Dear Sir,

On April 27th, 2015, the National Health Surveillance Agency of Brazil (ANVISA) approved the first biosimilar monoclonal antibody in Brazil. CT-P13 is produced by a South Korean pharmaceutical company and will be marketed and distributed in Brazil by a partnership between two American companies(1,18,19). CT-P13 is a biosimilar medication to Infliximab (IFX), which uses the original product, manufactured in the United States as the reference drug(1,2,3,6,18,19). This measure by ANVISA is primarily aimed at cost reduction, because most of the individuals currently using IFX can only do it due to reimbursement by the Brazilian public health system. The achievement is commendable and approved by all medical societies involved, in the specialties of rheumatology, gastroenterology and dermatology. However, scientific, safety and pharmacovigilance issues have arisen and should be carefully addressed and widely discussed within this new scenario for the benefit of patients. CT-P13 has been approved in Brazil based on comparability strictly following the regulations of ANVISA(1,18,19). The original IFX was approved in Brazil in 2000 for the treatment of luminal Crohn’s disease. This drug has been successfully tested in humans in two clinical studies in rheumatology patients: a phase I clinical study in ankylosing spondylitis and a phase III study in patients with rheumatoid arthritis(15,20). The use of CT-P13 for other diseases listed in the reference drug package insert was approved based on the concept of extrapolation of indications(1,18,19).

In October 2014 the Biosimilar commission of the Brazilian Study Group of Inflammatory Bowel Diseases (GEDIIB) submitted to ANVISA an opinion contrary to the approval of CT-P13 for patients with inflammatory bowel diseases (IBD)(6). Recently, the Brazilian Societies of Rheumatology, Dermatology and Gastroenterology (represented by GEDIIB) issued the same position(5). Exactly in accordance with the opinion of Health Canada, the local Canadian agency responsible for the medication control in that country, the position issued by GEDIIB made it clear that although the biosimilar is a positive and welcome evolution in the IBD setting, it would be essential to carry out clinical studies with biosimilar products in a specific population with IBD patients. Indeed, these studies could elucidate the controversial points regarding the efficacy and safety of the long-term use of this biosimilar drug(4).

A small number of cases of IBD patients treated with CT-P13 have been published to date(5,7,8,10-12,17,21). Moreover, it is also known that there is still no prospective head-to-head or non-inferiority randomized studies comparing CT-P13 with the reference IFX. On the other hand, after the product has been used for more than 2 years in eastern Europe and Korea, post-marketing studies presented at scientific meetings have described good results regarding the efficacy and safety of CT-P13 both in...
the adult and pediatric population with IBD\textsuperscript{(5,7,8,10-13,17,21)}. However, a retrospective study conducted in Ireland using a controversial methodology showed a significant increase in hospitalizations, use of corticosteroids and surgery in patients treated with CT-P13, as compared to those who received the reference drug IFX\textsuperscript{(14)}. As this is, to date, the only study showing discrepancies in efficacy and safety between the biosimilar and the reference drug, it is vital that we carefully analyze these results and that we remain alert and vigilant.

For sure more publications with biosimilars in the IBD scenario will arise in the years to come. Special attention to these new data must be given. The spread use of biosimilars is a question of time, as an important economic impact will benefit stakeholders. Consequently, the number of patients treated with monoclonal antibodies will increase over the years.

**Authors’ contributions**
Teixeira FV, Kotze PG and Damião AOMC drafted the article and gave final revision.

**Disclosure**
Teixeira FV, Kotze PG and Damião AOMC are speakers and consultants for Abbvie and Janssen. FVT is a speaker and consultant for Hospira. Kotze PG and Damião AOMC are speakers and consultants for Takeda. Damião AOMC is an employee for Nestle.