



„Challenges for the Pharmaceutical Sector in Bulgaria“



Conference
"Collaboration between Germany and Bulgaria in the
Health Industry"
Sofia, October 21, 2025

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Pharmaceutical Manufacturers in Bulgaria (ARPharM)*



ARPharM Member Companies



Rate of availability (2015 – 2018)

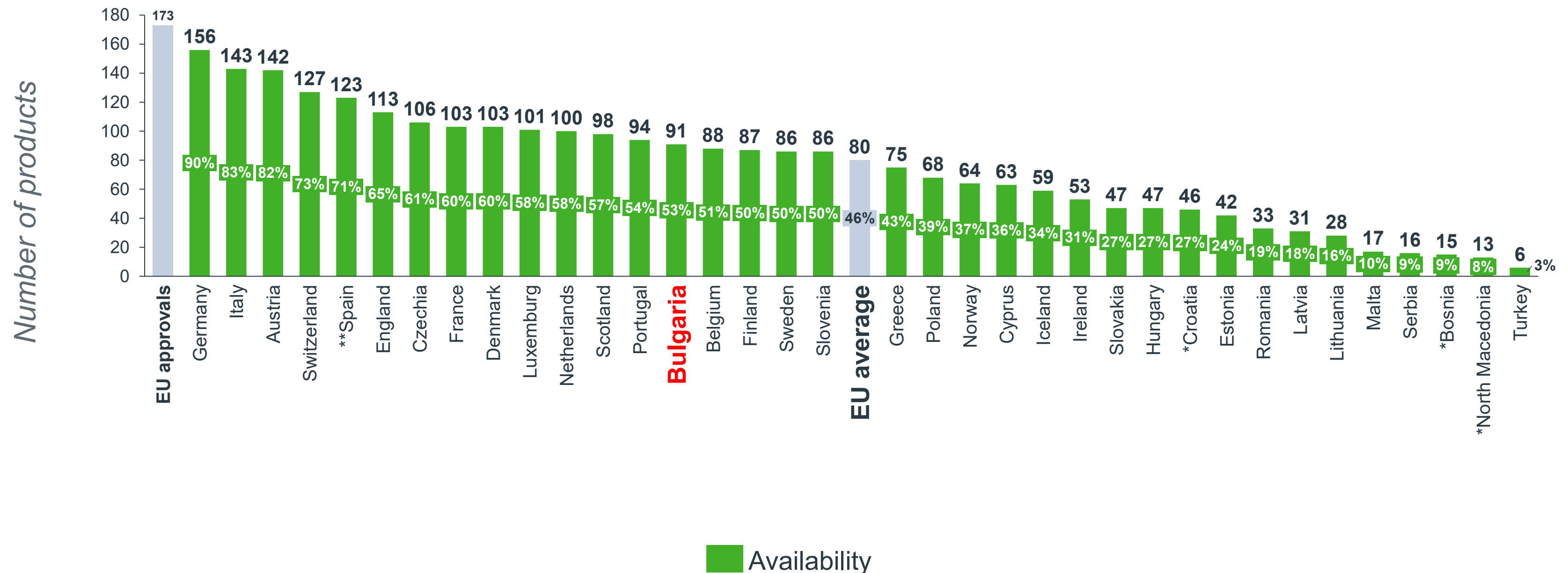
The **rate of availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list*), inc. limited availability



European Union average: 85 products available (49%) (excludes data from Cyprus, Malta, and Luxembourg for countries not included within the study); *In most countries patient access equates to granting of access to the reimbursement list, except in DK, FI, NO, SE some hospital products are not covered by the general reimbursement scheme; *Countries with a dataset <99% complete: Bosnia (16% complete), Macedonia (26% complete), Serbia (40% complete)

Rate of availability (2020-2023)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2025. For most countries this is the point at which the product gains access to the reimbursement list[†], including products with limited availability.



Increased access & investments in pharmaceutical innovation by 2025 saves and improves lives



- Oncological and hematological diseases;
- Diabetes mellitus;
- disorders of the blood and blood-forming organs treated with NOACs;
- Schizophrenia;
- Spinal Muscular Atrophy;
- Psoriasis, psoriatic and rheumatoid arthritis;
- Macular degeneration;
- Hepatitis C;
- Asthma;

2023 number of patients treated with some innovative therapies reimbursed by the NHIF

126 000

Quality-adjusted life years per patient

9.8

Quality-adjusted life years per whole population

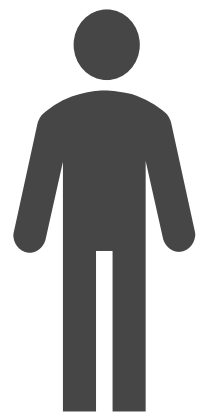
1 240 856,91

Total contribution to the Bulgaria GDP (million levs)

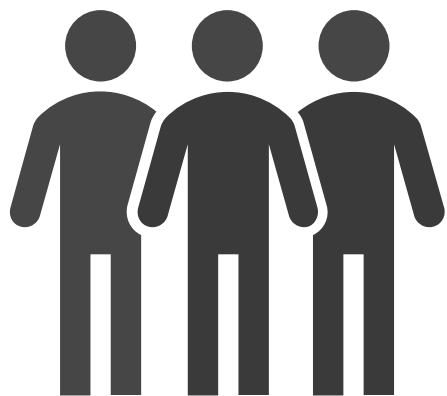
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Impact of Innovative Cancer Therapies on Health and Economic Outcomes in Bulgaria

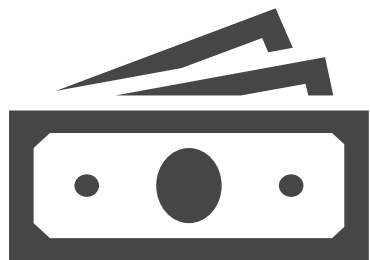
Innovative cancer therapies improve health outcomes and deliver economic benefits.



4.5
Average quality-adjusted life¹
years gained per patient

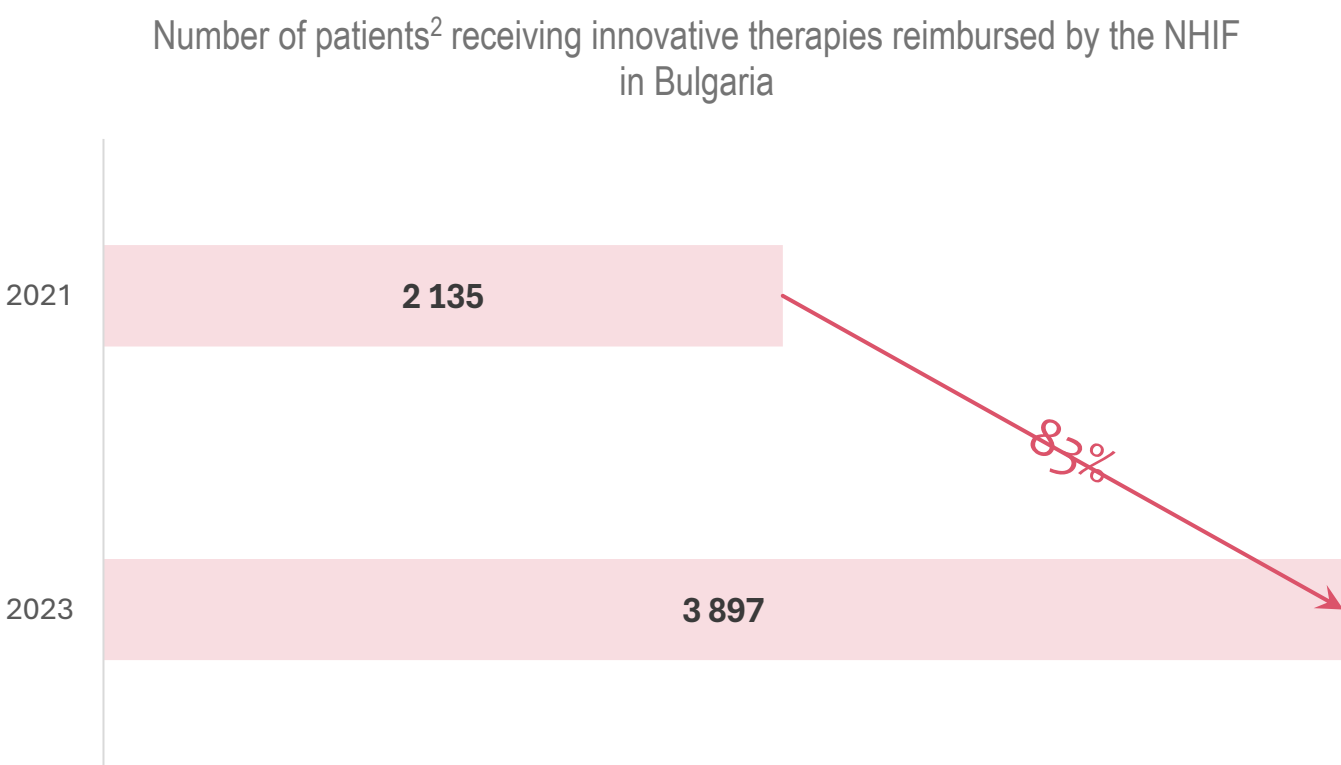


17,696
Total quality-adjusted life¹ years
gained for all patients



€188,649,793
Total contribution to
Bulgaria's GDP

Innovative immunotherapies and targeted therapies focus on cancer cells or abnormal immune responses, which increases treatment efficacy, extends patient survival, improves overall quality of life and results in fewer side effects compared to traditional therapies.

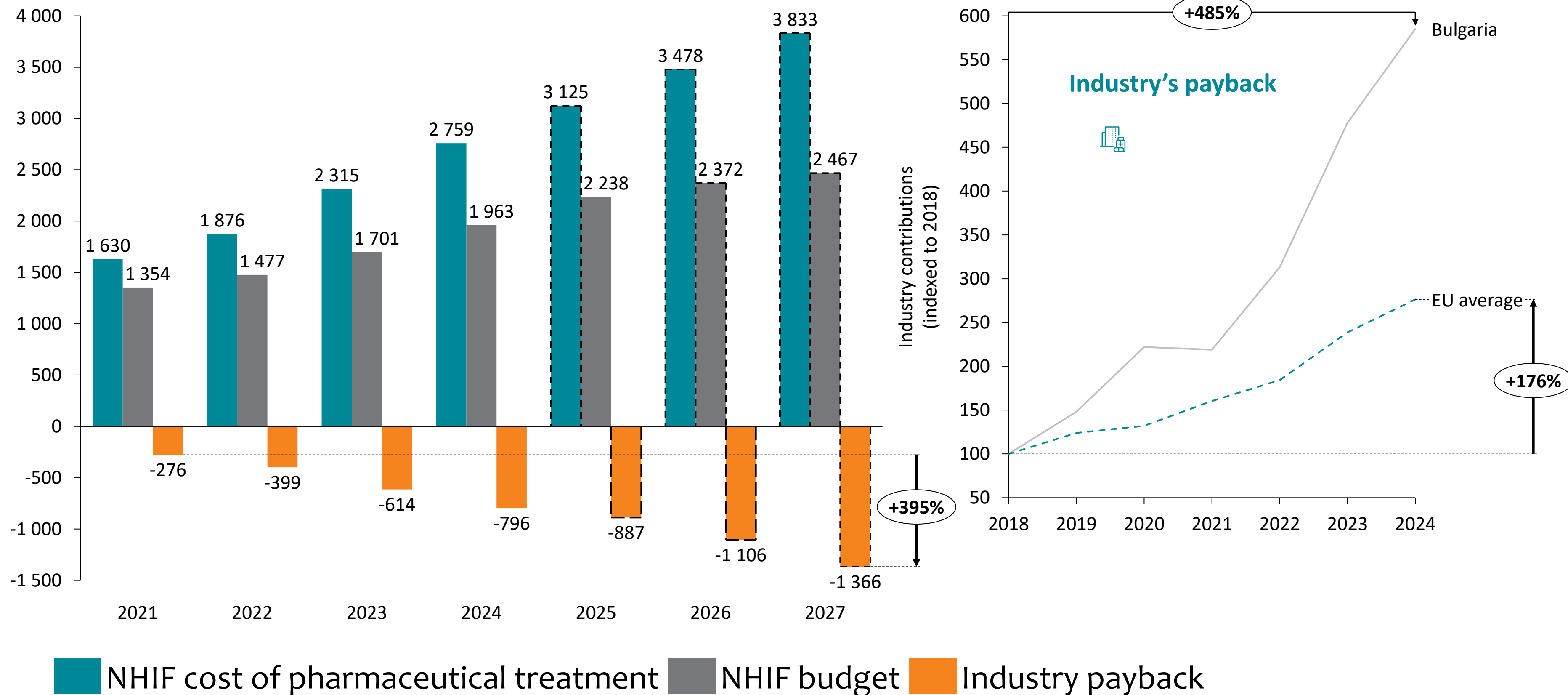


Source: Publicly presented analysis commissioned by the Association of Research-Based Pharmaceutical Manufacturers in Bulgaria (ARPharM) and conducted by HTA Ltd.

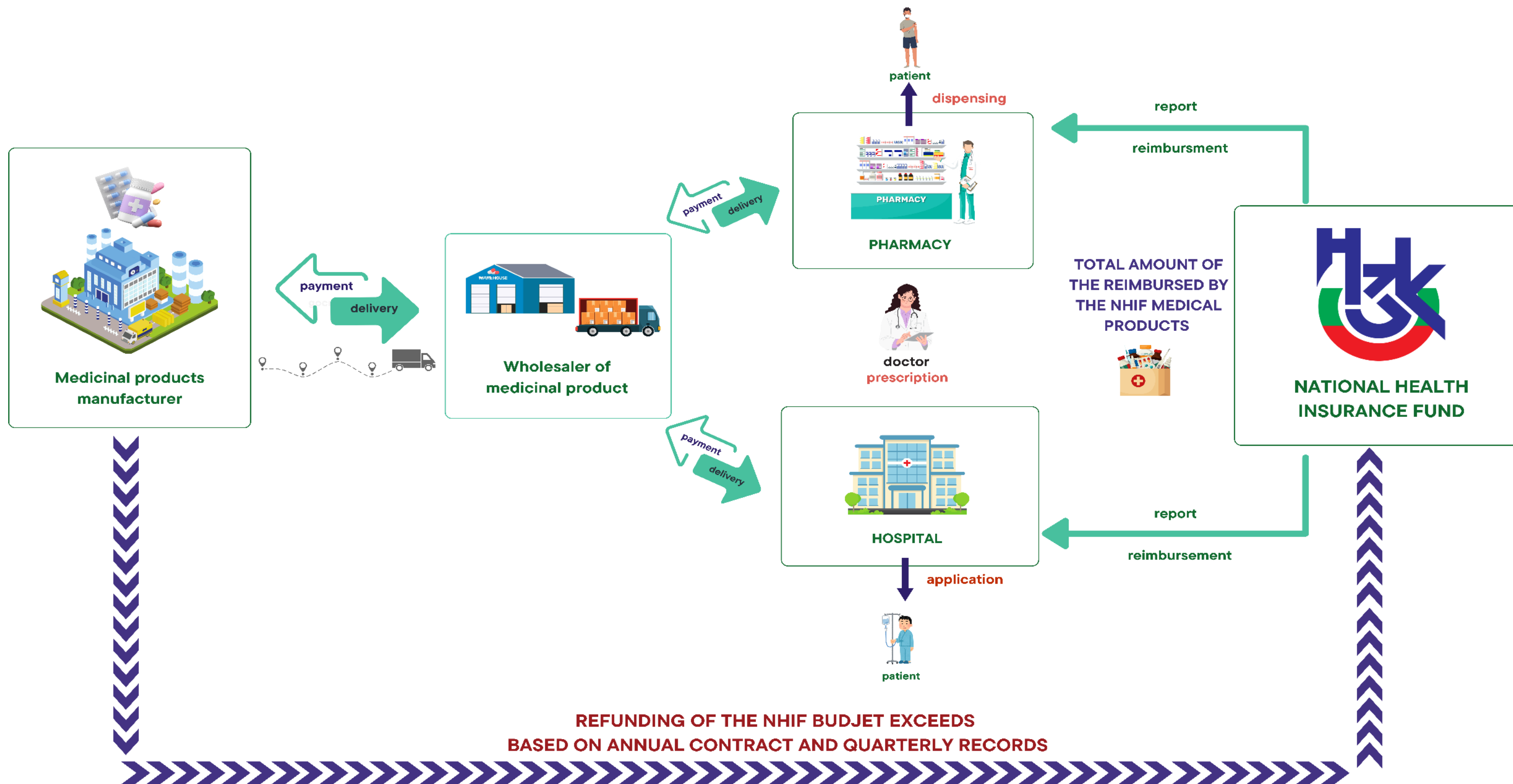
1. QALY values were calculated using modeling of clinical trial data
2. Patient numbers are based on NHIF data

The NHIF Budget does not cover the cost of treatment

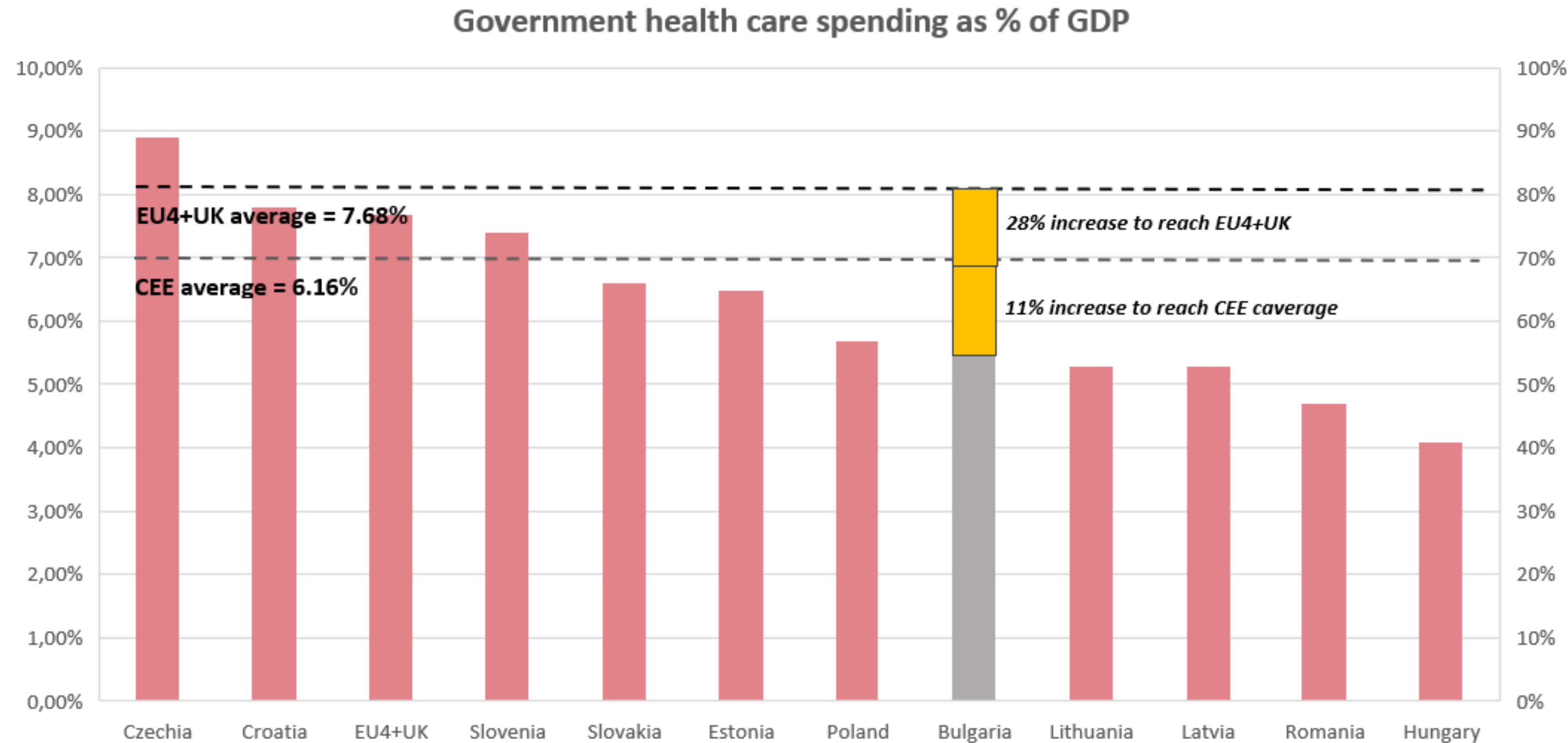
Industry's payback increase in Bulgaria is not sustainable



Supply, dispensing/application, reporting and reimbursement of medicinal products by the NHIF. Payback by the pharmaceutical companies



Government healthcare investment as % of GDP, 2023



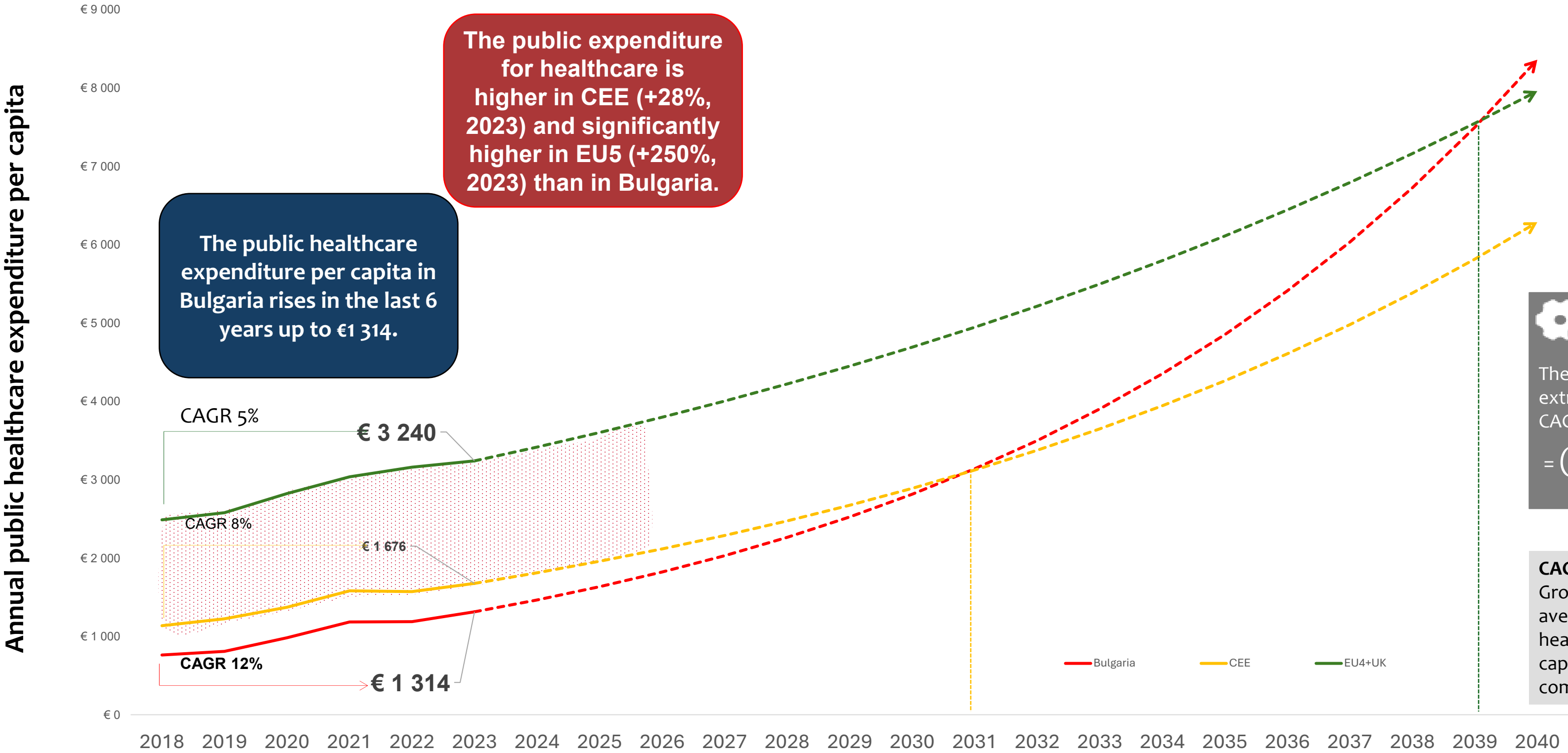
In 2023 the governments in the EU have spent 1,251 billion on “health” or 7.3% of GDP.

In 2023 the gap in government health care spending between the EU4+UK (7.68%) and the CEE countries (6.16%) countries remains high – 1.52%. Bulgaria is rated 7th among the CEE countries with healthcare expenditure of 5.50% in 2023.

Data is gathered and analyzed from Eurostat. The health care expenditure includes medical product and appliances and equipment, outpatient services, hospital services, public health services, R&D services and health n.e.c.

Public healthcare investment per capita in Bulgaria is rising faster than in CEE and EU4+UK, still not enough

Public healthcare expenditure in Bulgaria is projected to reach the CEE avg. by 2031 and the EU4+UK avg. by 2039



The public expenditure for healthcare is higher in CEE (+28%, 2023) and significantly higher in EU5 (+250%, 2023) than in Bulgaria.

The public healthcare expenditure per capita in Bulgaria rises in the last 6 years up to €1 314.

Methodology

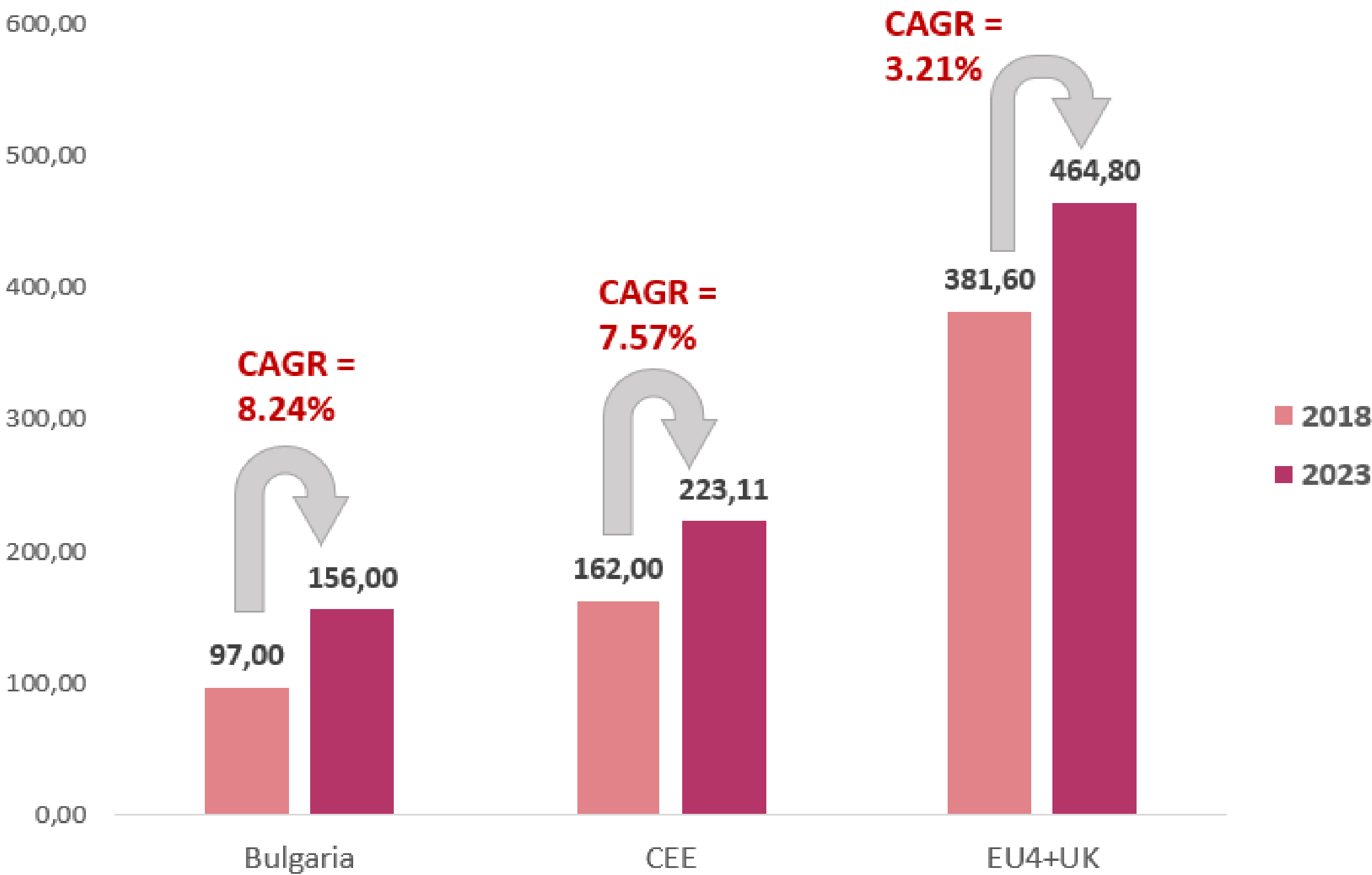
The 2018-2023 data is extrapolated based on the CAGR

$$= \left(\frac{\text{value in 2023}}{\text{value in 2018}} \right)^{1/6}$$

CAGR (Compound Annual Growth Rate): shows the average yearly increase in public healthcare expenditure per capita, assuming steady, compounded growth

Source: OECD, Health expenditure and financing, Government/compulsory schemes
The CEE average health care expenditures are calculated based on data from Croatia, Czech Republic, Estonia, Hungary, Poland, Romania, Slovakia, Slovenia, Latvia, Lithuania and Bulgaria.
The EU4+UK average health care expenditures are calculated based on data from Germany, Italy, Spain, France and United Kingdom.

Public net pharmaceutical expenditure, per capita, €



- Bulgaria has the lowest net pharmaceutical spending per capita, both in 2018 and 2023. On the other hand, the results show a promising trend – the country has the highest CAGR, compared to CEE and EU4+UK. With this pace, Bulgaria will reach EU4+UK in 2045.

Source of information: IQVIA

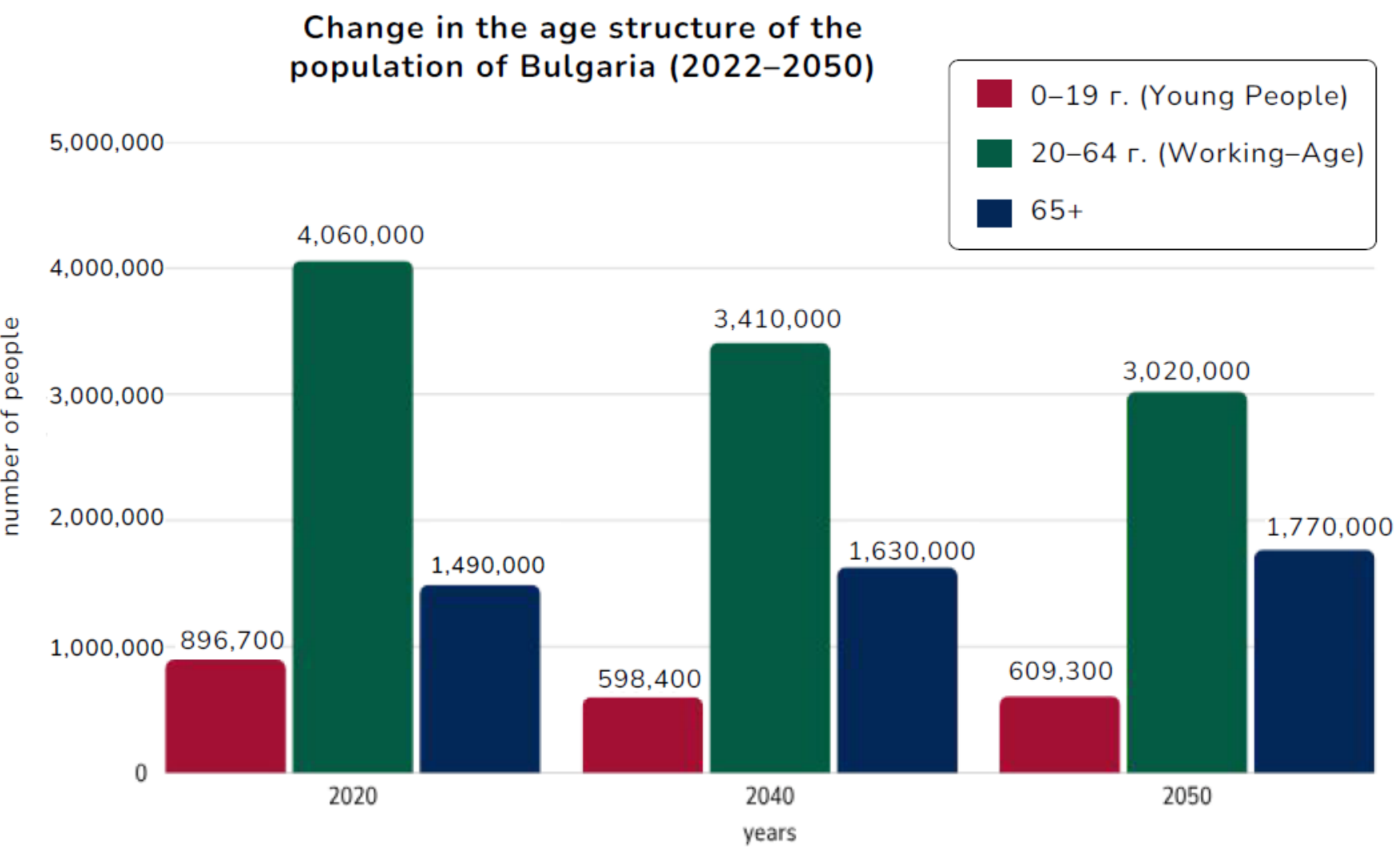
Methodology

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The relationship between the age of individuals and their use of health care:

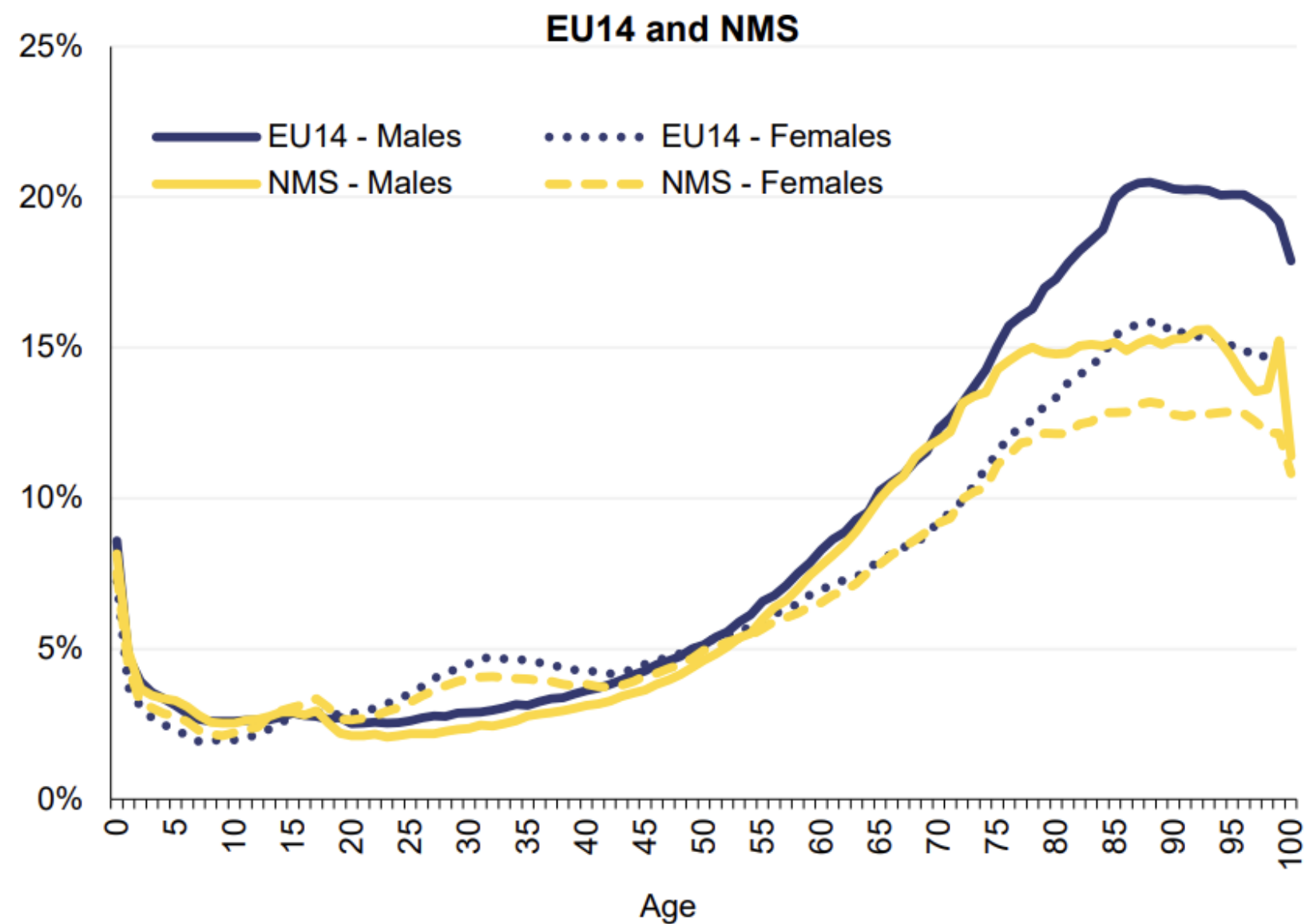
An aging population increases pressure on healthcare spending



According to the European Commission, per capita public expenditure in CEE countries increases significantly with age, especially beyond 55. This is largely due to the higher prevalence of multimorbidity and the associated need for resource-intensive healthcare.

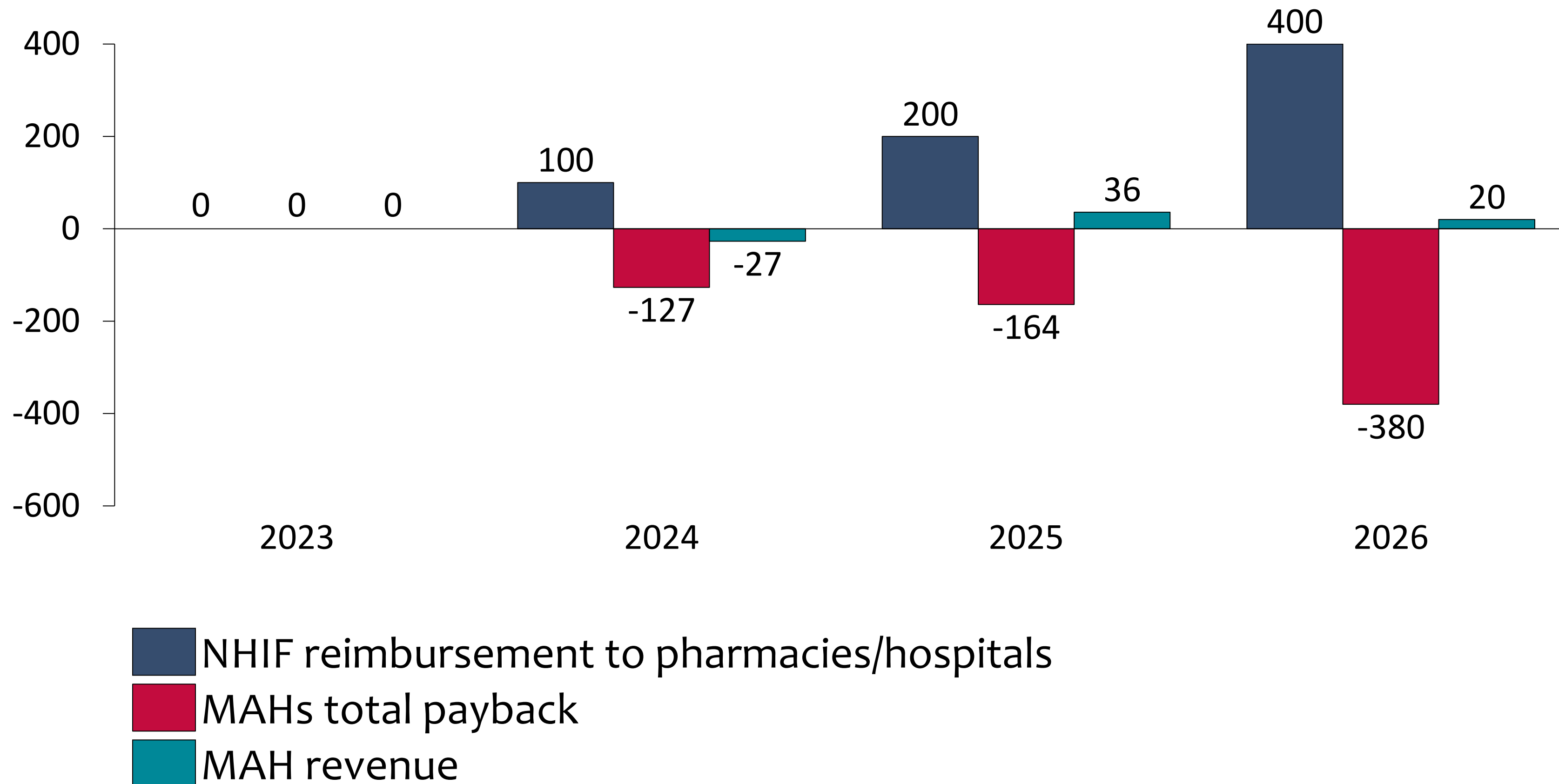
Bulgaria’s population is rapidly aging: the working-age group will shrink by over 1 million by 2050, while the number of older adults will rise. This demographic shift suggests growing economic and social pressures – shrinking labor supply, lower tax revenues, and increased demand for pensions and healthcare.

Age-related healthcare spending per capita as proportion of GDP per capita %, 2022



Source: HTA Ltd. AGING BULGARIA: Demographics, Healthcare Workforce, and Future Trends 2040 – 2050; European Commission (2024), The 2024 Ageing Report. Economic & Budgetary Projections for the EU Member States (2022-2070)
The EU14 aggregate includes the profiles of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain and Sweden. The NMS aggregate includes Bulgaria, Croatia, Czechia, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovakia and Slovenia. Romania did not provide an age-cost profile. It was imputed as the average cost profile of NMS.

Simulation of a new product launch – it's not worth it





Negative Effects for Patients of Pharmaceutical Underfunding as of 2025

Real Case Studies



What does it entail?

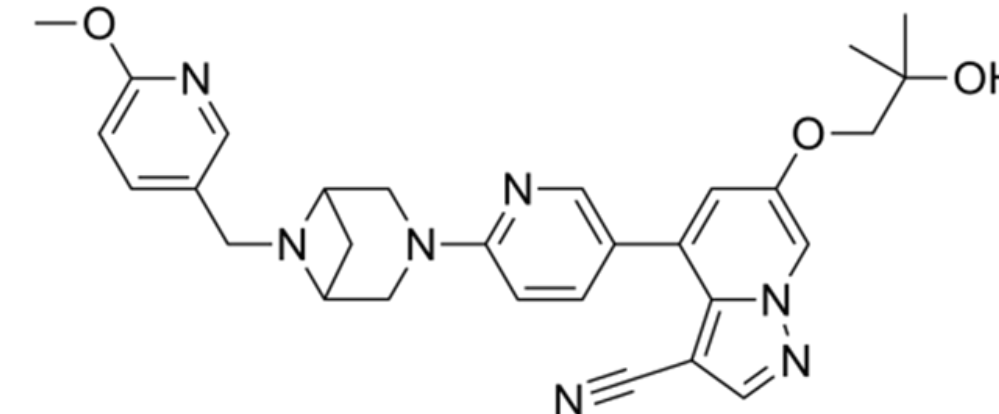


- Innovative medicinal therapies, approved by the European Medicines Agency, are not made available for Bulgarian patients. This is largely due to the high level of discounts and compensations to the NHIF, which averages 30% of the established lowest manufacturer price. In the first year of market entry (2025), these discounts and compensations may exceed 170% of sales.
- Consequently, numerous innovative and irreplaceable therapies do not reach Bulgarian patients





Case Study 1



NOT MADE AVAILABLE in Bulgaria

targeted therapy for the treatment of cancer in people whose tumors have a change (mutation or fusion) in a specific gene (RET – short for "rearranged during transfection").

DISEASE

The therapy was approved by the EMA in 2021 and is indicated for the treatment of adults with the following diseases:



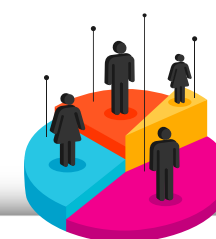
advanced RET fusion-positive **non-small cell lung cancer (NSCLC)** not previously treated with a RET inhibitor;



advanced RET fusion-positive **thyroid cancer patients who are radioactive iodine-refractory**;



advanced RET-mutant **medullary thyroid cancer (MTC)**



Affected population for Bulgaria

at least
35 patients



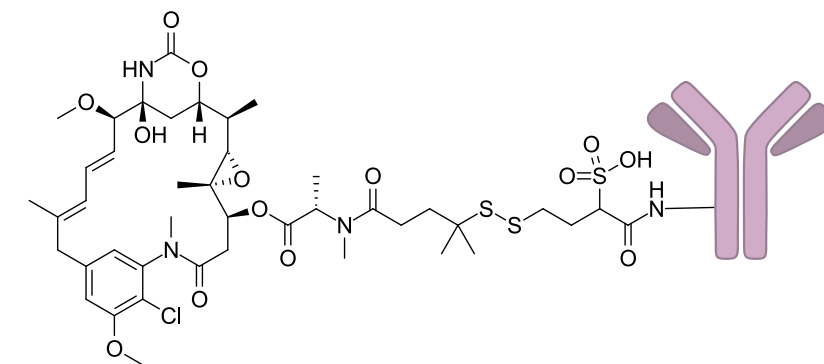
Negative effect on patients due to lack of access to therapy

Patients are deprived of high-end targeted therapy, which:

- significantly prolongs survival and improves quality of life in patients with RET-positive non-small cell lung cancer (NSCLC), papillary thyroid cancer, and medullary thyroid cancer;
- has good tolerance and low toxicity;
- It is based on an individualized approach and personalized medicine



Case Study 2



NOT MADE AVAILABLE in Bulgaria

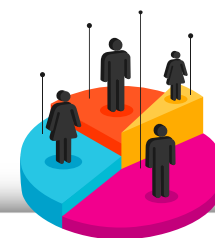
first in its class and the only FR α -targeted Antibody-Drug Conjugate Therapy (ADC) for patients with platinum-resistant ovarian cancer.



Ovarian cancer is the third most commonly diagnosed gynecological cancer worldwide, with the highest mortality rate among gynecological cancers due to late diagnosis, occurring in later stages due to non-specific signs and symptoms, as well as a high incidence of disease recurrence, due to the appearance of resistance to treatment (platinum-based chemotherapy).



Platinum-resistant ovarian cancer is an advanced, evolving, and difficult-to-treat form of OC with a poor prognosis



Affected population for Bulgaria

Approximately
60 patients

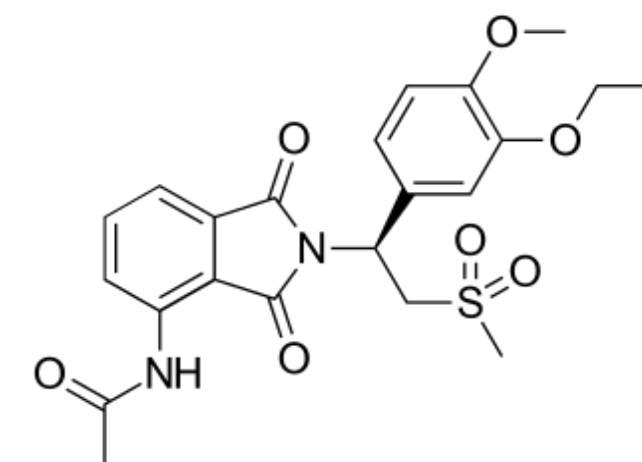


Negative effect on patients due to lack of access to therapy

- Poor prognosis for patients who have developed platinum resistance – they may lose their lives.



Case Study 3



NOT MADE AVAILABLE in Bulgaria

A low molecular weight drug approved for the treatment of plaque psoriasis (PsO), psoriatic arthritis (PsA), and Behçet's disease (BD).

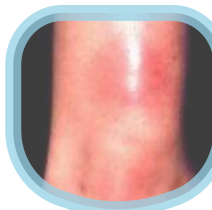
DISEASE



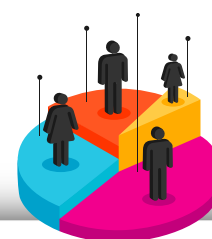
Plaque psoriasis is a chronic autoimmune skin condition characterized by red, scaly patches, often on the scalp, elbows, knees, and lower back



Psoriatic arthritis is a chronic inflammatory arthritis associated with psoriasis. It affects joints and entheses (where tendons or ligaments insert into bone), leading to pain, stiffness, and swelling.



Behçet's disease is a rare, chronic, multisystem vasculitis of unknown cause. It causes inflammation in blood vessels throughout the body, leading to a wide range of symptoms.



Affected population for Bulgaria

for PsO – between 100,000-150,000 patients
for PsA – between 30,000-45,000 patients
for BD – less than 500 patients



Negative effect on patients due to lack of access to therapy

Patients are deprived of therapy, which is:

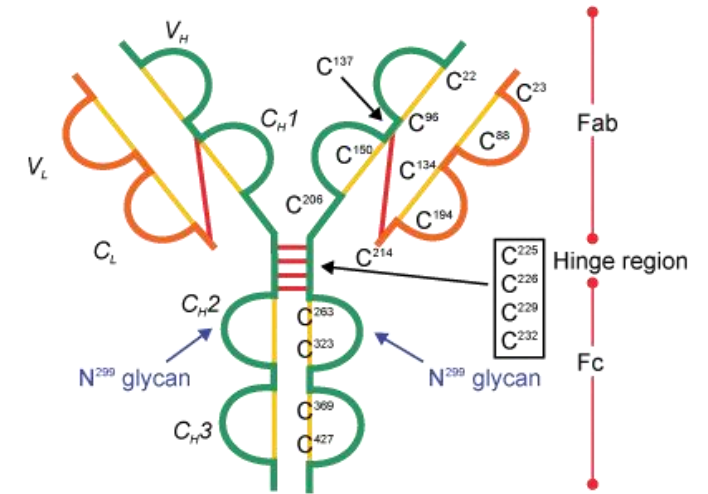
- in a convenient oral form that does not require routine laboratory monitoring and which could significantly improve treatment adherence and quality of life;
- with a wide range of symptom relief – especially for patients with complex or multisystem diseases;



Case Study 4

NOT MADE AVAILABLE in Bulgaria

therapy with a K-forming monoclonal antibody used to treat osteoporosis in postmenopausal women with a high or very high risk of fractures (HFR/VHFR) and men with an increased risk of fractures.

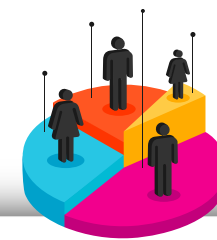


DISEASE



Osteoporosis is a chronic skeletal disorder characterized by compromised bone strength, leading to increased risk of fractures and silent progression, often undetected until a fragility fracture occurs.

It is the most common bone disease and a major global public health concern. Fractures are the hallmark of osteoporosis, especially in the hip, spine, and wrist.



Affected population for Bulgaria

between
140 000 - 220 000
patients



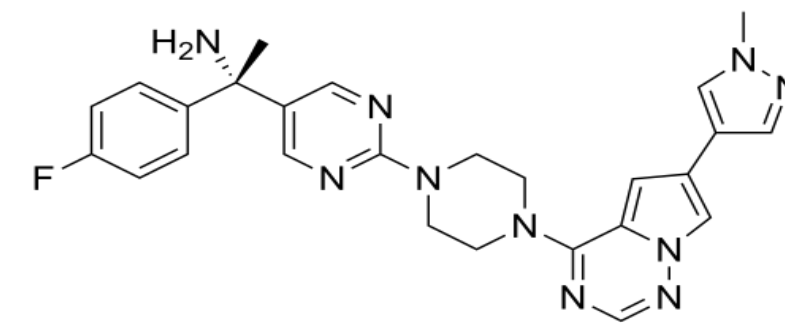
Negative effect on patients due to lack of access to therapy

Patients are deprived of therapy that:

- is extremely suitable for patients with a high or very high risk of fractures who do not respond adequately to the currently available therapeutic options;
- quickly reduces the risk of fractures;
- It is convenient to dosage and has a certain duration of treatment;
- leads to an improved quality of life for patients, associated with a reduction in fracture pain, immobility, and heaviness for the person caring for the patient.



Case Study 5



NOT MADE AVAILABLE in Bulgaria

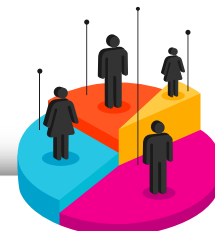
targeted therapy designed for the powerful and selective inhibition of cells positive for certain mutations. It is intended for the treatment of adult patients with aggressive systemic mastocytosis (ASM); systemic mast associated with blood cancer (SM-AHN); mast cell leukemia (MCL); inoperable or metastatic gastrointestinal stromal tumors (GIST) with certain mutations.



Systemic mastocytosis is a rare disorder characterized by the overproduction of mast cells (a type of white blood cell crucial for immune response) that accumulate in various tissues, including the skin, bones, liver, and gastrointestinal tract.



A Gastrointestinal Stromal Tumor (GIST) is indeed a rare, malignant (cancerous) solid tumor that arises from the connective tissue within the digestive system, and by its nature it belongs to sarcomas and is a rare disease.



Affected population for Bulgaria

at least 10 patients per year



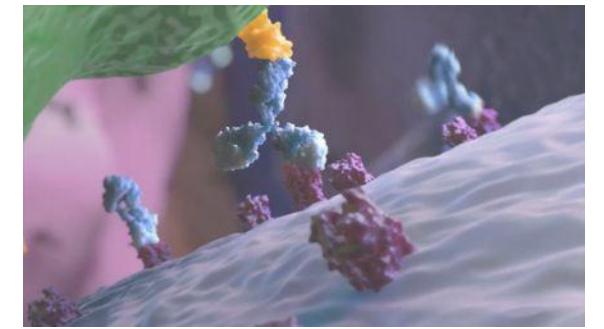
Negative effect on patients due to lack of access to therapy

Patients are deprived of the first and only high-end targeted therapy authorized for use by the EMA, which:

- Is intended for rare cancers with specific mutations, where conventional treatments failed, and the therapy has shown significantly higher survival and symptom reduction.
- has significantly higher survival and symptom reduction in the observed population.



Case Study 6

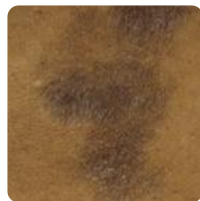


NOT MADE AVAILABLE in Bulgaria

targeted therapy with a monoclonal antibody, developed to bind to CCR4, a G-protein-coupled receptor (target).

It is indicated for the treatment of two types of cutaneous T-cell lymphoma – fungoid mycosis (MF) and Cesary syndrome (SS) in patients who have undergone at least one previous treatment that has not worked, or in whom the disease has recurred.

DISEASE



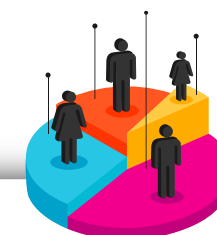
Cutaneous T-cell lymphoma (CTCL) is a rare, slow-growing, non-Hodgkin lymphoma that originates in T-cells, a type of infection-fighting white blood cell, when they become cancerous and accumulate in the skin, causing symptoms like itchy, red, scaly patches or lumps.



Fungoid mycosis (MF) is indeed the most common type of cutaneous T-cell lymphoma (CTCL). It's a slow-growing cancer of T lymphocytes that typically affects the skin, presenting with symptoms like a rash, itchy skin, scaly patches, plaques (thicker, raised areas), or sometimes tumors.



Sezary syndrome (SS) is a rare and aggressive form of T-cell lymphoma, characterized by the presence of malignant lymphocytes in the peripheral blood, erythroderma, as well as generalized lymphadenopathy. Pain and itching (pruritus) can be observed at all stages of the disease



**Affected population for
Bulgaria**

**at least 15
patients per year**



**Negative effect on patients due to lack of
access to therapy**

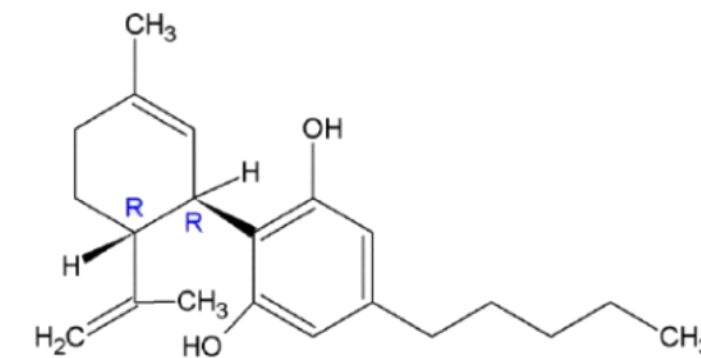
Patients are deprived of high-end targeted therapy, which:

- demonstrates greater effectiveness in patients who have not responded positively to previous treatment;



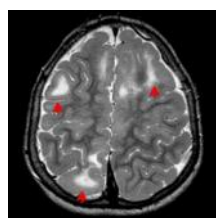


Case Study 7

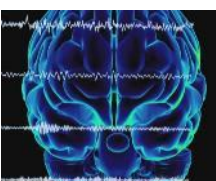


NOT MADE AVAILABLE in Bulgaria

an oral anticonvulsant/antiepileptic drug on the market in Bulgaria. It is indicated for treatment as adjunctive therapy for seizures associated with Tuberous Sclerosis Complex (TSC), with Lennox-Gastaut syndrome (LGS) and with Dravet syndrome (DS) in patients aged 2 years and older.



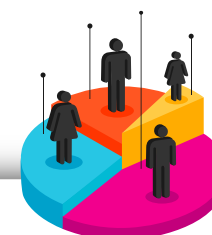
Complex tuberous sclerosis (TSC) is a genetic disorder causing non-cancerous tumors to form in various organs, including the brain, skin, kidneys, heart, and lungs. The clinical presentation is highly variable, encompassing a wide range of manifestations, including seizures, developmental delays, cognitive impairment, autism, renal lesions, cardiac tumors, skin lesions, and pulmonary involvement.



Lennox-Gastaut Syndrome (LGS) is a severe, lifelong childhood-onset epilepsy characterized by multiple seizure types, intellectual disabilities, and unique EEG patterns. It is a rare condition that is difficult to treat, with seizures being resistant to many medications, leading to poor quality of life and significant burdens for patients and their families.



Severe Myoclonic Epilepsy in infancy (SMEI, or Dravet syndrome) is a drug-resistant epilepsy that occurs in the first year of life of previously healthy children.



**Affected population for
Bulgaria**

at least 300
patients



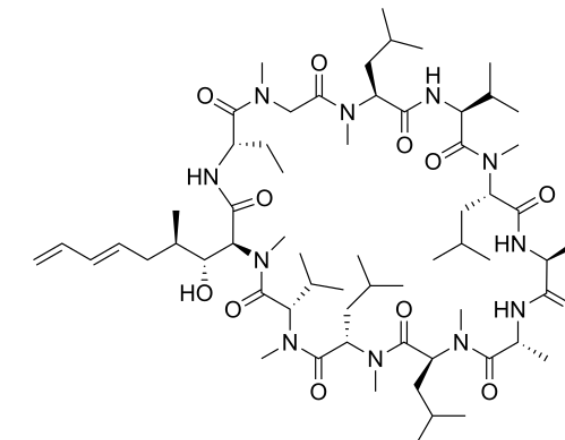
**Negative effect on patients due to lack of
access to therapy**

Patients are deprived of effective therapy that:

- leads to a significant reduction in the frequency of attacks and has a proven high safety profile;



Case Study 8

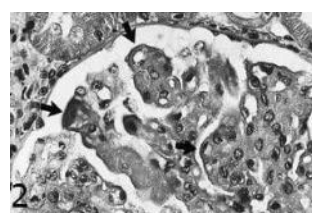


Unalternative therapy

NOT MADE AVAILABLE in Bulgaria

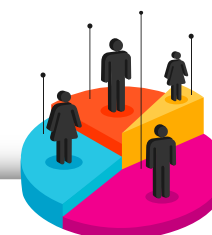
new effective next-generation calcineurin inhibitor, which is a human IgG1 λ monoclonal antibody that blocks the binding of soluble human B-lymphocyte-stimulating protein to its corresponding receptors on the surface of B cells. It is the only calcineurin inhibitor approved specifically for the treatment of adult patients with active lupus nephritis in combination with major immunosuppressive therapies.

DISEASE



Lupus nephritis (LN) is a severe complication of systemic lupus erythematosus (SLE), where the immune system attacks the kidneys, and is one of the most severe and common complications.

LN can cause permanent kidney damage and lead to chronic kidney disease, and is associated with a mortality risk that increases up to nine times compared to the general population.



Affected population for Bulgaria

at least 35 patients



Negative effect on patients due to lack of access to therapy

Patients are deprived of next-generation therapy that:

- provides a new, proven, more effective treatment option for adult patients with active form of lupus nephritis;

Possibilities for restoring sustainability and predictability of the Bulgarian pharmaceutical reimbursement system

Development of a mechanism for monitoring and analysis of the population's medical needs for pharmaceutical treatment to improve budget planning.

A sustainable increase of the healthcare and pharmaceutical public funding, corresponding to growing medical needs.

Limiting industry's payback increase

Thank you!
Time for questions?