CONCLUSION

Probiotics have gained significant commercial momentum and consumer acceptance in recent years due to increased awareness about health and prolonged history of safe use. Currently probiotic based products are available in market as food claiming nutritional values; and pharmaceuticals having therapeutic benefits.

Regulatory control of probiotics by various agencies across the globe under different categories and diverse laws has raised serious concerns. Consideration of probiotics under functional foods, dietary supplements, natural health products, food supplements in different countries have created an illusion for global acceptance of these products.

Furthermore application of probiotics as pharmaceuticals and their diverse spectrum of therapeutic effectiveness in treatment of various ailments (as co-therapy) has also contributed in its rapid success and market acceptance. However no consideration of these products under pharmaceuticals till date has some serious questions to be answered through regulatory laws in favor of public health and safety.

In order to address these concerns, present study was designed with an objective to propose a comprehensive draft of regulatory guidelines on various related aspects for probiotic products to be applied on global level. An in-depth comparative study of existing regulatory laws in various countries viz. FAO/WHO guidelines, FOSHU guidelines (Japan), EFFCA guidelines (Europe), SFDA guidelines (China), DSHEA, GRAS regulations, USFDA guidelines (USA), NHP guidelines (Canada), ICMR/DBT and ILSI guidelines (India), ANVISA guidelines (Brazil), FSANZ guidelines (New Zealand and Australia), Ministero Della Salute guidelines (Italy), Government Bureau of Food and Drugs (Philippines) etc. was initially done to identify the lacunas, ambiguities and common points to frame the proposed regulations.

A new definition of probiotic product is proposed as “Probiotics are viable microorganisms/spores; reach the intestine in active state, present either as mono or mixed culture, which upon ingestion in animal or humans in certain numbers and adequate amount imparts nutritional/health benefits” in place of existing definition given by FAO/WHO. Proposed definition clarifies ambiguities related to mono or mixed cultures of bacteria and fungus clarifies about dose and amount as well as also
includes both nutritional and pharmaceutical application of probiotics, which were not included in earlier definition.

Probiotic products are proposed to be categorized under ‘Nutribiotics’ and ‘Pharmabiotics’ based on the associated claims for the first time, which formed the base for subsequent framing of these guidelines on the basis of these categories.

Comparative study of existing guidelines had revealed that not even a single country has covered as the essential parameters related to probiotics viz. identification, evaluation, manufacturing, approval, proofs associated with health claims, packaging and labelling. Hence to bring harmonization of standards, separate guidance documents for these parameters were drafted in detail.

‘Guidance document for identification of probiotic microorganisms’ emphasized on use of polyphasic approach for proper identification of probiotic microbes up to strain level. Present draft has main focus on application of various molecular techniques, primers used for the same and functional approach to achieve strain level discrimination.

‘Guidance document for evaluation guidelines’ is drafted to access the quality of probiotics as foods and pharmaceuticals to ensure safety of consumer. Various in vitro and in vivo tests for identification, viability, establishment of probiotic potential as well as safety and efficacy assessment in normal, diseased and geriatric, paediatric population have been included in detail. Concept of GRAS and QPS are also considered on the basis of documented safe history of use.

Being a microbe based product, probiotics must be manufactured using Good Manufacturing Practices. Keeping this in view, proposed ‘Guidance document for Good Manufacturing Guidelines for probiotic formulations’ includes well defined regulations to reduce batch to batch variations and quality assurance. Hence the same has been drafted with reference to personnel, building and premises, equipment and utensils, production area, documentation and records etc.

‘Guidance document for approval of probiotic based products’ includes a functional pathway protocol and documents to be submitted for approval of probiotic products as per their intended use, either for nutritional or pharmaceutical benefits. A detailed
CONCLUSION

description of probiotic’s approval under food product, based on its safe history of use is given. While for pharmaceutical probiotic products, documents required to be submitted for approval, Investigational New Drug (IND) submission, New Drug Approval (NDA), phase wise clinical trials to establish evidences to substantiate health claims, dossier to be submitted and a descriptive process flow have been proposed for the very first time for known or novel therapeutic benefits.
In order to assure truthful and uniform labelling and packaging, ‘Guidance document for labeling, health claim, and packaging of probiotic formulations’ is drafted. Separate guidelines for labeling and packaging of probiotics with nutritional and health claims have been given to ensure proper labeling of these products. Detailed specifications for labeling of pharmabiotics related to their strain level identification, dose, route of administration, viability count, dosage form, manner of declaration, requirements for authorization of health claims etc. are included for better understanding of stakeholders.
The proposed guidelines has opened a new vista in harmonization of regulatory issues on international level to frame comprehensively developed guidelines for unified implementation at global level in order to assure same quality and efficacy irrespective of the product category.
More specifically, proposed comprehensive regulatory drafts on various aspects related to probiotic products shall be submitted to various authorities including WHO for further improvisation and enforcement for internationally acceptable harmonization of standards, enhanced customer acceptance and commercial acceptability of probiotic products. This may further help in development of new probiotic based medicines for therapeutic benefits with pre-defined safety, efficacy and proven clinical evidences.
Proposed guidelines may also help in reducing counterfeit and misbranded products with an increased awareness of product quality and trust of consumers.