Revista Española de Enfermedades Digestivas
THE SPANISH JOURNAL OF GASTROENTEROLOGY

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

Authors:
Federico Argüelles Arias, Joaquín Hinojosa del Val, Isabel Vera Mendoza

DOI: 10.17235/reed.2018.5456/2018
Link: PubMed (Epub ahead of print)

Please cite this article as:
Argüelles Arias Federico, Hinojosa del Val Joaquín , Vera Mendoza Isabel . Update of the SEPD position statement on the use of biosimilars for inflammatory bowel disease . Rev Esp Enferm Dig 2018. doi: 10.17235/reed.2018.5456/2018.

Revista Española de Enfermedades Digestivas
THE SPANISH JOURNAL OF GASTROENTEROLOGY

CE 5456

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

Federico Argüelles-Arias, Joaquín Hinojosa del Val and Isabel Vera Mendoza

Correspondence: Federico Argüelles-Arias

e-mail: farguelles@telefonica.net

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

Dear Editor,

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

Since then, 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 randomized controlled trial (4) in patients with immune-mediated diseases did not find any differences in the maintenance of remission or adverse events in patients that switched from the reference product *versus* patients with the reference product. Furthermore, a new position of the European Crohn's and Colitis Organisation (ECCO) 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, 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.

3. A license obtained for the management of a certain disease allows an extrapolation of results to a different disorder, if the European Medicine Agency considers it based on the results of trials mentioned previously.

4. The product label should clearly show the 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 is safe and effective in IBD, both in naïve and switched patients.

6. The appropriate use of the biosimilar always requires an interaction of physicians and patients with the aim of favoring the right of the health of the patient by offering quality, effective and safe products.

8. This task force favors the development of biosimilar drugs and therefore, their approval by regulatory agencies.

References

1. European Medicines Agency. CHMP assessment report Remsima (EMA/CHMP/589317/2013). London: EMA; 2013.

2. Argüelles-Arias F, Barreiro-de-Acosta M, Carballo F, et al. Joint position statement by "Sociedad Española de Patología Digestiva" (Spanish Society of Gastroenterology) and "Sociedad Española de Farmacología" (Spanish Society of Pharmacology) on biosimilar therapy for inflammatory bowel disease. Rev Esp Enferm Dig 2013;105(1):37-43.

3. Argüelles-Arias F, Barreiro-de-Acosta M, Carballo F, et al. New contributions to consensus on biosimilars. Rev Esp Enferm Dig 2014;106(3):228-9.

4. Jørgensen KK, Olsen IC, Goll GL, et al. Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. Lancet 2017;389(10086):2304-16. DOI: 10.1016/S0140-6736(17)30068-5.

5. Danese S, Fiorino G, Raine T, et al. ECCO position statement on the use of biosimilars for inflammatory bowel disease - An update. J Crohns Colitis 2017;11(1):26-34. DOI: 10.1093/ecco-jcc/jjw198