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Biopharmaceutical and biosimilar products in brazil: From political to biotechnological overview

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Abstract

According to the World Health Organization (WHO), one third of the world's population don´t have the necessary access to pharmaceutical products, including essential drugs. In Brazil, the Governmental Health System (SUS) has classified these drugs into three categories in the country: basic, strategic and specialized components. In 1993, the Ministry of Health created the Program for Specialized Medicaments, where all the drugs included in this category were distributed for free through Clinics and Hospitals. During the first year of this Program's implementation, there were 15 different items distributed into 31 distinct presentations. Nowadays, the list expanded to 150 different items dispensed into 310 presentations. Hence, the availability of imported pharmaceutical products in Brazil overloaded the expenses by the Brazilian Ministry of Health. Only during 2011, U$ 1.5 billion were spent on these products, where 30% of this amount was related to specialized ones. In order to reduce costs, the Brazilian Federal Government developed, in 2004, the Technological Innovation Law. According to the Decree number 6.041, the National Politics for Biotechnology and the National Committee of Biotechnology were created in order to stimulate the development of Biotechnology for human health, targeting mainly the national production of biopharmaceuticals. Furthermore, the end of patents for several medicaments during the last 5 years enhanced the motivation for national production of new drugs. In this way, some Governmental Institutions, in partnership with International Pharmaceutical Industries, started developing the first biosimilar molecules.

Biography

Patricia Pelegrini has completed her Ph.D at the age of 27 years from Catholic University of Brasilia and postdoctoral studies from three different Institutions: The International Centre for Genetic Engineering and Biotechnology - ICGEB, at New Delhi – India; the Institut de Recherche pour le Développement – IRD, at Montpellier –France and Embrapa – Genetic Resources and Biotechnology, at Brasilia – Brazil. She is the Director of Projects and Technologies of BioLife Brazil Ltda as well as a collaborator at Embrapa – Cenargen, contributing for the development of researches on Biotechnology field.