

COST OF TREATMENT WITH BIOSIMILARS – CASE WITH RITUXIMAB IN ONCOHEMATOLOGY

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INTRODUCTION

Rituximab is a chimeric monoclonal antibody targeted against CD20 which is a surface antigen present on B cells. In last 20 years Rituximab becomes a standard of care for treatment of several rare diseases like Chronic lymphocytic leukemia, Follicular lymphoma and Diffuse large B-cell lymphoma. It is expected that the entry of biosimilars on the market will lead to a reduction in the cost of drug therapy.

AIM OF THE STUDY

According to Price regulation in Bulgaria for the price registration of new Rx products International referencing price rule applies (IRP) – the price should be the lowest between 10 referent countries. For biosimilars, additional requirements exist from April, 2019 – the price must not exceed 80% of the price of the originator medicinal product included in the Positive Drug List. The aim of the study is to analyze the impact of the biosimilar's launch on National Health Insurance Fund (NHIF) costs.

MATERIALS AND METHODS

- ✓ Review of the marketing authorization (MA) status of Rituximab and its biosimilars in the EU and pricing registries in the selected countries.
- ✓ Analysis of the registered prices in Bulgaria, France, Greece and Slovakia and NHIF cost in Bulgaria have been performed.

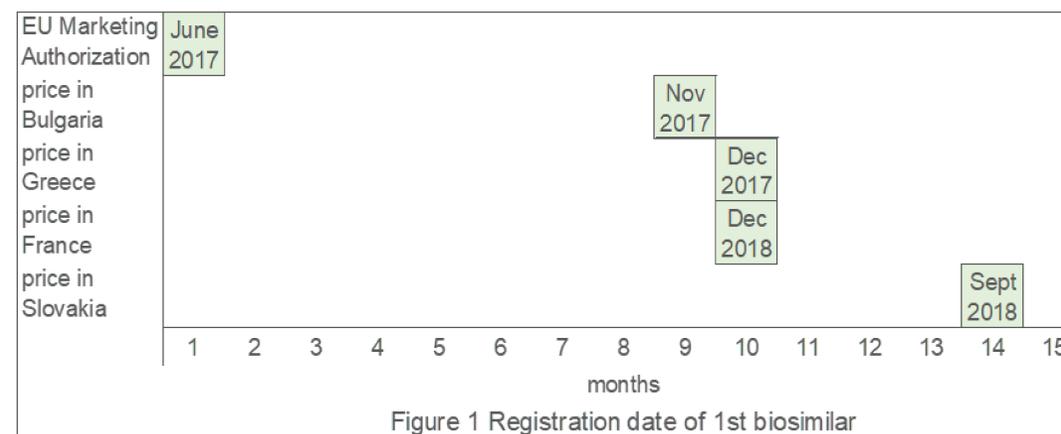


Figure 1 Registration date of 1st biosimilar

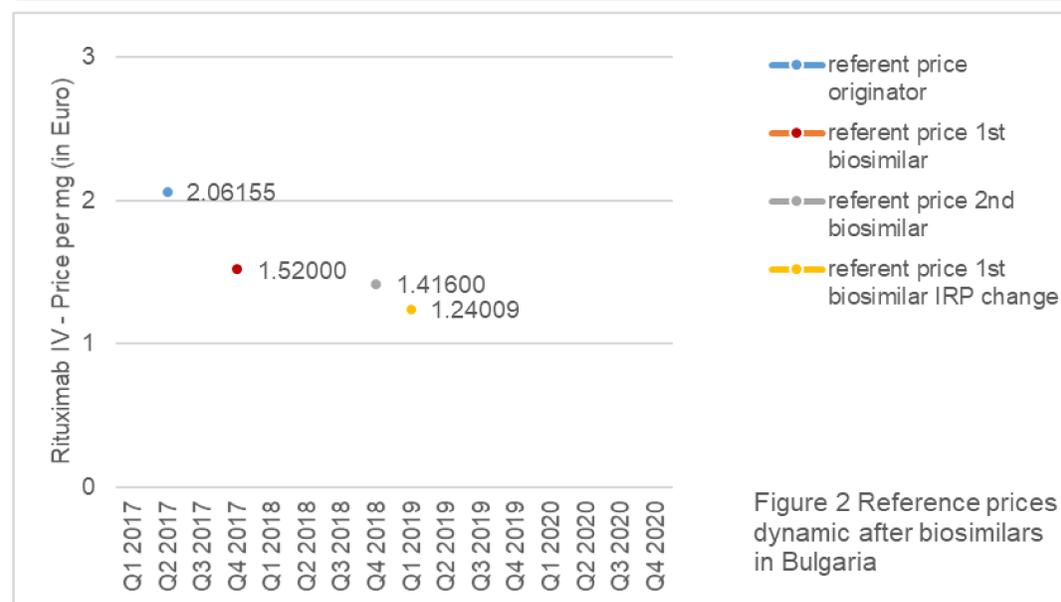


Figure 2 Reference prices dynamic after biosimilars in Bulgaria

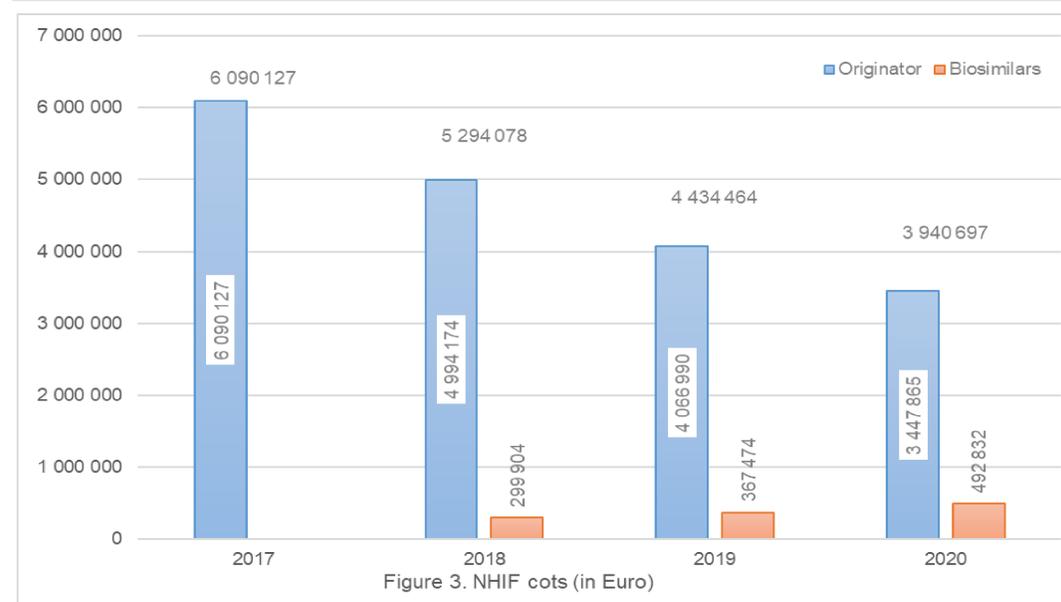


Figure 3. NHIF costs (in Euro)

RESULTS

- ✓ The first biosimilar of Rituximab has registered price between 9-10 months (Bulgaria, France and Greece), and 14 months (Slovakia) after MA in 2017 (Figure 1).
- ✓ The biosimilar's prices per mg are 34% on average lower than the originator (Figure 2).
- ✓ In Bulgaria and Slovakia the launch of the next Rituximab biosimilar leads to further price reduction.
- ✓ Biosimilar's launch in oncohematology in Bulgaria reduced with 35% NHIF costs: from 6 090 127 Euro in 2017 to 3 940 697 Euro in 2020 (Figure 3).
- ✓ In 2020, 29% of the NHIF costs of Rituximab intravenous (IV) are for biosimilars which are almost tripled compared to 2018.

CONCLUSIONS

The results of the review show that biosimilar's launch reduces the cost of therapy. The decrease in the registered prices of Rituximab is mainly due to regulatory requirements. Further reductions can be expected following the relevant tender procedures or specific agreements, as Rituximab in oncohematology is for hospital use, but due to confidentiality this information is difficult to be assessed. However, further analysis could be made as to whether the savings on drug therapy lead to an increase in patients' access to innovative drug therapies.

References

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