100 mg subcutaneous three times weekly was started, which was suspended in September 2015 due to severe renal failure and lack of response. In September 2015 etanercept 50 mg subcutaneous weekly was started but continued with fever outbreaks. There were four admissions due to decompensated heart failure in summer 2017 associated with outbreaks of FMF and anaemia (8.7 g/dL) despite darbepoetin. Other values: CRP:100 mg/L; neutrophils: 68.9%; and glomerular filtration:12 mL/min. In September 2017 treatment with canakinumab 150 mg subcutaneous every 8 weeks was requested, which was currently associated with colchicine 0.5 mg daily. The patient did not present an admission or febrile seizures since the onset of canakinumab: haemoglobin had reached normal values (13.7 g/dL), despite the fact that neutrophilia continued (83%), elevated CRP (70 mg/L) and deficient renal function (13 mL/min). No adverse reactions were reported.

Conclusion Canakinumab is a valid therapeutic alternative in the treatment of FMF in case of poor response to other therapies: the observed evolution is favourable until now, being also safe and well tolerated. However, more prospective studies are needed to assess their suitability in this context.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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INTRODUCTION OF BIOSIMILAR ETANERCEPT: AN ITALIAN DISTRICT ANALYSIS

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Background Since 2015, the Piedmont region has decided to invest in biosimilar medicines with the aim of obtaining price reductions and to promote the switch not only in naïve patients but also in those already treated with an ‘originator’. In 2017 an etanercept biosimilar was awarded in a regional tender and an exchange procedure was implemented by all the health services.

Purpose The aim of the work was to check the switch rate in 2017 from the etanercept originator to biosimilar and verify the adequacy of non-substitutability reports. Data collected were compared with the regional and national ones to understand the impact of the regional measure and, lastly, the economic implications of the operation were analysed.

Material and methods 2017 was the examined year. A drug dataset was extracted from data flow and processed to obtain the switch rate towards the biosimilar etanercept. Patients’ paper files were analysed to catalogue the non-substitutability reports. Data were compared with those published by the Italian Biosimilar Group at regional and national level. Any switch or swap from the etanercept originator to other active substances was verified and a data analysis was carried out to check dispensed units and the expenditure for their purchase from 2014 to 2017.

Results One-hundred and thirteen of 165 patients (68.5%) shifted towards the biosimilar compared to 12% at the national level. Twenty-four patients continued therapy with the originator, 20 switched to other active substances or to another dose of etanercept (25 mg) and eight stopped the treatment. Prescribing hospitals have non-substitutability rates ranging from 10% up to 40%–60%. The patient pool was unchanged from 2014 to 2017, while costs fell by about 19% in 2017 compared to the previous year.

Conclusion Biosimilars’ introduction is a valid chance to ensure quality, safety and effectiveness, even in a public spending rationalisation context. Etanercept, with its large pool of patients, is a significant cost-saving possibility. Results obtained confirm decisions implemented with high exchange rates compared to the other Italian regions, reduction in costs and the preservation of high assistance levels.

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Switching Biologic Treatments: Experience of a Regional Hospital

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Background Due to the approval of new biological treatments (BT) with innovative mechanisms of action (MOA), patients have more options to achieve clinical remission.

Purpose To analyse the reasons for switching to BT, evaluate their effectiveness and the costs associated.

Material and methods Retrospective study conducted between January to December 2017 in a regional hospital with a reference area of 1 10 000 inhabitants and 220 BT.

All patients who switched their BT were included. Data on relevant patient characteristics, diagnostics and treatment were collected.

Total drug costs were calculated from Botplus (September 2018). In the case of weight-dependent doses a standard weight of 70 kg had been considered.

Statistical analysis was carried out with SPSS Statistics v.22.

Results Thirty-eight (19.0%) patients were included; 12 (31.6%) males; and 48.9 (12.5) years old.

Distribution by diagnostics: 17 (44.7%) rheumatoid arthritis (RA), eight (21.1%) spondyloarthopathies, five (13.1%) psoriatic arthritis, three (7.9%) psoriasis, three (7.9) Crohn’s disease and two (5.3%) ulcerative colitis.

In 32 (84.2%) patients, the specialist waited for a minimum of 12 weeks to switch to BT (except in cases of adverse effects). Nineteen (50.0%) patients had received more than one BT previously. Two BT (infliximab) vs one BT (etanercept) were biosimilars.

Previous vs new BT: 31 (81.6%) vs 14 (36.8%) anti-TNFα and seven (18.4%) vs 24 (63.2%) drugs with different MOA (Chi square 15.75; p<0.001). Only four (10.5%) patients remained with an anti-TNFα after the switch.

Reasons for switching: 29 (76.3%) loss or lack of response, eight (21.1%) adverse effects and one (2.6%) new comorbidity that contraindicated the BT.

At the moment of the analysis, 22 (57.9%) BT remained active while 16 (42.1%) were stopped or switched again. Among the 22 patients in the same BT, 10 (45.6%) were in remission, six (27.2%) had low activity and six (27.2%) had moderate activity of the disease.

The incremental cost of switching was € 46,908.75 annually.