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Pharmabiotics: A regulatory hurdle in Europe

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Probiotics are defined by WHO as living microorganisms which when administered in adequate amount confer a health benefits on the host. In Europe, according to this definition, probiotics can be registered as food ingredients, food supplements or novel food and fall under the health claim regulation. The NDA panel of the European Food Safety Authority (EFSA) therefore is in charge of advising the European Commission on granting health claims (or not). In recent years, the importance of the microbiota in human health and disease has received massive attention through high impact papers. The possibilities to impact health through the administration of selected live microorganisms are more than ever being studied. Laboratory knowledge generated is gradually being introduced into the clinical practice and in health maintenance programs. Links between microbiota composition and allergy, obesity, diabetics, IBS, IBD, etc. are increasingly supported by metagenomic observations. The advanced prophylactic and therapeutic potential of 'Probiotics' has led to the term 'Pharmabiotics' in Europe and 'Live Biotherapeutic Products' in the USA. As the competent European authority for this type of medicinal application cannot be EFSA, the European Medicines Agency (EMA) should be envisaged. However, according to the current European pharmaceutical regulatory framework, Pharmabiotics do not belong to any defined type of 'medicinal products' creating a significant regulatory uncertainty. In order to support Pharmabiotic producers, the PRI is currently working at defining the best status for such products as well as defining good regulatory practices in Europe for Pharmabiotic applications.

Biography

Magali Cordaillat-Simmons earned her PhD in 2005 at the Universite Paris V Rene Descartes, France, in Cardiovascular Pharmacology. She then worked as a Research Associate at the University of Virginia, VA, USA, where she studied the influence of epigenetics on renin expression. Today, she works as the Executive Scientist at the Pharmabiotic Research Institute (PRI), located in Aurillac, France. This association is dedicated to supporting companies in the development of medicinal probiotics in Europe. She currently supervises the association's analysis of the European Pharmaceutical Legislation and the association's regulatory activities so Pharmabiotics become a therapeutic reality in Europe.

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