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Regulatory Perspectives of Herbal Medicinal Preparations Evaluation

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Herbal medicines derived from natural substance have been used with oriental philosophy and culture as important medical therapy of traditional medical systems in northeast Asia for thousands of years. Nowadays almost countries would treat and prevent diseases with natural products. As Herbal medicinal products have been perceived to be safer or better because they are natural, their demand escalates.

We review the efficacy and safety of natural new drug, herbal medicinal products according to Regulation of the Efficacy and Safety Evaluation of Drugs, etc (Notification No. 2003-17) [Appendix 4]. Herbal medicinal products is distinctly different from chemical drugs in origin of herbal plants, structure, components of herbal medicinal products, physicochemical and phytochemical properties, standardization and specification of drugs. Chemistry, manufacturing, and quality control of drugs should be considered first and important in new drug development. Submission data for application should include evidence for pharmacology and toxicology data except absorption, distribution, metabolism and excretion. Clinical trials should be ascertained the safety and efficacy of the herbal products according to good clinical practices in a large number of selected patients in order to determine the indication, dosage and administration, indication in use.

This presentation will analyze changing environment from industry, regulatory, and scientific perspectives. Future challenge is to revise new regulation by establishing standards of evidence by which to evaluate claimed benefits and product safety while allowing traditional use and custom to also be considered as admissible sources of evidence in support of claims.