SRS ADVOGADOS NEWS LETTER LIFE SCIENCES

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This issue

LIFE SCIENCES

LEGISLATIVE HIGHLIGHTS

PORTUGUESE LEGISLATION

I. ASSEMBLY OF THE REPUBLIC

Palliative Care

Order Nº 3426/2016 - Diário da República n.º 46/2016, Series II of 2016-03-07 - Health – Cabinet of the Secretary of State Assistant & of Health – Establishing the legal framework for the relationship between pain-therapy units and intra-hospital palliative care support teams and reinforcing the disclosure of information concerning those EIHSCP teams.

Delegations

Order Nº 3427/2016 - Diário da República n.º 46/2016, Series II of 2016-03-07 - Health – Cabinet of the State Secretary of Health – Sub-delegation of the State Secretary of Health's powers within the Health System Central Administration, I.P.

Tenders

Ad Procedure Nº 1364/2016 - Diário da República Nº 46/2016, Series II of 2016-03-07 - Hospital Centre Trás-os-Montes e Alto Douro, E. P. E. - 955-2016 – Intravitreal and cataract-phacoemulsifiction packages.

Ad Procedure Nº 1434/2016 - Diário da República Nº 48/2016, Series II of 2016-03-09 - National Institute of Health Doctor Ricardo Jorge, I. P. - 31-2016 – Acquisition of reagents.

Ad Procedure Nº 1441/2016 - Diário da República Nº 48/2016, Series II of 2016-03-09 - Hospital Doctor Professor Fernando Fonseca, E. P. E. - Inpatient facilities for 12 beds for patients in long-term care in the Western Regions(nuts iii-19), Grande Lisboa (nuts iii-20).

Ad Procedure Nº 1478/2016 - Diário da República Nº 49/2016, Series II of 2016-03-10 - Hospital Centre Trás-os-Montes e Alto Douro, E. P. E. (CHTMAD) - 366/2016 – Acquisition of a Knee Prostheses System, for CHTMAD, E.P.E

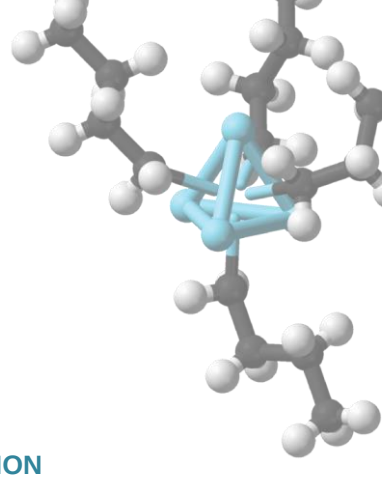
Urgent Ad Procedure Nº 29/2016 - Diário da República N° 50/2016, Series II of 2016-03-11 - Hospital Centre São João, E. P. E. - Acquisition of 2 echocardiography machines for the hospital centre in São João, E.P.E

Ad Procedure Nº 1521/2016 - Diário da República Nº 50/2016, Series II of 2016-03-11 - Regional Health Administration (North), I.P - Acquisition of Material Consumption Clinic

II. INFARMED (PORTUGUESE AUTHORITY OF MEDICINES & HEALTH PRODUCTS)

Monthly reports

Analysis of in-patient drug consumption – November 2015



Analysis of out-patient drug consumption – November 2015

Analysis of non-prescription drug consumption, sold outside of pharmacies - December 2015

- **Periods of drug distribution arising from the implementation of the Annual Price Review**

Information Circular **-** As disclosed in the Information Circular Nº 193/CD/8.1.6, of 25/11/2015, the distribution period of maximum-priced packages to pharmacies before they fall to the prices incurred by the Annual Price Review of Non-generic Drugs is as follows: 60 working days, starting on the 01-01-2016 (**until 28-03-2016**).
However, the INFARMED drug database previously calculated the expiry period incorrectly, giving 60 consecutive calendar days. After identifying and correcting this error, it is noted that the database has now been updated to show the aforementioned data.

III. GENERAL ADMINISTRATION OF HEALTH

- **Tenders**

Tenders for financial support allocated by the General Administration of Health, to non-profit collectives, as published as an open tender in the newspaper, "Público" on 31/12/2015, on the General Administration of Health's website, and in the National Programme for HIV/AIDS. This is in compliance with Decree-Law Nº 186/2006, of 12th September, as amended by Article 165º of the Law Nº 83-C/2013, of 31st December, and Decree Nº 258/2013, of 13st August, as amended by Decree Nº 339/2013, of 21st November.
Disclosure of the final lists of the support as approved and unapproved by the General Administration of Health. On this date, the candidates will be informed of the decision.

Tender SIDA-D-01-15 – Final list
Tender SIDA-D-02-15 – Final list
Tender SIDA-D-08-15 – Final list
Tender SIDA-D-10-15 – Final list

- **Reference Centre-Portugal**

Rule nº 005/2016 of **11/03/2016 - Terms of use of the term:** "Reference Centre - Portugal".

INTERNACIONAL LEGISLATION

I. E.U OFFICIAL JOURNAL

COMMISSION REGULATION (EU) .of the European Parliament and Council, concerning cosmetic products.

II. EUROPEAN COMMISSION

Minutes of meetings between the task groups of the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER), and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), taking place between 18th February and 3rd March. Meeting agenda for SCCS on 16th March.

SCCS - Minutes of Working Group Meeting on Nanomaterials in Cosmetic Products of 03 March 2016

SCHER - Minutes of 5th Working Group Meeting on Toys material ingested by children of 23 February 2016

SCHER - Minutes of 4th Working Group Meeting on Rapid Risk Assessment of 26 February 2016

SCENIHR - Minutes of Working Group Meeting on Tobacco additives of 18 February 2016

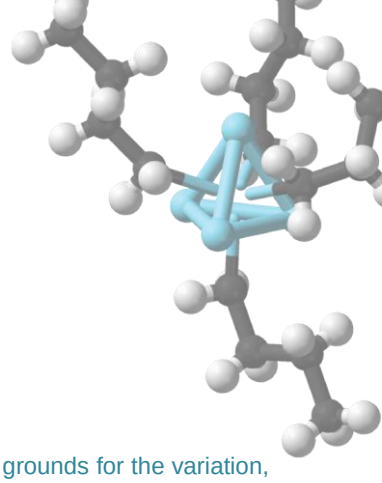
SCCS - Draft agenda of the 13th Plenary meeting, Luxembourg, 16 March 2016

III. EUROPEAN MEDICINES AGENCY

- **Launch of PRIME – Paving the way for promising medicines for patients**

The European Medicines Agency launched its new PRIME (PRIority MEdicines) scheme to strengthen support to medicines that target an unmet medical need. The scheme focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options. These medicines are considered priority medicines within the European Union.

- **Updates EMEA on Competition Matters**



Scientific conclusions and grounds for the variation, amendments to the Product Information and timetable for the implementation: ticlopidine PSUSA/00002952/201505

Minutes of the COMP meeting 19-21 January 2016

Template letter of intent for request of scientific advice - veterinary

Cebranopadol - Notification of discontinuation of a paediatric development which is covered by an agreed paediatric-investigation-plan decision

Annual renewal of conditional marketing authorisations: questions and answers

Extension applications: questions and answers

Type-II variations: questions and answers

Pre-submission guidance: questions 1 to 11

Pre-submission guidance: questions 45 to 56

Development support and regulatory tools for early access to medicines

Transfer of MA templates Attachment 4

Transfer of MA templates Attachment 6.1

Information required for early identification of a need for pre-authorisation GCP inspections

PDCO monthly report of opinions on paediatric investigation plans and other activities 24-26 February 2016

Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures adopted at the CHMP meeting of 22-25 February 2016, adopted

List of nationally authorised medicinal products:
oxaliplatin PSUSA/00002229/201504
gadoteridol PSUSA/00001507/201504
pamidronate PSUSA/00002269/201505
ticlopidine PSUSA/00002952/201505
tiagabine PSUSA/00002942/201506
tianeptine PSUSA/00002943/201506
sertindole PSUSA/00002695/201507

CMDh: Scientific conclusions and grounds for the variation, amendments to the Product Information, and timetable for the implementation: oxaliplatin PSUSA/00002229/201504

Scientific conclusions and grounds for the variation, amendments to the Product Information, and timetable for the implementation: gadoteridol PSUSA/00001507/201504

Scientific conclusions and grounds for the variation, amendments to the Product Information, conditions to the MA and timetable for the implementation: pamidronate PSUSA/00002269/201505

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

Scientific guideline (Adopted): Revised note for guidance on limitations to the use of ethylene oxide in the manufacture of medicinal products

Public statements:
Public statement on Nuedexta: Withdrawal of the marketing authorisation in the European Union

Public statement on Paglitaz: Cessation of validity of the marketing authorisation in the European Union

Public statement on Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostic: Expiry of the marketing authorisation in the European Union

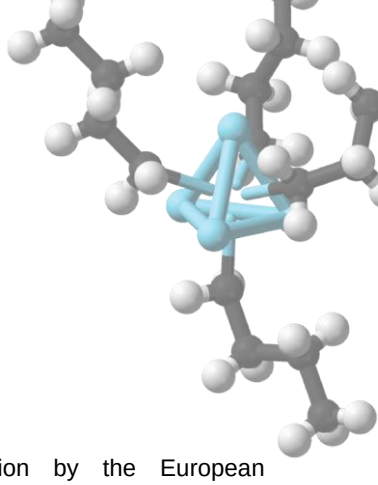
Agenda: Agenda - European Medicines Agency Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting Session on communication and information on medicines

Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure

IV. HEADS OF MEDICINES AGENCIES

Best Practice Guide on handling of PSURs in MR-DC procedures
CMDh Strategy to 2020

Outcome of the public consultation on the CMDh strategy to 2020



PSUR assessment for acitretin; cabergoline; mepivacaine, mepivacaine/adrenaline, mepivacaine hydrochloride/dextrose monohydrate; piretanide; ramipril; risperidone

Summary of CMDh activities 2015

2015 - Statistics for New Applications (MRP/DCP), Variations and Referrals

- **Updates**

Information on national timeslot booking systems and recommendations for requests to act as RMS

Corrected PAR for ethinylestradiol and drospirenone - Deletion of interaction between broad spectrum antibiotics and combined oral contraceptives

Chapters 4, 5, 6 7 of the Best Practice Guide on Variations

CMDh Best Practice Guide on the processing of renewals in theMRP/DCP
CMDh SOP - Disagreement in procedures -Referral to CMDh

Q&A on referrals

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

V. EFPIA

- **Country Reports in the European Semester 2016**

EFPIA welcomed the publication by the European Commission of the Country Reports as part of the European Semester 2016. The reports highlight, among other things, issues relating to health status and healthcare systems in the EU Member States – albeit primarily from a perspective of financial sustainability – and will hopefully lead to important discussions around healthcare reform in the EU Member States that improves health outcomes of patients. For more information on the Country Report for Portugal: Country Report 2016

VI. U.S. FOOD AND DRUG ADMINISTRATION

- **FDA approves first coagulation factor-albumin fusion protein to treat patients with hemophilia**

The U.S. FDA approved Idelvion, Coagulation Factor IX (Recombinant), Albumin Fusion Protein, for use in children and adults with Hemophilia B. Idelvion is the first coagulation factor-albumin fusion protein product to be approved, and the second Factor IX fusion protein product approved in the U.S. that is modified to last longer in the blood. Idelvion is manufactured by CSL Behring, headquartered in King of Prussia, Pennsylvania.

- **FDA permits marketing of device that senses optimal time to check patient's eye pressure**

The U.S. FDA allowed marketing of a one-time use contact lens that may help practitioners identify the best time of day to measure a patient's intraocular pressure (IOP). Elevated IOP is often associated with the optic nerve damage that is characteristic of glaucoma. The Triggerfish is manufactured by Sensimed AG of Lausanne, Switzerland.