# TNF-α INHIBITORS IN THE CZECH REPUBLIC: HOW BIOSIMILARS AFFECT OVERALL CONSUMPTION AND COSTS?

Petra Chytilová[1], Matěj Haluska[1,2], Radka Mahovská[1], Tomáš Mazel[1], Ivana Štefančíková[1], Marie Strnadová[1], Milan Vocelka[1]

[1] State Institute for Drug Control, Prague, Czech Republic

[2] Faculty of Pharmacy, University of Veterinary and Pharmaceutical Sciences Brno, Czech Republic

## OBJECTIVES

The introduction of biosimilars into clinical practice has been associated with reduced treatment costs and increased availability of high cost biological treatment for patients. Based on available clinical evidence and established regulatory rules, the efficacy and safety of biosimilars is similar to that of reference products. Still, there are concerns influencing the uptake of biosimilars: uncertainty about effectiveness and safety of extrapolated indications, interchangeability of biosimilars with their reference product, immunogenicity.

In the Czech Republic, a system of reference groups (RGs) is in place. A RG is a group of medicines with comparable effectiveness, safety profile and clinical use. All medicines within the same RG have the same reimbursement price per usual daily dose. When the first biosimilar product is launched, both its maximum and reimbursement price are lowered by 30% (before 4/2017 it was lowered by 15 %). Consequently, reimbursement price of all medicines in the RG are lowered.

In this study, we analyzed the change in the consumption and costs of TNF-α inhibitors (TNFis) after the launch of the first biosimilar product (infliximab) in 2013.

## METHODS

Firstly, we extracted publicly available data about medicine consumption in the Czech Republic and analyzed all annual reports from 2010 to 2018[1]. Data for relevant medicines were sorted by active substance, type of authorization process, unit and real-world market prices. Identified price decrements were cross-checked with data from national list of reimbursed medicines[1].

## RESULTS

The consumption of all TNFis has almost doubled with an 87% increase over the last 5 years. Infliximab and adalimumab are the most commonly used substances of this RG. In 2018, biosimilars market share reached 33% of the total TNFi market. Despite the fact that there are no biosimilars of certolizumab and golimumab, the consumption of certolizumab and golimumab has grown up more than three and two times respectively.

Since 2017, biosimilar infliximab has been much more used than original infliximab. Between 2013 and 2018, cost per daily dose has, on average, decreased by 24%. The decrease in daily costs significantly differed among substances. The most significant decrease occurred for infliximab followed by golimumab. The smallest decrease occurred in case of etanercept.

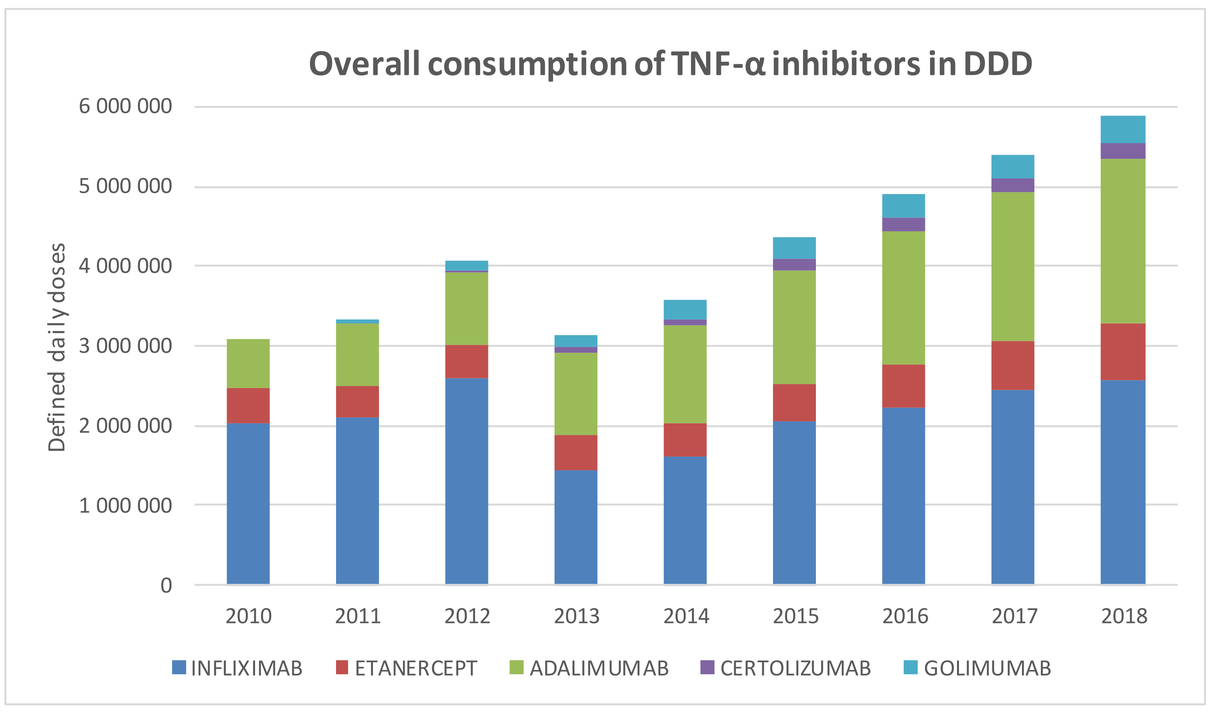


**Figure 1** Consumption of TNF-α inhibitors from 2010 to 2018

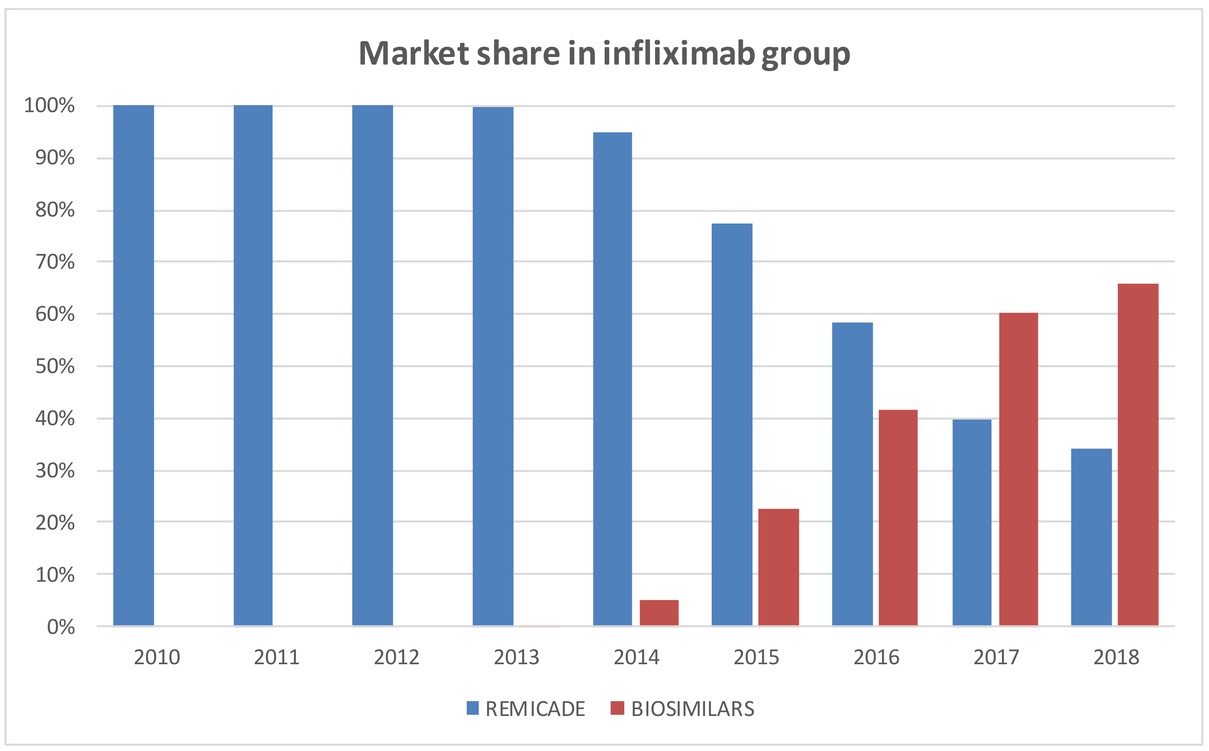


**Figure 2** Comparison of market share of infliximab based on the type of registration

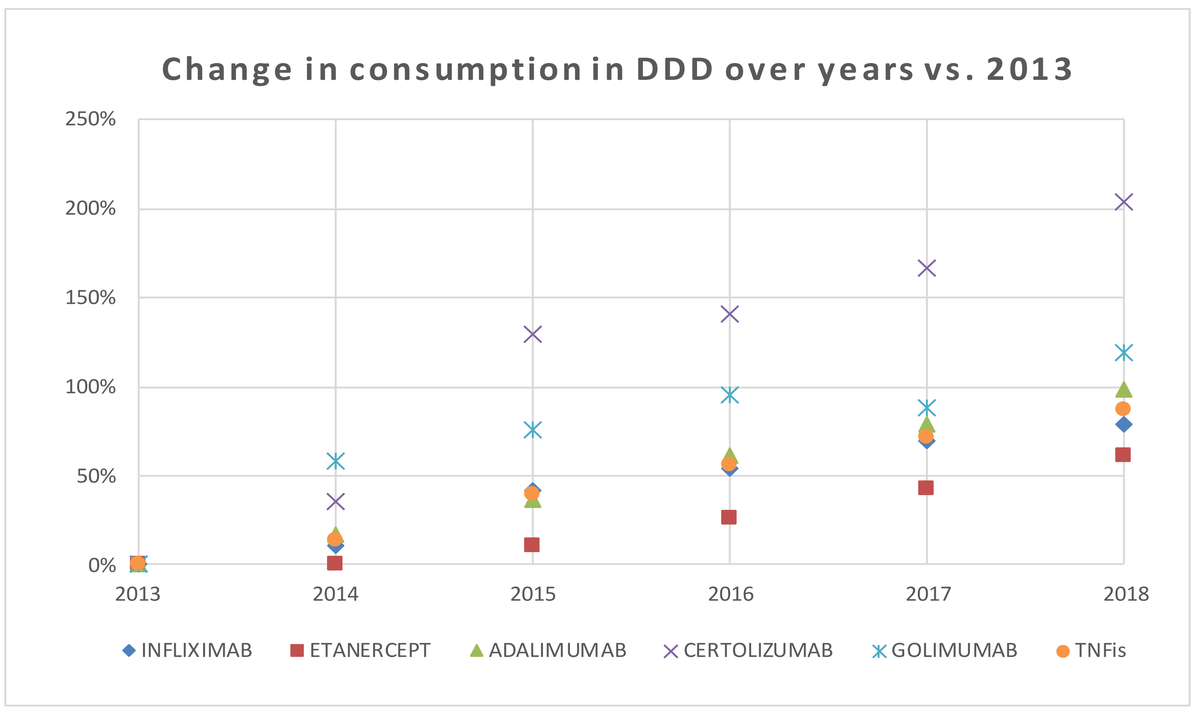


**Figure 3** Change in consumption of TNF-α inhibitors over years vs. 2013

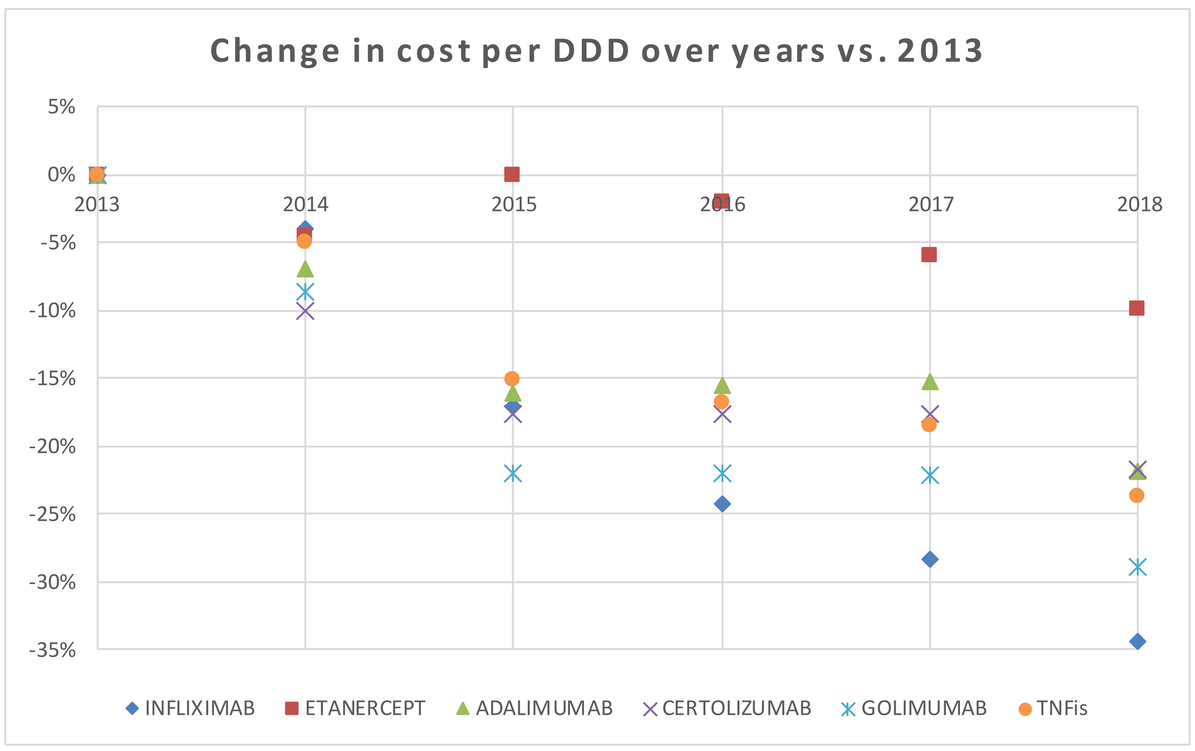


**Figure 4** Change in cost per DDD over years vs. 2013

## DISCUSSION

The consumption of TNFi has still been growing and patient access to biological treatment in general has been improving over time. The first launched biosimilar in 2013 improved access to TNFi therapy. The following decrease of unit costs over the years has been primarily caused by reimbursement reassessments of the TNFi reference group, price contracts between health insurance funds and pharma companies and market competition. Decrease as a voluntary reaction to „reimbursement reassessments“ it appears that the costs are not maximum ex-fact prices set by SUKL.

Moreover, in 2019, the second rapid reassessment of TNFi group was performed. Lowering the reimbursement price for usual daily dose within the RG by additional 40 %. The actual maximal reimbursement price of all TNFis is currently based on an agreement between health insurance companies and a pharmaceutical company and equals 17 EUR (432 CZK) per usual daily dose. Overall savings generated by this reassessment are estimated at approx. 51 milion EUR (1.3 billion CZK ). These savings will further improve access to biological treatment for Czech patients.

## REFERENCES

1. www.sukl.cz

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