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Exploring the Complexities of Probiotic Regulatory Guidelines in Latin America

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The complicated systems in the human body depend on multiple external factors for seamless functioning. We have known for centuries the importance of micronutrients and other elements of a healthy lifestyle in supporting nourishment. Microorganisms play an important role in various important body functions. But unlike with nutrients, it has been relatively complicated to understand the specific function of microorganisms in maintaining and advancing human health. Over time, we have managed to achieve significant progress in decoding the puzzle called ‘friendly microbes’.

We have been aware of invisible forces helping us live better, even though we could not put a finger on specific elements in our yoghurt or beer. Modern Science helped us visualise the minute world of microbes and identify those species which are helpful and supportive to human life. This has led to the emergence of advanced healthcare products containing friendly microbes which are broadly termed Probiotics.

Understanding Probiotics

Probiotics simply contain friendly microbes in live or spore forms which get activated once they enter the body. Typically, the probiotics contain a specific strain of bacteria made available to the consumer in a specific dosage form. The specific strain of bacteria is expected to enter the human body and provide benefits associated with it. Some of the products also contain a combination of different strains to enhance and optimise the benefits. Although, conceptually, this may appear to be a straightforward recipe for a great product line unfortunately, it is not that simple.

Regulatory Landscape for Probiotics

Products which have health benefits or claims associated with them are under the purview of health authorities and regulatory bodies in various countries. In the last few decades, there has

been a systematic evolution of regulatory frameworks for healthcare products having chemical or biological origins. At the same time, there is a cohesive trend in the acceptance of nutraceuticals globally. But if we try to apply a basic understanding of these product categories, we end up in a highly confusing situation. Hence even after the established benefits of probiotics, there has been a complicated regulatory landscape emerging in various countries globally.

Classification of Microorganisms and Credibility of Claims

We need to understand the basic classification of microorganisms to assess the complexity involved in categorising these products. Bacteria are divided into multiple groups, based on specific traits. For example, during the gram staining process, depending on the colour of the stain retained by bacteria, they are classified as either gram-positive or gram-negative. The groups of bacteria have multiple subgroups in which different species are categorised. Most of the bacteria species show minute variations depending on the genetic makeup giving rise to a high number of strains of almost every species. Theoretically, every strain may have variations in the expressions leading to differences in their activity.

While this phenomenon expands the horizon of probiotics in various applications, it also raises a question mark on the credibility of the claims associated with different strains of the same species. Recently, specific strains of the same species of bacteria have shown benefits in different human organ systems. A classic example is *Lactobacillus rhamnosus*, which has shown activity in various functions like gut health, immunity, and urinary tract infection. This has led to the question whether different strains of the same species should be treated as having similar actions or not.

Regulatory Guidelines in Latin America

Probiotics have a unique composition where the active ingredient is of biological origin but still does not qualify to follow the stringent requirements of biological products. Most regulatory authorities have not specified guidelines for probiotics and end up qualifying them as biologicals. For example – certain probiotics like *Bacillus Clausii* are categorised as biological products in countries like Costa Rica, Mexico etc. So, it becomes mandatory for the

manufacturer to follow stringent guidelines like Good Manufacturing Practice (GMP) approvals, and clinical trials, to launch the product in these countries.

The Brazilian health authority (ANVISA) has adopted a two-stage approach for any probiotic having a strain that has a specific beneficial claim. The first stage is focused on establishing the safety of the probiotic strain through adequate clinical studies and relevant literature research, followed by a presentation of data related to the dosage form and product quality. Typically, it takes 18 to 24 months post-filing for ANVISA to approve the market of the product as a food supplement. This is a unique pathway unlike any other regulated market globally and hence the entry of probiotics in the Brazilian market is an expensive and time-consuming activity.

Marketing Probiotics in Different Countries

Most countries allow certain strains below the threshold of specific concentration as notification products. Such products can be marketed without any restrictions in the country. The same rule applies to a combination of multiple strains below a certain concentration and without a specific claim or indication associated with it. Interestingly, some countries also allow the combination of a probiotic strain and some micronutrients to be marketed under the rule mentioned earlier.

Conclusion

The evolving landscape of probiotic regulatory guidelines in Latin America, presents a lucrative opportunity for companies working on quality probiotics backed with appropriate studies and literature references. Hopefully, we will see positive updates in the regulatory guidelines, allowing entry for companies with quality probiotics in the high-potential Latin American markets. The age-old friendly microbes shall find a new scope in the complex and advanced world created by humans!

Read online: https://nuffoodsspectrum.in/views/24/19896/exploring-the-complexities-of-probiotic-regulatory-guidelines-in-latin-america.html

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