MAN_03 - Interchangeability of Adalimumab originator and biosimilars in Brazil: real-life evidence opportunity

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Introduction: The Brazilian Health Regulatory Agency's position about the interchangeability between biologic originator and its biosimilars is that it is related to clinical praxis and every decision on the subject should be taken on a case-by-case basis. Furthermore, the practice of multiple switching is not endorsed by the Brazilian health authorities, which recommend a minimum 12 straight months treatment with a single presentation. Two Adalimumab biosimilars manufactured in Brazil became available to the Unified Health System in September 2022. Given the current scenario, the Ministry of Health (MoH) elaborated a distribution plan as an attempt to ensure the minimum treatment time before switching: patients in some states would keep being treated with Humira (originator), and patients in other states would switch to Idacio or Hyrimoz after the observance of the recommended time. Each state allocated in the switching group was supposed to be supplied by a single biosimilar, but both are being dispensed in São Paulo (SP) according to MoH public data, despite SP allocation in the Idacio group.

Objectives: Given the resulting opportunity, the study aimed to provide a starting overview of the SP status after the measure's implementation.

Methodology: Assessment of prevalent and incident patients in treatment with Adalimumab in SP from September 2022 to December 2023 and the frequency of treatment combinations.

Results: There were 16,686 patients in treatment in the period. Single presentation treatments and all possible combinations were observed: Humira (979), Idacio (7,717), Hyrimoz (1,121), Humira-Idacio (1,713), Humira- Hyrimoz (479), Idacio-Hyrimoz (3,122), Humira-Idacio-Hyrimoz (1,555). Discontinuing rates for Humira- containing treatments were higher, Idacio-containing were lower.

Conclusion: The multiple switching suggests non-medical substitutions. It is reasonable to hypothesize it happened in other states allocated in the switching group. The discontinuing rates for Humira can suggest medical indications for disease-modifying drugs other than Adalimumab. The results highlight the evidence of a no longer preventable scenario and its consequent opportunity to produce interchangeability safety and effectiveness evidence based on observational data.

Keywords: Adalimumab; Interchangeability; Real-world evidence