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 - Third Edition - Quarter 3

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 third Edition of 2017:

EMA and FDA encourage use of innovative approaches in the development of medicines for Gaucher disease.

The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) have developed a joint proposal to promote the use of innovative approaches in the development of medicines for Gaucher disease, which can apply to rare diseases in children in general.

This strategic collaborative approach from EMA and the FDA discusses possible ways to enhance the efficiency of medicine development in Gaucher disease, a rare lysosomal storage disorder, which is used as a model to reflect on recent progress made in the area of data extrapolation. The strategy document encourages medicine developers to make better use of:extrapolation of available clinical data, including through appropriate modelling and simulation techniques, to predict how a medicine may work in children and adolescents on the basis of studies conducted in adults or other paediatric populations; the possibility to test the safety and efficacy of medicines developed by different companies in one single trial, so-called multi-arm, multi-company clinical trials. As the same control arm is used to compare more than one medicine under evaluation, this approach facilitates the

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clinical testing of medicines while reducing the total number of children included in trials.

EMA Revised guideline on first-in-human clinical trials

The European Medicines Agency (EMA) has revised its guidance on first-in-human clinical trials to further help stakeholders identify and mitigate risks for trial participants. First-in-human trials are a key step in medicines development, where a medicine already tested in vitro, in animals or in other preclinical studies is administered to people for the first time. Participants in these trials, often healthy volunteers, face an element of risk as the ability of researchers to predict the effects of a new medicine on people is limited before it is studied in humans. Only on exceedingly rare occasions, however, have participants experienced serious harm.

The safety and well-being of trial participants should always be the utmost priority when designing early clinical trials. The guideline puts emphasis on the sponsor's responsibility to define the uncertainty associated with the medicine tested at each step of the development and to describe how the potential risks that might arise from this uncertainty will be addressed within the design and conduct of the trial. The approach must be supported by a well-documented scientific rationale from the outset and be responsive to data emerging over the course of the trial itself.

FDA provides new tools for the development and proper evaluation of tests for detecting Zika virus infection

As an additional measure in the fight against Zika virus, today the U.S. Food and Drug Administration announced that it has made available a panel of human plasma samples to aid in the regulatory evaluation of serological tests to detect recent Zika virus infection. "At the onset of the Zika virus outbreak, when little was known about the disease or how to diagnose it, the FDA worked quickly with manufacturers to encourage the development of diagnostic tests and ensure they were available using its Emergency Use Authorization authorities," said FDA Commissioner Scott Gottlieb, M.D. "By providing manufacturers of these tests with standardized patient samples to use in properly validating these diagnostics, we will be able to better assess how well their tests perform. This is part of our effort to ultimately bring these tests through the FDA's formal review process to better ensure their reliability, and to enable broader access to Zika diagnostic testing."

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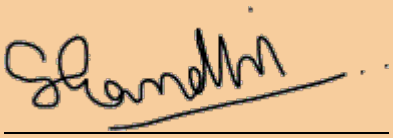

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