

Europe Legal and Regulatory Affairs

Watchdog Update



This European watchdog is providing information relevant to ISCT areas of concern, including: 1) recent and upcoming workshops or meetings, 2) recently published regulatory documents, and 3) guidelines currently opened for public consultation.

European network of paediatric research at the European Medicines Agency (Enpr-EMA) Awareness Webinar on 1 December 2016, 14:30 to 15:30 GMT

Enpr-EMA was set up to facilitate the conduct of clinical studies in children. It is an umbrella network of 39 national and international networks recognised for their paediatric research experience. It acts as a platform for sharing good practices as well as a pan-European voice to foster high-quality, ethical research on the safety and effectiveness of medicines for children.

The webinar will aim to raise awareness on Enpr-EMA and illustrate the benefits Enpr-EMA and clinical research networks can offer. A Q&A session will follow the presentations.

More information about this webinar can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2016/11/event_detail_001364.jsp&mid=WC0b01ac058004d5c3

Creation of an innovation office at the Health Products Regulatory Authority (HPRA) in Ireland

The Innovation Office will be focused on directly assisting innovators (individuals, academics, SMEs, pharmaceutical and medical device companies, and other groups) to understand and comply with EU and national regulations when developing novel health products or new approaches for manufacturing or testing of such products. It will provide regulatory support in respect of all areas regulated by the HPRA including medicines, medical devices, drug-device combination products and cosmetics.

More information on HPRA website: <https://www.hpra.ie/innovation-office>

Update of the “User guide for micro, small and medium-sized enterprises (SMEs)”
published by EMA on 19 October 2016

The European Medicines Agency (EMA) has updated its user guide for SMEs operating in the pharmaceutical sector.

The guide aims to support SMEs to better understand the EU legislative framework relating to medicines and the requirements for the development and authorisation of medicines for human or veterinary use. The guide, which follows the chronological stages of developing a medicine, has been completely revised to clarify existing sections and add new ones relating to compassionate use, Priority Medicines (PRIME), post-authorisation measures that can be imposed at the time of marketing authorization and the proactive publication of clinical data for medicinal products for human use.

Link to the EMA News:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/10/news_detail_002623.jsp&mid=WC0b01ac058004d5c1
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/10/news_detail_002623.jsp&mid=WC0b01ac058004d5c1

Link to the user guide:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004134.pdf

Commission notice on the application of Articles 3, 5 and 7 of Regulation (EC) No 141/2000 on orphan medicinal products (2016/C 424/03) published by the European

Commission (EC) on 18 Nov 2016

This notice replaces the Communication 2003/C 178/02. Its scope is the same: it is intended to facilitate the application of Articles 3 (criteria for designation), 5 (procedure for designation and removal from the register) and 7 (Union marketing authorisation) of Regulation (EC) No 141/2000.

The communication can be found here:

[http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC1118\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC1118(01)&from=EN)

Public consultation on strengthening EU cooperation on Health Technology Assessment (HTA) from 21 October 2016 to 13 January 2017

The purpose of this consultation is to collect from all stakeholders information, views and opinions on the European HTA cooperation. Specifically, stakeholders are invited to share their experiences in the current system and the on-going cooperation mechanisms, their needs in the future and their opinion on the proposed approach in the “Inception Impact Assessment”.

Through the current cooperation the European Commission already has a good first indication of the needs and the concerns of the main stakeholder groups, and studies are being launched to provide further data. Yet, understanding and assessing the views and opinion of the broader constituency of stakeholders will be crucial in order to develop an initiative that meets expectations, demonstrates EU added value and allows for effective implementation.



More information about this consultation can be found here:

http://ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_en.htm

Public consultation on the Pediatric Regulation by the European Commission (EC) from 15 November 2016 to 20 February 2017

The European Commission (EC) launched a public consultation in preparation for its second report on the Paediatric Regulation after nearly ten years of implementation.

The consultation is based on an EMA/PDCO report on experience with implementing the Regulation. The report shows that paediatric medicine development has improved in the European medicines regulatory network over the last ten years but also highlighted challenges to be addressed.

The consultation includes 17 questions regarding pediatric medicines and their development. Its objective is to help the EC to inform its second report on the Pediatric Regulation, ten years after its implementation.

The European Commission expects to publish the final report in 2017. More information about this consultation can be found here:

http://ec.europa.eu/health/human-use/paediatric-medicines/developments/2016_pc_report_2017.htm

Guidelines opened for public consultation

Draft guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products until 28 February 2017.

http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500216158&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc