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Healthcare as Investment

Report of the Healthcare Committee of the American Chamber of Commerce in Bulgaria

May 2021

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Intro and objectives of the report

The report aims to assess the current state of the HC system in Bulgaria and illustrate the long-term benefits of its optimization

Background

Investment in Healthcare needs to be on the **strategic agenda** of every government to put necessary **focus on people's health** and has become an absolute necessity to ensure long-term and sustainable economic growth

The impact of delayed or insufficient investment in healthcare results in indirect increases in Healthcare costs, as well as **long-term decrease in labor productivity and GDP output**

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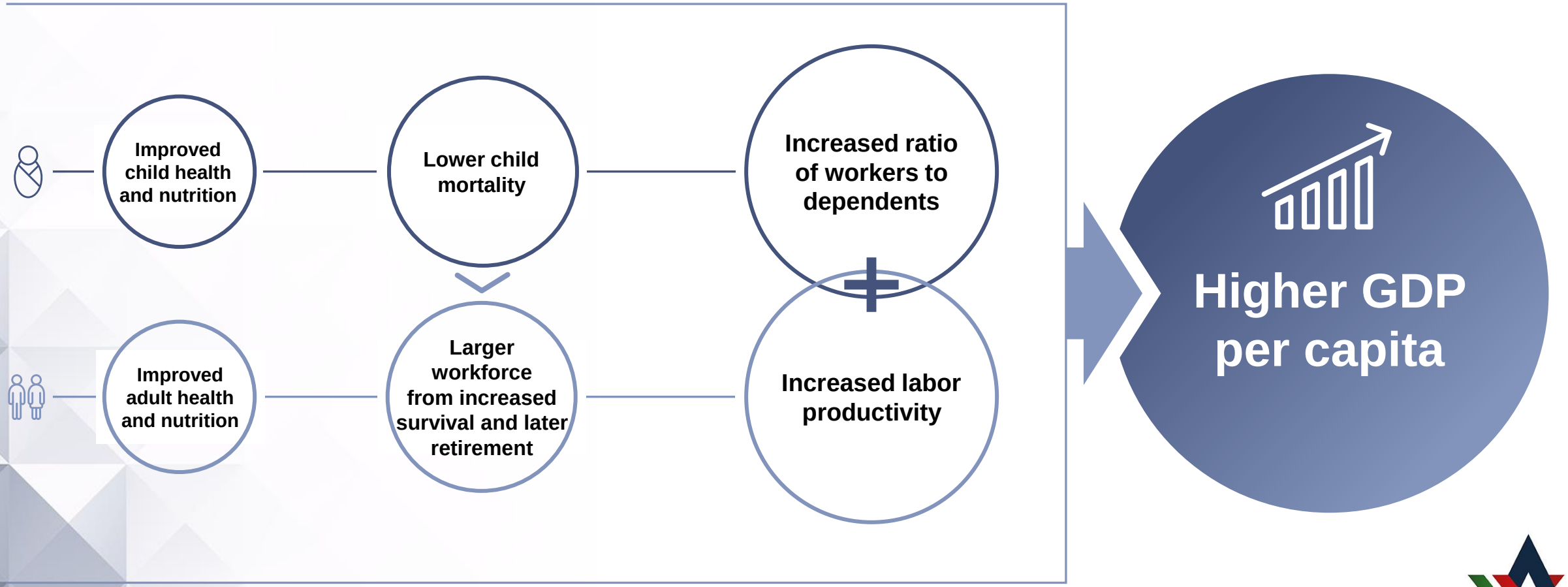
Investment in Healthcare has become an absolute necessity to ensure long-term and sustainable economic growth

Background



Source: OECD, Eurostat, IQVIA

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Importance of investment in healthcare

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Expand equitable access to modern, comprehensive, quality-, people- and community-centered healthcare

Despite a significant progress, the Bulgarian healthcare system still needs an updated comprehensive investment strategy

Summary

The Bulgarian healthcare system has experienced **notable progress** for the past **20 years, increasing**

years of life expectancy

healthcare spending more than 3 times

However, Bulgaria is currently caught up in a **vicious circle** of

*EUR PPP per capita

Worsening demographic trends

- Ageing population: **2y avg age increase** in a decade
- Growing old age dependency ratio: **50% increase** from 2010
- Suffering working population

Healthcare spending

- Growing healthcare needs
- Extremely high **OoP spending close to 40%**, placing spending ceiling
- Rising pressure on the system

Poor scoring compared to EU average on

- Life expectancy: **75y** (BG) VS. **81y** (EU)
- Amendable mortality (per 100k): **427** (BG) VS. **256** (EU)
- Infant mortality (per 1,000): **5.8** (BG) VS. **3.8** (EU)
- Access to healthcare

Healthcare spending can possibly reach up to **50% of the disposable income** of the working population by 2030

In order to reverse the pattern, we need structural changes – increased investments in healthcare, coupled with comprehensive strategies to target these investments to the areas that have the highest impact

Sources: Eurostat, OECD, NHIF, NSI, IQVIA

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Although Bulgaria has strongly increased healthcare spending, outcomes are still to catch-up w/ EU – structural changes needed

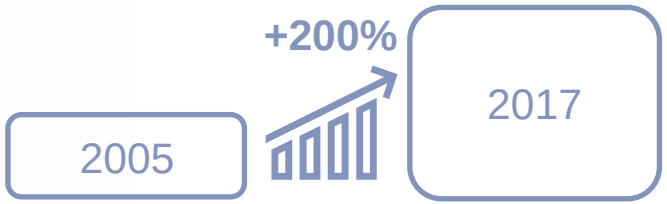
Country profile – Bulgaria

Overview

- Increase in healthcare spending highest among regional peers
- However, OoP* spending still among the highest in EU, damaging therapy access
- As a result, although outcomes have significantly improved over recent years, Bulgaria still lags in:
  - Effectiveness
  - Unmet needs
- Hence, to change direction, structural changes/ reforms needed

Health system & Accessibility

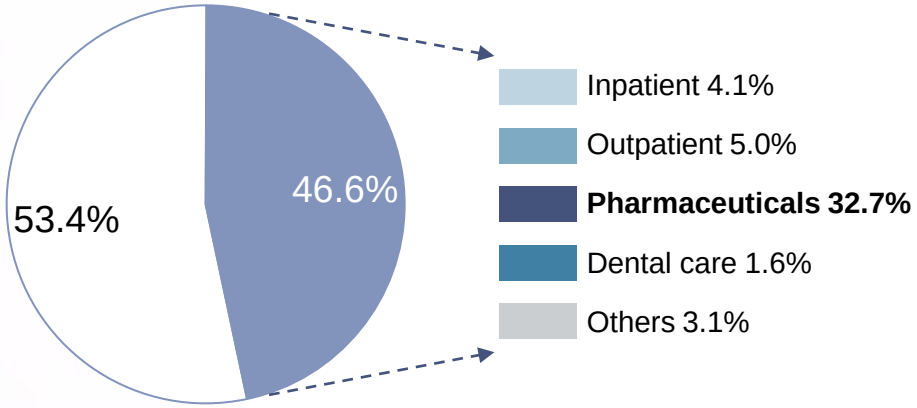
Yearly health spending



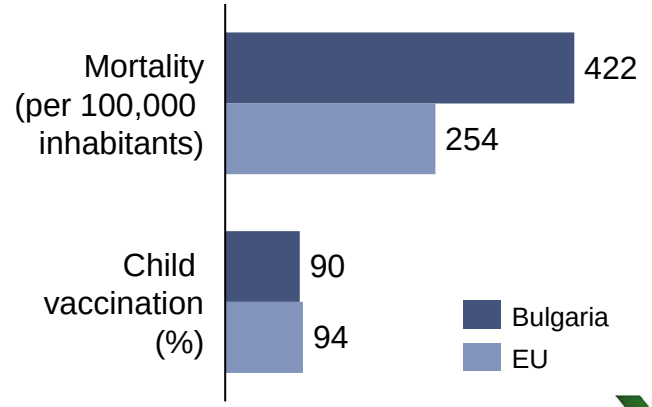
Unmet needs statistics

Low-income vs High-income unmet needs

OOP Spending in Bulgaria**



Effectiveness



*Out of pocket; **2017 data

Source: IQVIA, OECD iLibrary

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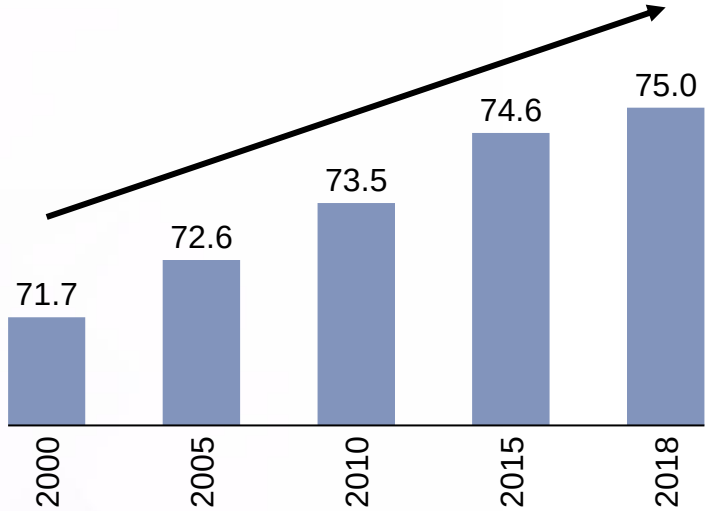
The life expectancy of people in Bulgaria has improved and spending for healthcare per capita continues to grow

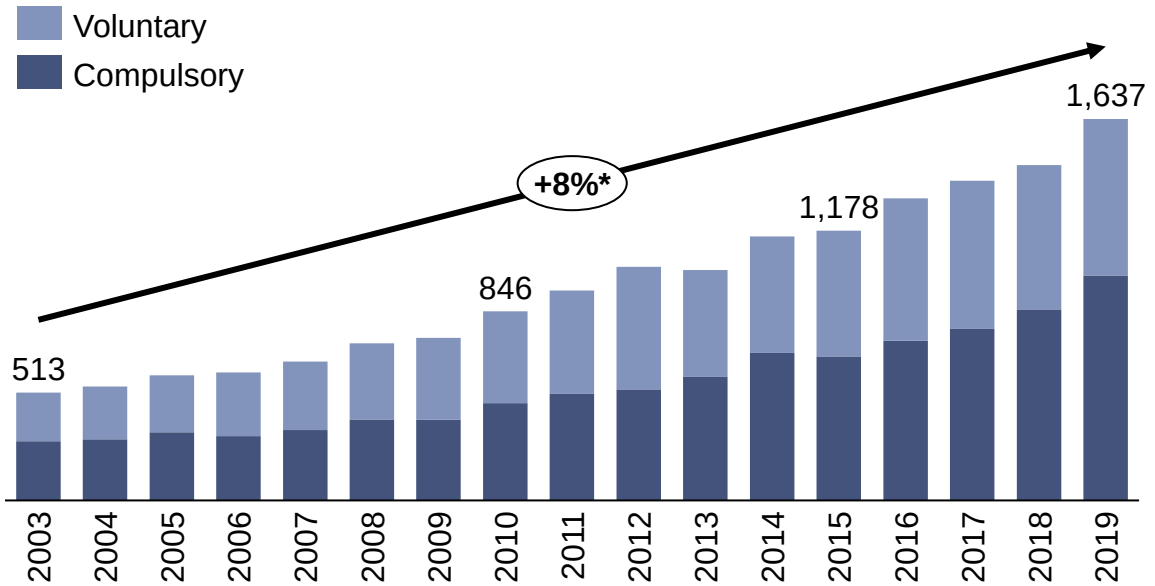
Health status and health system

Life expectancy at birth, years



Life expectancy at birth was 71.7 years in 2000, and increased to 75 in 2018

Per capita spending for healthcare (EUR PPP)



Total spending for healthcare per capita increased substantially in the last years

*Compound growth rate

Source: The World Bank, World Development Indicators; OECD

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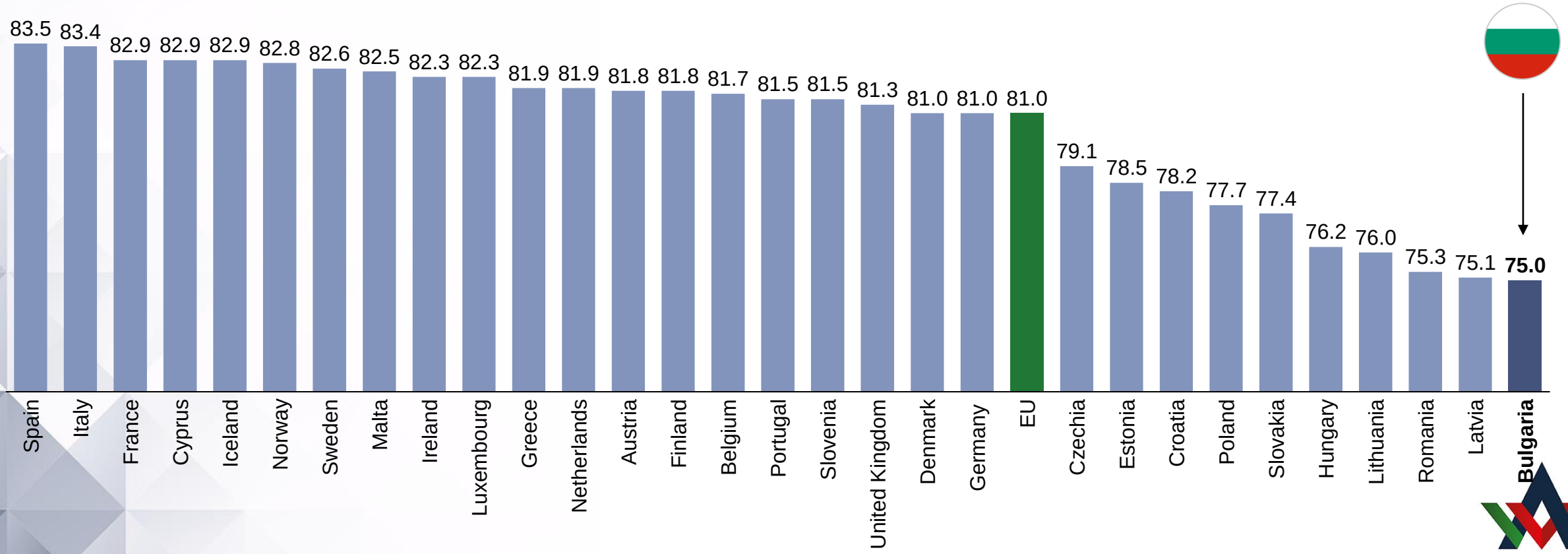
However, there is still catching-up to do with the rest of the EU in terms of health outcomes and thus life expectancy

Life expectancy in the EU

Life expectancy at birth, years, 2018



Source: The World Bank, World Development Indicators

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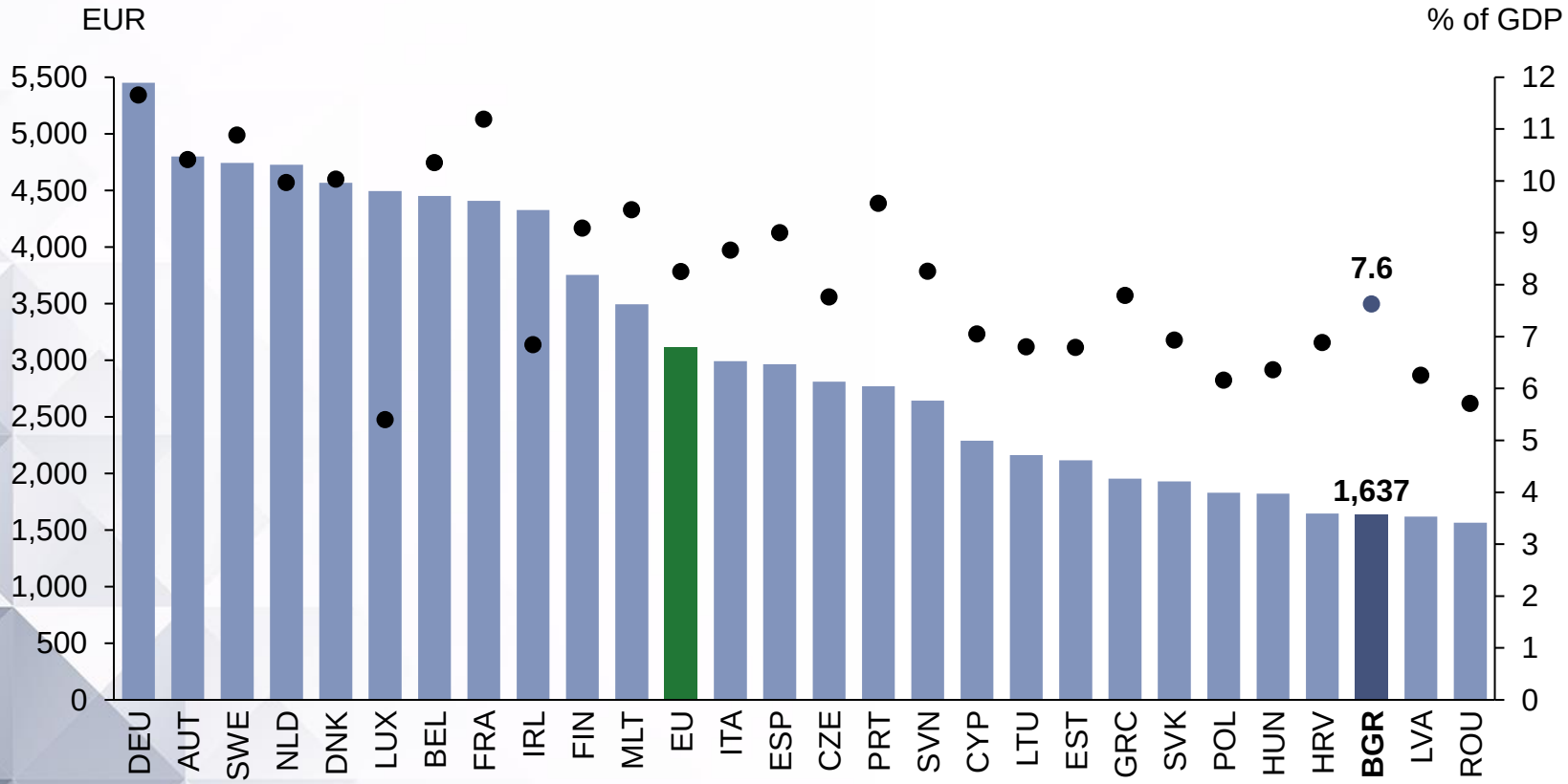
To do this catch-up, additional investment in healthcare is necessary to reach at least average EU levels

Healthcare spending

Per capita spending for healthcare (EUR PPP); % of GDP, 2019



Per capita spending remains comparably low, with the EU average being

EUR 3,110

however, healthcare spending occupies a substantial part of the GDP

● Share of GDP

EUR PPP per capita

Source: The World Bank, World Development Indicators; Eurostat

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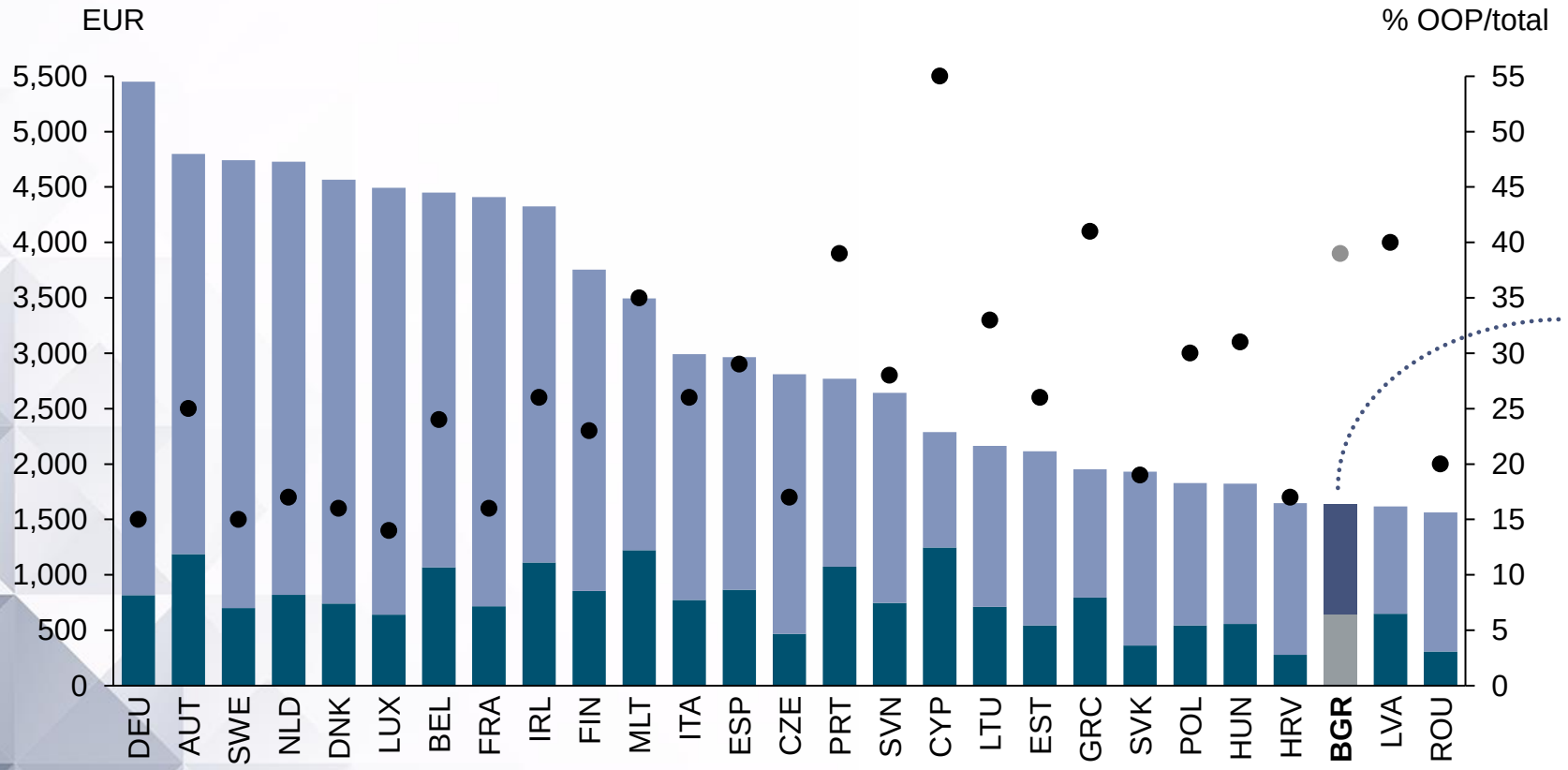
… and there is not so much room for filling that gap through further out of pocket payments

Total spending for healthcare

Per capita spending for healthcare (EUR PPP), 2019



Bulgaria has exceptionally high

39.3% **out of pocket**

spending, the 4th highest in the EU, following Cyprus, Greece and Latvia

This high portion of out-of-pocket spending deepens the issue of inequality and accessibility to basic health care, which worsens overall results

Source: The World Bank, World Development Indicators; OECD

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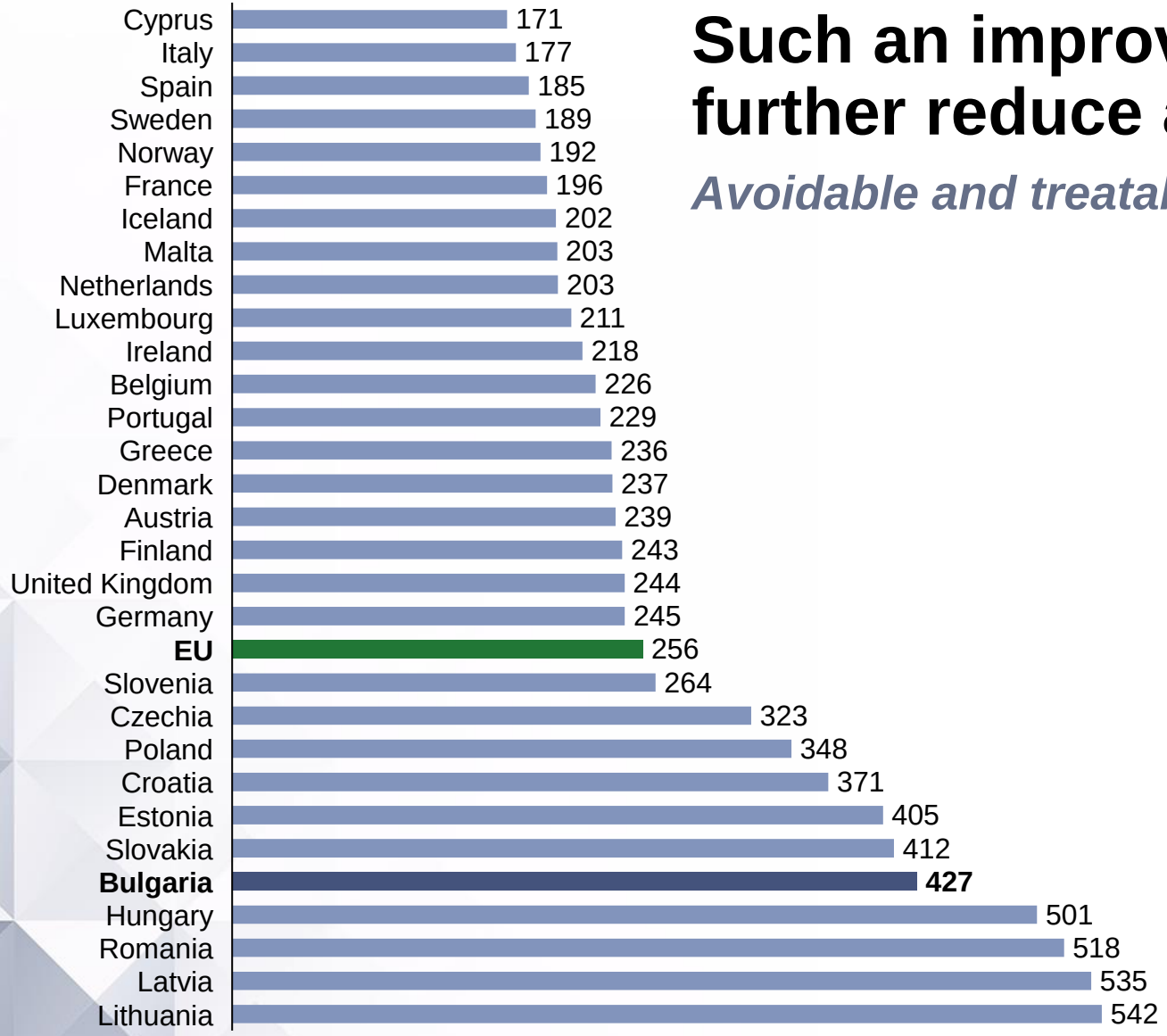
Such an improvement will help Bulgaria further reduce amenable mortality* rates

Avoidable and treatable mortality



Amenable mortality per 100,000 inhabitants, 2017

- Despite the increasing spending on healthcare, amendable mortality is nearly twice as high as the EU average
- The most important contributor is the persistently high mortality from cardiovascular diseases (CVDs), as well as cancer:

Stroke more than **4 times** than the **EU average**	Hypertension more than **4 times** than the **EU average**	Ischaemic heart disease **1.5 times** greater than the **EU average**

- If Bulgaria could reduce at least CVD mortality to the EU average, it would push all-cause mortality below the EU average

*Amenable mortality is defined as premature deaths that could have been avoided through timely and effective health care

Source: Eurostat

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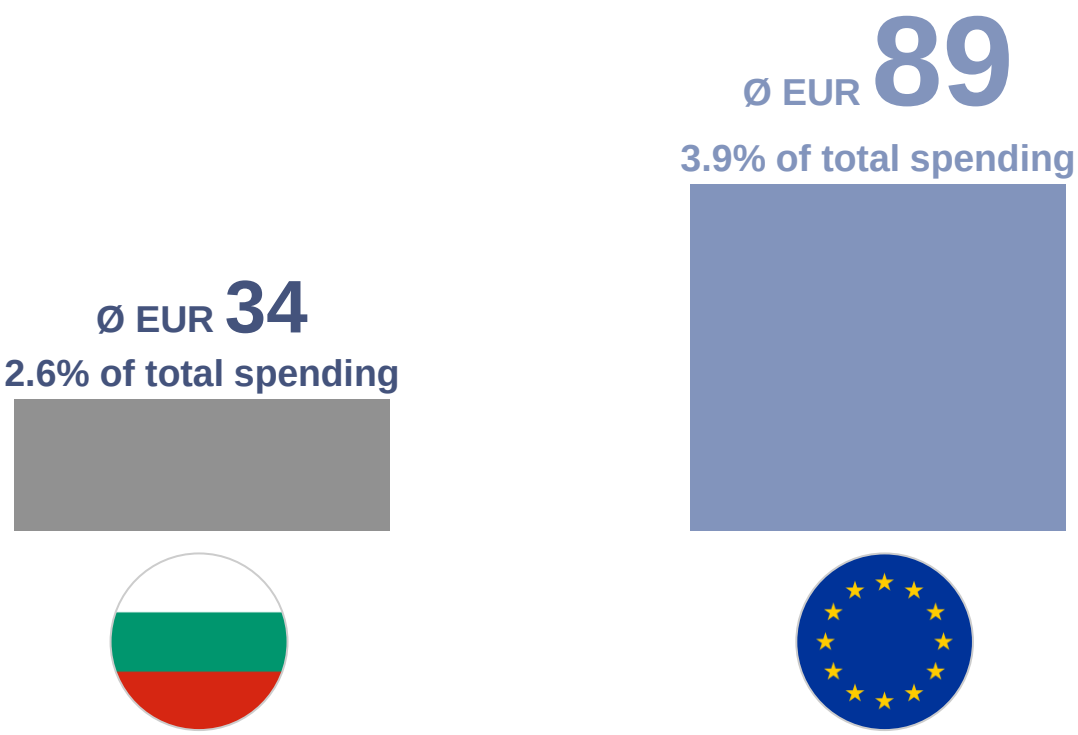
While prevention plays a major role, it remains underdeveloped within the local healthcare system and investment strategy

Spending on prevention

A substantial proportion of **deaths could be prevented** by tackling behavioral risk factors and strengthening primary prevention

- Improvements in CVD prevention and treatment are possible and could have a large impact on population health
- However, the frequency of preventive CVD check-ups remain low: just 38% of the population in 2018*

Average yearly spending on prevention per capita



*According to NHIF data

Source: Eurostat, WHO, NHIF

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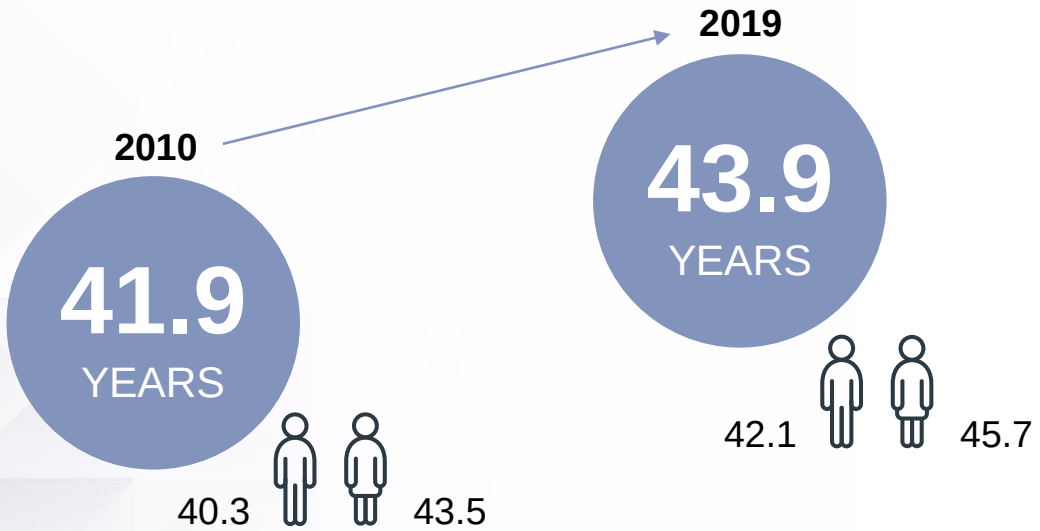
Early age prevention is even more important in the context of an ageing population to contain economic losses

Ageing population

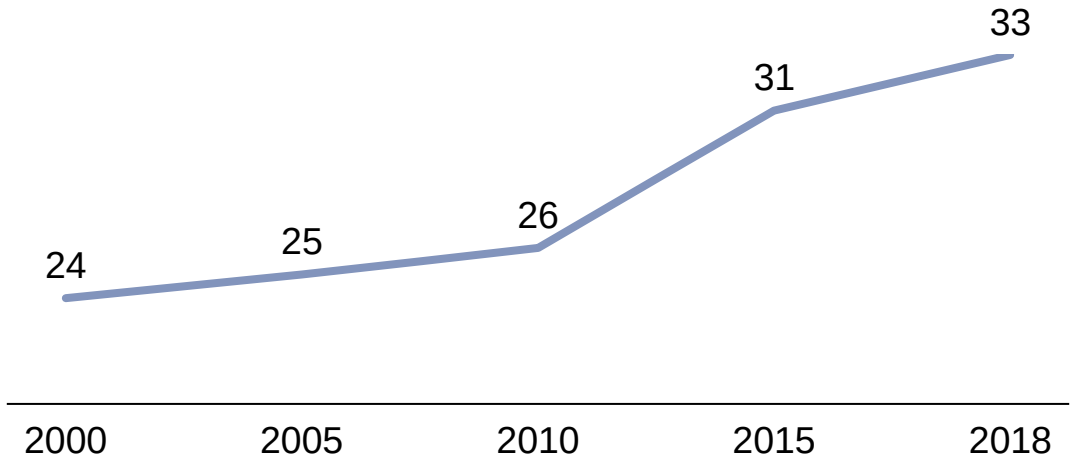
Average age of the population



The average age of the Bulgarian population is growing steadily

Old age dependency ratio

measures the ratio of the number of persons aged 65 and more per 100 persons aged 15-64 years



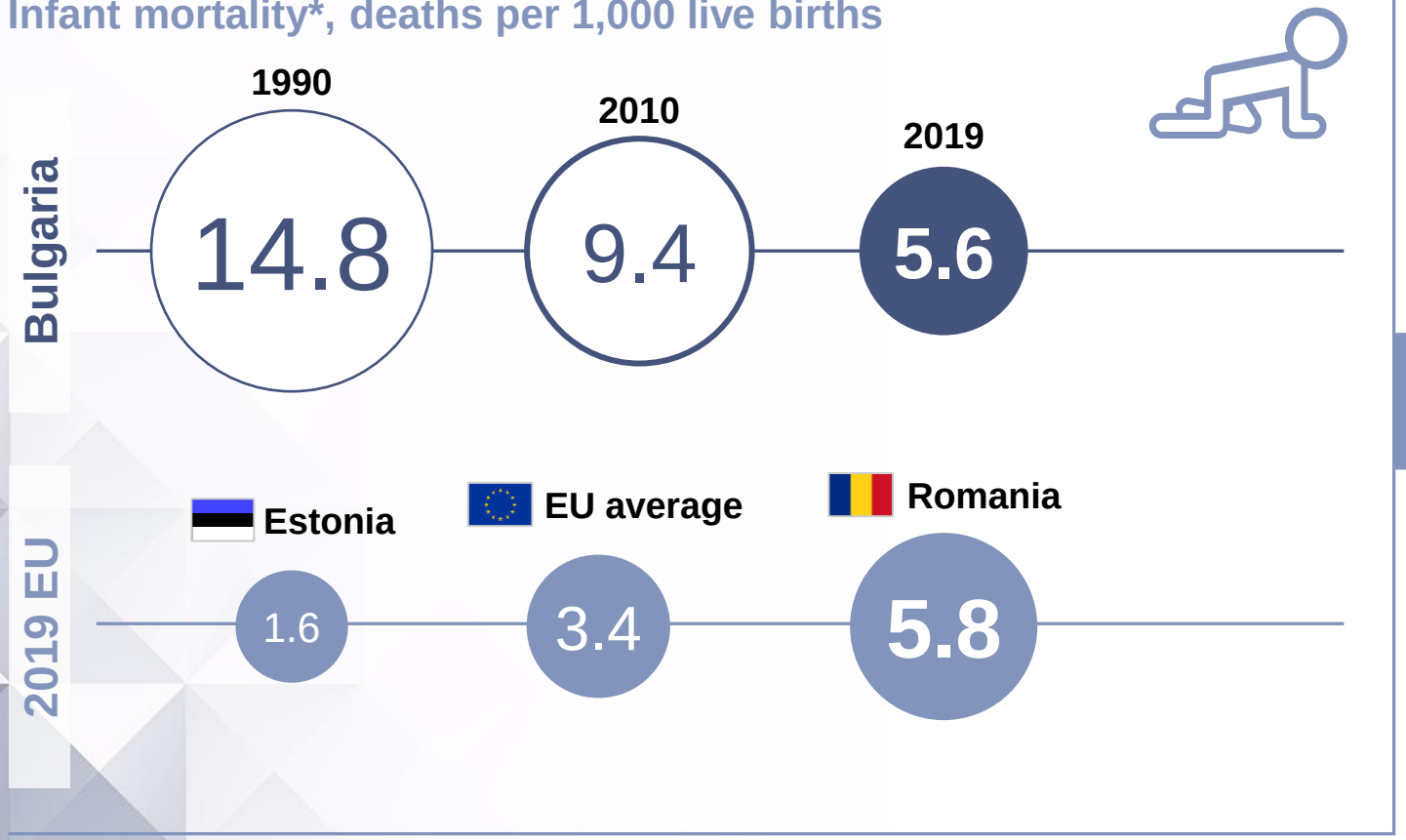
The population over working age will continue to increase, contributing to potential economic losses

Source: NSI

Moreover, further reducing infant and child mortality would sustainably impact economic development indicators

Infant mortality

Infant mortality*, deaths per 1,000 live births



- Infant mortality in Bulgaria fell steadily for the last 30 years
- However, in 2019 it is still the 2nd highest infant mortality rate in the EU
- Prenatal care practices and screening/prevention programs from a very early age have the potential to reduce the mortality rate further

- In turn, this will have a sustainable effect on the country's economic development through improving the demographic situation

*Children died before reaching one year of age

Source: Eurostat

The current model places the Bulgarian healthcare into a vicious circle, structural changes are needed to break it

Future outlook

2020 → 2030 → ...

Current model results in:

- Low life expectancy
- High amendable mortality
- Still high infant and child mortality
- Lack of sufficient prevention

2,700 EUR → 6,360 EUR → 6,885 EUR

If the model persists:

- Excessive amount of healthcare costs per capita, compared to average income
- Increasing disproportion of dependable people and affordability

Per capita spending for healthcare development

EUR 11bn total spending	**EUR 26bn** total spending	**EUR 26bn** total spending
4.2 million non-dependable people*	**4.2 million** non-dependable people	**3.9 million** non-dependable people
34.3 dependency ratio**		**38.48** dependency ratio
EUR 9.200 avg. gross salary		**EUR 18.000** avg. gross salary

Need for fundamental and structural changes

*People with 18-65 years of age; **People 65 years or older for 100 people 15-65 years

Source: IQVIA, NSI, OECD;

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Holistic view on Healthcare as Investment

Increased investment now = substantial cost savings tomorrow

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Explore solutions on how to meet future needs in healthcare to save lives and enhance efficiency

We offer a few examples of necessary steps and policies as means to save costs and, potentially, lives

Summary

The implementation of screening and prevention strategies, and the use of innovative medicine is a

central instrument to save costs and potentially lives

1 **Prevention & vaccination**

Comprehensive prevention strategies, including active promotion of vaccinations, limit the onset of preventable diseases

e.g., HPV vaccinations can generate BGN 110m* contribution to GDP in a year

2 **Screening**

Active screening campaigns catch diseases in their earliest stages

e.g., colorectal cancer screening could lead to 16% reduction of incidence rate and 26% reduction of mortality rate**

3 **Innovative medicine**

Use of innovative medicines as early as possible can save preventable complications in the future, and hence costs and lives

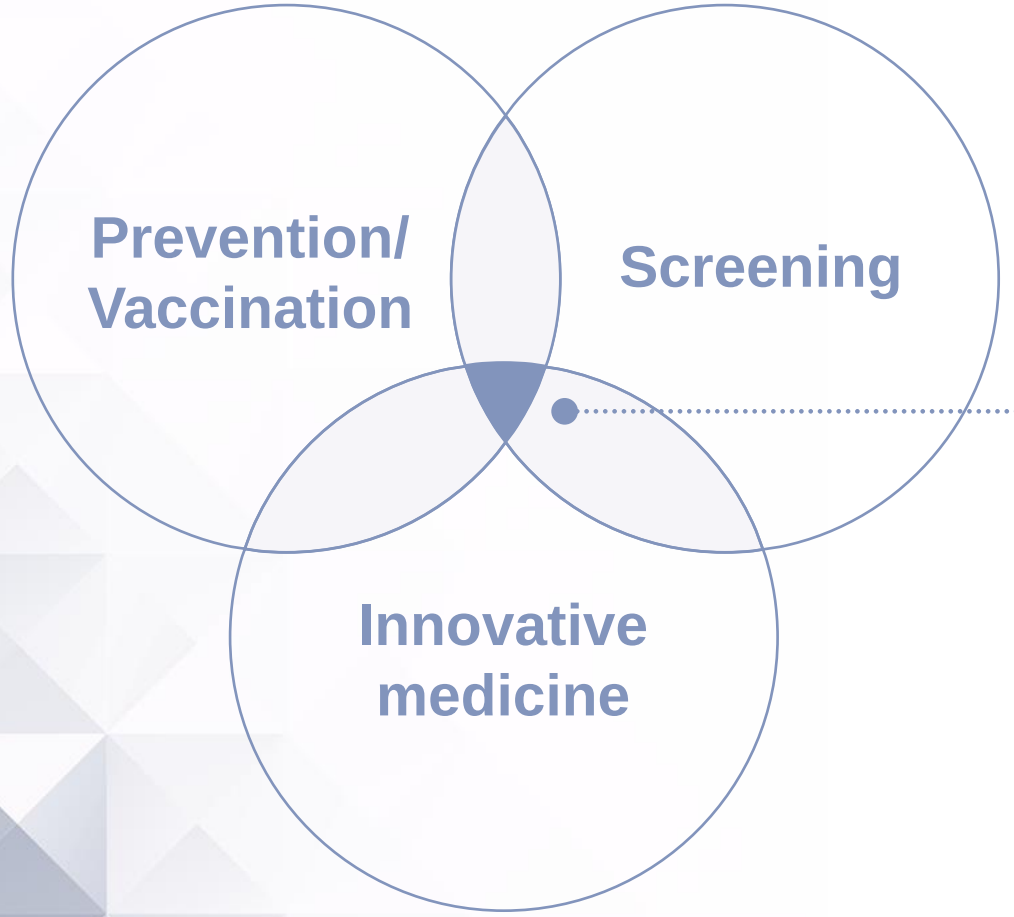
e.g., innovative diabetes treatments could save up to BGN 250m by reducing preventable complications

Investment alone is not sufficient - such campaigns need to be accompanied by effective communication to raise awareness and dispel misinformation (e.g. around vaccination programs)

Sources: Eurostat, IQVIA, NHIF, Bulgarian Onco Registry, *Medinfo, **Strengthening health systems through smart spending - EFPIA 2020 report, International Diabetes Federation

Implementation of screening and prevention strategies, and the use of innovative medicine are an important step to sustainability

Systematic approach



Improve **quality of health care** and patients' health

Tackle extensive **inefficient healthcare spending**

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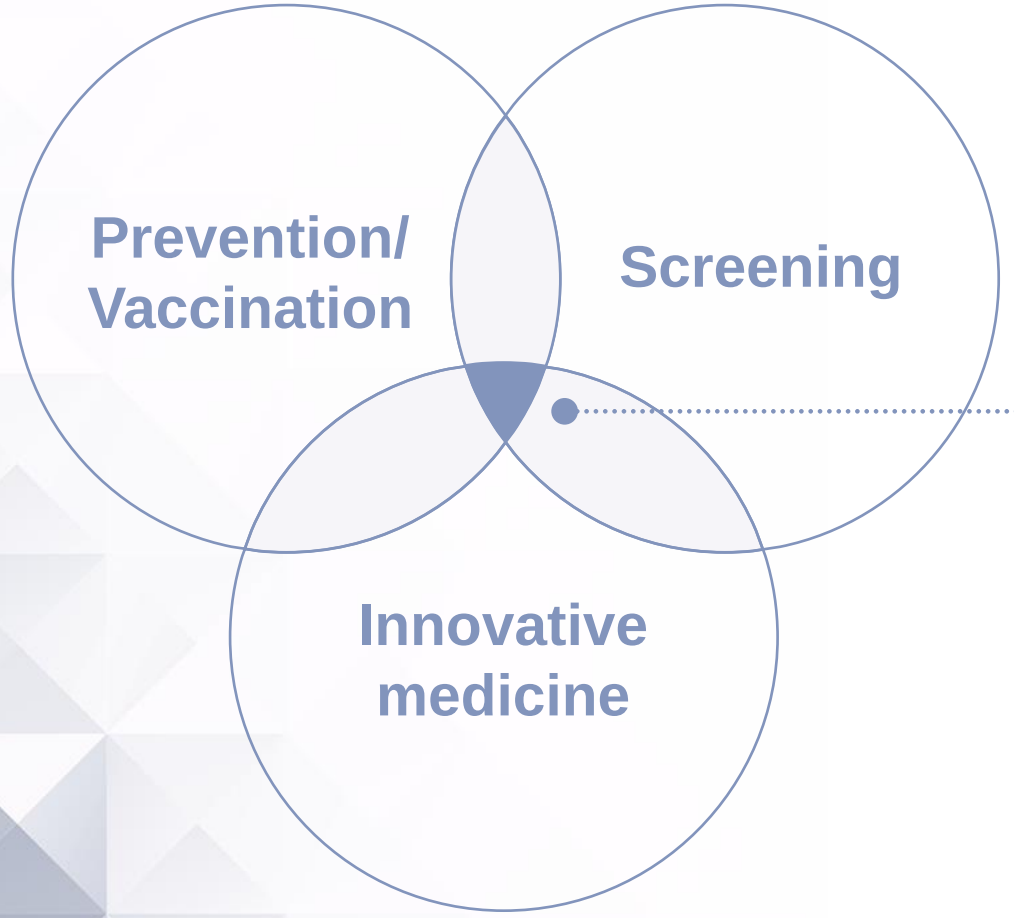
While securing investment is essential, the institutions should also play an active communication role among the population

Systematic approach



Effective communication important to:

- Raise awareness for the importance of the topic
  - Dispel misinformation, e.g. vaccines
    - Encourage responsible behavior

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The most cost-effective way of achieving good health is often to prevent the onset of the disease as early as possible

*Example: the case of HPV**

- A rising challenge, both globally, and in Bulgaria, is the increasing cancer mortality
- Cancer is a leading contributor to Bulgaria's high amendable mortality rates

- While vaccination against HPV is free, and initial coverage was at 30% in 2012, it fell to currently less than 7%
- Vaccination is highly recommendable in case of high prevalence, such as in Bulgaria
- However, there are no government-organized plans and awareness campaigns to promote HPV vaccinations in the country

EXAMPLE: CERVICAL CANCER

HPV

Infection with some types of the **Human papillomavirus** is the greatest risk factor for cervical cancer, causing **more than 85%** of its incidence

Cervical cancer

is the **2nd most common cancer** in women aged 15 to 44 years in Bulgaria

Each year

an average of **369 women are dying** from and **1,112 are newly diagnosed** with cervical cancer in Bulgaria

SDR**

for cervical cancer in Bulgaria is **9.4 per 100,000 women**, more than double the EU average

*HPV = Human papillomavirus, **SDR = standardised death rate

Source: Eurostat, WHO, NHIF

A broad vaccination against HPV has the biggest potential in terms of health outcomes, as well as cost-savings

Example: the case of HPV

Investment in vaccination against HPV can lead to

BGN 110 million

contribution to GDP

Economic cost estimate for different alternatives for one year

1. **Vaccination: BGN 26m**
   for wide vaccination of girls, including costs for vaccines and their administration

2. **Screening: BGN 69m**
   for screening of women between 25-65 years, including costs for medical checks, tests, one-time screening organization and coordination; excluding costs for treatment of diagnosed cases

3. **Passive behavior: BGN 133m**
   including minimum cost of treatment for patients at each stage and the economic losses from premature death

Source: IQVIA, NHIF, Bulgarian Onco Registry, Medinfo

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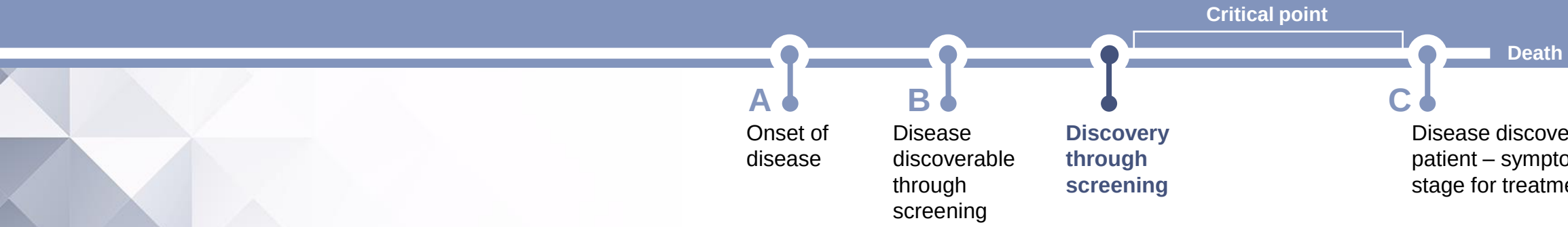
Systematic screening can detect cancer early on and thus significantly reduce avoidable mortality

Example: screening for colorectal cancer

- The colorectal is the **2nd most common cancer death cause in males – 9%, and 3rd for females – 10.2%*** in Bulgaria
- As few as 10% of the yearly diagnosed patients are diagnosed in Stage I of the disease, while between 40-50% in Stage III/IV
- Prevalence and death rates in Bulgaria are higher than the EU average, while the 5 years survival rate is as low as 45.2%
- Treating colon cancer at stage IV instead of I is 4 times more expensive**, while survival rates much lower



*last available data for 2017; **estimates based on UK data

Source: Strengthening health systems through smart spending - EFPIA 2020 report; Bulgarian Onco Registry

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A screening with a 72% participation rate in the Spanish Basque country generated nearly EUR 100m savings

Example: screening for colorectal cancer

CASE: SPAIN, BASQUE COUNTRY
COLORECTAL CANCER SCREENING PROGRAMME

The Basque Country has a population of **2.2 million**

Target for the screening were **586,700** residents

72%
achieved participation rate

-16% in cancer incidence

-26% in cancer mortality

EUR 93 Million
net savings through saved costs on treatment and prevented economic losses through saved lives

Source: Strengthening health systems through smart spending - EFPIA 2020 report

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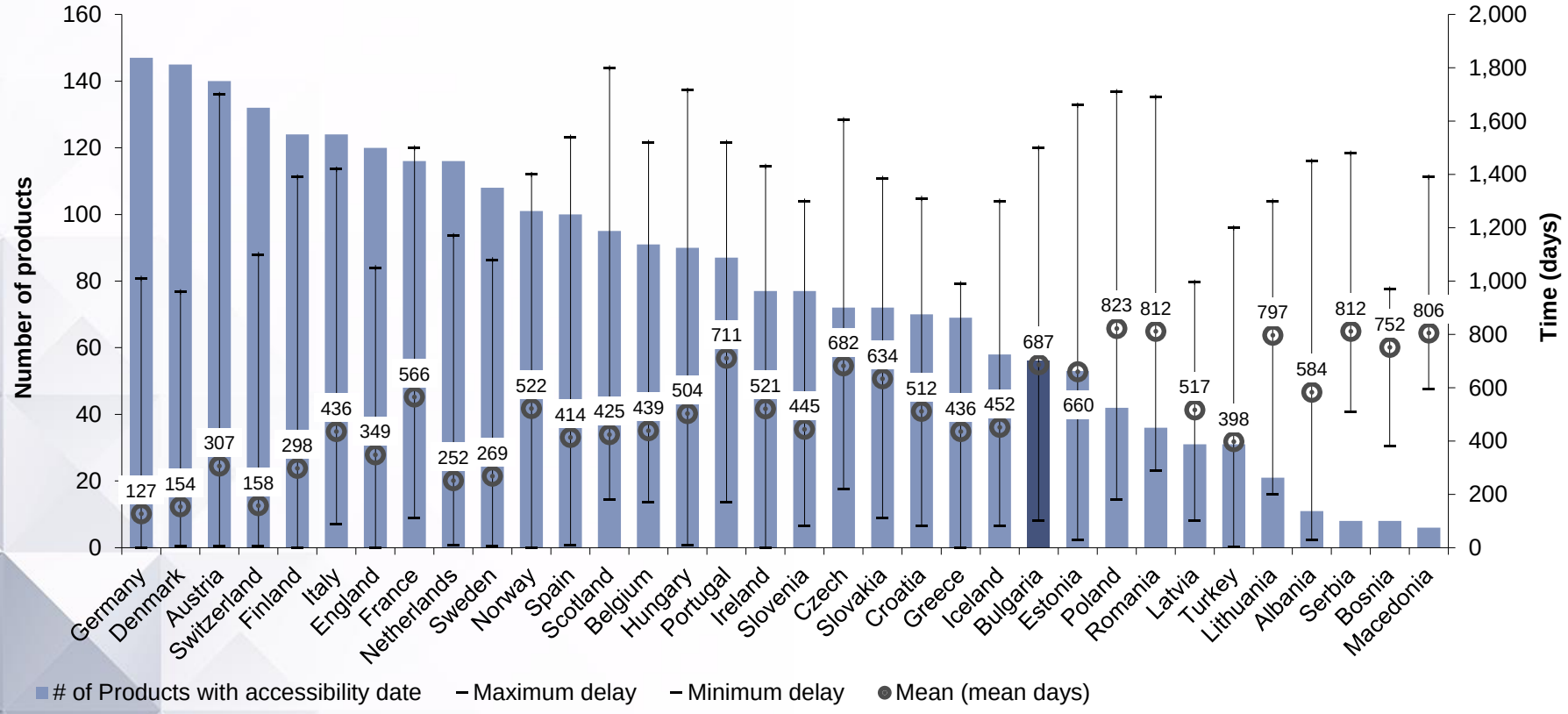
Adoption of innovative pharmaceuticals can also avoid unnecessary costs in other parts of the healthcare system

Access to innovative medicine

Time to availability (2018) of innovative medications



- Bulgaria still has a lower rate of availability of medications, as well as one of the longest time to availability (the days between EMA marketing authorization and the date of availability to patients)
- Innovative pharmaceuticals play a crucial role in improving the health of patients, and can avoid unnecessary costs in other parts of the healthcare system

Source: IQVIA; Strengthening health systems through smart spending - EFPIA 2020 report

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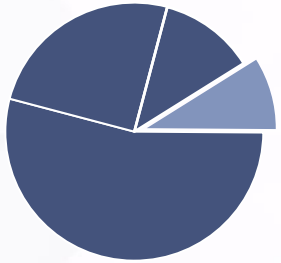
Diabetes can serve as an example of the potential impact from the early introduction of innovative treatments

Example: diabetes costs



9%

Of the total health expenditure in the EU is spent on diabetes

75%

Of those costs are triggered by preventable diabetes-related complication

Diabetes is

the main cause of blindness and kidney failure

the 2nd most common cause of **amputation**

caused by lack of prevention, early diagnostic, and insufficient and timely control of the disease

BGN 550m

Diabetes related expenditure in Bulgaria yearly

60%

Allocated to hospitalizations due to complications

BGN 250m

Could be potentially saved* through prevention and the adoption of innovative medicine to help reduce preventable complications

The systematic use of already available innovative medicines could contribute to reducing mortality rates, as well as improve overall outcomes and hence lower future costs. Still, only 6.2% of diabetes expenditure within the EU goes to medicines.

*Excluding cost of medicines

Source: Strengthening health systems through smart spending - EFPIA 2020 report; International Diabetes Federation

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Cost optimization potential & smart spending in healthcare

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Implement smart strategies and policies for a sustainable and predictable healthcare system

Various cost optimization opportunities exist to help sustain the overall healthcare spending

Summary

There are several potential sources for cost optimization to support targeted strategies and to sustain the needed overall increase in healthcare investments

	Possible sources of optimization	*Possible initiatives*
Healthcare infrastructure	• Relatively high **density of doctors** with 4.2 per 1,000 inhabitants • Second lowest **number of nurses** in the EU • **Ageing** healthcare personnel • **Fragmented** regional distribution, increasing **migration** • **Weak outpatient care** • **Inefficient use** of medical devices and procedures	• Address fragmented distribution across the country, increasing migration & ageing talent • Availability and utilization of medical devices and specialists • Active cost control – UK NHS as an active example
Loss of exclusivity and horizon scan	• More than BGN 30m per year freed up resources through cost reduction from loss of exclusivity • Reallocation of resources to new or so far not affordable higher-cost therapies	• Analysis of upcoming loss of exclusivity • Horizon scan of upcoming innovative medicine
Reimbursement spending	• Currently BGN 42m per year spent on reimbursed medication <3 BGN • Reallocation to otherwise unaffordable higher-cost therapies	• Optimization of reimbursement policies, e.g., low-cost medicine
Digitalization	• No comprehensive approach towards digitalization • Cost-savings throughout the entire healthcare system with the use of digitalization	• Possible digitalization initiatives: telehealth, digital patient records, e-prescriptions, and advanced data analytics

Sources: NSI, OECD, Eurostat, IQVIA

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Allocation of already existing funding could be optimized, and savings could be achieved by first focusing on four areas

Cost optimization opportunities

By identifying

inefficient spending

and reallocating these resources, significant improvements in patients' health outcomes and quality of care could be achieved

Understanding and addressing inefficiencies in hospital spending and spending distribution

Loss of exclusivity potential and horizon scanning of innovative medicines

Optimization/ reallocation of reimbursement spending

Digitalization possibilities in healthcare and cost-savings potential

Allocation of already existing funding could be optimized, and savings could be achieved by first focusing on four areas

Cost optimization opportunities

Understanding and addressing inefficiencies in hospital spending and spending distribution

Loss of exclusivity potential and horizon scanning of innovative medicines

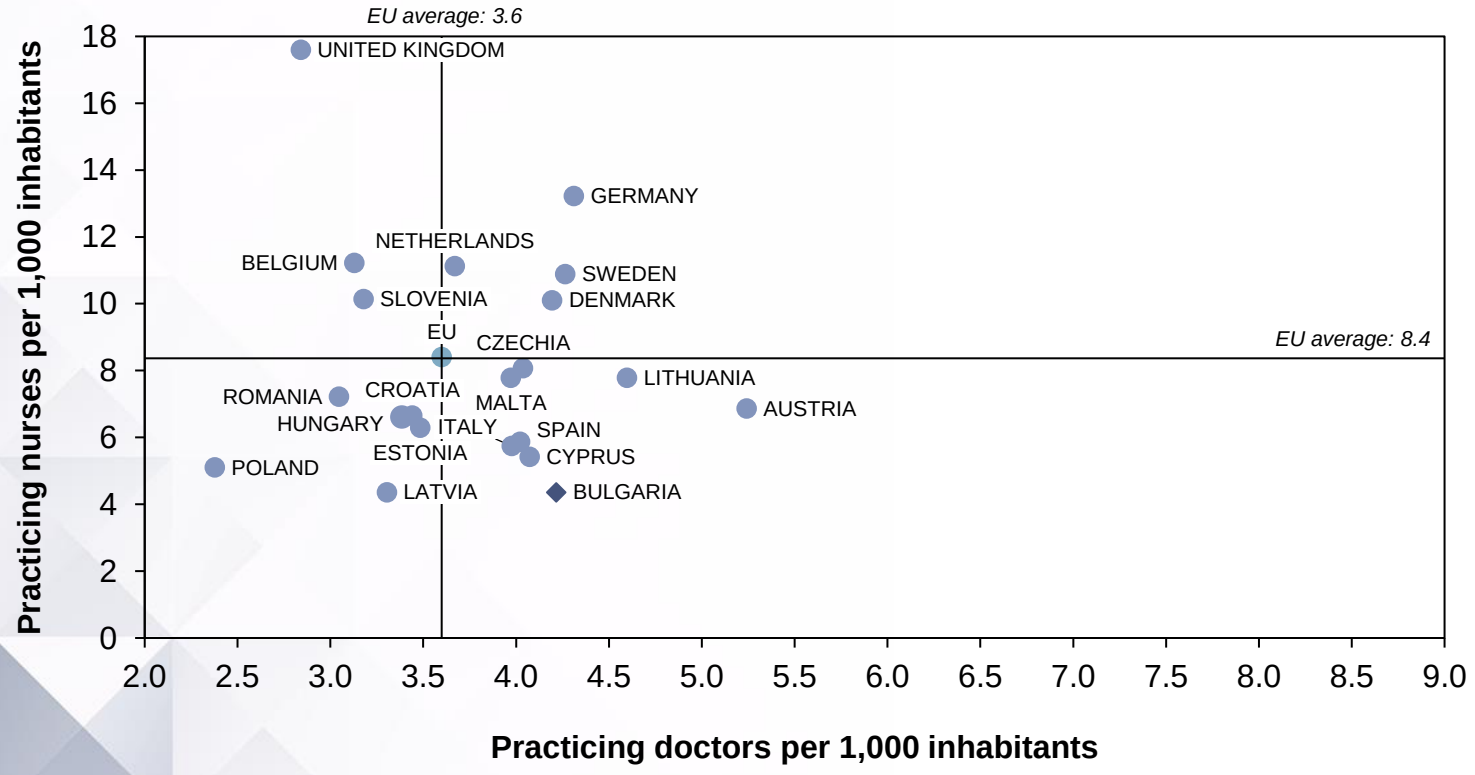
Optimization/ reallocation of reimbursement spending

Digitalization possibilities in healthcare and cost-savings potential

Understanding the structure of healthcare provision and availability in Bulgaria is essential for its cost optimization

Medical infrastructure

Doctors and nurses per 1,000 inhabitants, 2018*



* Or latest data available

Source: Eurostat

+ Bulgaria has a relatively high number of practitioners, being in the leading 10 countries in the EU with 4.2 doctors per 1,000 inhabitants
- However, 63% of all doctors are of more than 51y of age
- Notable fragmentation in their distribution across the country
- In contrast, the country has the second lowest proportion of nurses in the EU, twice as little as the EU average
- The average age of all nurses is also notably high – 55y

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The workforce is challenged by a fragmented distribution and a persistent migration problem

Medical infrastructure

250-300 doctors

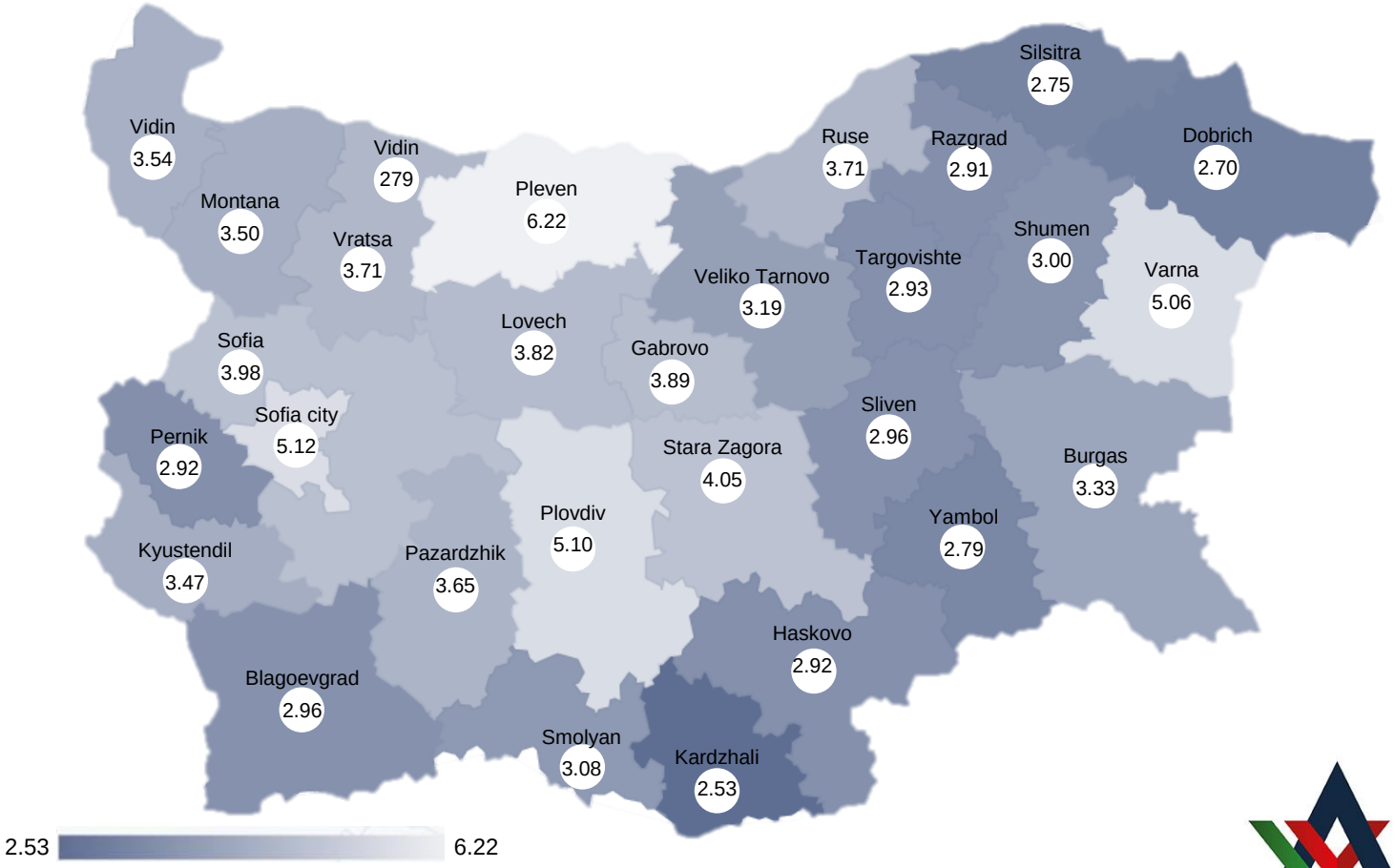
on average leave Bulgaria yearly due to low recognition and low pay at home, which accelerates the shortage of medical personnel

It is, therefore, essential to take necessary action to tackle the persisting problems and negative trends:

- Provide **regional incentives**
- Support **educational initiatives**
- Raise salaries for **paid specializations**

Source: NSI, OECD, Eurostat

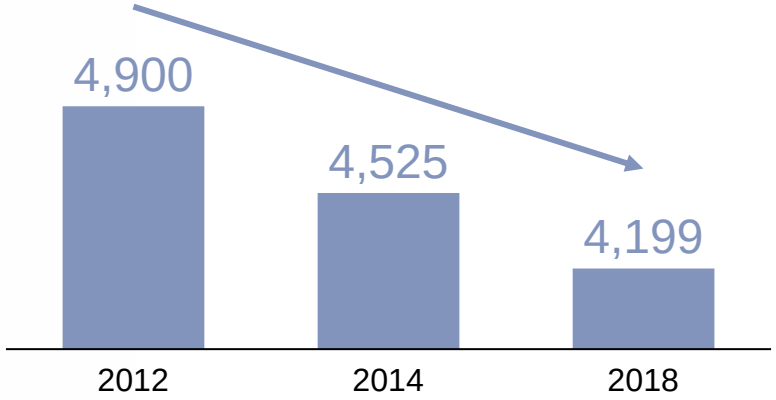
Medical specialists per 1,000 inhabitants, 2019



Hospital care remains dominant mainly due to weak primary and outpatient care causing unnecessarily high costs

Medical infrastructure

Number of general practitioners



Ratio of general practitioners

5.9

specialists to GPs ratio

3.1

specialists to GPs ratio

GPs are supposed to act as gatekeepers to the healthcare system, being the first point of contact

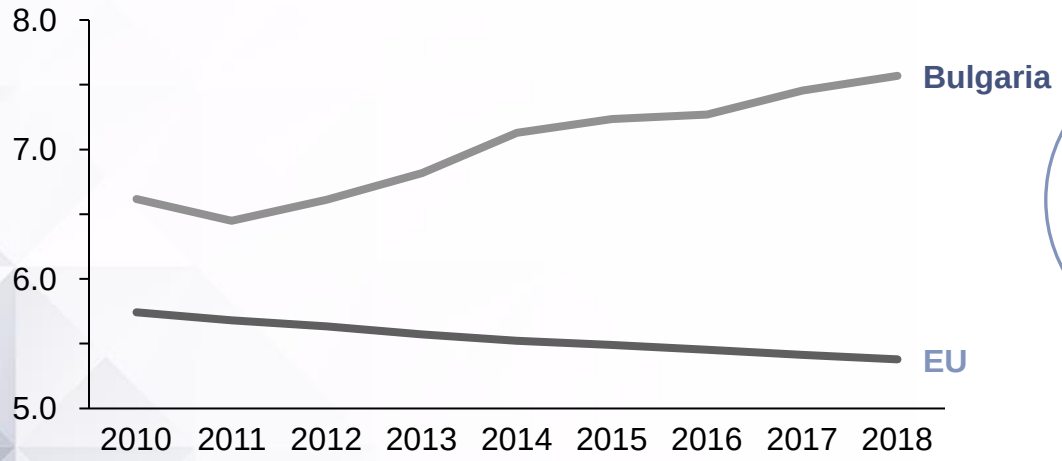
Low concentration of GPs, lack of availability and often wrong incentive elements result in a **weak primary care system** and thus high dependency and **over-reliance on inpatient care**

Source: Eurostat

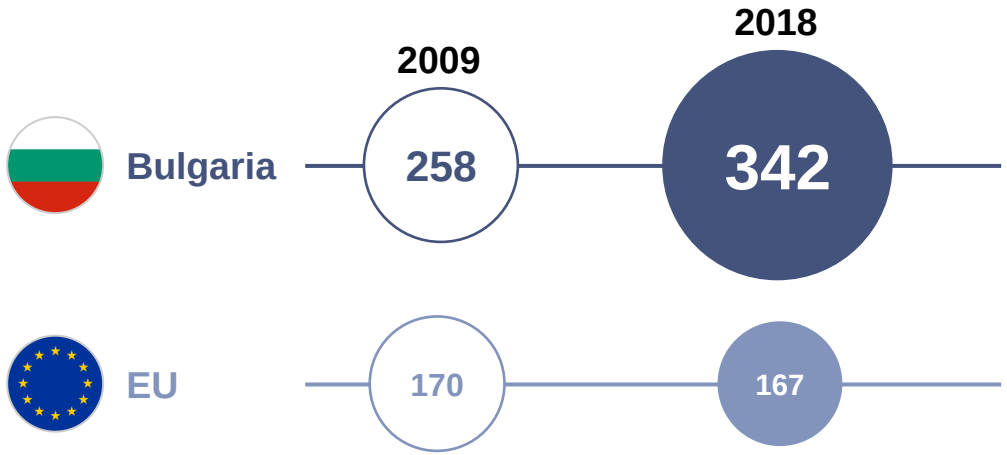
Primary care and outpatient accessibility need to be drastically improved to reduce avoidable inpatient care

Medical infrastructure

Number of hospital beds per 1,000 inhabitants



Yearly hospital discharges per 1,000 inhabitants



Cost-saving potential

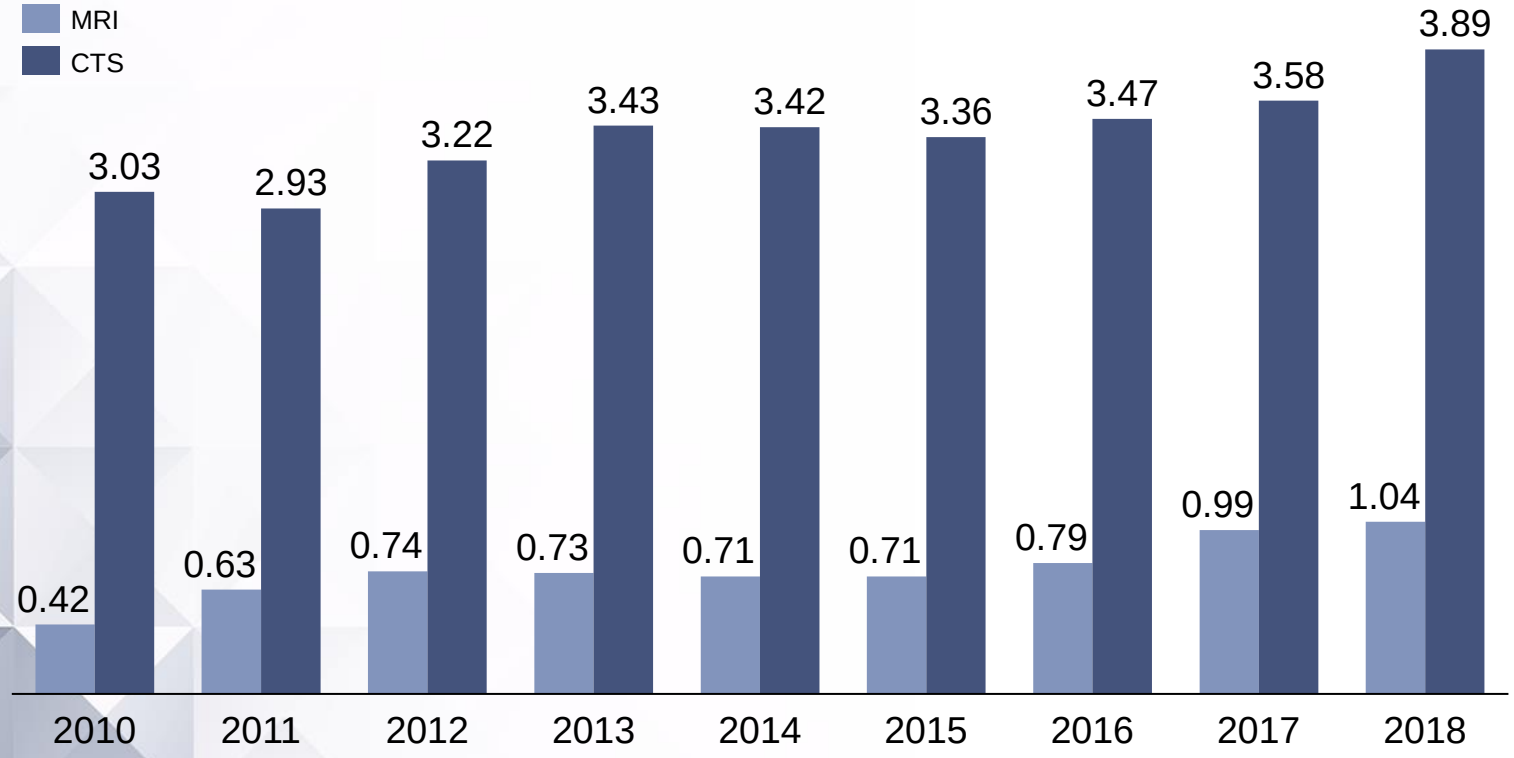
- Bulgaria takes the first place in the EU when it comes to hospital beds, as well as hospital discharges per capita
- Compared to outpatient care costs, inpatient care takes up twice as much from the total spending; in contrast, on average in the EU, those are equal
- 20% of all hospitalizations could have been avoided and conducted in outpatient settings
- Hospitalizations are often the result of the limited number of referrals in primary care

Source: NHIF, Eurostat, OECD

When it comes to medical devices, Bulgaria has followed a positive trend, slowly increasing availability of some devices

MedTech landscape

MRI and CTS Units per 1,000 inhabitants, 2018



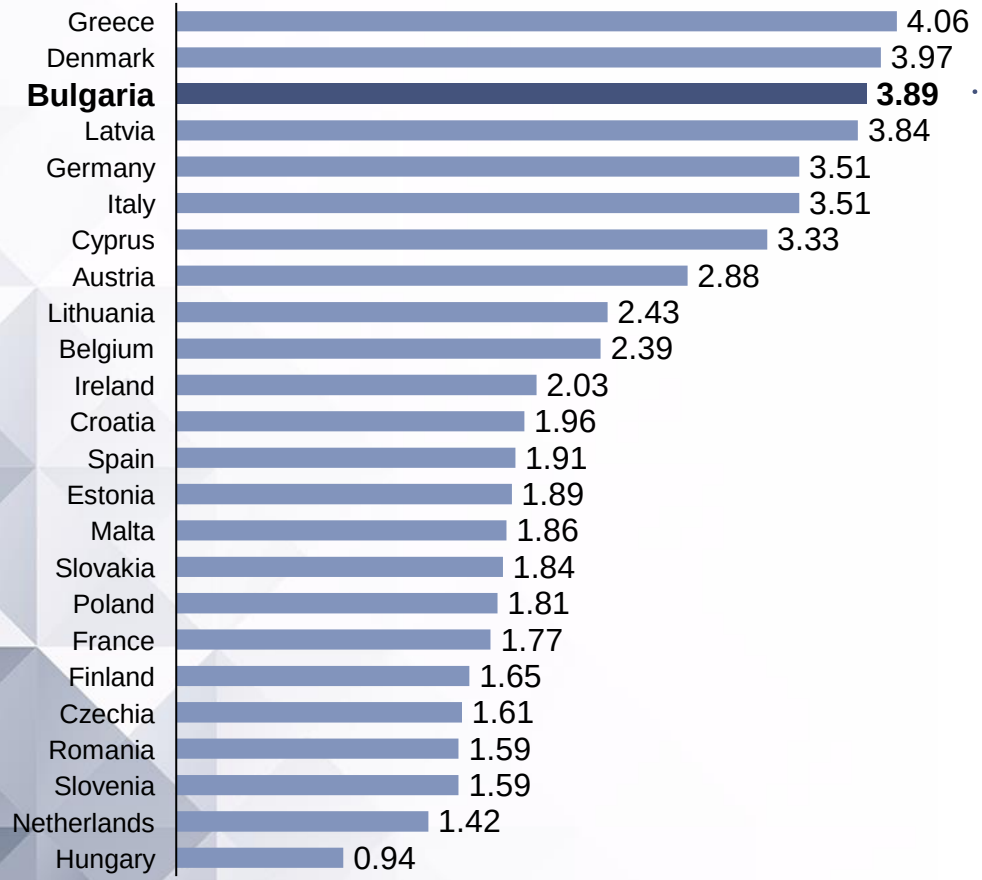
- Both Magnetic Resonance Imaging Units and Computed Tomography Scanners have become more available since 2010
- However, there is a limited understanding of the maintenance efforts of medical devices across the country
- Disproportionate regional distribution poses another threat on general accessibility
- Lack of sufficient data collection for exact country-wide distribution

Source: OECD

While density of CTS is comparably high within the EU, they remain vastly underutilized

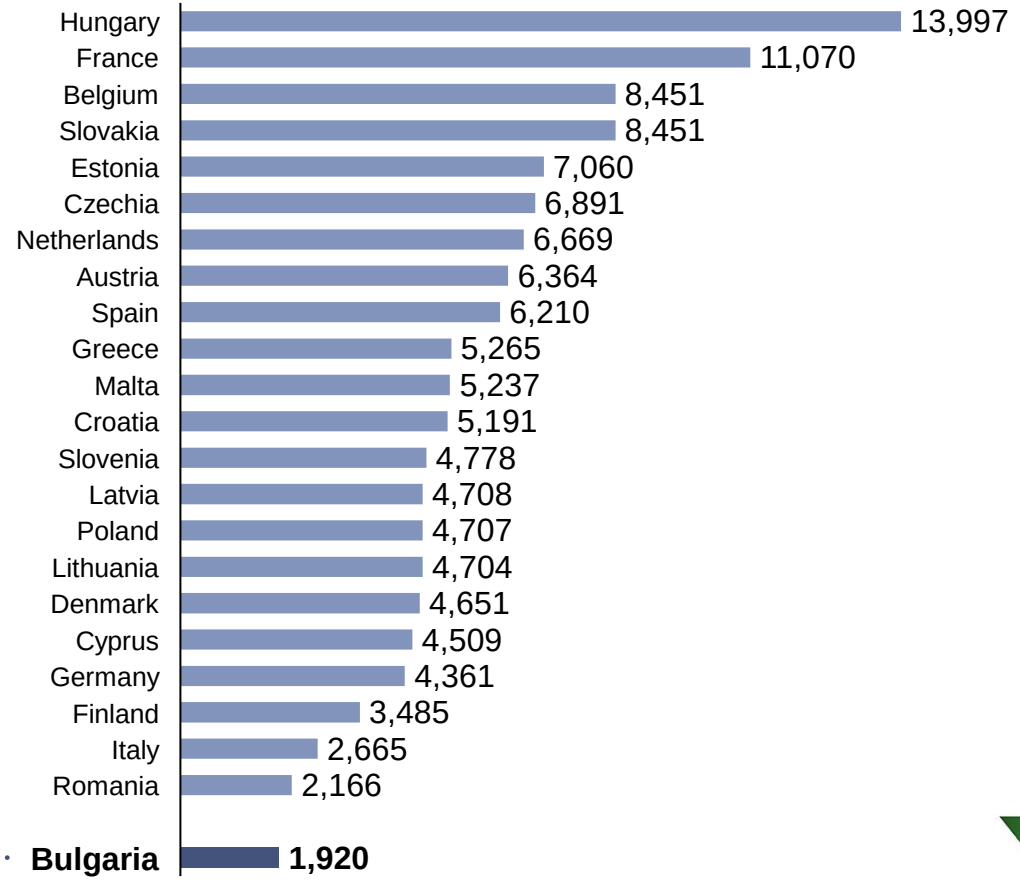
MedTech landscape

CTS Units per 100tsd inhabitants, 2018



Source: Eurostat

CT Scans per machine, 2018



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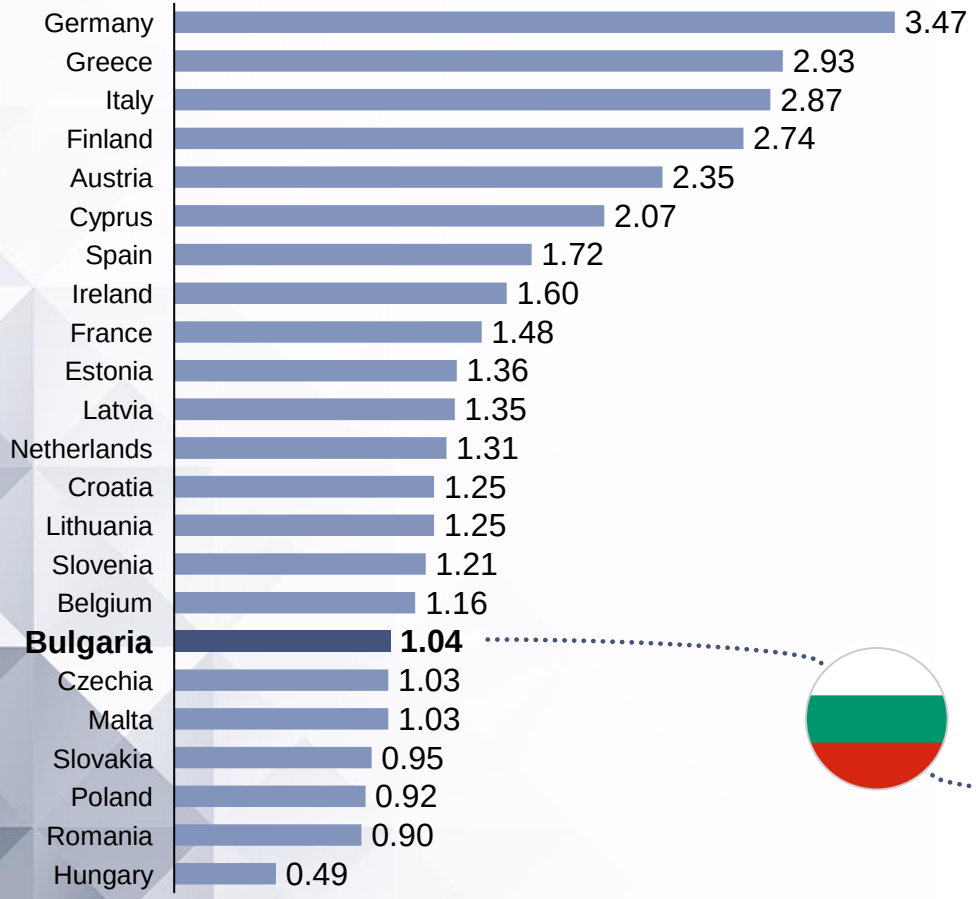
MRI units are a comparably scarce resource, however, even so have an extremely low utilization rate compared to EU countries

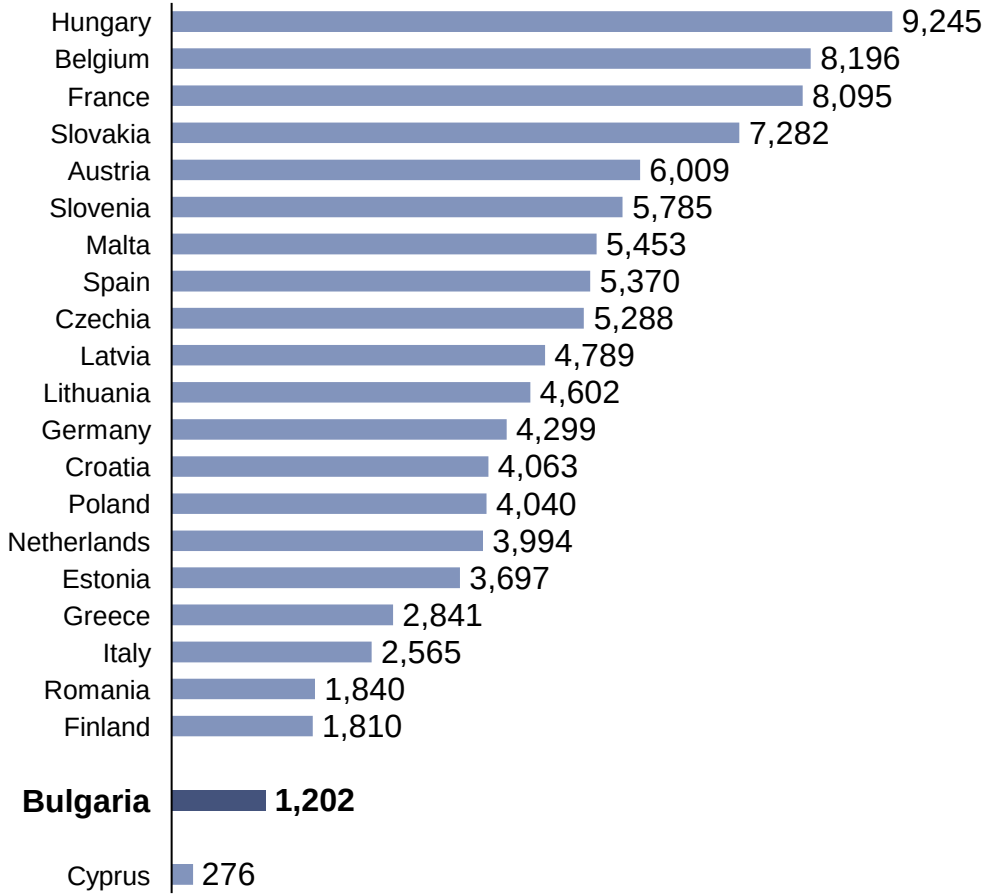
MedTech landscape

MRI Units per 100tsd inhabitants, 2018



Source: Eurostat

MRI Scans per machine, 2018



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In the UK, country-wide mandatory costing mechanisms incentivize hospitals to gain transparency and drive value

Example: Gaining cost transparency

All NHS trusts

need to comply with a

yearly cost collection

based on pre-outlined costing guidance

- Aim towards achieving goals of the NHS Long-Term Plan, as well as tackle short-term deficits
- Transition from using reference costs to a hybrid of patient level cost and aggregate cost collection, to reach a full patient level cost collection over the next years
- Support the development of new models of care and reduce variation in the use of resources
- Benchmark healthcare providers
- Collected data is used on both national and provider levels to:
  - identify operational and clinical efficiencies
  - informing the national tariff and other pricing discussions
  - informing the relationship between provider characteristics, patient characteristics and cost

Source: IQVIA, NHS E&I

Bringing transparency and analytics into the spending will help further optimize the costs

Example: Gaining cost transparency

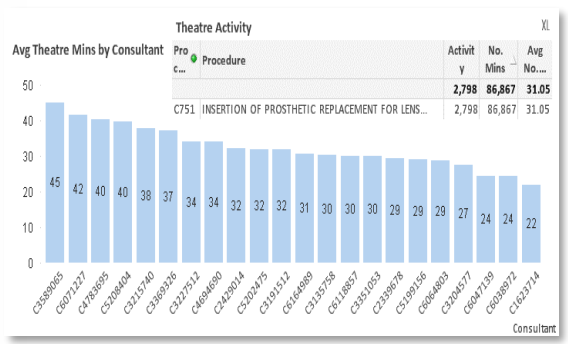
Example: Hospital costing system deployed at over 260 NHS organizations in the UK

Patient level information costing

- Gather and analyze patient level information
- De-compose each patient bill for each hospitalization, gaining understanding of costs per resource groups and utilization across the stay
- Utilization of clinical and support staff

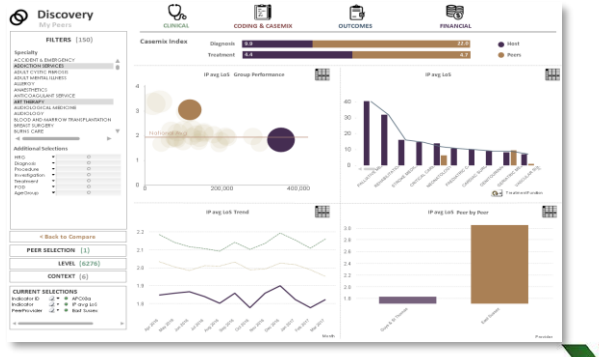
Integrated service line reporting

- Monitor the financial efficiency of clinical decisions
- Implement monthly budgetary statements and service line analysis reports
- Understand profitability of different services provided, possibility to drill down into details of activity by individuals



Benchmarking solutions

- Compare financial and operational activity performance with peers across the country to identify and share clinical and financial best practices
- Identify patient cohorts suitable for Clinical Trials



Source: IQVIA

Instead of reducing costs through internal trading, profitability could be improved by optimizing the whole patient pathway

Example: Gaining cost transparency

Case study: Understanding the patient pathway in health care for older people

SEE

- Patient level information costing system has been used to shift a paradigm from a focus on reducing costs through internal trading to being able to look at whole pathway costs
- Allows for sensitivity analysis how increases in diagnostic costs can reduce length of stay and improve overall profitability of the service

DO

- Behavior and culture changes have been established
- Systems have been put in place to monitor diagnostic testing; meaningful discussion are now taking place around clinical variation
- Increased engagement and understanding of costs
- Understanding patient pathway cohorts

GET

Improved discharge planning

Reduction of length of stay

Supports frailty unit model

Earlier diagnostic testing

Source: IQVIA

Allocation of already existing funding could be optimized, and savings could be achieved by first focusing on four areas

Cost optimization opportunities

Understanding and addressing inefficiencies in hospital spending and spending distribution

Loss of exclusivity potential and horizon scanning of innovative medicines

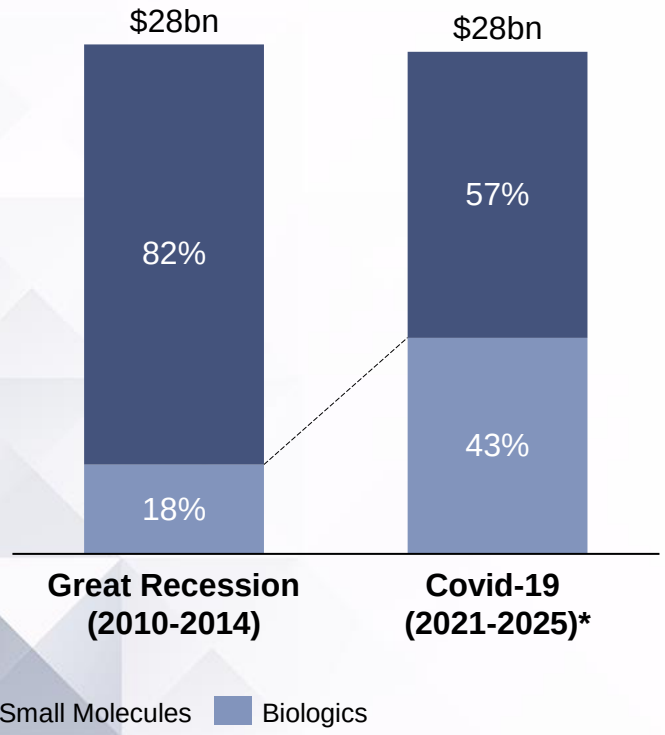
Optimization/ reallocation of reimbursement spending

Digitalization possibilities in healthcare and cost-savings potential

LoE forecast and the savings potential it will generate are about to have a paradigm shift in the upcoming years

Loss of exclusivity analysis

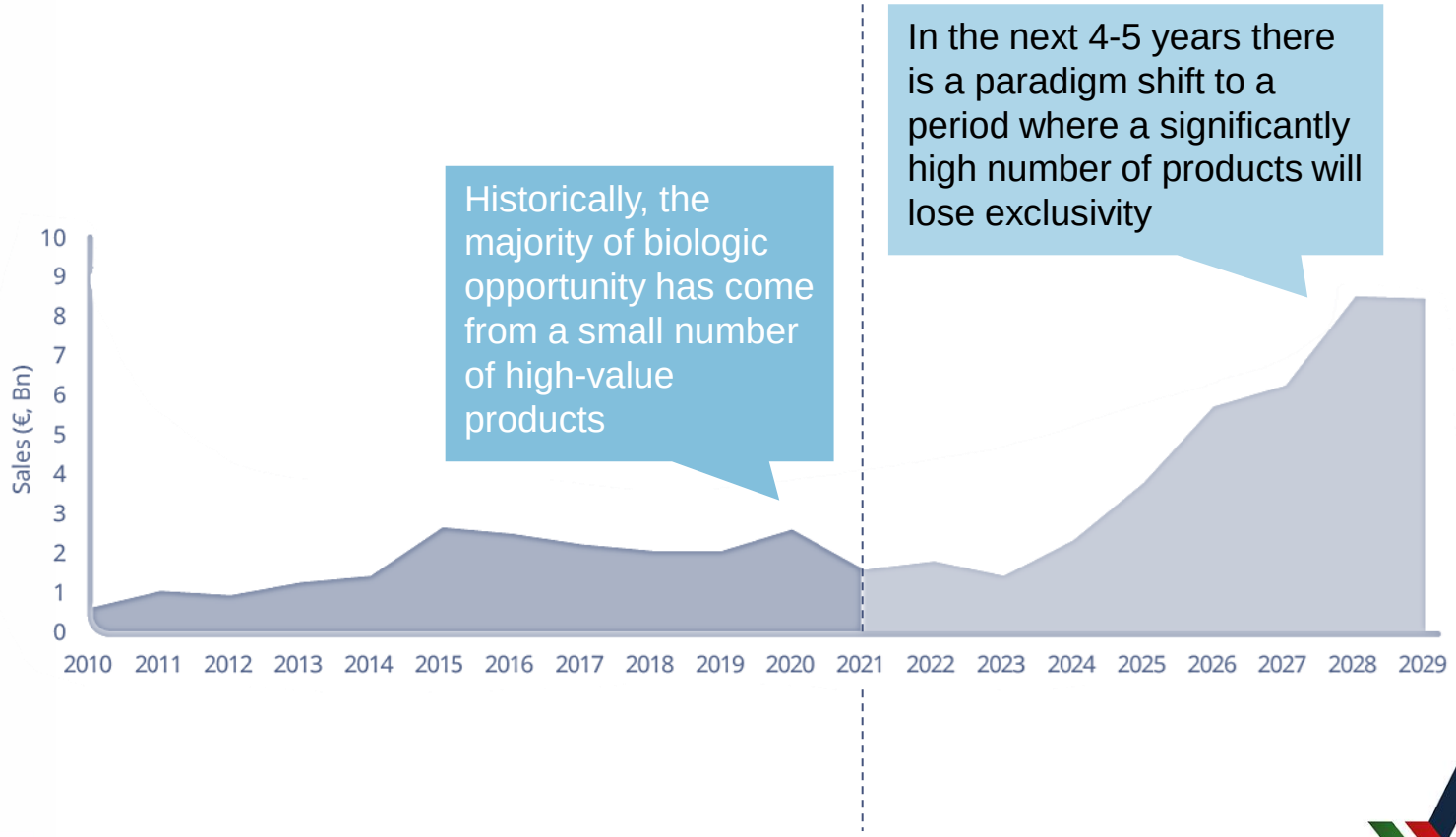
EU5 Loss of Exclusivity Potential (bn USD)



*based on 23 European countries

Source: IQVIA

Biologic loss of exclusivity, forecast*



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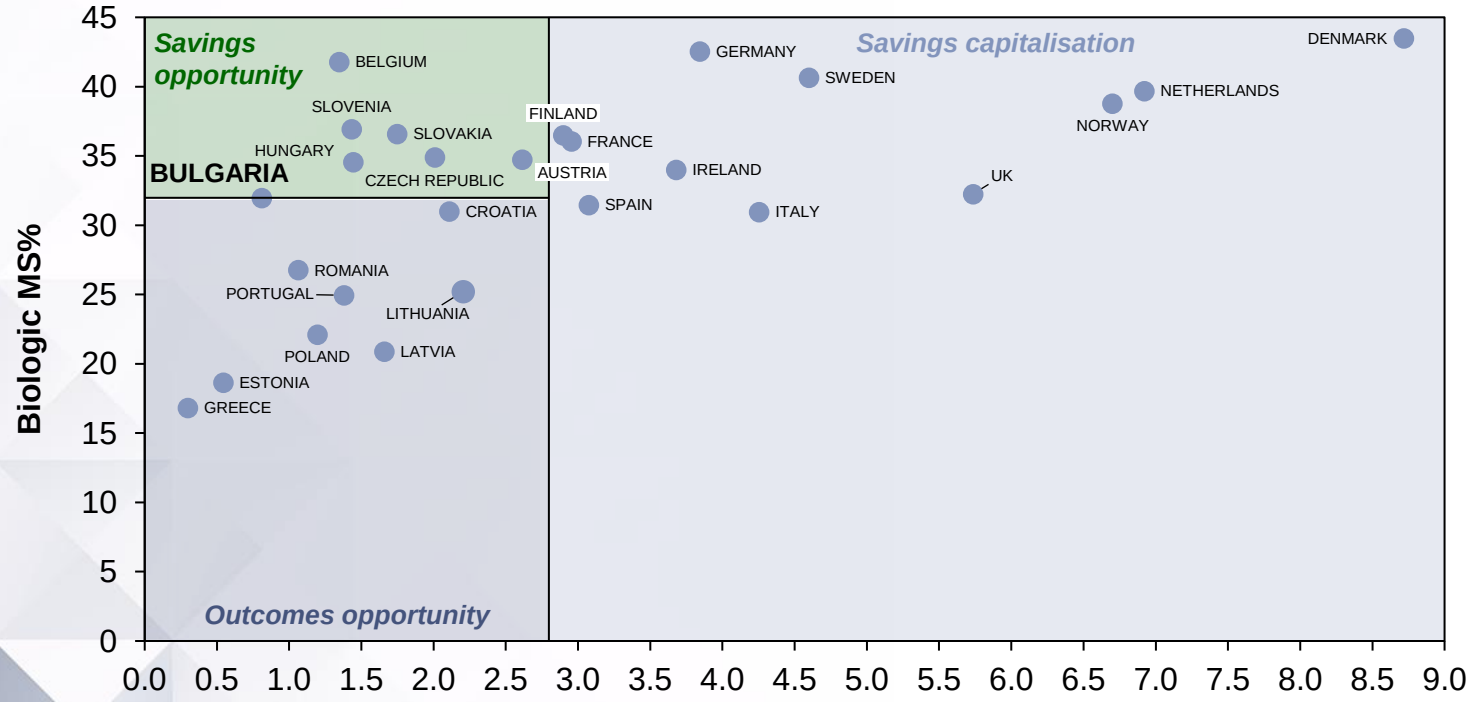
LoE savings potential for Bulgaria depends strongly on the direction it will move to regarding biologics and biosimilars

Loss of exclusivity analysis

EU usage of biosimilars in 2020 (bn USD)



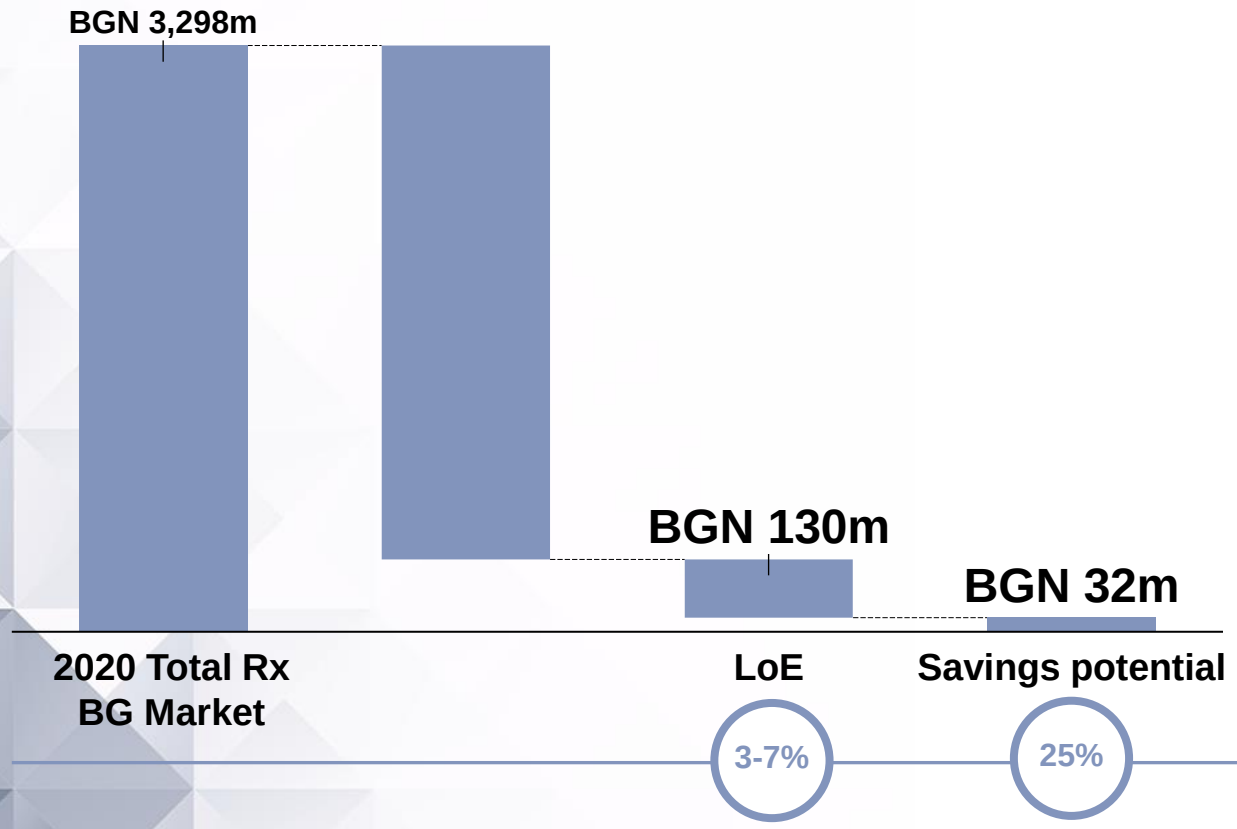
- Bulgaria has a substantial growth in the use of biologic medications in the recent years
- If this growth continues, it is important to keep track of potential loss of exclusivity expected in the upcoming years
- In the 5-year horizon, there might be significant savings opportunities to be capitalized

Source: IQVIA

Indirect savings through price reductions from LoE could be a source for funding of innovation, however, are not sufficient

Loss of exclusivity analysis

Estimated savings potential for 1 year based on 2020 Rx Market



- Based on EU5 market analysis, LoE accounts for 3-7% of the total market value
- While 130m BGN are 4% of the Bulgarian Rx market in 2020, the market continues to grow, hence so will this amount
- Assumed potential savings from price reductions due to LoE could be re-allocated to innovation needs

Source: IQVIA market data

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Digitalization possibilities in healthcare and cost-savings potential

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Significant opportunities exist in the optimization of reimbursement policies in order to improve access to therapies

Optimization/ reallocation of reimbursement spending

110

molecules

(432 brands) are reimbursed at <3 BGN per pack in the Retail segment by the NHIF in Bulgaria

0.5%

of avg. income

in Bulgaria[1] is what the cost of BGN 3 represents

BGN 42m

total expenditure

p.a. can be saved if all reimbursements <3 BGN are stopped[2]

Amount can be used instead to increase reimbursement level for other categories (CVD and Diabetes) and reduce OOP burden for patients

1. Average income per person for 2019 of 544 BGN per month (including salary payments, pensions, social payments, other incomes, divided by entire population);
2. Total amount reimbursed in 2019 for all drugs for which reimbursement amount <3 BGN per pack in the Retail segment (110 molecules, 432 brands)

Source: NHIF, NSI

Allocation of already existing funding could be optimized, and savings could be achieved by first focusing on four areas

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Digitalization in healthcare can be an enabler to save costs, improve treatment access and gain effectiveness

Digitalization initiatives and their benefits

Telehealth	• Ease of access otherwise difficult due to regional disbalance and/or scarce resources • Management and regular check-up of chronic illness • Telemedicine and healthcare access in the context of a pandemic
Remote monitoring and sensors	• Keeping track of chronic illnesses • Reducing amenable mortality rates
Electronic patient record	• Better accessibility and quality of the full patient history • Clearer patient pathway
E-prescription	• Saving costs and time on both the patient and doctor sides • Transparency and data collection
E-referral	• Ease of access to specialists • Re-focusing GPs and primary care's visits, allowing for better outpatient and reduced inpatient care
Data analytics	• Identification of high-risk patients • Prevention of diseases using predictive analytics • Cost-savings and efficiency gains through patient pooling and analysis

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Digital healthcare is dependent on the presence of 4 core pillars – Bulgaria has already made progress, but further work is needed

From IT health to digital health

Digital healthcare pillars

Strategy design

- Identification of healthcare needs & requirements
- Definition of what the full spectrum of digital healthcare should include (short- mid- and long-term)
- Definition of Data sources and outputs and analytics
- Involvement of key strategic stakeholders
- Design of the overall Digital roadmap until 2030

Legislative basis

- Introduction of electronic patient record and its role in healthcare
- Legal changes which describe rights & responsibilities and set the IT framework
- Data protection and data ownership rights
- Revision of existing legal texts to ensure compatibility/ consistency

IT infrastructure

- Overall technical infrastructure
- Data Warehouse and Data Lake
- Software backbone
- Database definitions and standards
- Data encryption and anonymization
- Peripheral tools/hardware (e.g. plastic cards, readers, etc.)

Systems integration

- Interfaces between various systems & databases
- UIDs to ensure data matching
- Clarification of ownership & responsibilities

» While some initiatives are already in place, a successful implementation requires a comprehensive effort as combination of all pillars, **combined with information and educational campaigns to foster effective adaptation**

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Optimized funding models

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Foster potential funding, investments and transformation to value-based healthcare

There are also a number of options to reform the overall healthcare funding model in the longer run

Summary

There are several options to reform the overall healthcare funding model in the longer run

Systematic change

- De-monopolize NHIF
- Various models possible, e.g.:
  - Private complements public payer
  - Multiple public & private players
  - Fully private system

Innovation funds

- Establish dedicated innovative funds
- Innovative funds can be targeted at:
  - All innovative medicines
  - Certain therapeutic areas
  - Selected patients

Taxes

- Re-allocate funding to Healthcare from excise taxes
- Target products hazardous for human health:
  - Tobacco
  - Alcohol
  - Fuel
- 10% reallocation of taxes could contribute close to BGN 550m

EU funds

- Leverage EU funds to finance structural reforms, e.g.,:
  - Latest COVID-19 related **recovery and resilience package**: one-off opportunity of EUR 6.3bn in grants
  - other mechanisms within the MFF*, e.g., **EU4Health** - EUR 5.1bn to EU member states

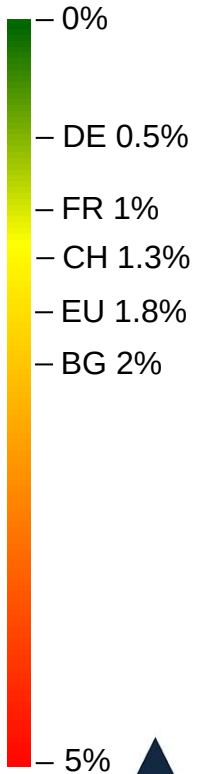
*Multiannual Financial Framework

Sources: Eurostat, IQVIA, OECD, EKIP, European Commission

Pressure on healthcare funding not only a challenge for Bulgaria – various examples exist of how others are addressing it

Country overview

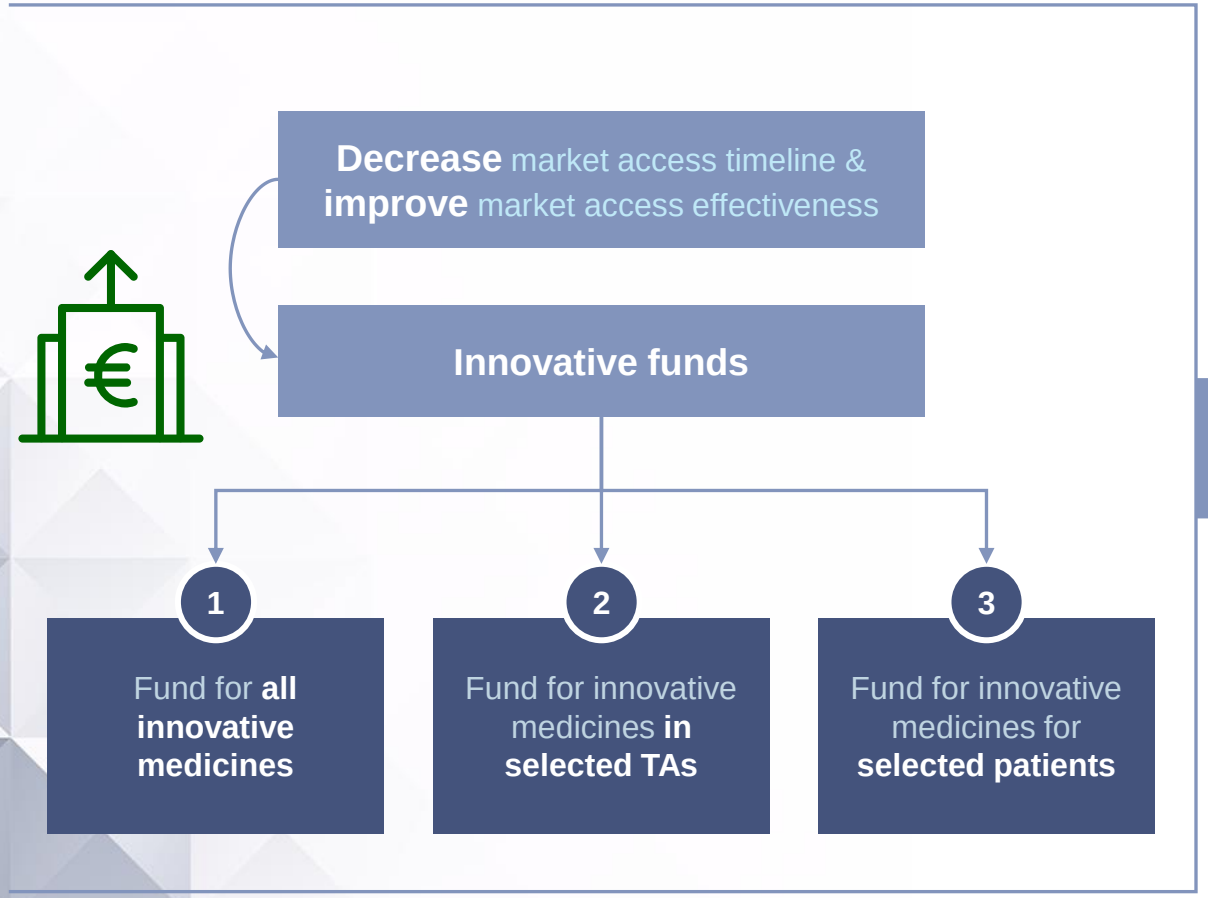
Country	Payer type	Response to funding challenges	Accessibility	Unmet needs
	Universal private or public	• A large number of private and public payers introduced • Patients can choose between private and public (once private, difficult to go back to public) • Payment system reformed to close inequalities between private & public as private patients used to be more profitable for doctors	**Germany records 0.5% of unmet needs** ✓ *Patients have a right to choose payer (private or public)* × *Preference of private patients over public*	
	Universal private	• Via mandatory health insurance, patients have direct access to all levels of care with minimal waiting times • Payment contributions determined by private market • Government closely regulates system & subsidizes healthcare for low-income people to ensure accessibility	**Switzerland records 1.3% of unmet needs** ✓ *All citizens have access to private healthcare* × *Mandatory higher taxes*	
	Universal public + complementary private	• Private insurance introduced to complement public one – extra funding for the system • Employers contribute additionally to private system • Unemployed or socially disadvantaged people still guaranteed access to healthcare	**France records 1% of unmet needs** ✓ *All citizens and foreigners have access to healthcare* × *Long waiting times*	



Source: IQVIA, OECD iLibrary

Introduction of a dedicated innovative fund for new innovative medicines could ensure faster and easier market access

Types of innovative funds and funding possibilities



Possible funding sources for innovative funds

- Dedicated **governmental funds**
- **EU recovery funds**
- Portion of **excise taxation**

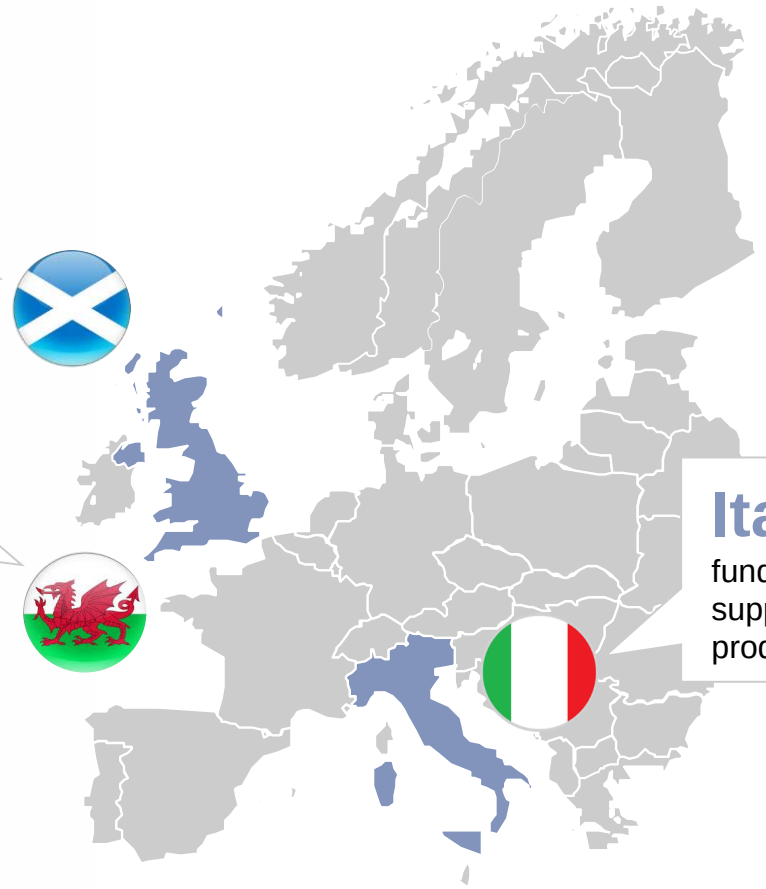
Source: IQVIA

Several countries across Europe serve as an example of successfully introduced innovative funds in the last years

Innovative funds in place

Scotland has a dedicated New Medicines Fund in place with the goal to improve access to orphan, ultra-orphan and end of life medicines

Wales has implemented the so-called New Treatment Fund to speed access to newly approved medicines across all treatment areas



Italy has established two innovative funds to speed up patient access and to support the reimbursement of innovative products in specific therapeutic areas

Source: IQVIA

Funding can be generated through one-time state contributions or portion of overall dedicated resources to health

Innovative funds in place

	Wales	Italy	Scotland
Purpose	Wales has the New Treatment Fund in place, to speed access to newly approved medicines	Italy has established two funds, to speed up patient access and to support the reimbursement of innovative products	Scotland has the New Medicines Fund in place, to improve access to orphan, ultra-orphan and end of life medicines
Drug categories covered	All new therapies	• **1st fund:** Mainly dedicated to **HCV products** but also other products are included • **2nd fund: Oncology** products	Licensed **orphan, ultra-orphan and end of life medicines**
Time horizon	From 2017 to 2021	• **1st fund:** 2015 - 2019 • **2nd fund:** 2017 - 2019	Until the end of the 2018 calendar year – intention to continue the fund
Funding	• **£80M** over the course of 5 years • The fund is **on top of the provisional budget** for the NHS Wales	• **1st fund: €500M** initially powered by a state contribution and a portion of the resources of the National Health Plan • **2nd fund: €500M** as portion of National Healthcare spend	Funded through a portion of the rebate to the Scottish Government made by the Pharma Companies • For 2015-2016 the funding allocated was **£85M** • For 2016-2017 the funding allocated was **£53M**
Criteria for inclusion	**New medicines** recommended by NICE and the All-Wales Medicines Strategy Group (AWMSG)	Based on AIFA algorithm: **therapeutic need, added therapeutic value and level of clinical evidence**	Licensed **orphan, ultra-orphan and end of life medicines**
Patients' participation in HTA process	No	No	Yes

Source: IQVIA

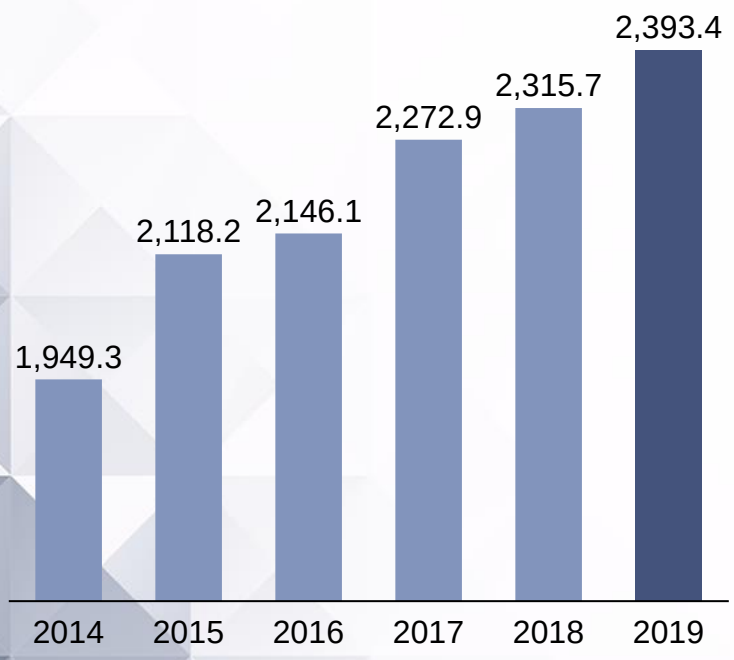
Additional funding could be generated through taxes and levies on health-impacting products

Income from excise taxation

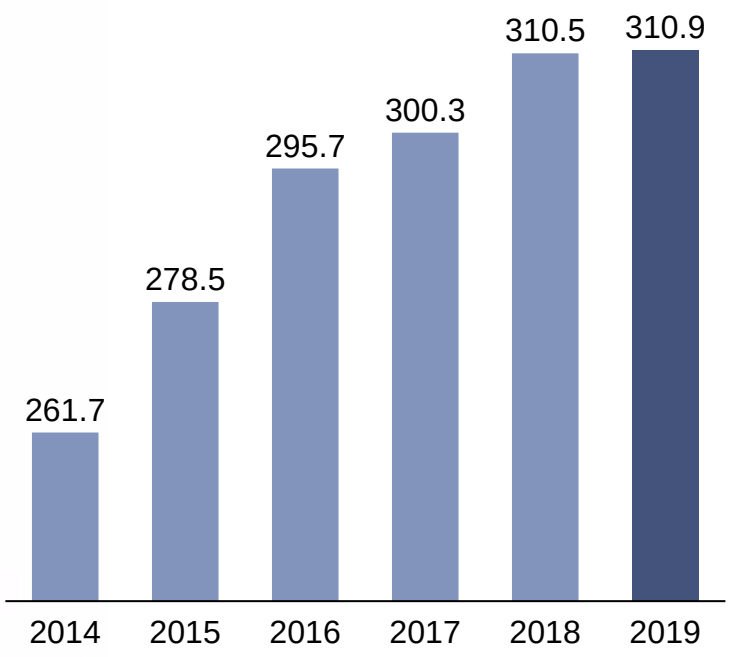
Due to increasing consumption, as well as ascending rates, income from excise taxation on fuel, alcohol and tobacco is continuing to grow

Portion of this income can be used as funding to innovative funds, or, in general, contribution to healthcare spending

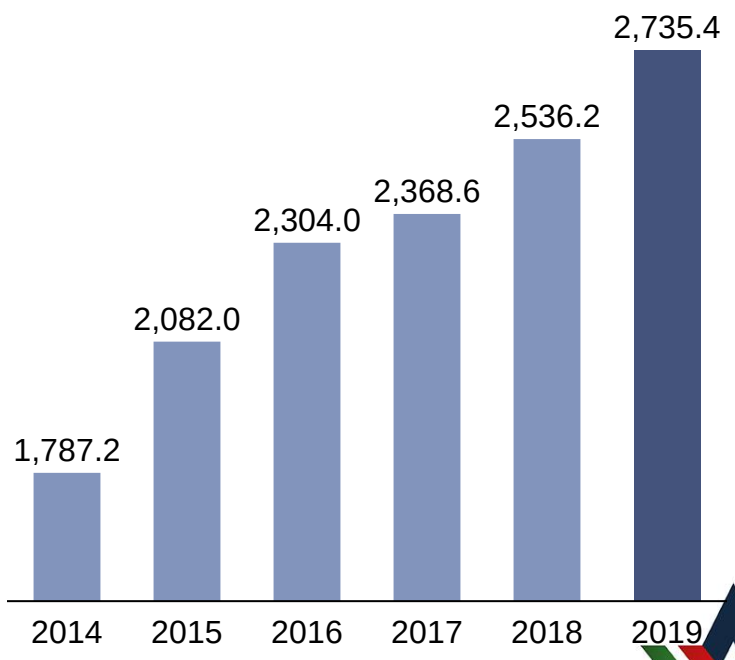
Fuel, mBGN



Alcohol, mBGN



Tobacco, mBGN

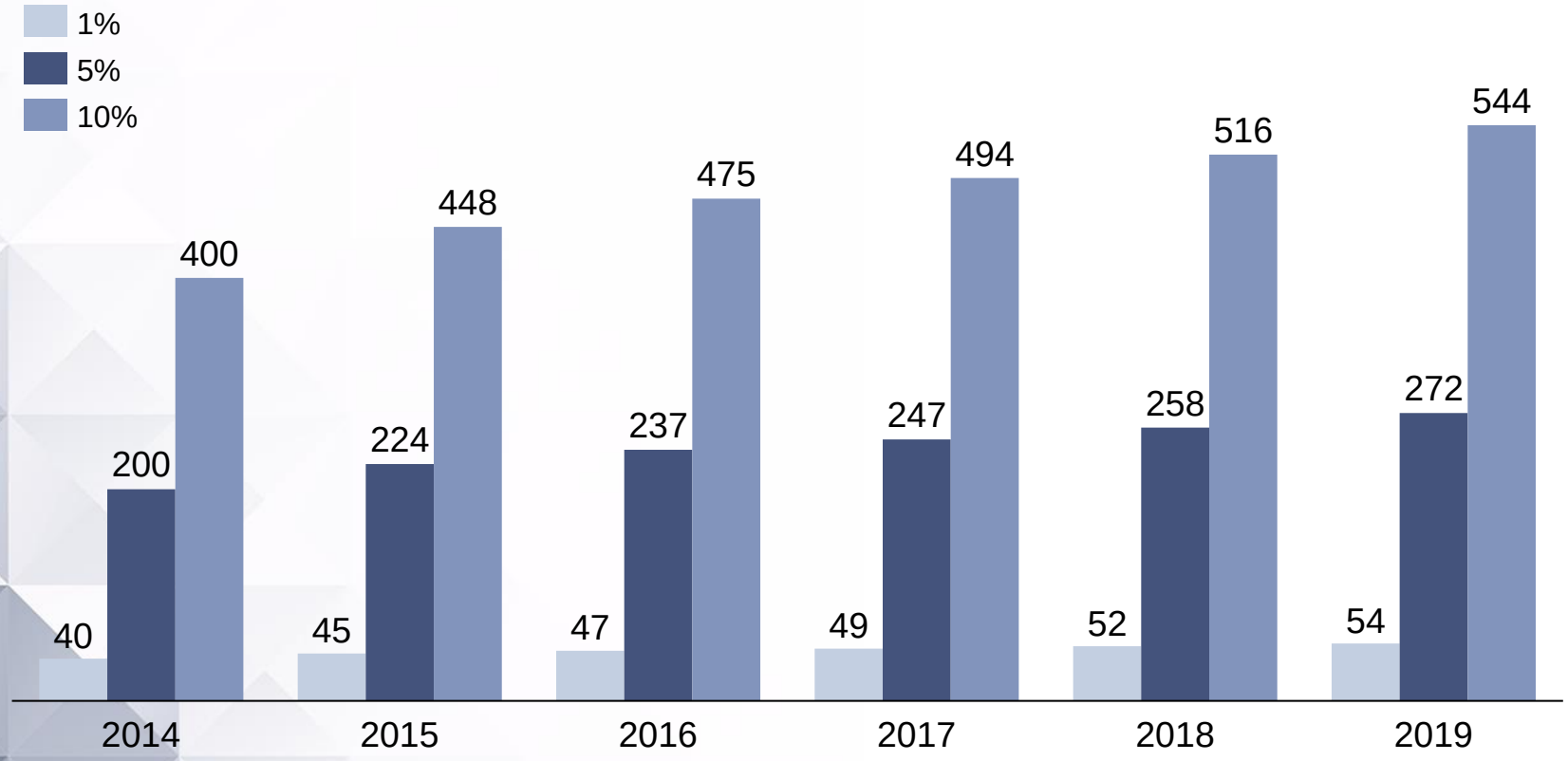


Source: EKIP

In case the target allocation is 10% of all taxes, additional contribution could be more than BGN 540m

Income from excise taxation

Target allocation of total taxes for fuel, alcohol and tobacco, mBGN



544m BGN

Could be allocated to:

- Prevention and treatment of conditions caused by risk factors
- Innovative funds
- Total healthcare spending

Source: EKIP

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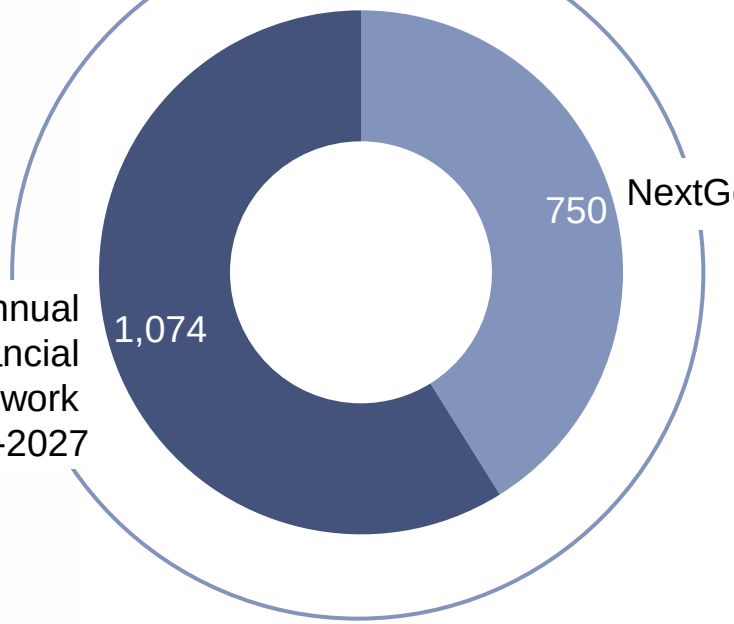
The EU is set to increase its long-term budget to help rebuild a post-COVID-19 Europe, stimulus can be allocated to healthcare

Recovery plan and EU Budget for 2021-27

EU stimulus package 2021-2027

Total:
EUR 1,824 bn



Including the EU4Health mechanism

Recovery and resilience facility package:

- EUR 390bn in grants
- EUR 360bn in loans

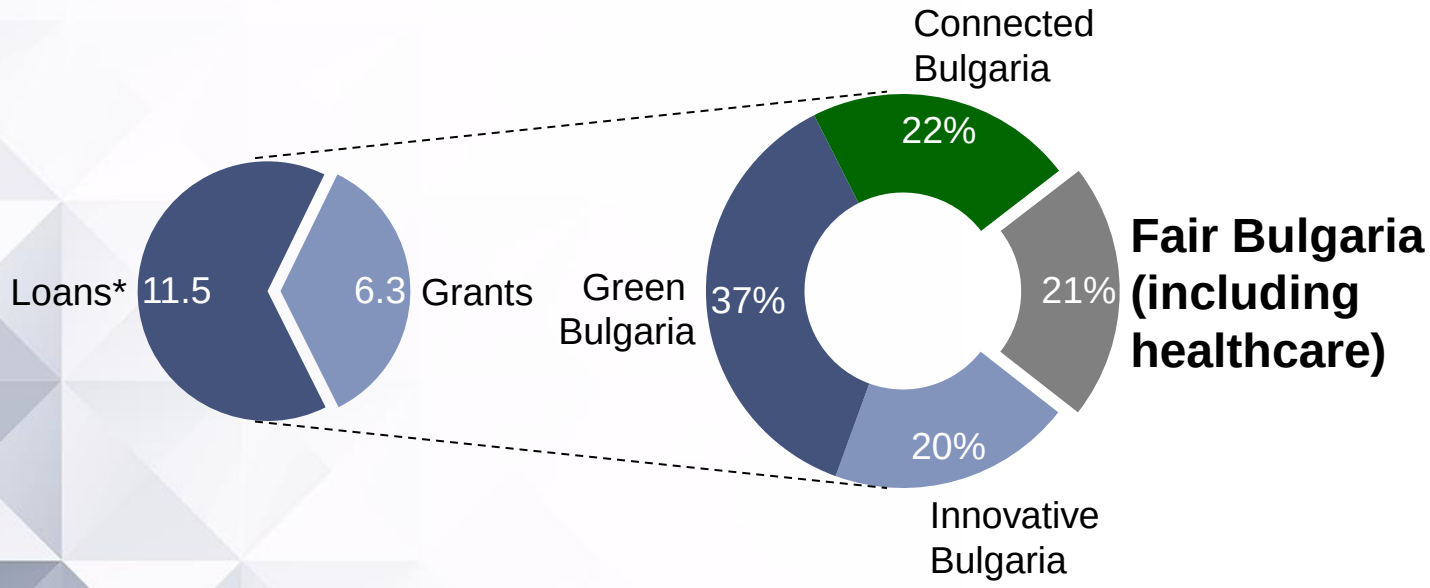
- EU funds offer a short-term/mid-term funding solution, offering investment in structural reforms
- However, focus should remain seeking for more sustainable ways of funding

Source: European Commission

Bulgaria is set to receive a EUR 6.3bn grant from the COVID-recovery package, so far less than 7% are planned for healthcare

Recovery plan and EU Budget for 2021-27

Bulgaria Recovery and resilience facility package 2021-2027 & draft spending plan, bnEUR



<7%

Is currently planned for healthcare initiatives

approx.

EUR 430m

cover five specific areas in the draft plan

funding allocated to healthcare can reach

EUR 1bn

if ~15-16% of the grants are used therefor, similarly to Germany and Spain

*Loans could be applied for up to 6.8% of a country's 2019 Gross National Income

Source: European Commission, Bulgaria Recovery and Resilience Facility Package 2021-2027 draft spending plan

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Governments, companies and other organizations are all eligible to receive extra funds from the EU4Health mechanism

Recovery plan and EU Budget for 2021-27

EU4Health

is another mechanism within the MFF 2021-27 stimulus package, providing

EUR 5.1bn

to EU member states

Funds can be used for:

- strengthening **preparedness and response** capabilities
- disease **prevention** and health promotion in an ageing population
- **digital transformation** of health systems
- **access** to health care for vulnerable groups

The Bulgarian government, as well as companies,

can use the opportunity to access additional funding for initiatives highly relevant to the needed structural reforms

- AmCham is an available partner to support such projects, incl. digitalization initiatives

Source: European Commission

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Role of the industry as key contributor

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Integrate healthcare models based on partnerships for planning, management, delivery and evaluation of services and resources

The industry also stands firmly as a partner in the process and is ready to contribute to the change

Summary

The industry also stands firmly as a partner in the process and constantly contributes through:

Direct contribution to public spend

Pharma companies contribute directly to the public spend on a solidary basis at a level of **more than 20%** from NHIF expenses

Employment creation

More than 13,000 people are currently employed by the industry in Bulgaria

Clinical trials contribution

Close to

BGN 180m market value of clinical trials

& BGN 42m direct contribution to the state budget

Ø 140 CTs started each year for the last 5 years, with

Ø 130,000 patients target enrollment in CTs starting each year

CTs additional impact through:

- giving access to patients to latest innovative therapies
- creating employment, educating and retaining talent
- creating additional income for doctors
- generating tax contributions to the state budget
- technology transfer and know-how sharing

Source: IQVIA, NHIF, Clinical trials in Bulgaria - KPMG 2018 report

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In the scope of clinical trials, the healthcare system further benefits on critical points, such as cost reduction and accessibility

Impact of clinical trials

ø 140 CTs

started each year for the last 5 years,

113 in 2020

ø 130,000 patients

target enrollment in CTs starting each year,

for the last 5 years

~ 95% of all CTs

are fully or partially funded by pharma companies,

92%, on average, are fully sponsored by pharma companies

- Access to higher quality treatment for patients (innovative molecules)
- Access to high quality paraclinical investigation for patients
- Contribution to the public healthcare system (reduction of the NHIF reimbursement costs)
- Education and professional development
- Contribution to the economy (including related taxes)
- Technology transfer and know-how sharing
- Employment opportunities
- Increase of public hospital funds
- Retention of medical personnel

Source: IQVIA, clinicaltrials.gov

The clinical trials industry contributes close to a fourth of the generated revenues directly or indirectly to the state budget

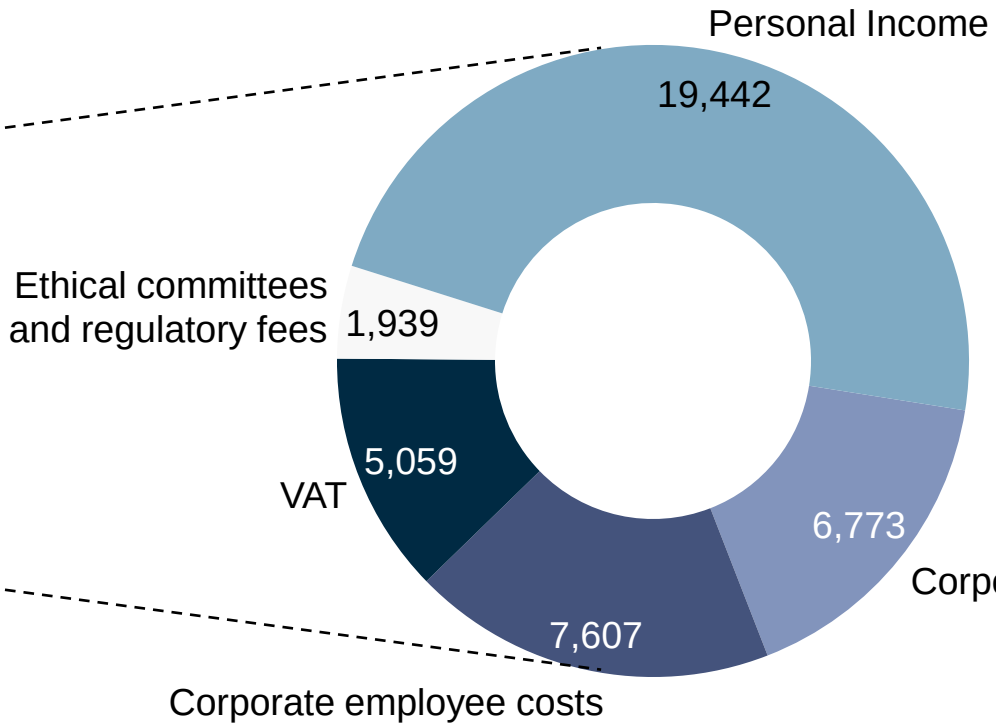
Clinical trials contribution

Estimated market value of CT, 2017

BGN 178m

Total

Estimated contribution to the authorities / state buddget, 2017, tsd BGN



BGN 42m

Source: Clinical trials in Bulgaria - KPMG 2018 report

Moreover, the size and development of the industry leads to growing employment

Employment in the pharma sector

more than

13.000 people

are currently employed by the industry in Bulgaria*

- All functions within pharma companies
- Clinical research organizations
- Medical technology and devices companies
- Pharmaceutical & Medical Device Distributors

*Estimate based on company information and expert interviews

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Conclusion and Call for Action

Call for Action (1/3)

Investment and Funding

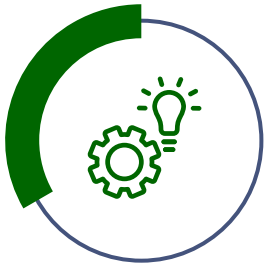
Close the Gap

- **Increase total Healthcare investment** as 10% of GDP to close the gap with average EU benchmarks
- **Increase state investment** to reduce **OoP spending to less than 20%**, close to EU average
- **Launch** a dedicated **Innovation Fund** to drive early access to innovative medicines to patients

Spend Efficiently

- Increase **efficiency in healthcare spend**, focusing on Hospital segment
- Introduce **transparent cost tracking** and benchmarking among hospitals as first step
- Conduct **regular horizon scan** exercise to estimate and plan potential budget impact from LoE and new product launches

Innovate Funding



- Implement **new ways of funding**:
  - **Re-allocate** funding from existing **taxes** and levies on health-impacting categories (tobacco, alcohol) towards investments in healthcare
  - Prioritize and **channel investments in Healthcare as part of EU Funds** (Recovery and Resilience facility and EU4Health mechanisms)

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Call for Action (2/3)

Strategic Priorities to Drive Healthcare Forward

1 Invest in Prevention and Screening

- Set up government-supported specific strategies around:
  - **Prevention** (Vaccination programs)
  - Early **screening**
  - **National Cancer Strategy** and set up of a National Cancer Registry
- Drive awareness and dispel misinformation through **educational communication campaigns** (e.g. vaccination)

2 Stabilize Workforce Dynamics

- Provide comprehensive **incentives programs for young doctors** to remain in Bulgaria and to **address regional disparities**
- **Support public/private partnerships** (government, academia and private companies) to invest in medical education
- Channel resources to **address funding gap for nurses** and personnel in hospitals

3 Advance Outpatient Care

- **Strengthen** provision of **outpatient and ambulatory** care
- **Reduce hospital duration** and re-allocate inefficiently spent resources from inpatient care

4 Implement Digital Health

- Set up a **Digital Health Roadmap** with clear vision, priorities and milestones until 2025
- **Finalize** full implementation of **e-prescription** and set up of EMR
- **Revise legislative base** to allow for professional and publicly funded provision **of telemedicine services**
- **Harmonize public databases** to allow for data interconnectivity

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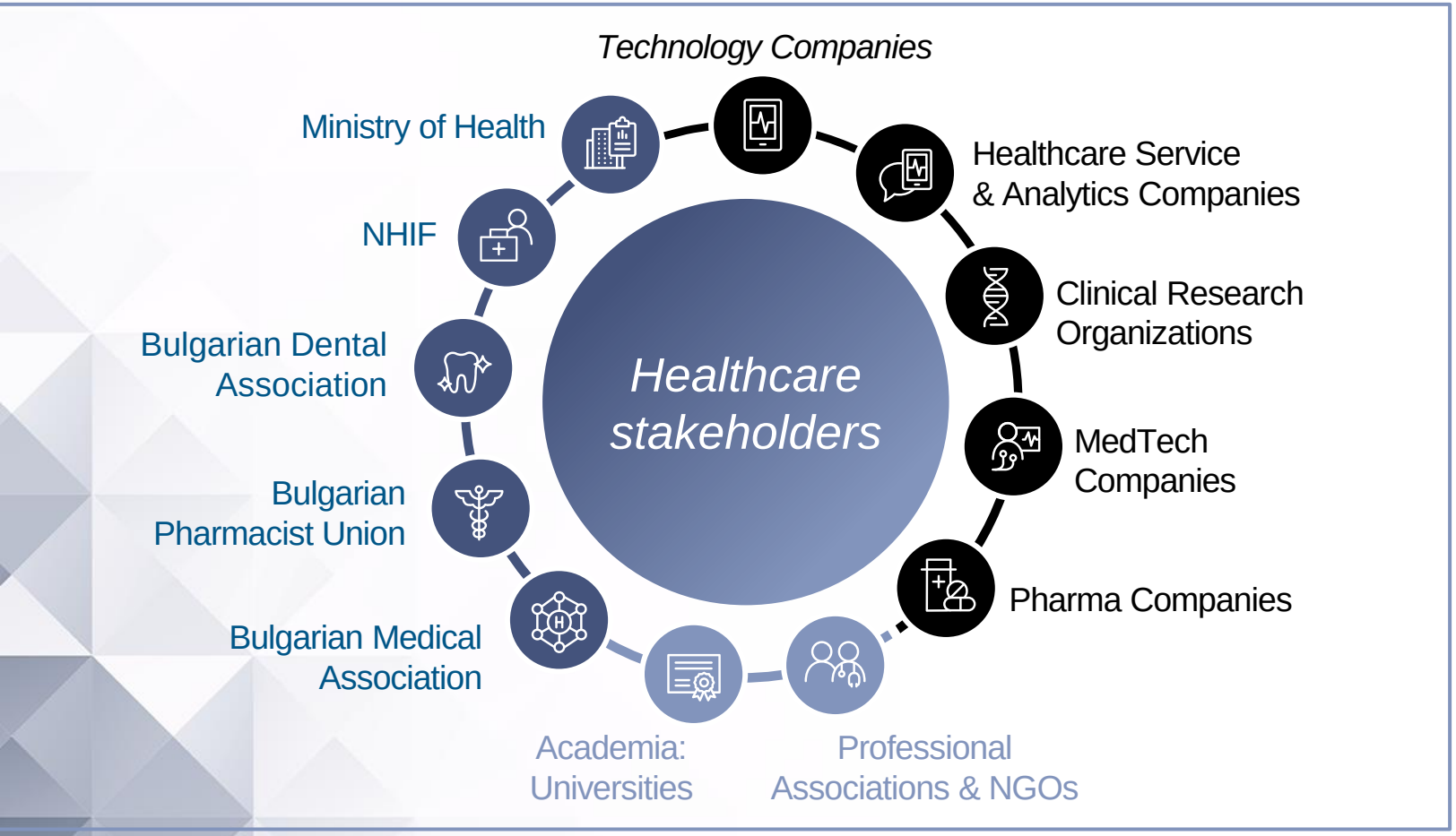
Call for Action (3/3)

Open up for Public-Private Partnership to drive Healthcare Forward



Healthcare is a complex topic that requires a holistic approach and various capabilities

By combining efforts of different experts – innovative projects and strategic initiatives can be successfully implemented

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Thank you!

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