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The regulation of herbal medicines in Brazil

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The Brazilian market of herbal medicines have grown about 12% per year and is becoming more significant each year in the overall pharmaceutical market where it represents around 3%. In Brazil, the herbal medicines are regulated by the RDC 14/2010 which requires proof of safety and efficacy of these products, as well as strict quality controls that cover the drug plant, the plant input and the finished product. Brazilian legislation does not allow associations of medicinal plants unless their safety and efficacy is proven through clinical trials. In this way, the Brazilian market for herbal medicines is characterized mainly by products containing only one species in the light of the difficulties and high costs involved in clinical trials. Brazilian legislation has driven the technological development in the area of quality control of herbal medicines and, as a result, the quality of existing products in the market has evolved constantly. However, in some ways, the herbal medicines are treated as synthetic drugs and inherent characteristics to natural products such as the variation of content of active markers or chemical markers are not considered. In this way, strict quality controls imposed by Brazilian law, at the same time that produce improvements in the quality of these products, also contribute to the rejection of many registration processes of herbal medicines in the Brazilian Ministry of Health (ANVISA). Recent data show that 50% of these products were registration requests rejected by ANVISA and the main reason is related to the quality control. More than 80% of the quality control problems identified are related to the quantitative testing and validation of analytical methods. As a result, the number of pharmaceutical industries that produce herbal medicines has been reduced from year to year. Currently, the pharmaceutical industries, together with the Government, Ministry of Health and the Academy have developed actions to encourage the development of herbal medicines in Brazil which has one of the largest biodiversity of the world.

Biography

Laerte Dall'Agnol has completed her specialization in Natural Products at the age of 28 years from Universidade Federal do Paraná-Brasil. She has 20 years of experience in quality control and regulatory affairs in herbal medicines. She is the director of DALL Soluções Analíticas e Empresariais, company specialized in pharmacotechnical development, quality control and regulatory affairs of new herbal medicines. She is Professor of specialization courses in herbal medicines and author of the book "Qualification of Suppliers of Medicinal Herbs and Condiments, 2000".

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