

# Access to innovation – Where is Serbia today?

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# Value of innovation



- **Innovative new medicines provide tremendous value to patients and society:** In recent years, medicines have resulted in significant progress against some of the most complex and costly diseases. New medicines are increasingly attacking not only symptoms but the root causes of debilitating diseases.
- **Medicines benefit patients in many ways:**
  - saving and extending lives
  - halting or slowing disease progression
  - reducing side effects
  - improving quality of life
  - preventing unnecessary hospitalizations and other costly health care services

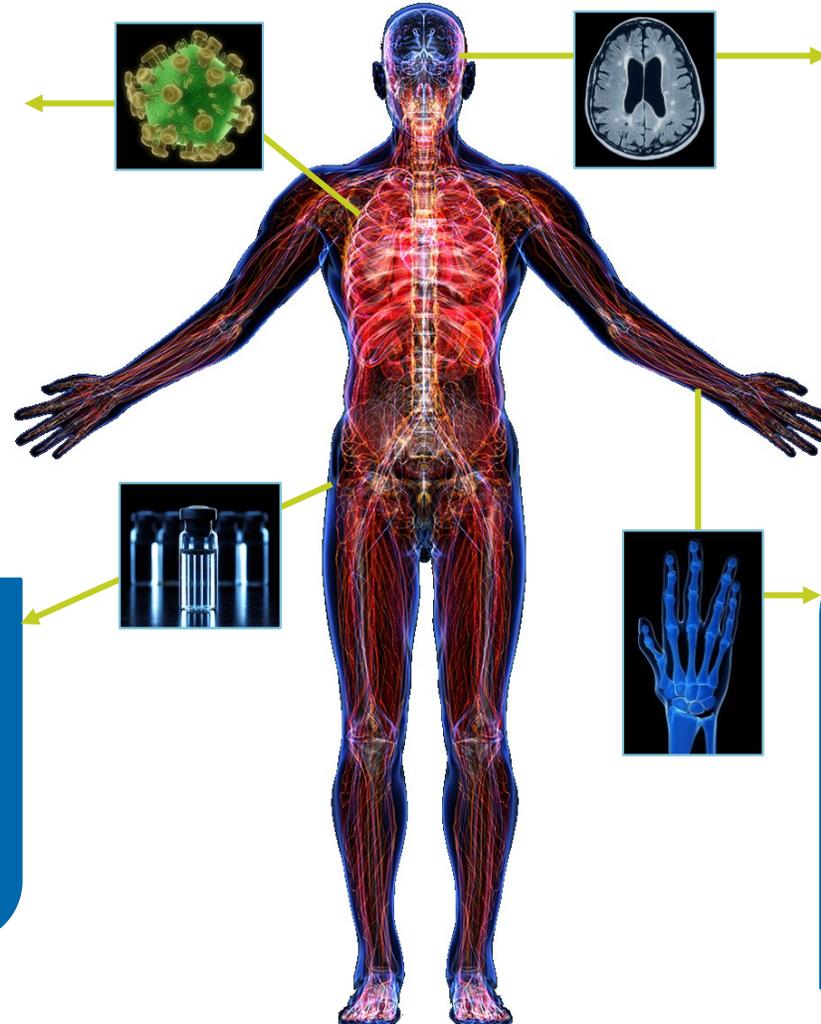
# Medicines Are Transforming the Treatment of Many Difficult Diseases

## HIV/AIDS

In the last two decades, advances in treatment have contributed to a more than 80% decline in death rates and transformed the disease from an acute, fatal illness to a chronic condition.

## Cancer

New therapies have contributed to a 20% decline in cancer deaths since the 1990s. Today, 2 out of 3 people diagnosed with cancer survive at least 5 years.



## Multiple Sclerosis

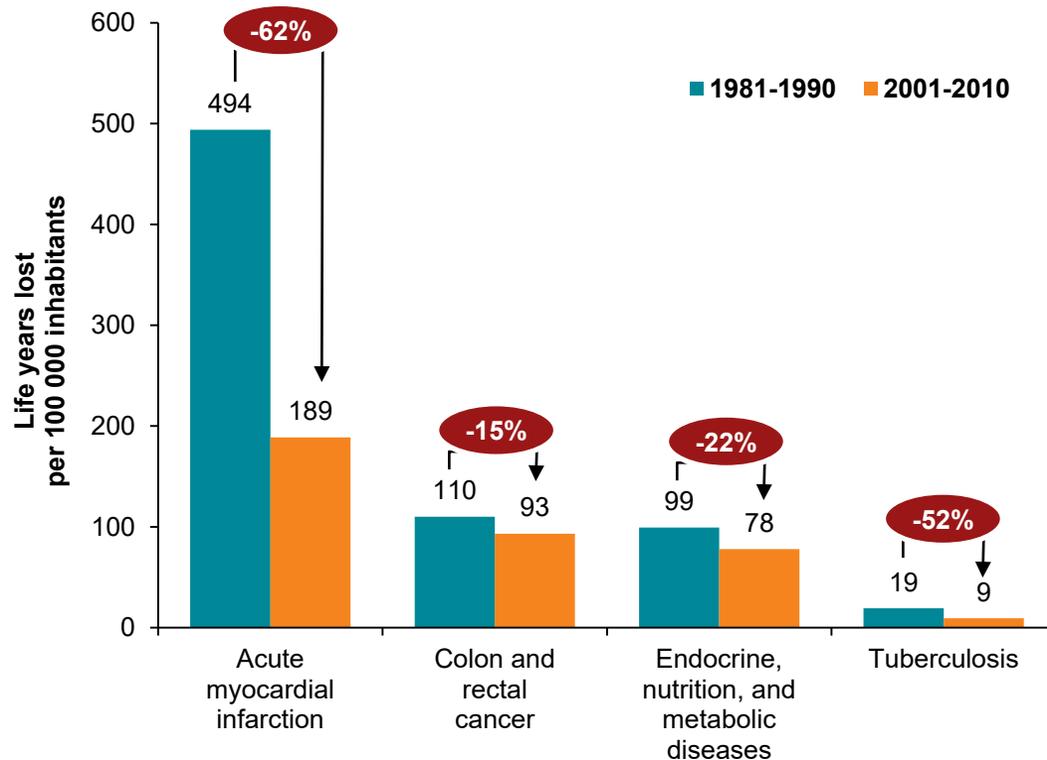
Oral and biologic treatments approved over the past 15 years have dramatically improved outcomes for MS patients, slowing disability progression and offering fewer relapses.

## Rheumatoid Arthritis

Therapeutic advances have transformed the RA treatment paradigm over the last 20 years, from focusing on symptom management to now aiming for slowed disease progression and even disease remission.

# Medicines have improved quality of life in Europe by providing multiple treatment options for previously untreatable conditions

Standardised life years lost to previously untreatable conditions per 100 000 of population 

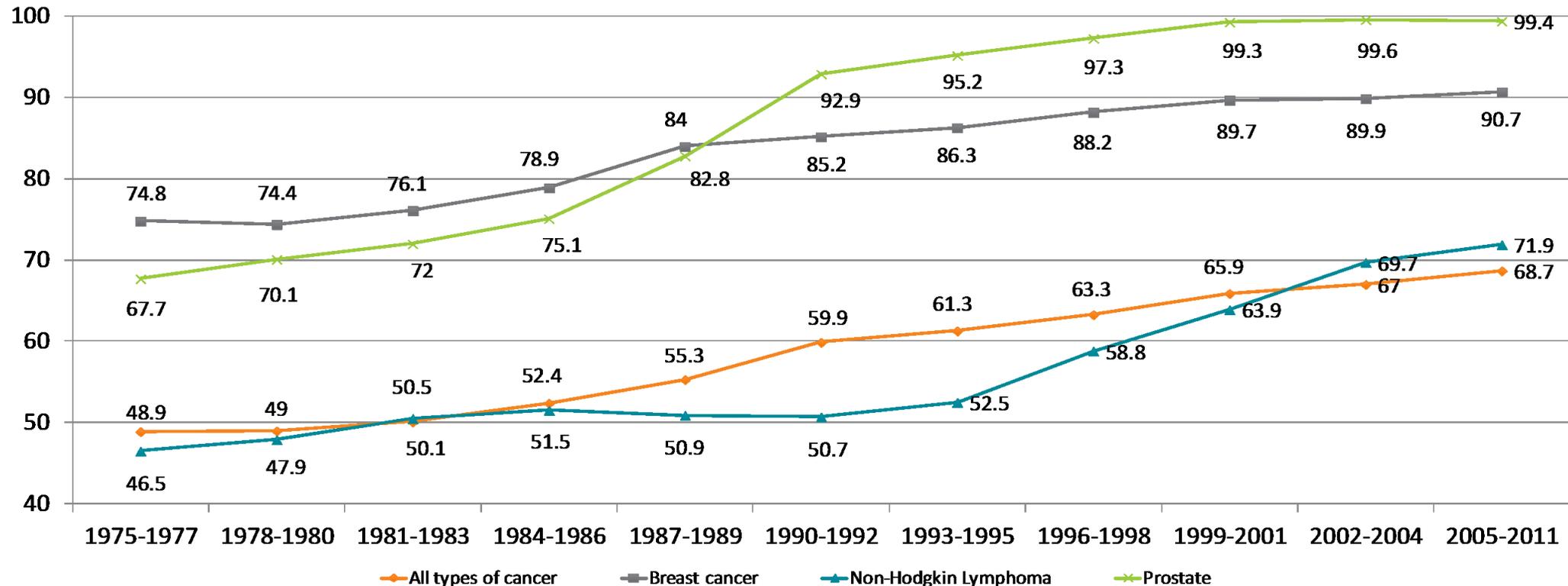


- \* Treatment and reduction of contributing factors to heart attack has substantially reduced mortality rates from myocardial infarction
- \* Colon cancer, which in past would be fatal for the sufferer, can now be treated and cured
- \* Since the development of Streptomycin, tuberculosis has been almost eradicated

# Improvement in treatments & earlier detection have contributed to an increase in cancer survival rates



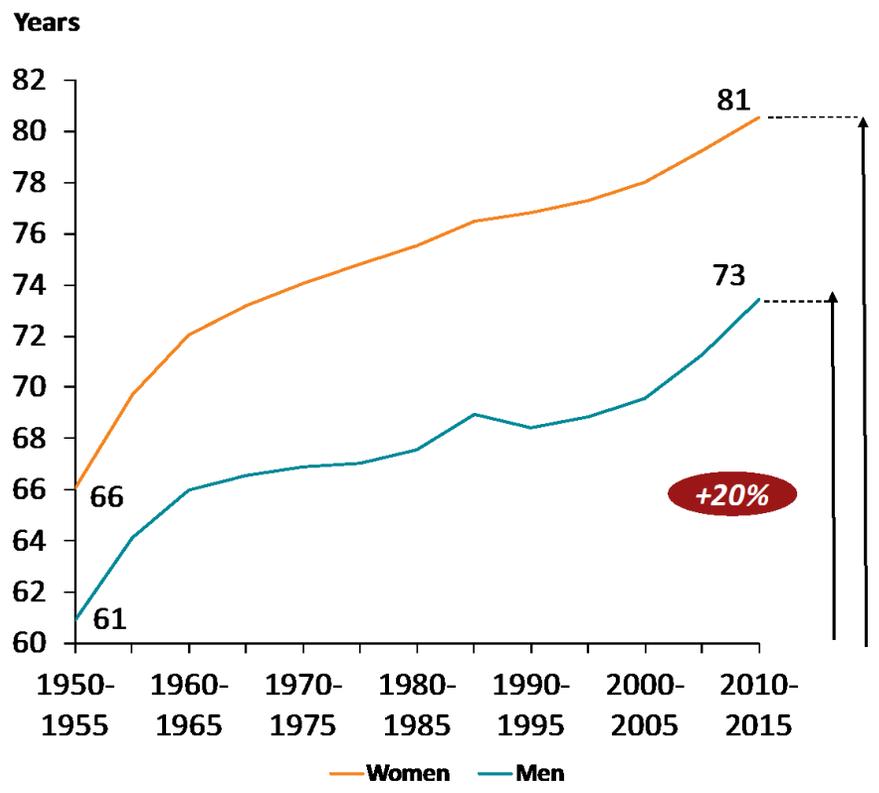
5 years cancer survival rates by year of diagnosis (%) 



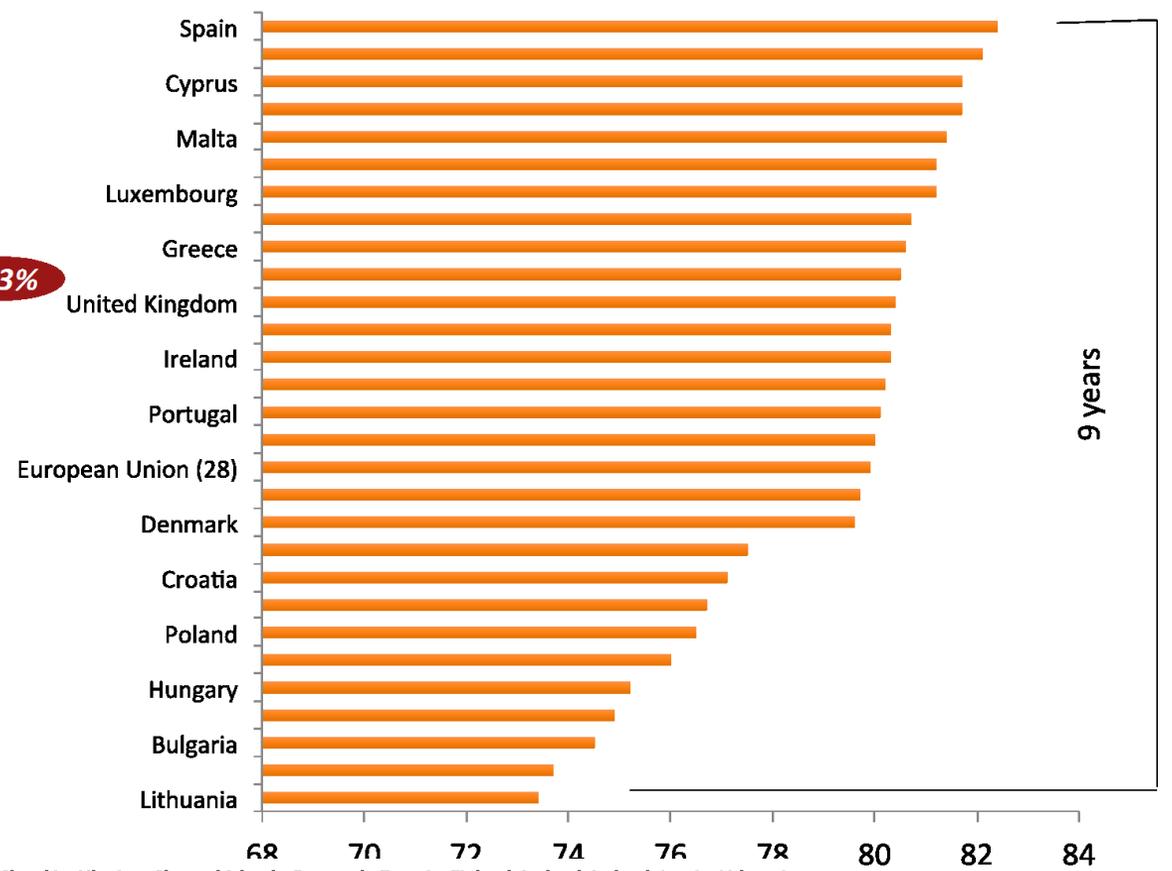
# Although Europe has shown substantial improvements in life expectancy over the last 65 years, major disparities persist across countries



## Life expectancy at birth in Europe\*



## Life expectancy at birth in EU28 (2013)<sup>†</sup>

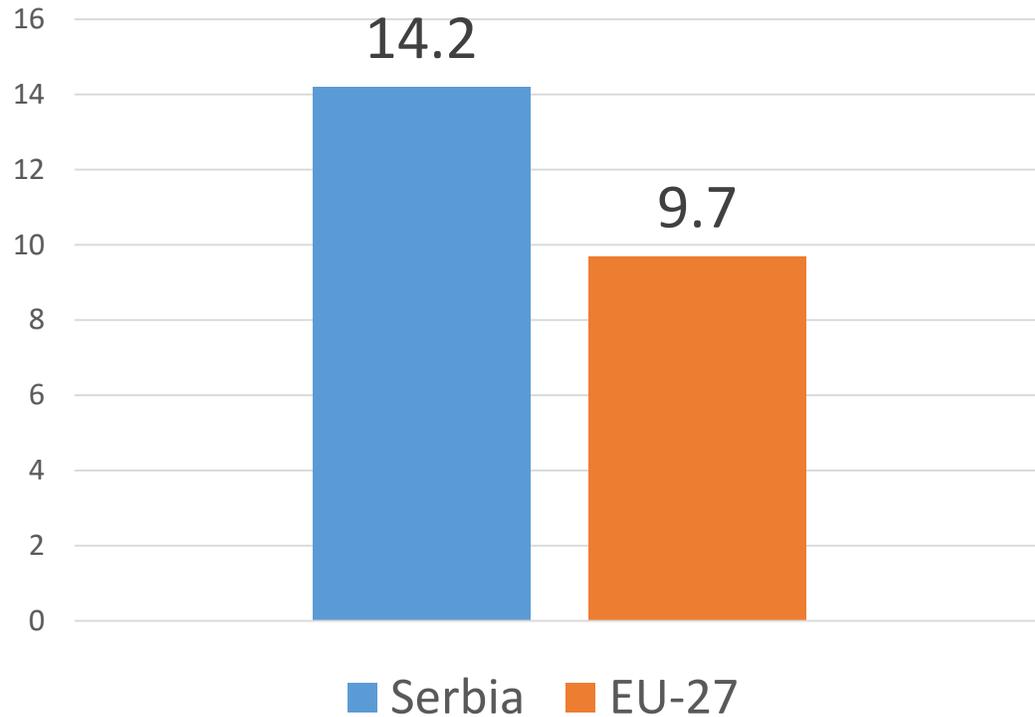


\*Projected life expectancy for Belarus, Bulgaria, Czech Republic, Hungary, Poland, Republic of Moldova, Romania, Russian Federation, Slovakia, Ukraine, Channel Islands, Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Norway, Sweden, United Kingdom, Albania, Bosnia and Herzegovina, Croatia, Greece, Italy, Malta, Montenegro, Portugal, Serbia, Slovenia, Spain, TFYR Macedonia, Austria, Belgium, France, Germany Netherlands, Switzerland.  
 Source: United Nations: World Population Prospects – The 2015 Revision (2015) accessed via the United Nation database on life expectancy at birth (accessed in August 2015); <sup>†</sup>Eurostat database (accessed in May 2015)

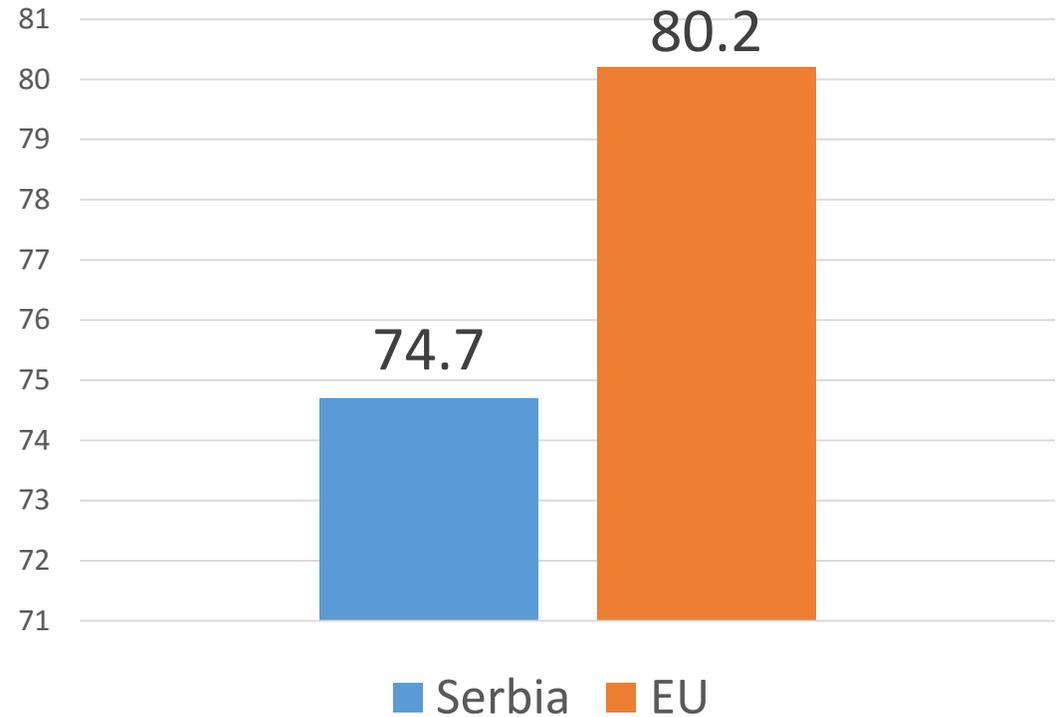
# Comparison – Serbia & EU-27

## Institute for Public Health (Batut), 2015

### Total mortality (per 1'000 population)



### Average life expectancy (years)



# The Patients W.A.I.T.\* indicator

\*Waiting to Access Innovative Therapy

- Yearly survey by EFPIA measuring delayed access to new medicines
- Serbia participating since 2011

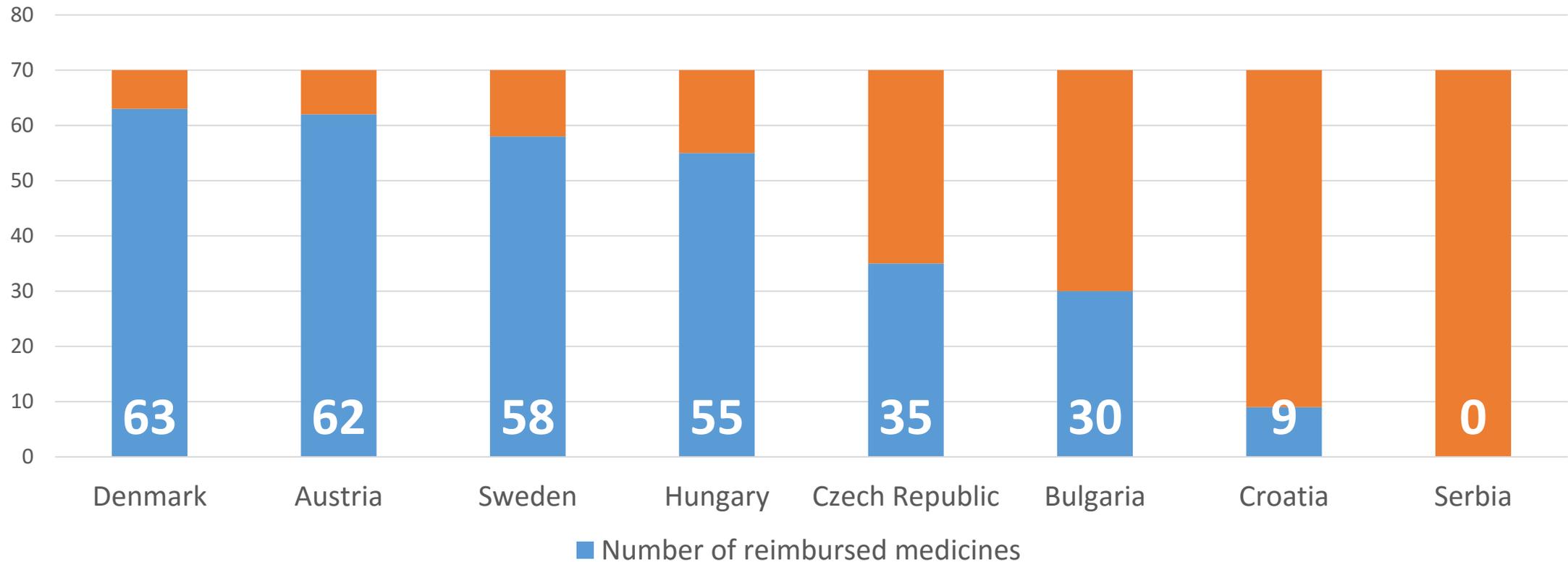
The rate of availability,  
measured by the number  
of reimbursed medicines  
available to patients in  
European countries

The average time  
between marketing  
authorisation and patient  
access through  
reimbursement

# Last official data – 2013

## Medicines getting MA in EU 2010 – 2012

Between 2010 – 2012 **70** new innovative medicines granted MA in EU

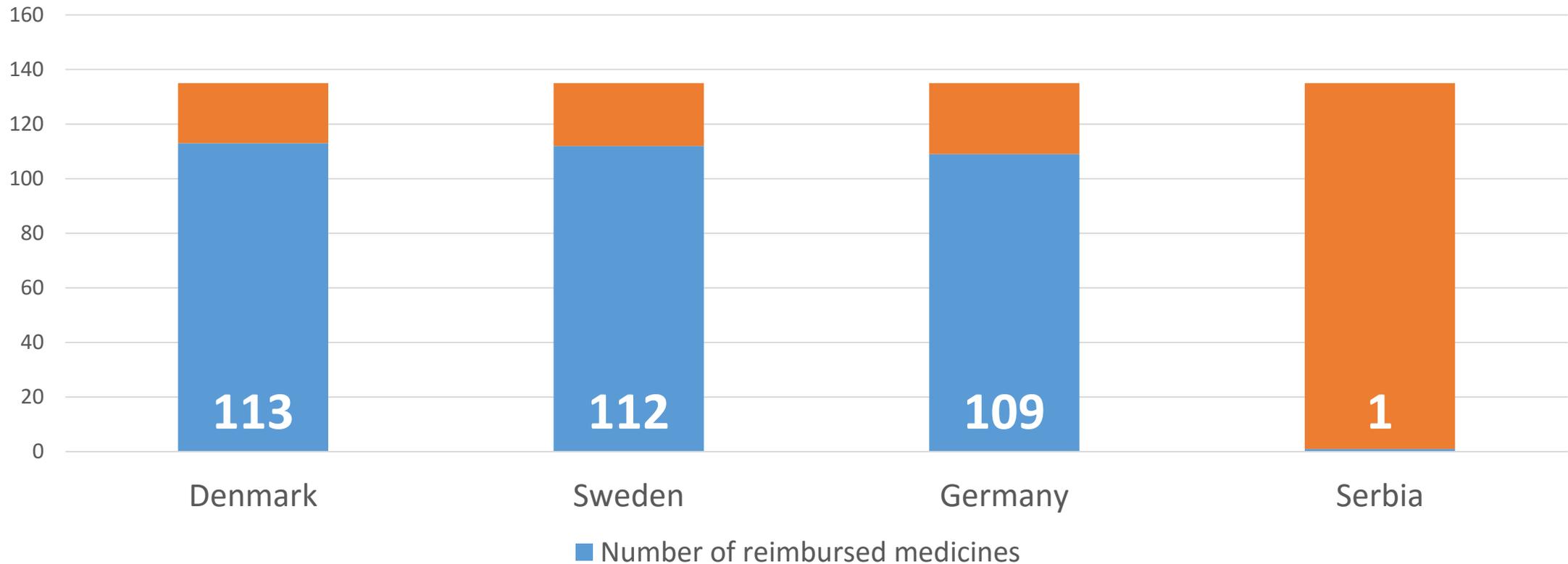


# Preliminary data - 2015

## Medicines getting MA in EU 2010 – 2012



Between 2010 – 2012 **135** new innovative medicines granted MA in EU



# Average time delay between marketing authorization and reimbursement



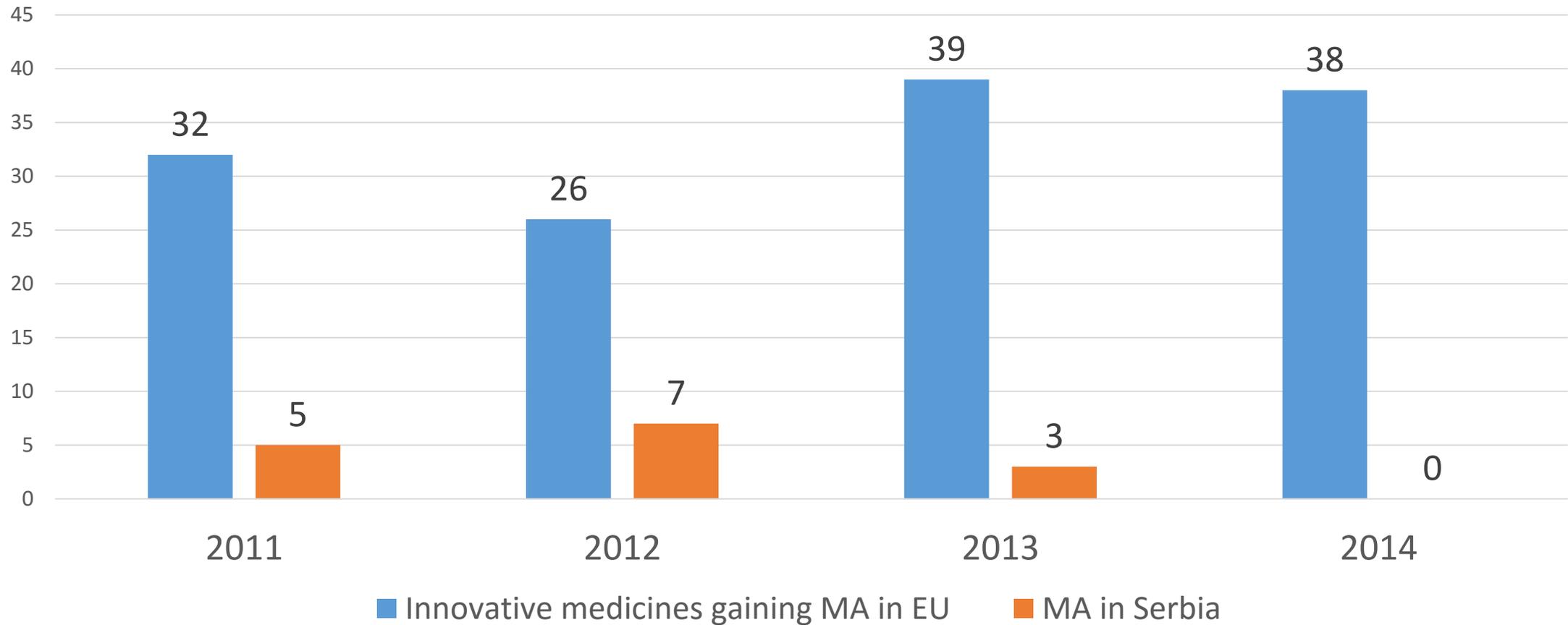
## 2013

Denmark	102
Austria	131
Sweden	364
Hungary	611
Czech Republic	524
Bulgaria	956
Croatia	520
Serbia	~

## 2015

Denmark	112
Sweden	318
Germany	109
Serbia	707

# Worrying trend: Number of new MA for innovative medicines



## International comparison of Serbian market

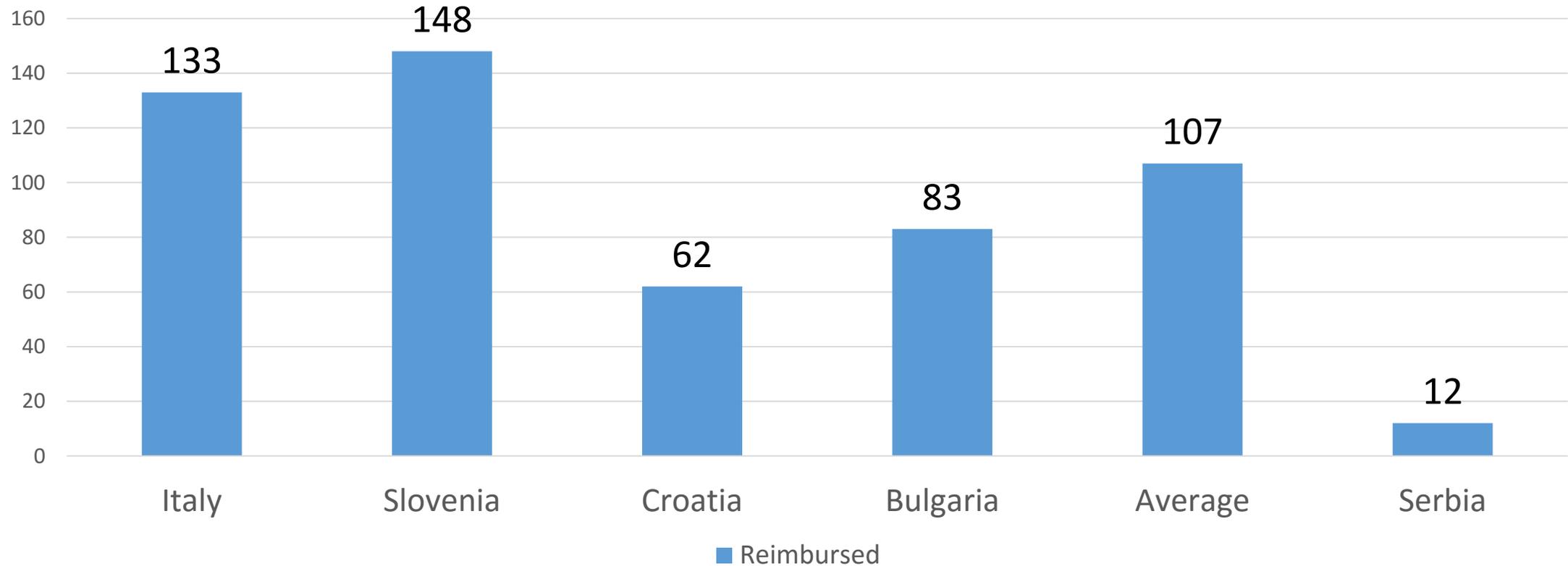
Final deliverable  
November 2014



# Serbia provides lowest access to innovative therapies compared to the region

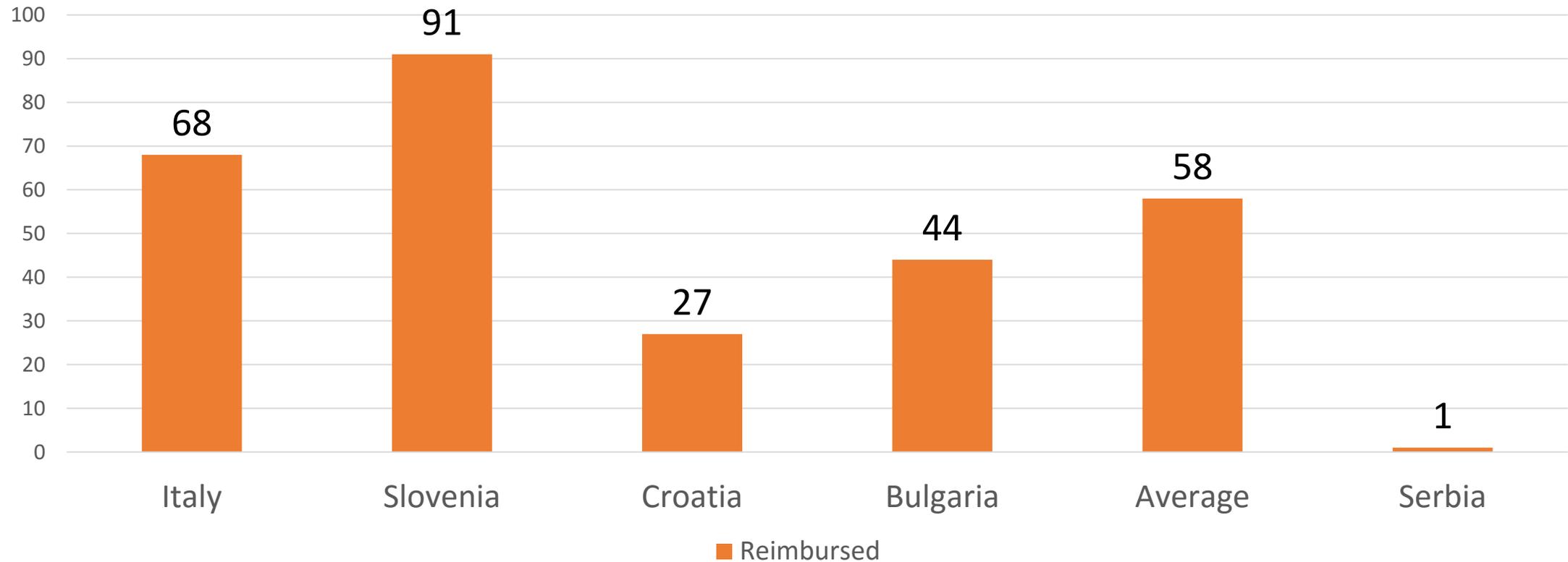


Since the beginning of 2007, total of 228 new innovative drugs were registered in EU



# Difference is particularly high with newer medicines

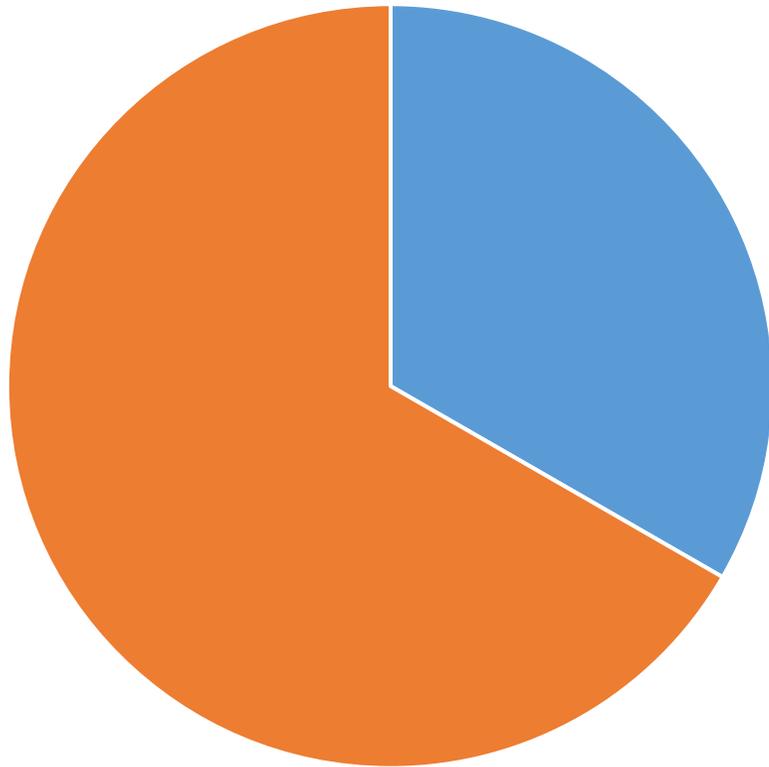
Since the beginning of 2010, total of 139 new innovative drugs were registered in EU



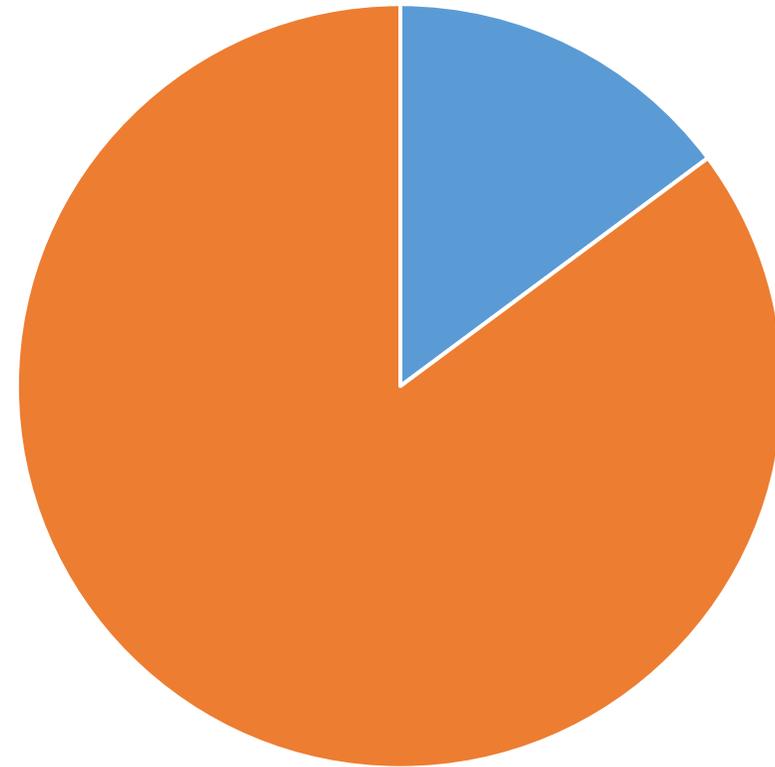
# Out of 216 medicines not reimbursed in Serbia, one third is reimbursed in at least $\frac{3}{4}$ comparator countries



72 medicines reimbursed in 3/4 countries



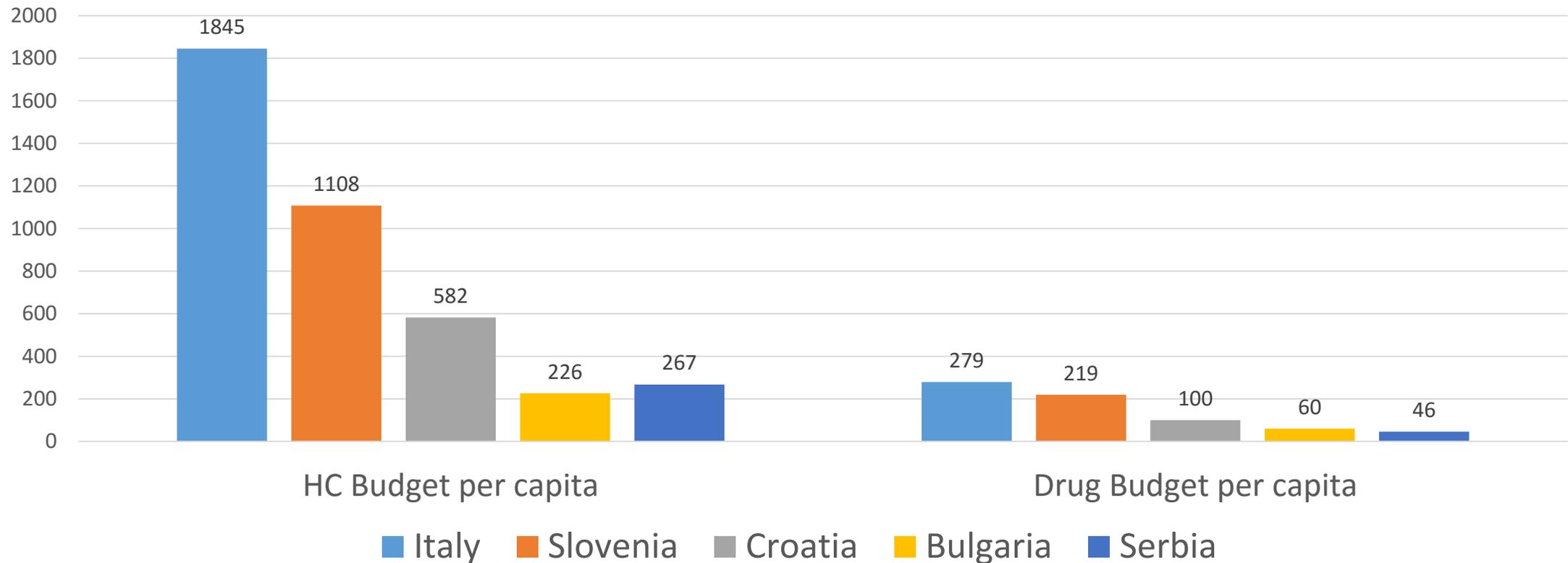
32 medicines reimbursed in all 4 countries



# Serbian Healthcare and Drug Budgets are among the lowest in the region



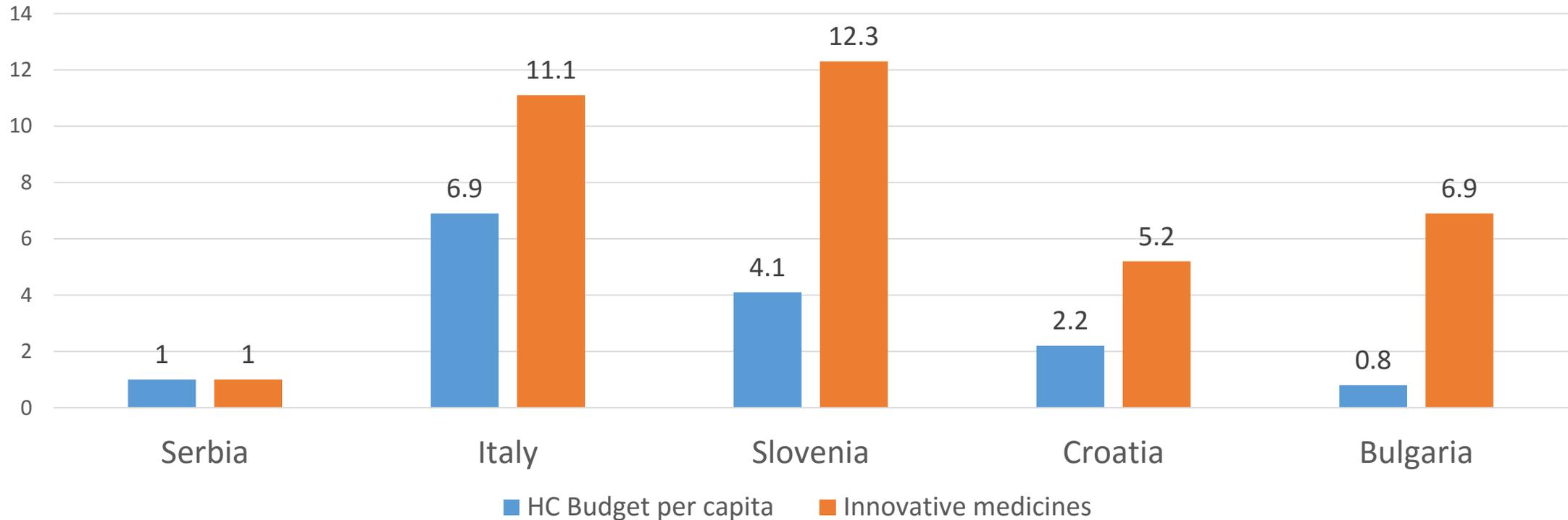
Healthcare (HC) and Drug Budgets per capita (EUR)



# Relation between HC budget and number of reimbursed innovative medicines



Difference in HC budget per capita does not explain difference in reimbursed medicines

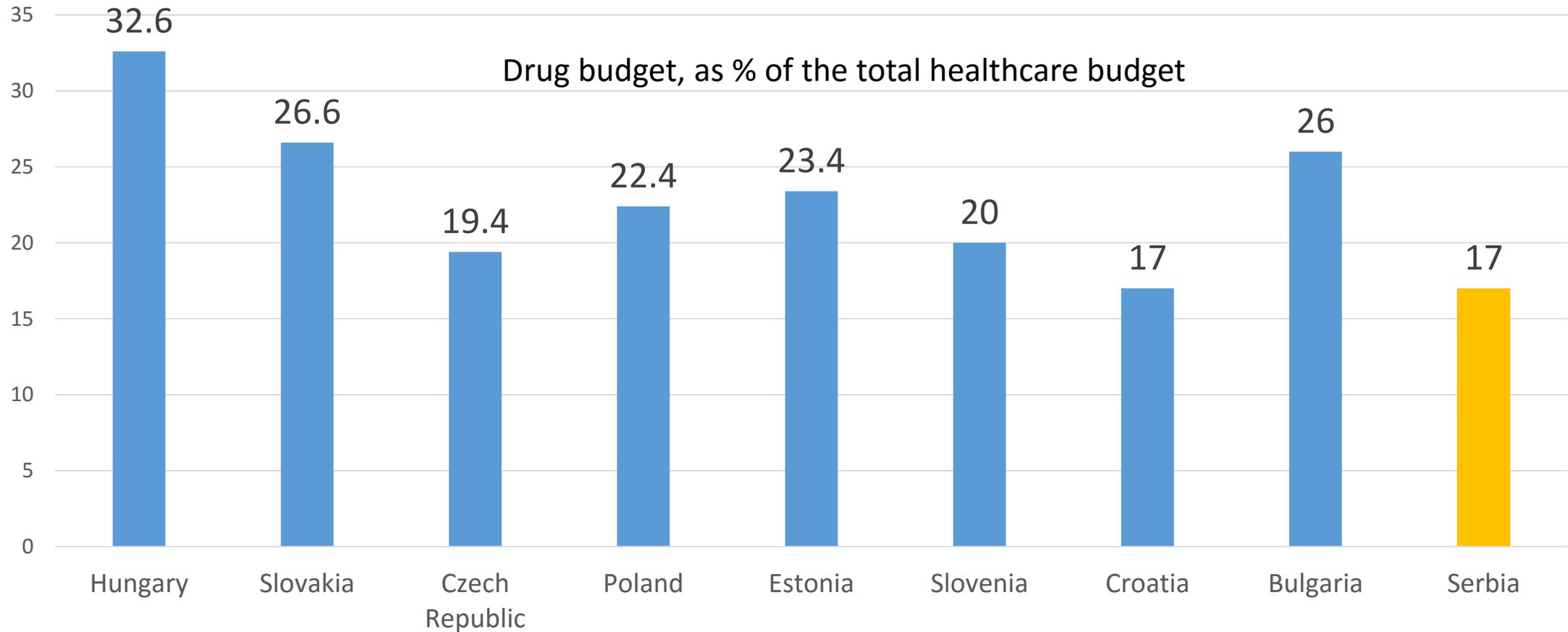


# Direct comparison



	<b>Bulgaria</b>	<b>Serbia</b>
Population (million)	7.3	7.2
GDP 2013 (billion EUR, World Bank)	39.9	33.5
HC Budget (billion EUR, IMS)	1.7	1.9
Drug Budget (million EUR, IMS)	440	330
Drug Budget as % of HC budget (IMS)	26	17
Reimbursed new innovative drugs (registered after 2007; IMS)	83	12

# Andreas Seiter, World Bank: “Serbian drug budget should grow at the double rate of the GDP growth”



OECD Health Data, 2011 (Hungary, Slovakia, Czech Republic, Poland, Estonia)

IMS Health International Comparison of Serbian Market, 2014 (Slovenia, Croatia, Bulgaria, Serbia)

# Ways forward



- Investing in health is „smart“\* expenditure
  - Further erosion of the drug budget would lead to additional lagging behind the region in access to innovation
  - Savings in „off-patent“ segment achieved through changes of the Rulebook, as well as savings achieved through public procurement should be reinvested in drug budget an entrance of new innovative medicines
- Managed entry agreements are great opportunity

# Example: Managed Entry Agreements in Italy

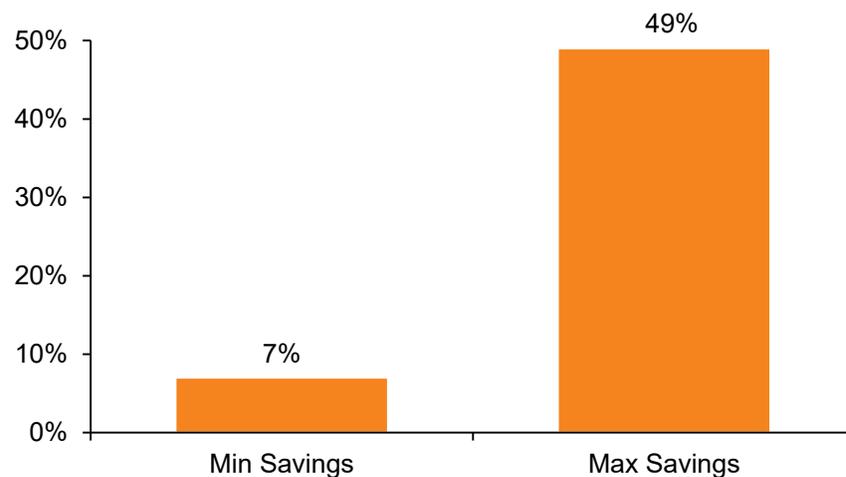
Example: Oncology

## Oncology Risk Sharing Schemes in Italy



### Benefits for the Payers

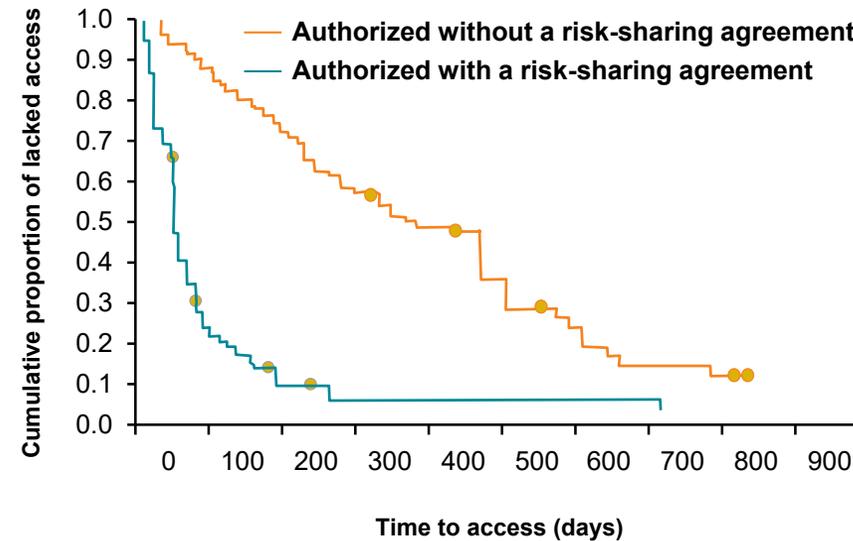
Average “savings” to payer of risk sharing per patient / average oncology therapy costs



\* Improved economic terms for payers through risk-sharing

### Benefits for the Manufacturers

Drugs uptake time (in days) of oncology medicines enrolled in risk sharing vs. others



\* More rapid market access for innovation

# Conclusions



- Overall medicines costs represent small fraction of total healthcare expenditure
  - Only 17% of the budget dedicated to drugs; >20% on average in the region
- Appropriate medicines usage can create additional capacity throughout the health system; paramount role of innovative medicines
  - Positive impact on healthcare system through extended life expectancy, lower morbidity, better quality of life and increased productivity
- Better communication, procedural transparency and fairness and partner-based relationship is needed
  - With its experience and capacity, industry needs to be recognized as partner in the process of improvement of Serbian HC system