International Journal of Drug Regulatory Affairs
Associated with Delhi Pharmaceutical Sciences & Research University
(Established under Act 07 of 2008, Govt. of NCT of Delhi)

Online ISSN: 2321-6794 Print ISSN: 2321-7162

Editorial note – 2017 - First Edition - Quarter 1

Dear Readers,

It is pleasure to editorial note for International Journal of Drug Regulatory Affairs. It covers summary across globe from all health Authorities and major action in the industry.

IJDRA is Quarterly Open-access and peer-reviewed Journal circulated electronically and Print since 2013 to provide the quality information on the latest updates on Drug regulation. It is the first Journal for subject Drug Regulatory Affairs in India, and it publishes Research articles, Review articles, and Case studies on all aspects of Drug Regulatory Affairs, Pharmaceutical Development, Medical and Health Sciences in association with Delhi Pharmaceutical Sciences and Research University (DPSRU), New Delhi, India. The journal serves researchers from academia and industry and intended to be of interest to a broad audience of Pharmaceutical, Medical and Health professionals.

Please refer followings for the first Edition of 2017:

Statement from FDA Commissioner Robert Califf, M.D. announcing FDA Oncology Centre of Excellence launch

U.S. Food and Drug Administration is establishing the Oncology Center of Excellence (OCE) and appointing Dr. Richard Pazdur as its director. This will make oncology the first disease area to have a coordinated clinical review of drugs, biologics and devices across the agency's three medical product centers.

The FDA is taking important steps to formalize the structure and implementation of the OCE as part of its overarching effort to better address the needs of cancer patients, through reorganization within the FDA's Office of Medical Products and Tobacco. While the review criteria and application requirements for medical products, as well as the work of review staff in the centers will not change, uniting experts to collaborate on the clinical review of oncology products will enhance the agency's work in approving safe and effective cancer products.

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In addition, the FDA's Oncology Center of Excellence will improve the agency's ability to advance oncology-related regulatory science and policy and streamline stakeholder engagement.

FDA approves Odactra for house dust mite allergies.

The U.S. Food and Drug Administration approved Odactra, the first allergen extract to be administered under the tongue (sublingually) to treat house dust mite (HDM)-induced nasal inflammation (allergic rhinitis), with or without eye inflammation (conjunctivitis), in people 18 through 65 years of age. "House dust mite allergic disease can negatively impact a person's quality of life," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "The approval of Odactra provides patients an alternative treatment to allergy shots to help address their symptoms."

House dust mite allergies are a reaction to tiny bugs that are commonly found in house dust. Dust mites, close relatives of ticks and spiders, are too small to be seen without a microscope. They are found in bedding, upholstered furniture and carpeting. Individuals with house dust mite allergies may experience a cough, runny nose, nasal itching, nasal congestion, sneezing, and itchy and watery eyes.

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 17-19 January 2017

CVMP **opinions on veterinary** medicinal products

The Committee adopted by consensus a positive opinion for a grouped type II variation application for RESPIPORC FLU3 regarding quality changes.

The Committee adopted by consensus positive opinions for type IB variation applications (subject to a worksharing procedure), regarding quality changes, for:

ZULVAC 8 Bovis, ZULVAC 1+8 Ovis, ZULVAC 1 Ovis, ZULVAC 1+8 Bovis, ZULVAC 8 Ovis and ZULVAC 1 Bovis; and

Clomicalm, OSURNIA, ZOLVIX, Econor, FORTEKOR PLUS, Onsior and Prac-Tic.

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EMA to set up technical group in the context of the publication of clinical data

The European Medicines Agency (EMA) has today launched a call for applications to join a technical anonymisation group (TAG) that will help the Agency to further develop best practices for the anonymisation of clinical reports. The goal is to set up a multidisciplinary team with a broad range of expertise.

As of October 2016, EMA gives open access to clinical reports on medicines under phase I of its policy on the publication of clinical data (EMA Policy 0070). This requires the anonymisation of reports in line with European personal data protection law.

Anonymisation of clinical reports poses a major challenge to those directly involved (pharmaceutical industry, clinical research organisations and EMA) and to those accessing the data (patients, healthcare professionals and academia). The Agency has already published comprehensive guidance on the anonymisation of the reports. However, as data anonymisation is a rapidly evolving field, EMA wants to keep abreast of developments and continue to update the guidance with the support of experts.

For further any information you can reach out to the email with the following contact details:

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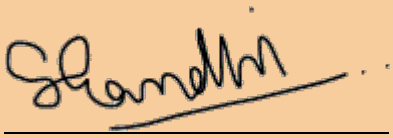

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