Material and methods In June 2018 the patient's data were collected from the electronic medical records (Whospital) in our hospital: the literature was reviewed using the Pubmed database.
Results A 50 years' old male, with perianal CD since 2000, was diagnosed with APL in March 2018 after a bone marrow biopsy for grade 3/4 neutropaenia during an episode of pulmonary embolism and deep vein thrombosis. Infliximab therapy began in 2003 and was intermittent, with discontinuation in 2004 and 2006 because of good therapy response. He was unresponsive to these prior therapies: steroids, azathioprine and adalimumab. In 2015 he was enrolled for a few months, without good response, in a clinical trial with ustekinumab. After APL diagnosis, infliximab was discontinued and induction therapy for APL with arsenic trioxide and tretinoin (ATO +ATRA) was started. Remission began in April 2018, maintenance ATO +ATRA therapy was started and was still continuing in June 2018. The review of the literature found five reports of leukaemia cases after infliximab therapy in patients with CD (three), rheumatoid arthritis (one) and ankylosing spondylitis (one); three were males and two were females; the mean age of the patients was 46. The review also showed a higher risk of the occurrence of malignancies in patients on immunosuppressive therapy and/or with autoimmune/inflammatory disorders.
Conclusion Our patient presented APL after a long exposure to infliximab, which raises the concern that infliximab may be involved in leukaemia development. The presence of an autoimmune disease, such as CD, and prior immunosuppressive therapies, such as azathioprine and TNF-alfa inhibitors, may also have caused the development of leukaemia. Risk estimation is difficult. However, we suggest prompt evaluation for patients who develop haematological abnormalities when treated with infliximab.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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5PSQ-073 MUCORMYCOSIS INDUCED BY INAPPROPIATE USE OF ORAL CORTICOIDS – A CASE REPORT

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Background Invasive fungal infections such as Mucormycosis are considered opportunistic infections that occur almost exclusively in immunosuppressed patients, causing high morbidity and mortality. The use of long-term steroids may favour the state of immunosuppression, increasing the likelihood of acquiring this type of severe infections. The errors of therapeutic compliance are one of the possible causes of long-term treatment with corticosteroids.
Purpose The aim of the study was to discuss, through a clinical case, the consequences of an error in compliance with corticosteroid therapy.
Material and methods Observational, retrospective and descriptive case report of a patient diagnosed with mucormycosis due to the inappropriate use of corticoids. The data were obtained by review of the electronic clinical history (JARA) and the pharmacy service managing software (FARMATOOLS).
Results The patient was a 47 years' old male with a clinical history of arterial hypertension, dyslipaemia, morbid obesity, with smoking and alcoholic habits. In August 2018, he was operated on for an acute subdural haematoma. After being discharged from the hospital, the doctor prescribed Dexamethasone 4 mg every 12 hours, descending gradually. Due to the patient's misunderstanding, he kept the same medication dose (8 mg Dexamethasone daily) and did not comply with the gradual withdrawal of the medication. Fifty days' later, the patient was admitted to hospital with acute hepatitis, necrotising fasciitis in the right lower limb after trauma and intense palate pain. Suspecting mucormycosis and bacterial infection, the patient was treated with the empirical treatment: liposomal Amphotericin B, Isavuconazole, Daptomycin, Amikacin and CLindamycin. The presence of *Rhizopus spp*. was confirmed and invasive rhinosinusal mucormycosis secondary to immunosuppression due to the continued dose of corticosteroids was diagnosed. Finally, the patient died nine days after hospital admission due to multiorgan failure.
Conclusion In this case, the main cause of the development of mucormycosis came from a medication error in corticosteroid therapy compliance. Aiming to improve this kind of medication error, it is important to highlight the need to enhance pharmacotherapeutic monitoring, information and education for patients with the aim of improving therapeutic compliance.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.

5PSQ-074 CANAKINUMAB IN FAMILIAL MEDITERRANEAN FEVER AND SECONDARY AMYLOIDOSIS: A CASE REPORT

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Background Familial mediterranean fever (FMF) is an autosomal recessive disease characterised by repeated and self-limited seizures of fever and serositis. Classically, FMF has been treated with colchicine, although currently we have interleukin-1δ inhibitors such as anakinra or canakinumab.
Purpose To describe a case of FMF and secondary amyloidosis in current treatment with canakinumab.
Material and methods Description of a case of FMF, in follow-up in our hospital and in current treatment with canakinumab. Data was collected from the electronic medical record and analytics were reviewed in the laboratory application. The variables analysed were sex, age, neutrophil value, haemoglobin, C-reactive protein (CRP) and renal function before and after treatment with canakinumab and adverse reactions to treatment.
Results A 74-year-old female diagnosed with FMF, chronic kidney disease and hypertensive heart disease was followed up in our hospital since 2006. Treatment with colchicine 0.5 mg daily since then. Febrile episodes in 2009. Period 2010–2014 practically asymptomatic, with some episodes of fever that were self-limited with acetaminophen. She was admitted to hospital in December 2014 due to a fever outbreak and amyloidosis with renal insufficiency. In January 2015, anakinra

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.

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5PSQ-075 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 substancies 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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5PSQ-076 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%) spondyloarthropathies, 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.