



The impact of first generic entrance on public spending and medicines cost: a case study in Bulgaria

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Introduction

- ❖ Patent registration allows exclusive rights for the 20-year period of the company MAH. (1)
- ❖ The penetration of generic medicines is very important as it ensures low prices of medicines and savings in the healthcare system which makes their regulation essential for pharmaceutical system (2)

Objective

- ❖The study explores and analyzes the impact of market protection expiration and generics entrance on public expenditures and medicines prices in the Bulgarian healthcare sector.

Methods

- ✓ The study is retrospective, observational analysis of differences in public expenditure and prices of originators before and after generics entry on the Bulgarian market.
- ✓The study compares generic and originators prices.
- ✓The official database of National Council of prices and reimbursement was reviewed in order to extract the new medicines data and price changes during the observed period
- ✓The price differences were compared during the year: from January 2022 to February 2023.
- ✓The price changes are presented in %.
- ✓The public expenditure are calculated in order to compare the differences before and after inclusion of interchangeable products

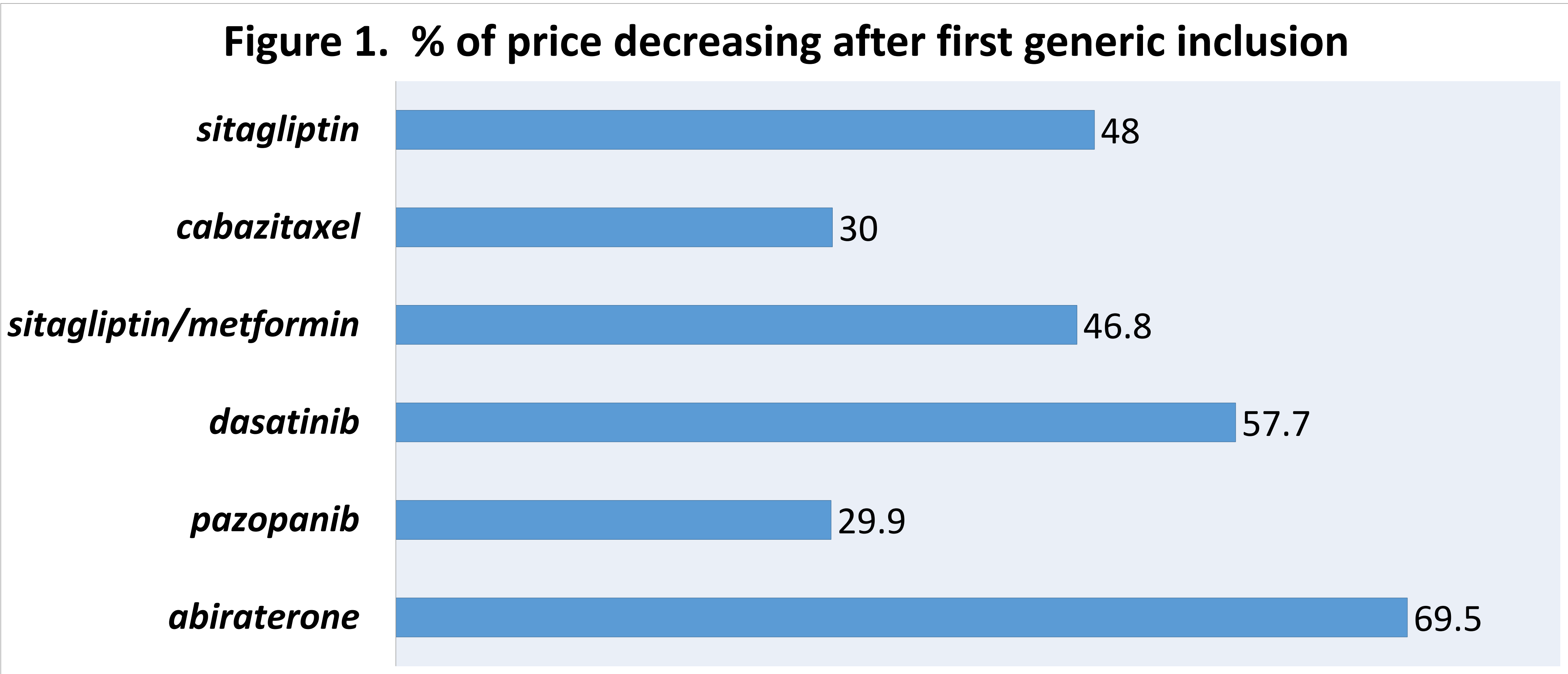
Results

- ❖ A total of 6 INNs with the first generics approved(*abiraterone*, *pazopanib*, *dasatinib*, *sitagliptin/metformin*, *cabazitaxel*, *sitagliptin*) are found in the Positive Drug List.
- ❖Within a year, the prices of the originators and generics decreased significantly after the first generic approval.
- ❖The introduction of new cheaper alternatives on the market leads to a significant decrease in the costs of the payment institution - NHIF. The decreasing rate is about 55.39%.

Results

INN	Medicinal products prices in Positive Drug List in 01/2022, BGN	Medicinal products prices in Positive Drug List after inclusion of first generic/ biosimilar, BGN	The price reduction starts at:
Abiraterone	6232.76	1903.12	Oct-22
Pazopanib	5414.57	3793.79	Feb-22
Dasatinib	6249.29	2644.67	Dec-22
Sitagliptin/metformin	58.34	31.02	Oct-22
Cabazitaxel	7493.05	5248.72	Feb-22
Sitagliptin	50.57	26.40	Nov-22

Table 1: Medicines prices changes after first generic inclusion in PDL



The results showed a significant reduction in public expenditures after inclusion of interchangeable medicinal products in Positive Drug List (Annex 1 and Annex 2):

- *Abiraterone therapy reduced costs by 75.16%;*
- *The reduction in public spending on Pazopanib is 40%;*
- *Dasatinib decreases by 53.28 %;*
- *Sitagliptin/Metformin FDC shows that costs decrease by about 53.12%.*

Conclusion

The study confirms the correlation between price decreasing due to first and subsequent generics entrance and public expenditure. A substantial reduction in public spending was found, which highlighted the generics important role in public expenditure and potential for cost saving. Assessment in the long-term is necessary in order to find real market impact and the overall consequences on public spending.

References

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