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Effectiveness and safety of switching to adalimumab biosimilar ABP 501 in Crohn's disease

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Authors' contributions

The article was conceived and written by Angelo Viscido. Giovanni Latella was involved in the writing and revision of the letter. All authors gave their final approval.

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Dear Editor,

We read with great interest the article "Effectiveness and safety of adalimumab biosimilar ABP 501 in Crohn's disease: an observational study" by Ribaldone et al., which was recently published in your journal (1). The authors report the first real-life study of the adalimumab biosimilar ABP 501 in Crohn's disease (CD). The study investigated the short-term effectiveness and safety of ABP 501 in 87 patients with CD, 25 patients naïve to adalimumab and 62 switched from the adalimumab originator. A meaningful proportion of CD patients treated with ABP 501 showed clinical benefit with a satisfactory safety profile until the end of follow-up (1).

We would like to remark on the concept that a biosimilar, e.g. ABP 501, is guaranteed to be interchangeable with its originator by the European Medicines Agency (EMA). However, while the use of a biosimilar in naïve patients is generally accepted, a "forced switch" to a biosimilar in a patient successfully treated with the originator can be a matter of concern for many clinicians (2).

ABP 501, like all the other biosimilars approved by EMA, underwent a rigorous step-wise demonstration of its similarity with the originator (2). First, *in vitro* assays demonstrated that ABP 501 has similar physicochemical properties and pharmacological activity respect to the originator

(3,4). Second, *in vivo* studies demonstrated similarity in the pharmacokinetics features (5). Finally, clinical randomized controlled studies demonstrated a similar efficacy, safety and immunogenicity (1,2). It is noteworthy that all the EMA approved biosimilars underwent the same step-wise rigorous controls.

In conclusion, switching from the originator to its biosimilar, whatever the type, is acceptable for both naïve and non-naïve patients because this approach is safe, efficacious and leads to a significant cost saving for the health care system.

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