REGULATORY CONSIDERATIONS OF BIOSIMILARS AND CLINICAL DILEMMA OF THEIR USE

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Abstract
Biomedical products are complex molecules, produced by living cells, molecules that are naturally produced in the human body, like hormones or growth factors, monoclonal antibodies, blood products, immunological medicinal products, sera and vaccines, allergens, and advanced technology products such as gene and cell therapy products. Copies of these drugs, known as biosimilars are comparable but not identical and are not generic version of innovator biological products. Specific regulatory requirements and abbreviated registration process apply in the case of biosimilars, in order to demonstrate efficacy and safety profile and prove that product is similar to the original biomedical product. Like all medicines, biological medicines work by interacting with the body to produce a therapeutic outcome, but the mechanisms by which they do this may vary from product to product and across indications. Therefore the role of the physicians in treatment of patients with these complex medicinal products is particularly important. Regulatory issues, manufacturing, safety, physicians have part in developing use of biosimilars as much as generic drugs. Even though, the most important factor for the market of biosimilars is the commercial factor, still, real clinical dilemma of their use is present, so it is necessary to have clear regulatory framework and postmarketing data on the use of biosimilars.

Keywords: biosimilars, innovate product, monoclonal antibodies, regulatory