What is the use of granulocyte colony-stimulating factors biosimilars in routine care? Results from a multicentre, population-based study from four Italian regions in the years 2009-2013

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Granulocyte colony-stimulating factors (G-CSFs) are approved for the treatment of neutropenia in patients with Human Immunodeficiency Virus (HIV) or hepatic cirrhosis or undergoing bone marrow/liver/kidney transplantation or for the treatment of chemotherapy-induced neutropenia. Biosimilars of G-CSFs are available on the European market since 2007. Aim of the study was to investigate the prescription pattern of G-CSFs in four large Italian geographic areas, where different health policy interventions, promoting the use of biosimilars in routine care, were taken.

This retrospective, population-based, drug utilization study was conducted during the years 2009-2013, using administrative databases of Tuscany Region, Caserta, Treviso and Palermo Local Health Units (LHUs). G-CSFs users were characterized and prevalence and switching pattern of different G-CSFs (biosimilars, reference products and drugs whose patent has not expired) were calculated over time and across centres, stratifying by indication for use. The exposure of interest was: Filgrastim (both reference products and biosimilars), Pegfilgrastim and Lenograstim. The proportion of biosimilar users was calculated on the total of G-CSFs users.

Overall, 20,726 patients were treated with G-CSFs in the years 2009-2013. Of these, 19,757 (95.3%) were naïve users. Overall prevalence of use of G-CSFs slightly increased from 2009 to 2012 (from 0.8 to 1.0 per 1,000 inhabitants) while it was stable in the following year. The proportion of biosimilar users, on the total of G-CSFs users, raised during the five years in the four centres from 4.3% in 2010 to 61.2% in 2013. Analysing data in detail, the proportion grew more significantly in Treviso (0.0-80.2%) and Tuscany (5.5-79.2%), than Palermo (0.0-47.8%). In Caserta, the proportion of biosimilar users increased from 0.8% in 2010 to 26.2% in 2012, but a decrease was observed in 2013 (9.6%), due to issues related to administrative flows. During the first year of treatment, switching between different G-CSFs was frequent (28.1%), especially towards Lenograstim (32.8% of the total switchers).

In conclusion, the use of G-CSFs biosimilars significantly increased over time and gained greater values in comparison to other biosimilars (erythropoiesis stimulating factors and somatropin), even though some differences may be observed across the four geographic areas, due to the adoption of different health policy interventions. New strategies are necessary to further improve the penetration of low cost medicines, such as biosimilars, into the market as well as to harmonise effective healthy policy interventions aimed at optimizing pharmaceutical expenses across all Regions.