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Global Regulatory News

International

EMA and European Commission Renew Confidentiality Arrangement with Canada[1]

The European Medicines Agency (EMA) and the European Commission's Directorate General for Health and Consumers have renewed their confidentiality arrangement with the Health Products and Food Branch of Health Canada, the Canadian regulatory authority for medicines, for a further five-year period. The renewal builds on the success of the original 2007 confidentiality arrangement. It will allow the two parties to continue to exchange regulatory information related to the authorization and supervision of medicinal products for human and animal use for a further period of five years, with tacit renewal for subsequent five-year periods.

EMA and European Commission Renew Confidentiality Arrangement with Japan[2]

The EMA and the European Commission's Directorate General for Health Consumers have renewed their confidentiality agreement with the Japanese medicines regulatory authorities for a further five-year period. The renewal of this arrangement allows the Agency to continue the exchange of confidential information on the regulation of human medicines with Japan's Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency until February 2018, with the possibility of further extensions for five-year periods.

Middle East

Saudi Arabia

SFDA Launches Code of Ethics for Marketing of Pharmaceutical Products[3]

The Saudi Food and Drug Authority (SFDA) has launched the Saudi Code of Ethics for practicing pharmaceutical products marketing in the Kingdom. This code of ethics is considered a moral and ethical agreement for practicing pharmaceutical and drug marketing by all drug factories and organizations working in this field and practitioners in the healthcare sector, including physicians and pharmacists in the public or private sectors.

Asia/Pacific Rim

China

Chinese SFDA Issues Opinions on Drug Evaluation and Approval Reform and Drug Innovation[4]

The Chinese State Food and Drug Administration (SFDA) recently issued the Opinions on Deepening Drug Evaluation and Approval Reform and Further Encouraging Drug Innovation. Focusing on the aspects of changing the evaluation concept for innovative drugs, adjusting the evaluation strategy for generic drugs, strengthening quality management for drug clinical trials, and encouraging the research and development of children's drugs, the Opinions aims at deepening reform, encouraging innovation, and using the limited evaluation resources mainly for innovative drugs with clinical value and generic drugs urgently needed in clinical treatment.

Chinese SFDA Adopts Revised Good Supply Practice for Pharmaceutical Products[5]

The newly revised Good Supply Practice (GSP) for Pharmaceutical Products was recently adopted at the executive meeting of the Ministry of Health and officially issued. It will go into effect 1 June 2013. The revision of GSP is an action of China to adjust the policy for supervision of drug distribution. The revised GSP sets higher qualification requirements and higher standards for engaging in drug distribution. Compared with the current GSP, the newly revised GSP has higher requirements for quality management, which will effectively enhance the capability to control drug quality risk in the distribution process. The revised GSP comprises 187 articles in four chapters, including the General Provisions, Quality Management for Wholesale of Pharmaceutical Products, Quality Management for Retail of Pharmaceutical Products and Supplementary Provisions.

India

Slow Approvals Put India's Drug Trials Industry at Risk[6]

Slower government approval for testing new medicines is threatening India's aspirations to be a fast-growing, low-cost hub for clinical trials, and has prompted some drugs firms to shift operations elsewhere, adding to their costs.

Europe

European Union

New Members of EMA Management Board Appointed[7]

In December 2012, four new members were appointed to the Management Board of the European Medicines Agency (EMA); all are representatives from the doctor's and patient's organizations. Dutch citizen Wim Wientjes was elected as a representative from the umbrella organization International Diabetes Federation.

European Commission Publishes Draft Guidelines on Principles of Good Distribution Practices for Active Substances[8]

This new guideline covers manufacturing activities consisting of repackaging, re-labeling, or dividing up of active substances. It can be found at: http://ec.europa.eu/health/files/gmp/2013-02_gdp_for_api_cons.pdf.

EMA Revises Guidance to Include Orphan-Related Information[9]

The EMA has revised three guidance documents to include information related to orphan medicines. These documents provide guidance to applicants in relation to pre-authorization and post-authorization procedures and applications for marketing authorization of generic/hybrid medicinal products. The revision includes questions and answers related to medicines that have been designated as orphans or for indications in which there are already orphan medicines authorized. In the latter case, there is a need for assessment of similarity in comparison with the authorized orphan medicine and, where applicable, the assessment of any of the derogations in the Orphan Regulation.

Europe Split Over New Rules on Medical Devices[10]

EU health representatives are considering the introduction of two new pieces of legislation on the approval of medical devices. While stakeholders agree with the need to beef up patient safety with improved checks and changes to the system of Notified Bodies, whose job it is to review and approve products in each of the EU member companies, they could not come to a consensus on whether to insist devices should have EU premarket authorization.

Tackling Medication Errors: EMA Workshop Calls for Coordinated EU Approach[11]

A close collaboration between national patient safety authorities, national competent authorities, the EMA, and the European Commission is necessary to tackle the issue of medication errors causing harm in Europe. This collaboration should engage patients and healthcare professionals. This was the conclusion of the workshop on medication errors organized by the Agency from 28 February to 1 March 2013.

EMA Focuses on New Legislation, Increased Efficiency and Transparency in 2013 Work Program[12]

The EMA has published its work program for 2013. This year, the Agency's priorities are to:

- continue to ensure that assessment activities are conducted to the highest levels of quality and of regulatory and scientific consistency
- continue to implement the pharmacovigilance legislation, depending on resources
- continue to prepare for the implementation of the falsified-medicines legislation
- prepare for the outcome of the European Commission's impact assessment on revision of the veterinary-medicines legislation
- further develop the communication and transparency activities of the Agency

European Union Adopts Good Distribution Practice Guidelines[13]

The EU Commission's new guidelines on Good Distribution Practice of medicinal products for human use have been adopted and published. The guidelines will enter into force 8 September 2013. They can be found at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:068:0001:0014:EN:PDF.

EMA Updates Product-Information Template as Part of Pharmacovigilance Legislation[14]

As part of the implementation of the European Union (EU) pharmacovigilance legislation, the EMA has updated the product-information template to allow easy identification of human medicines that are subject to additional monitoring and to encourage adverse-reaction reporting for all medicines.

Great Britain

MHRA Publishes Annual Report on Regulation of Medicines Advertising[15]

The Medicines and Healthcare Products Regulatory Agency (MHRA) published an annual report, "Delivering high standards in medicines advertising regulation." This covers the year 2012. It provides details of the activities of the Advertising Standards Unit, including vetting of advertising and complaints investigated and the development of guidance with self regulatory bodies to promote high standards.

MHRA Looking to Appoint New Chief Executive[16]

The MHRA is looking to appoint a new Chief Executive who, in addition to leading the MHRA and working with the Department of Health, will be an ambassador representing the MHRA within Europe and wider global circles. The new Chief Executive will be accountable for ensuring the interests of the public are protected, and that a first class service is provided to agencies and the public.

MHRA Launches "Innovation Office" to Encourage Development of Novel Medical Products and Devices[17]

The MHRA is launching an "Innovation Office" to help organizations who are developing innovative medicines, medical devices, or using novel manufacturing processes to navigate

the regulatory processes in order to be able to progress their products or technologies. The main aim of the "Innovation Office" will be to promote early dialogue between innovative organizations and the MHRA to help facilitate their understanding of the regulatory considerations applicable to their innovation. For example, the MHRA can advise on the development of innovative products like advanced therapies, nanomedicines, and drug device combinations.

MHRA Marks First Ever Successful Prosecution under Good Laboratory Practice Regulations[18]

A man was found guilty at Edinburgh Sherriff's Court for altering preclinical trial data designed to support applications to perform clinical trials. Steven Eaton was prosecuted under the Good Laboratory Practice Regulations 1999 - the first time the MHRA has successfully used these regulations to bring a prosecution. Eaton is a former employee of Aptuit, a large research organization formerly based in Edinburgh.

Netherlands

Dutch MEB Releases Draft Strategic Business Plan for 2014-2018[19]

The Dutch Medicines Evaluation Board (MEB) released its draft Strategic Business Plan (SBP) 2014 – 2018. This SBP will determine the direction of the organization for the next five years and will form the basis of the annual plans by the MEB. The new SBP is partly a continuation of the strategy set out over the past years, but important sections will be intensified and new directions will be taken. The new SBP has been submitted to the Minister of Health, Welfare and Sport for final approval and will be presented at the MEB Day 5 June 2013.

North America

Canada

Information Available on Classification of Health Products at the Device-Drug Interface[20]

Products at the device-drug interface are products that do not readily fall within the definition of "device" or "drug" as set out in Health Canada's Food and Drugs Act, therefore present a challenge when determining which regulations apply. Health Canada's website provides information on how such products are classified. It can be found at: http://www.hc-sc.gc.ca/dhp-mps/dev-drug-instr-drogue/index-eng.php.

United States

Working with the US FDA Office of the Ombudsman[21]

Like many federal agencies, the FDA has a robust ombudsman program that addresses concerns and complaints from regulated industry and the public. At FDA, most product evaluation centers house their own ombudsman staff that address center specific issues. The FDA Office of the Ombudsman, as part of the Office of the Commissioner, provides this function for the agency as a whole. A new brochure, which can be found at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/ExecSec/UCM164330.pdf, provides guidance on working with the Office of the Ombudsman at FDA.

US FDA Names Kathleen Uhl Acting Director, Office of Generic Drugs[22]

The FDA has named Dr. Kathleen Uhl Acting Director of its Office of Generic Drugs as it initiates a nationwide search for a full-time replacement for Dr. Gregory Geba, who resigned in March.

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