November, 2021

EXTENSION OF THE LIST OF REFERENCE PRODUCTS FOR BIOSIMILARS

On November 16, 2021, Decree No. 62 of November 9, 2021, was published in the Official Gazette which amends Decree No. 945 of 2014 which approves Technical Norm No. 170 regarding the Sanitary Registration of biotechnological products derived from recombinant DNA techniques.

The main modifications are the following:

1. Reference biotechnological products: Expands the number of reference biotechnological products, incorporating, in addition to those included in the list, those that are recognized as such by the FDA (Food and Drugs Administration), EMA ("European Medicines Agency") and the Pharmaceuticals and Medical Devices Agency of Japan.

2. Update of Numeral X of the Technical Norm: The tables called *"Active ingredients and their respective presentations for which abbreviation of clinical studies may be admitted in the sanitary registration process"* and *"List of Biotechnological Reference Products"* were updated and replaced by a single table called *"List of its reference products and its biotechnological active ingredients, for which abbreviation of clinical studies may be admitted in the sanitary registration process"*.

The above-mentioned will enter into force on November 16, 2021.

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