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The regulatory framework for similar biotherapeutic products in Cuba

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The high development achieved by the biopharmaceutical industry in the world has allowed count in the present with innovative medicines for the treatment of chronic, life threatening and severely debilitating diseases. Recombinant proteins and monoclonal antibodies represent a great percent within the medicinal products used for the treatment of diseases such as cancer, arthritis, cardiac dysfunctions and AIDS. Access to therapies based on the use of biological products has been limited, particularly in the third world countries, as a result of the high costs stipulated by the pharmaceutical companies that developed and patented these products. The expiration of patents and data protection for many of these products in the coming years opens the opportunity to other manufacturers to produce and market, with acceptable prices, new versions of the innovator, facilitating the access to them, which in turn translates into greater benefit for our patients. Cuba has a biopharmaceutical industry capable of responding to the increasingly rising needs of its National Health System and it is qualified to develop new products and obtain other, for examples the biosimilars. These industries might provide so much the domestic market as that of other countries of the region. In consequence with this situation, establishing the guidelines guaranteeing the quality, safety and efficacy biosimilars products is a challenge for the National Regulatory Agency (Center for State Control on the Quality of Drugs; CECMED). CECMED has faced during the latest years the challenge of regulating a national industry with a great scientific and high innovative potential. The methodology to elaborate guidelines for this type of products was mainly based on the revision of the legal and regulatory international framework and the evaluation of the current and prospective developmental stage of the technology in. A first draft of the regulatory document was compared to guidance drafts issued by other regulatory agencies (such as OMS and EMEA) and extensively reviewed by CECMED specialists as well as by experts of the local biotech industry. As a result, a regulation project was elaborated, and its applicability tested whiles the assessment of an application for scientific advisory, related biosimilars product. Finally, the regulation was approved, being applicable for ¨Known Biological Product¨, term adopt in Cuba for the biosimilars products.

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