SAÚDE

LEGISLAÇÃO

Portaria n.º 260/2014 - Diário da República n.º 241/2014, Série I de 2014-12-15 **Ministérios da Administração Interna e da Saúde** Aprova o Regulamento do Transporte de Doentes	NACIONAL

REGULAÇÃO

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	INFARMED
Concurso 2014 / 11 - Estimulantes da eritropoiese — Programa de Concurso — Caderno de Encargos — **Lista de Entrada em Vigor CPAs** _17/12/2014	SPMS
Research and Generic/Biosimilar Industries Call for Integrated Life Sciences Strategy for Europe Ahead of the adoption of the European Commission Work Programme, the European Federation of Pharmaceutical Industries and Associations, and the European Generic medicines Association (EGA), would like to reiterate their joint Europe 2020 Strategy submission to welcome Commission President Juncker Commission's work programme for an industrial policy for the globalisation era, and the value it places in the pharmaceutical sector. The joint submission highlights key proposals on how to successfully integrate the pharmaceutical sector for an industrial policy that will boost European health and wealth alike.	EFPIA
Q&A | Pharmacovigilance Legislation	EMA
Human Medicines | Type-IA variations: questions and answers (updated) **Human Medicines | Submission of Article-46 paediatric studies**: questions and answers (updated) **Human Medicines** | **Withdrawn-product notification:** questions and answers (updated)	EMA

Human Medicines | **European Medicines Agency practical guidance** on the application form for centralised type IA and IB variations

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

Human Medicines | Regulatory and procedural guideline: Dossier requirements for referral procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs) (updated)

Human Medicines | Regulatory and procedural guideline: Dossier requirements for referral procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs) (updated)

Human Medicines | Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated)

Parallel distributors are only required to inform the EMA of changes to the labelling or leaflet related to any update of the annexes of marketing authorisation once a year in their annual update application, except in cases related to safety or quality issues.

Human Medicines | Regulatory and procedural guideline: Procedure for reporting of pharmacovigilance inspections requested by the CVMP, adopted (updated)

Human Medicines | Quality control of medicinal-product data submitted as per the legal requirement introduced by Article 57(2) of Regulation (EC) No 726/2004 (updated)

Human Medicines | Report: Electronic submission of medicinal product information by marketing-authorisation holders

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

Human Medicines | The European Union regulatory network incident management plan for medicines for human use (updated)

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Human Medicines | Scientific guideline: Guideline on quality of transdermal patches

This guideline addresses new marketing authorisation applications (including generic or abridged applications) and subsequent variation submissions for transdermal patches for systemic delivery.

Guidance is provided on the quality requirements for the description, development, manufacture, characterisation of excipients, control of drug product, packaging and stability of transdermal patches. In particular, in vitro performance testing with respect to drug release, adhesion and skin permeation is discussed, together with its relation to clinical and in vivo performance

Human Medicines | Scientific guideline: Guideline on the use of phthalates as excipients in human medicinal products

This guideline covers the phthalates most commonly used as excipients in medicinal products authorised in the EU.

Human Medicines | Report: Assessment report for Article-5(3) procedure: **Medicinal products under development for treatment of Ebola**

Human Medicines | Guideline on the use of minimal residue disease as an endpoint in chronic lymphocytic leukaemia studies

The scope of this document is to describe the basis and regulatory requirements for the use of minimal residue disease (MRD) as an intermediate endpoint to predict clinical benefit in trials in chronic lymphocytic leukaemia (CLL). At present, this guidance is not applicable to other clinical settings.

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