

BUDGET CAP WITH PAY BACK AS MANAGED ENTRY AGREEMENT POLICY: BULGARIAN EXAMPLE FOR RHEUMATOLOGY MEDICINES

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INTRODUCTION

- ✓ Rheumatoid arthritis (RA) is one of the largest markets with high costs medicines including both biological and biosimilar products [1]. Treatment of patients demand therapeutic monitoring and consume additional resources as hospitalizations and rehabilitation. Entrance of new molecules and inflation are the main cost drivers, especially in the field of biological products [2].
- ✓ Due to constantly rising medicines expenditures was introduced new budget cap with pay back managed entry agreement (MEA) in 2019 in Bulgaria.

AIM OF THE STUDY

To analyse the influence of budget cap with pay back MEA as cost-containment measure in Bulgaria on public spending for RA medicines.

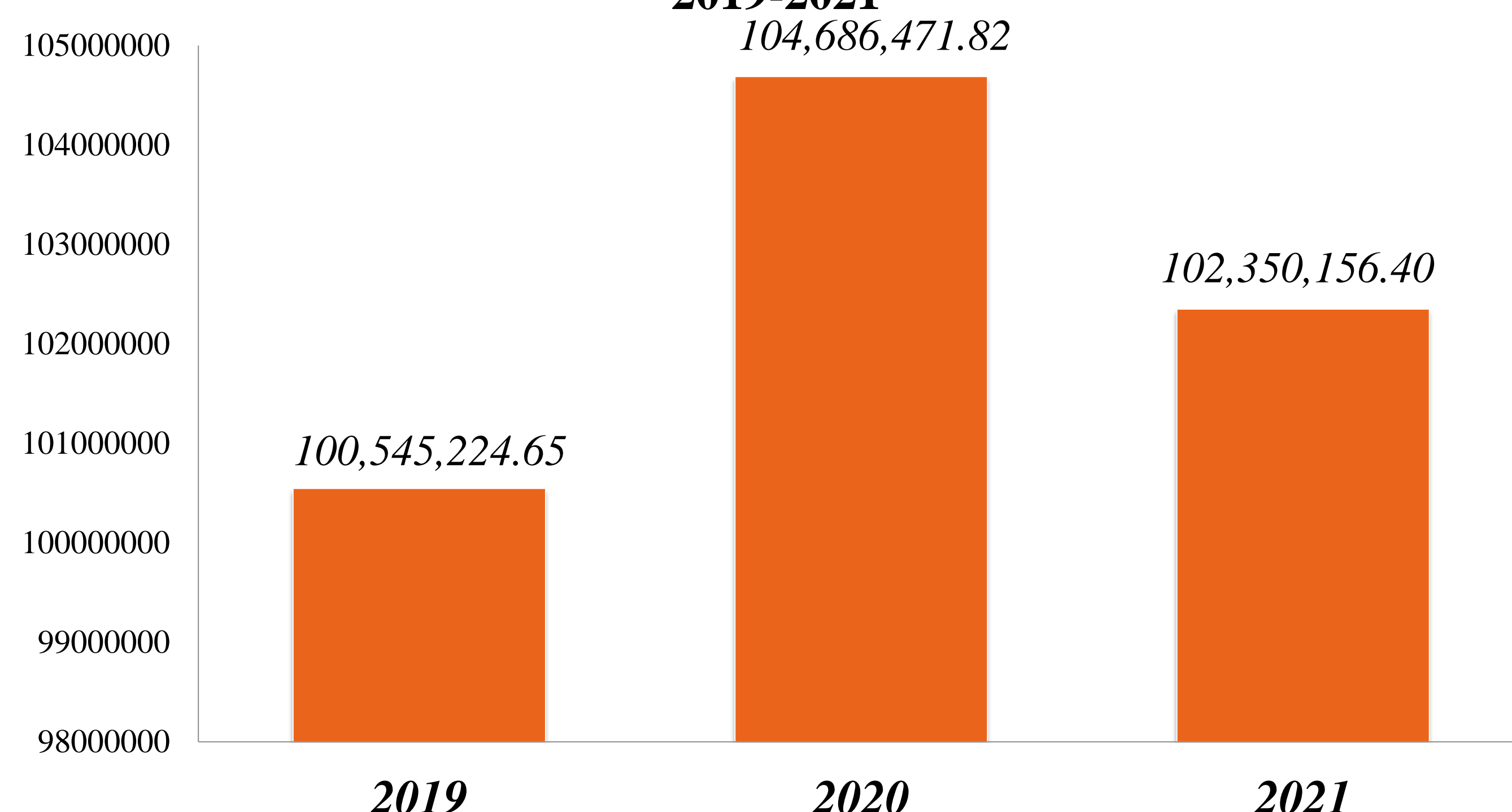
MATERIALS AND METHODS

- ✓ Retrospective, observational, macroeconomic analysis of reimbursed spending on rheumatology products during 2019 – 2021 after the introduction of budget cap with pay back MEA from the National Health Insurance Fund (NHIF).
- ✓ On total 17 medicines (INNs) were extracted from the official registers of NHIF.
- ✓ Their reimbursed spending were calculated as per three main groups of MEAs (group A, B, and C) and the differences were statistically tested.
- ✓ Costs are presented in national currency BGN (ex-change rate 1 BGN=0.95 Euro).

RESULTS

- ✓ Total reimbursed costs for RA medicines is performing an increase with 4 mln in 2020 and then decrease with 2 mln in 2021, despite the entrance of new molecules.

FIGURE 1: NHIF REIMBURSED SPENDING DURING 2019-2021



RESULTS

- ✓ RA medicines from Group A (prescribed after a consultation with committee from 3 specialists) includes 13 biologicals and 1 JAK inhibitor with the overall budget share about 99% from all RA budget.
- ✓ Group B (all other medicines out of group A) includes methotrexate and NSADs with budget of 25,000BGN.
- ✓ Group C (oncology and life-saving medicines) includes only dexamethasone. The reimbursed spending is 105,000 BGN.
- ✓ Reimbursed budget for group B and C declined during 2019-2021 ($p < 0.05$), while for group A is rising.
- ✓ Spending for top five RA medicines follow similar tendency with small increase and then decrease in the second year of MEA introduction except for adalimumab and etanercept.

ATC code	INN	Reimbursed amount, BGN 2019	Reimbursed amount, BGN 2020	Reimbursed amount, BGN 2021
L04AB04	Adalimumab	40,081,190	43,480,149	44,195,386
L04AB01	Etanercept	17,192,397	16,188,070	12,926,063
L04AC07	Tocilizumab	13,910,008	15,202,132	14,611,012
L04AC05	Ustekinumab	8,937,586	8,272,261	7,248,820
L04AB06	Golimumab	5,713,222	5,139,612	4,924,063

Table 1. Top 5 most costly medicines for RA therapy

CONCLUSION

- ✓ Financial results of introduced budget cap with pay back MEA as cost-containment measures are not yet evident three years after its introduction but are promising.
- ✓ Only the budget for NSADs and non-biological products decreased.
- ✓ On opposite the budget for biologicals increased in line with their rising utilization

FUNDING

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