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SAÚDE

LEGISLAÇÃO

NACIONAL

Decreto-Lei n.º 54/2013. D.R. n.º 75, Série I de 2013-04-17

Ministério da Saúde

Procede à definição do regime jurídico da prevenção e proteção contra a publicidade e comércio das novas substâncias psicoativas

Portaria n.º 154/2013. D.R. n.º 75, Série I de 2013-04-17

Ministério da Saúde

Aprova a Lista de novas substâncias psicoativas

REGULAÇÃO

INFARMED

Deliberação n.º 051/CD/2013 de 19 de março - Aquisição directa de medicamentos para as unidades de diagnóstico e terapêutica na área da Medicina Nuclear

Publicação para efeitos do artigo 15º-A do Decreto -Lei n.º 176/2006, de 30 de Agosto - pedidos de autorização de introdução, ou registo, no mercado de medicamentos genéricos

COMISSÃO EUROPEIA

Notice to applicants, medicinal products for human use, volume 2B, module 1.2 administrative information application form

The revised version of the application form is published (version 10 from April 2013). Applicants shall use it as from Monday 3 June 2013, but may use it before.

The electronic version of this application form is currently prepared and should be available in May 2013

EFPIA

European Pharmaceutical Industry welcomes the compromise on the Priority Substances proposal

EFPIA, AESGP & EGA, as the collective voice of the European pharmaceutical industry, welcome the compromise announced yesterday by the Irish presidency on the Priority Substances proposal in the Water Framework Directive. The compromise reached between the European Parliament and the Council includes three pharmaceutical substances, diclofenac, ethinylestradiol and estradiol, in the Watch List for a monitoring exercise.

Position Paper - **Disappointing decision by the Indian Supreme Court to deny a first patent to Novartis' break through medicine Glivec**

This week the Indian Supreme Court denied the patent application of Novartis for its breakthrough medicines Glivec even though it was rewarded a patent in 40 other countries including China, Russia and Taiwan. We as an industry believe that this decision will undermine incentives for innovation in the long term in India but also in other emerging countries and is detrimental for patients. It also confirms the deteriorating standards in India regarding intellectual property protection and that these are not well-adapted to the realities of pharmaceutical R&D while being in variance to those of many other countries, including its main trading partners.

Artigo - **Considering the Impact: A European Patent with Unitary Effect and Unitary Patent Court**

After 40 years of false starts, a European Patent with Unitary Effect (the UP) and a Unitary Patent Court (the UPC) is expected in the near future. The biopharmaceutical industry strongly supports a unitary patent and court even though the UP and UPC will not launch in all EU Member States initially (Italy and Spain are yet to join) and with legal uncertainties that may see an incremental engagement of biopharma with the UP/UPC.

EMA

Veterinary Medicines | Scientific guideline: Concept paper on assessing the toxicological risk to humans and the environment of veterinary pharmaceuticals in groundwater (Consultation end date 30/06/2013)

This intended guideline should provide further technical support to the implementation of the VICH 19 guidelines GL6 and GL38 on the environmental risk assessment (ERA) of veterinary medicinal products (VMPs).

Veterinary Medicines | **Questions and answers** on adverse event reporting

Veterinary Medicines | **Questions and answers** on serious non-fatal adverse events and reporting rules

Veterinary Medicines | Regulatory and procedural guideline: Substances considered as not falling within the scope of Regulation (EC) no 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

Veterinary Medicines | **Questions and answers** related to management and assessment of periodic safety update reports (PSURs)

Human Medicines | Scientific guideline: Guideline on good pharmacovigilance practices (GVP): Product-or population-specific considerations I: Vaccines for prophylaxis against infectious diseases (consultation end date - 12/06/2013)

The objective of this module is to strengthen the conduct of pharmacovigilance for vaccines. It should be noted that the overall objectives and processes of pharmacovigilance are no different for vaccines and other types of medicinal products and this guidance does not replace the information provided in the other modules of the good pharmacovigilance practices (GVP). This module focuses on vaccine-specific aspects and unique challenges that should be borne in mind when designing and implementing pharmacovigilance activities for vaccines.

Human Medicines | Scientific guideline Guideline on good pharmacovigilance practices (GVP): P I - Vaccines for prophylaxis against infectious diseases – Definitions for inclusion in GVP annex I (consultation end date - 12/06/2013)

Human Medicines | Scientific guideline: Guideline on good pharmacovigilance practices: Module II – Pharmacovigilance system master file ((updated))

This Module provides detailed guidance regarding the requirements for the pharmacovigilance system master file, including its maintenance, content and associated submissions to competent authorities, applicable from July 2012, during the transition period (as described in Article 2 of Directive 2010/84/EU and Article 3 of Regulation (EU) No 1235/2010), and after 2015.

Human Medicines | Guidelines on good pharmacovigilance practices: Introductory cover note, last updated with revision of module II

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