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Regulation of stability studies to enhance the efficiency of drug registrations to regulatory authorities

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Stability testing is an important tool to assess the quality of drug substances and products which may vary with time under influence of variety of factors such as temperature, humidity and light. Stability studies of drugs are designed according to the climatic zones to establish a retest period for active drug substance or a shelf life for the finished product as well as to recommend the storage conditions. The strict regulatory requirements on designing, performing evaluating stability study to claim the expiry date and shelf life of drug products are based on a series of regulatory requirements and advisory guidelines that have been developed by regulatory authorities of US, Europe and Japan which were harmonized through the development of the 5th International Conference and Exhibition on Harmonization (ICH) procedures. To assess the stability of drug substances and products, the design and conduct of stability studies, defining relevant thresholds for impurities testing is required with a current good manufacturing practice based risk management approach to achieve a robust stability of pharmaceutical dosage forms. There are relevant requirements that cover new drug substances and products as well as new dosage forms containing existing active ingredients and vice versa.

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Innovation respecting IPR for lifting millions out communicable and non-communicable diseases

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With a lack of new blockbuster drugs in the pipeline, the global pharmaceutical industry is increasingly under financial pressure. Such financial pressures resulted big-pharma for rushing to set up collaborations with local companies in cost-effective locations like India. India is known as a major supplier of generic drugs and begun to forge new alliances with big US and European pharma companies. India is a hotspot of many communicable diseases (i.e. malaria, tuberculosis, leishmaniasis and AIDS/HIV) and non-communicable diseases (cancer, diabetes, cardiovascular, CNS- and neurological disorder). Therefore, there is big market coupled in one side and financial pressure on the other side compels innovative pharmaceutical companies to locate local companies for joint R&D and market new pharmaceutical products in collaboration with local companies in India. In addition, the recent restructuring of both a 1970 Patent Act and the Indian Drugs and Cosmetics Act of 1940 has made India attractive for drug discovery. In 2005, India adopted a new patent regime that is in compliance with Trade Related Intellectual Property Rights under the World Trade Organization agreement. Prior to 2005, India only granted drug companies 'process patents,' which protect the chemical processes for production of the drug but not the drug itself. This enabled Indian drug companies to use modified processes or "reverse engineering" to produce generic versions of branded drugs. Under the new law, India now allows the granting of "product patents," which protect the final drug product and are recognized worldwide. Such collaborations are helping to collaborate Indian drug companies into a new era of innovative drug discovery, but regulations governing patents, drug approvals, and clinical trials are still in the process of being updated. The section 3(d) and compulsory licensing of Indian Patent Act may not be appealing to Pharmaceutical companies but it need to discussed in holistic manner. To adhere Section 3 (d) of Indian Patent Act, big-pharmaceutical companies must show there is no cosmetic change in their product and efficacy data obtained from multi-location trial. The above two issues sometimes confused to the Examiner of Patents, Controller of Patents and Judges of the Courts. In compulsory licensing judge should examine formal databases from Ministry of Health instead relying on competitors claim for compulsory licensing. Our extensive study on malaria and tuberculosis clearly showed patent is not the sole cause for affordability and accessibility of drugs in these two diseases but lack of concrete business of model is sole reason. Global pharmaceutical companies may explore demand centric solutions and engage with innovation proficient countries (USA and EU countries) and innovation starved countries (SAARC) for bringing them in a single platform to lift millions of out of devastating communicable and non-communicable diseases.

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