Update of the SEPD position statement on the use of biosimilars for inflammatory bowel disease

Key words: Biosimilar. Inflammatory bowel disease. SEPD position statement.

Dear Editor,

In 2013, EMA approved the biosimilar of infliximab (CT-P13) for the full range of indications of the originator product, based on data coming from two trials conducted in rheumatoid arthritis and ankylosing spondylitis (1). That year, our Society published a position Statement (2), reviewed later (3).

Since that, many studies in inflammatory bowel diseases (IBD) have been published and have supported the biosimilarity of CT-P13 with the reference product. Recently, a well-known nationwide Norwegian randomised controlled trial (4) on patients with immune-mediated diseases also found no differences in maintenance of remission, or adverse events in patients switched from the reference product *versus* patients with the reference one. Also, a new ECCO position has been published (5).

Based on these data, the followings statements have been approved:

1. A biosimilar is a drug that, using molecular biology techniques, has a similar even though not identical structure to the original product, that is intended to provide an action equivalent to that of the product it attempts to copy and requires a complex process based on all the preclinical and clinical trials demanded by European Law.
2. To obtain license for the treatment of a certain disease, a robust preclinical and clinical trials program must demonstrate biosimilarity with the reference drug.
3. A license obtained for the management of a certain disease may allows an extrapolation of results to a different disorder, without clinical data, only if the European Medicine Agency considers it based on the results of preclinical trials mentioned previously.
4. The product label should clearly show the trade name of the biosimilar so that the drug a patient is taking may always be identified.
5. Based on the data published, the biosimilar CT-P13 presents a good safety and efficacy profile in IBD, both in naïve and switched patients.
6. The appropriate use of the biosimilar requires always interaction by physicians and patients with the aim of favoring the right to health of patients by offering quality, effective and safe products.
7. This task force favors the development of biosimilar drugs and therefore their approval by regulatory agencies.

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