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 – Fourth Edition - Quarter 4

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 Forth Edition of 2017:

FDA awards six grants for natural history studies in rare diseases

The U.S. Food and Drug Administration today announced it has awarded six new research grants for natural history studies in rare diseases. The aim of the research is to inform medical product development by better understanding how specific rare diseases progress over time. One potential application of these studies is the opportunity to eventually use natural history models to augment the need for placebo arms in studies of drugs that target very rare disease, where trial recruitment can be challenging. This is the first time the FDA is providing funding through its Orphan Products Grants Program to conduct rare disease natural history studies. The FDA is providing a total of $6.3 million over the next five years to fund four natural history studies. In addition, through a partnership with the National Institutes of Health's (NIH) National Center for Advancing Translational Sciences (NCATS), the FDA received $3.5 million to be combined with FDA funding to fund an additional two studies. NCATS' support was made

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possible through its Therapeutics for Rare and Neglected Diseases (TRND) program.

FDA permits marketing of device to treat diabetic foot ulcers

The U.S. Food and Drug Administration permitted the marketing of the Dermapace System, the first shock wave device intended to treat diabetic foot ulcers. "Diabetes is the leading cause of lower limb amputations," said Binita Ashar, M.D., director of the division of surgical devices in FDA's Center for Devices and Radiological Health. "The FDA is dedicated to making technologies available that can help improve the quality of life for those with chronic diseases. Additional options for successfully treating and healing ulcer wounds may help prevent lower limb amputations." An estimated 30.3 million people in the United States have been diagnosed with diabetes, according to the Centers for Disease Control and Prevention. Diabetes damages blood vessels and nerves, particularly in the feet, and can lead to severe infections that are difficult to treat. About 25 percent of people with diabetes will experience a foot ulcer in their lifetime. Amputation is sometimes necessary when circulation is so poor that a foot ulcer fails to heal or when treatment fails to stop the spread of an infection.

Crysvita, a medicine for the treatment of X-linked hypophosphataemia, recommended for conditional approval by EMA

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting a conditional marketing authorisation in the European Union for Crysvita (burosumab), a medicine for the treatment of X-linked hypophosphataemia (XLH) with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons. XLH is an inherited disorder characterized by low levels of phosphate in the blood. The phosphate is abnormally processed in the kidneys, which causes a loss of phosphate in the urine (phosphate wasting) and leads to soft, weak bones (rickets). In most cases, the signs and symptoms of hereditary hypophosphataemic rickets begin in early childhood. Characteristic features include bowed or bent legs, short stature, bone pain, and severe dental pain.

The CHMP recommended conditional approval for the medicine. This is one of EU's regulatory mechanisms to facilitate early access to medicines that fulfil unmet medical need. Conditional approval allows the Agency to recommend a medicine

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for marketing authorisation in the interest of public health where the benefit of its immediate availability to patients outweighs the risk inherent in the fact that additional data are still required.

Improving the availability of vaccines for animals within the EU

The Committee for Veterinary Medicinal Products (CVMP), at its November meeting, accepted PDF icon recommendations to clarify the need for conducting field efficacy trials , i.e. trials in animals under real-life conditions in the field, to support the authorisation of veterinary vaccines. Improving clarity on this topic will facilitate the availability of veterinary vaccines in the European Union (EU).These recommendations were made by the joint European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) Steering Group on veterinary vaccine availability on the basis of the PDF icon outcome of a joint EMA/HMA stakeholder focus group meeting held in June 2017, which brought together regulators, industry and academic experts. According to EU legislation, the efficacy and safety of veterinary vaccines should be demonstrated in laboratory trials, and then supplemented by data from field trials, unless an acceptable justification can be provided for not providing this data. The role of veterinary field trials is primarily to confirm that the performance of the product observed under controlled experimental conditions is verified under actual conditions of use.

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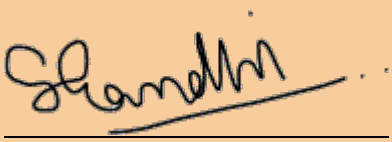

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