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# Editorial note – 2017 - Second Edition - Quarter 2

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 second Edition of 2017:**

## FDA allows marketing of first whole slide imaging system for digital pathology

The U.S. Food and Drug Administration permitted marketing of the Philips IntelliSite Pathology Solution (PIPS), the first whole slide imaging (WSI) system that allows for review and interpretation of digital surgical pathology slides prepared from biopsied tissue. This is the first time the FDA has permitted the marketing of a WSI system for these purposes.

"The system enables pathologists to read tissue slides digitally in order to make diagnoses, rather than looking directly at a tissue sample mounted on a glass slide under a conventional light microscope," said Alberto Gutierrez, Ph.D., Director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "Because the system digitizes slides that would otherwise be stored in physical files, it also provides a streamlined slide storage and retrieval system that may ultimately help make critical health information available to pathologists, other health care professionals and patients faster."

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Pathologists are medical doctors who specialize in understanding the cause and development of a disease or condition. In pathology, biopsied tissues are mounted onto glass slides and stained for viewing and evaluation. The PIPS uses proprietary hardware and software to scan and digitize conventional surgical pathology glass slides prepared from biopsied tissue at resolutions equivalent to 400 times magnification. These digitized images can then be reviewed and interpreted by pathologists.

**FDA approves new combination treatment for acute myeloid leukemia**

The U.S. Food and Drug Administration approved Rydapt (midostaurin) for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who have a specific genetic mutation called FLT3, in combination with chemotherapy. The drug is approved for use with a companion diagnostic, the LeukoStrat CDx FLT3 Mutation Assay, which is used to detect the FLT3 mutation in patients with AML.

AML is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of white blood cells in the bloodstream. The National Cancer Institute estimated that approximately 19,930 people would be diagnosed with AML in 2016 and 10,430 were projected to die of the disease.

"Rydapt is the first targeted therapy to treat patients with AML, in combination with chemotherapy," said Richard Pazdur, M.D., acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research and director of the FDA's Oncology Center of Excellence. "The ability to detect the gene mutation with a diagnostic test means doctors can identify specific patients who may benefit from this treatment.

**Optimising safety information for medicines in Europe throughout product lifecycle**

New guidance and process improvement for periodic safety update reports

Following two years of experience with safety monitoring of nationally authorised medicines via the single assessment of periodic safety update reports (PSURs), the European Medicines Agency (EMA) has issued additional guidance and recommendations as part of its commitment to continuous process improvement.

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PSURs are reports that evaluate the benefit-risk balance of a medicine as evidence is gathered in clinical use. They are submitted by marketing authorisation holders at defined time points following a medicine's authorisation. The Agency uses the information in PSURs to determine if there are new risks linked to a medicine or if the balance of benefits and risks of a medicine has changed. Based on this information, EMA decides whether further investigations are needed or whether measures have to be taken to protect public health, generally via updated product information for healthcare professionals and patients. If medicinal products contain the same active substance or the same combination of active substances, the related PSURs will be jointly assessed in a single assessment procedure.

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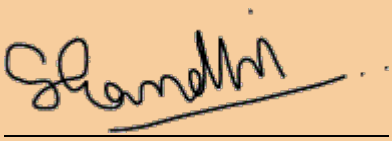

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