Abstract

Drug utilization of specific biotherapeutic agents and biosimilars in the Czech Republic

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Introduction: Biosimilars represent an alternative to innovative biological medicinal products, contribute to improvement of the effectiveness of treatment and enable to gain access to expensive therapy of serious diseases.

Objective: The objective of the practical part of the diploma thesis was to analyze trends in drug utilization of specific biotherapeutic agents and biosimilars in the Czech Republic between 2008–2022. The secondary aim of the practical part was analysis of the expenditures for specific biotherapeutic agents and biosimilars in given period.

Methods: Drug utilization from the database of the State Institute for Drug Control has been evaluated from 2008 until 2022. The values of defined daily doses were used to process the results, which were subsequently converted to the number of defined daily doses per 1000 inhabitants per day (DID). Descriptive statistics was used for the retrospective analysis of the drug utilization. The following drugs were included in the analysis: filgrastim, pegfilgrastim, lipegfilgrastim, teriparatide, denosumab, somatropin, somatrogon and mecasermin.

Results: During the given period, the total utilization of biosimilar granulocyte colony-stimulating factors (G-CSF) increased. The total utilization of filgrastim almost tripled by 2022 (from 0.016804 to 0.048459 DID). Since 2012, the utilization of filgrastim biosimilars has dominated and between 2019–2022 accounted for 100% of the total filgrastim utilization. The expenditures for filgrastim decreased despite increasing utilization. Total utilization of pegfilgrastim doubled by 2022 (from 0.034748 to 0.067504 DID). Biosimilars of pegfilgrastim started to exceed from 2019 and reached 99.2% of total pegfilgrastim utilization in 2022. The overall expenditures for pegfilgrastim also decreased. From 2021, total

pegfilgrastim utilization exceeded the total utilization of filgrastim. The total utilization of lipegfilgrastim was lower than the total utilization of filgrastim and pegfilgrastim with an overall decreasing trend in recent years.

Total utilization of teriparatide increased (from 0.019944 to 0.045728 DID) by 2022. From 2021, teriparatide biosimilars exceeded and accounted for 69% of total teriparatide utilization in 2022. Total utilization of denosumab increased (from 0.000899 to 5.856159 DID).

The total utilization of somatropin increased during the given period (from 0.237333 to 0.438971 DID). The utilization of somatropin biosimilar was only 6% of the total utilization of somatropin.

Conclusion: An increasing utilization trend was noted for biosimilars of G-CSF and teriparatide, as well as for denosumab and somatropin in overall. In the future, an increasing trend in the utilization of biological treatment, and especially biosimilars, can be expected with a simultaneous reduction in the expenditures for treatment, which may become more accessible to a larger number of patients.

Key words: biosimilars, biotherapeutic agents, similar biotherapeutic agents