidemiological data on blood transmissible infections](#)

[Advice on the impact on public health and animal health of the use of antibiotics in animals \(colistin\) following the recent discovery of the first mobile colistin resistance gene \(mcr-1\)](#)

[Good pharmacovigilance practices](#)

[Archive of development of good pharmacovigilance practices](#)



[Presentation - SME workshop: Session 3: Statistical considerations in confirmatory clinical trials I \(Norbert Benda\)](#)

[Presentation - SME workshop: Session 1: Statistical common types of clinical trial design, study objectives, randomisation and blinding, hypothesis testing, p-values and confidence intervals, sample size calculation \(David Brown\)](#)

[Presentation - SME workshop: Session 4: Statistical considerations in confirmatory clinical trials II \(Oliver Keene\)](#)

[Presentation - SME workshop: Session 2: Statistical considerations in exploratory studies \(Byron Jones\)](#)

III. HEADS OF MEDICINES AGENCIES

▶ Updates

['Blue-box' requirements](#)

[Report from the meeting held on 22-24 February 2016](#)

[PSUR assessment for quetiapine fumarate](#)

IV. U.S. FOOD AND DRUG ADMINISTRATION

▶ **FDA providing \$2 million in new grants for natural history studies in rare diseases**

The [U.S. Food and Drug Administration](#) announced the availability of \$2 million in research grants to fund natural history studies in rare diseases. The aim is to collect data on how specific rare diseases progress in individuals over time so that knowledge can inform and support product development and approval. This will be the first time the FDA will provide funding through its Orphan Products Grants to conduct these types of studies for rare diseases.

▶ **FDA issues recommendations to reduce the risk of Zika virus transmission by human cell and tissue products**

As an additional [safety measure](#) against the emerging Zika virus outbreak, the U.S. Food and Drug Administration issued new guidance for immediate implementation providing recommendations to reduce the potential transmission risk of Zika virus from human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance addresses donation of HCT/Ps from both living and deceased donors, including donors of umbilical cord blood, placenta, or other gestational tissues.

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