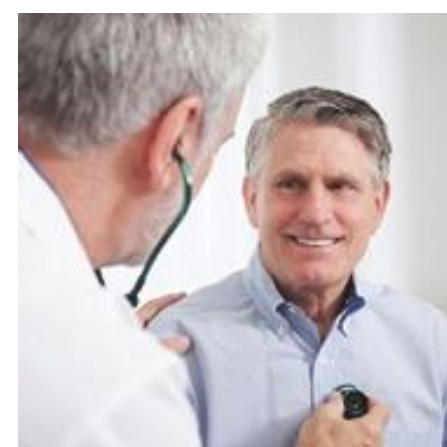




European Federation of Pharmaceutical
Industries and Associations

EFPIA's Collaboration with the College of European Studies Parma (Italy)

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The EFPIA PRIZE
Parma, 1st April 2016



Collaboration with the College of European Studies

- The pharmaceutical industry has a long tradition of collaboration with academics, especially in scientific and medical areas.
- The sector is also interested in expanding academic collaboration in other areas, including economics, legal and social science.
- EFPIA has a genuine interest in academic research on topics relevant to its main activities and it robust academic research that would allow better understanding of the specificities of the sector, providing evidence-based analysis that can underpin public policy.

The College of European Studies warrants high-quality and rigorous independent academic work that the pharmaceutical sector could benefit from in designing its public policy proposals.

EFPIA Mandate

“The aim of the European Federation of Pharmaceutical Industries & Associations is to promote pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide.”

EFPIA, which has no profit-making purpose, pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

EFPIA's represents the pharmaceutical industry operating in Europe. Its direct membership includes **33 national associations** and **40+ leading companies**. Two specialised groups within EFPIA represent vaccine manufacturers – **Vaccines Europe - VE**, with 12 member companies and **European Bio-pharmaceutical Enterprises – EBE** with 50+ member companies.

“Partners in Research” is constituted of non-pharma companies that collaborate in the IMI public-private membership. This constituent entity, created in June 2014, counts 13 members.

EFPIA Structure



EFPIA BOARD
Joe Jimenez (Novartis), President
Stefan Oschmann (Merck), Vice President
Marc de Garidel (Ipsen), Vice-President

General Management

BOARD-SPONSORED COMMITTEES

Patient Access Adam Schechter MSD	Innovation Jean-Christophe Tellier UCB	International David Ricks Eli Lilly	Finance & Operations Stefan Oschmann Merck
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Priority Working Groups

EUROPEAN MARKETS COMMITTEE
Andrew Hotchkiss (Eli Lilly), Chair
vacancy, Vice-Chair
Thomas Cueni (Interpharma), Vice-Chair

HEADS OF MEMBER ASSOCIATIONS

Outline of EFPIA's Key Priorities

Vision

Shift the healthcare policy debate from a transactions focus to an outcomes focus

Patient Access

Objective	KPI	Status	Deliverables	Status
Reduce market access delays for innovative medicines	Δ Patient (WAT indicator (e.g. EU weighted average))	●	<ul style="list-style-type: none"> Conduct benchmarking based on WAT indicator Monitor implementation of Transparency Directive (delays) in Member States Advocate for improved access in problematic countries 	●
Increase uptake for innovative medicines	Δ Composite uptake indicator (Patient WAT + SIS turnover)	●	<ul style="list-style-type: none"> Conduct benchmarking based on composite indicator Address lack of uptake in problematic countries through advocacy 	●
Improve alignment of national HTA systems with EFPIA HTA principles	Δ changes in countries	●	<ul style="list-style-type: none"> Identify and address bad practices in Member States Develop pragmatic HTA model for CEE countries (fitting into the PSA process) and initiate dialogue with key priority countries 	●
Mitigate spill-over effects of international reference pricing (IRP)	% countries complying with acceptable IRP practices	●	<ul style="list-style-type: none"> Define acceptable practices in IRP and monitor their implementation Identify 2 countries whose IRP system has the most negative industry impact (in country and spill-over) Develop action plan with relevant national associations to implement acceptable practices (in particular maintain confidentiality of net prices) Influence future EU reflection on impact of IRP (Working Party on Public Health at Senior Level) 	●
Ensure legislation on biologics complies with EFPIA principles	% of countries complying with principles	●	<ul style="list-style-type: none"> Develop policy principles for efficient and sustainable biopharma markets (avoid policy leading biotech as generic) 	●

Develop EU and national competitiveness policies for the pharma industry, focusing on patient access for new products

Innovation

Objective	KPI	Status	Deliverables	Status
Drive collaborative medicines development across sectors	MS-2 framework set-up (D1)	●	<ul style="list-style-type: none"> Complete MS legislative package, ensuring flexibility and key IP features Agree MS2 project portfolio (incl. MSAPPs programme) supported by companies science leadership 	●
Reduce time to market for new medications including new	% Enablers of MSAPPs (development, financing & access) addressed in MS Projects	●	<ul style="list-style-type: none"> Implementation of AI pilot project in line with MSAPPs principles Launch MS2 MSAPPs programme 	●
Drive global regulatory convergence between EU & US	# Products submitted for EMA adaptive licensing pilot	●	<ul style="list-style-type: none"> Ensure MRA on GMPs, paediatric and CT data fields in line with EFPIA-PhRMA objectives 	●
Shorten time for approval of clinical trials	% of EFPIA-PhRMA objectives included in TTIP	●	<ul style="list-style-type: none"> Drive implementation of CT regulation, including efficient operation of EMA's CT database 	●

Modernise the research, development and regulatory model to restore Europe's competitiveness and speed up access to medicines

International

Objective	KPI	Status	Deliverables	Status
Ensure TTIP includes key commitments to strengthen regulatory alignment and promotes transparency and access to innovative medicines	% industry regulatory proposals regulated in TTIP	●	<ul style="list-style-type: none"> Promote short-term outcomes, e.g. MRA on GMPs Secure concrete commitments for continued improvement of IP protection and enforcement (e.g. Early Resolution Mechanism) Secure Annex on Pharmaceuticals, in line with EU-Korea FTA 	●
Strengthen EU support for IP through a balanced narrative on access to medicines and the role of IP in fostering economic development and EU competitiveness	% industry IP proposals regulated in TTIP	●	<ul style="list-style-type: none"> Execute successfully the agreed IP advocacy programme, including Global Health Initiative and IP advocacy Provide input to EU institutions on IP access issues in key third markets Create and mobilise cross-sectoral coalition to seek improved business conditions in India and rebalance EU-India trade agenda to incorporate enhanced engagement on IP 	●
Leverage regulatory reforms to align with international standards and improve IP in China, while positioning industry as trustworthy & cooperative	% core transparency and P&R principles regulated in TTIP	●	<ul style="list-style-type: none"> Ensure EFPIA President, DG and ISMC Chair jointly advocate in Beijing industry priorities for regulatory reform and good governance Address all regulatory priorities at EU-China High Level Regulatory Dialogue Support specific projects developed under EU IP Key Program in Beijing 	●

Secure improved market access conditions, high regulatory and IP standards in international growth markets

Finance & Operations

Implement best practice financial management and operations systems at EFPIA

Governance & Processes

Working groups

	Board				
BSCs	Patient Access	Innovation	International	Finance & Operations	Director-General
Priority WGs (cross-functional)	HTA	IMI/ Collaboration Strategy	U.S. & Canada		Ethics & Compliance
	Biologics ^{**^}	Clinical Trials	Growth Markets		Communications
	Orphan Drugs ^{***}	Data Privacy	Global Health*		Brussels Advocacy
	Supply Chain	Adaptive Models			
	Health Systems	PMs/ ATMPs ^{**}			
	Pricing/ Reimbursement				
Expert WGs (functional)	Competition	IP	International Regulatory		
	Patient Think Tank	EU Regulatory	International Security Forum		
		Preclinical Safety			
		Pharmacovigilance			
		Clinical Development			
		Regulatory IT			
		Technical Development			
		EHS			
		Animal Welfare			

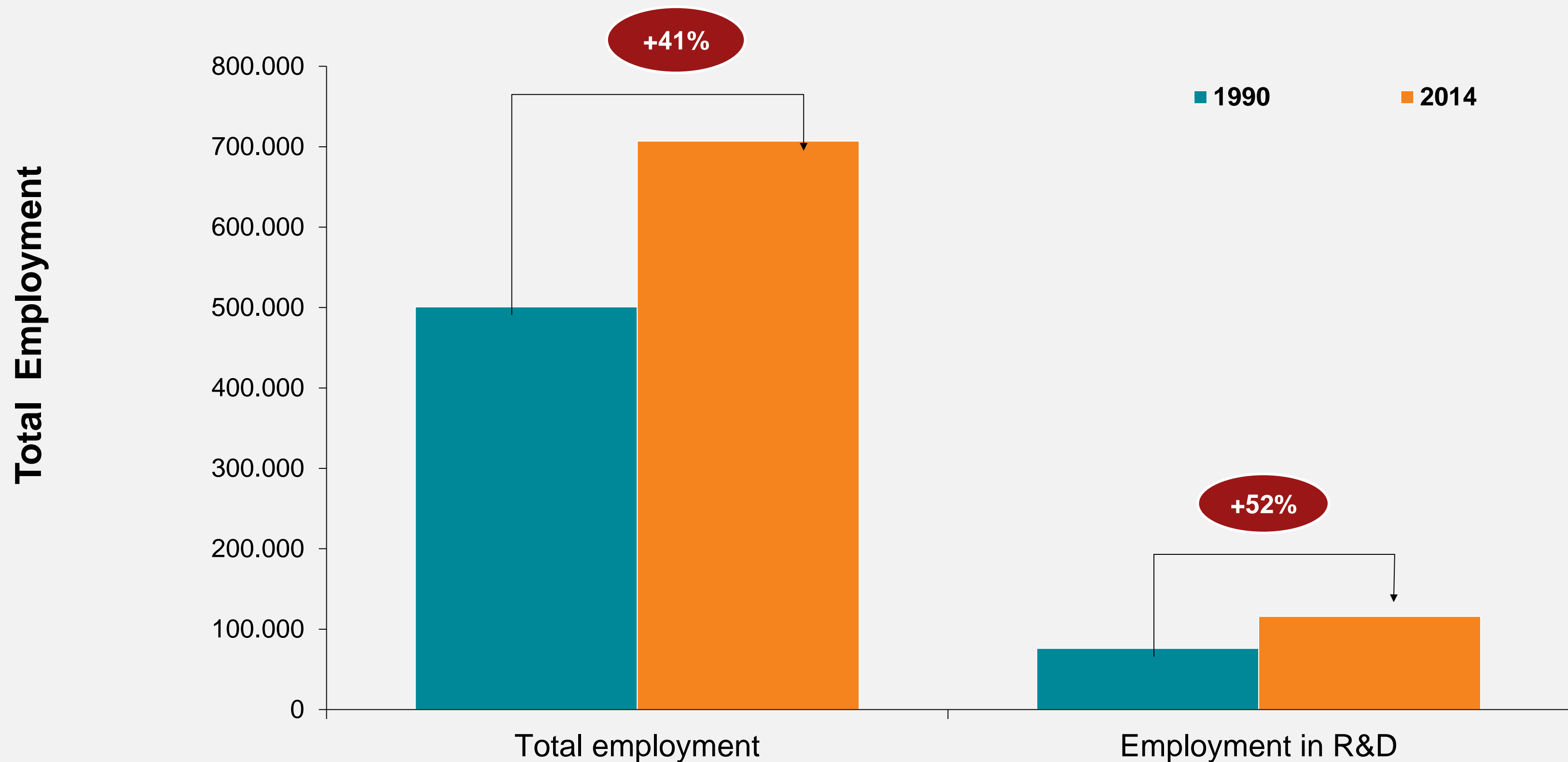
Notes: *With IFPMA/ PhRMA; **With EBE; ***With EBE/ Europabio; ^Covering Access, not Regulatory; **BSC** = Board-Sponsored Committee; **WG** = Working Group; **PM** = Personalised Medicines; **ATMP** = Advanced Therapy Medicinal Product; **HTA** = Health Technology Assessment; **IMI** = Innovative Medicines Initiative; **EHS** = Environment, Health, Safety

A leading economic sector in Europe

WEALTH CREATION & GROWTH

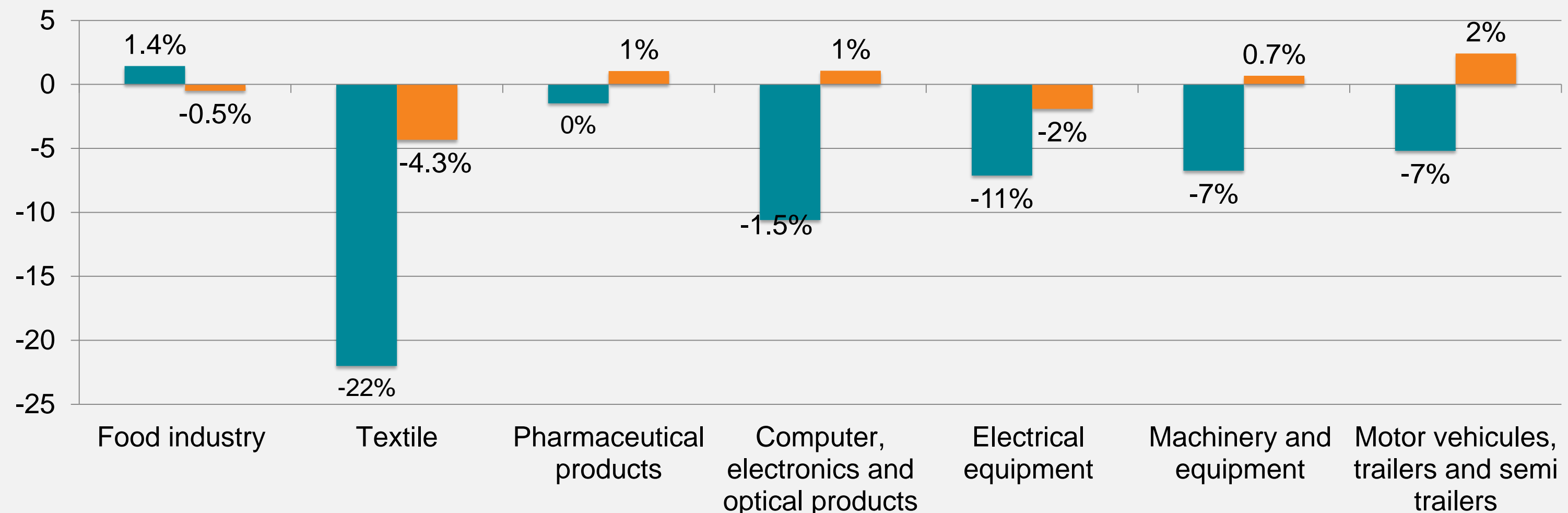
The research-based pharmaceutical industry is a major high-technology employers in Europe

Employment in the pharmaceutical industry in EU (1990-2014)



Despite the crisis, employment in the pharmaceutical industry has proven more resilient than many other sectors

Percentage change in employment in selected industries (2008-2012)



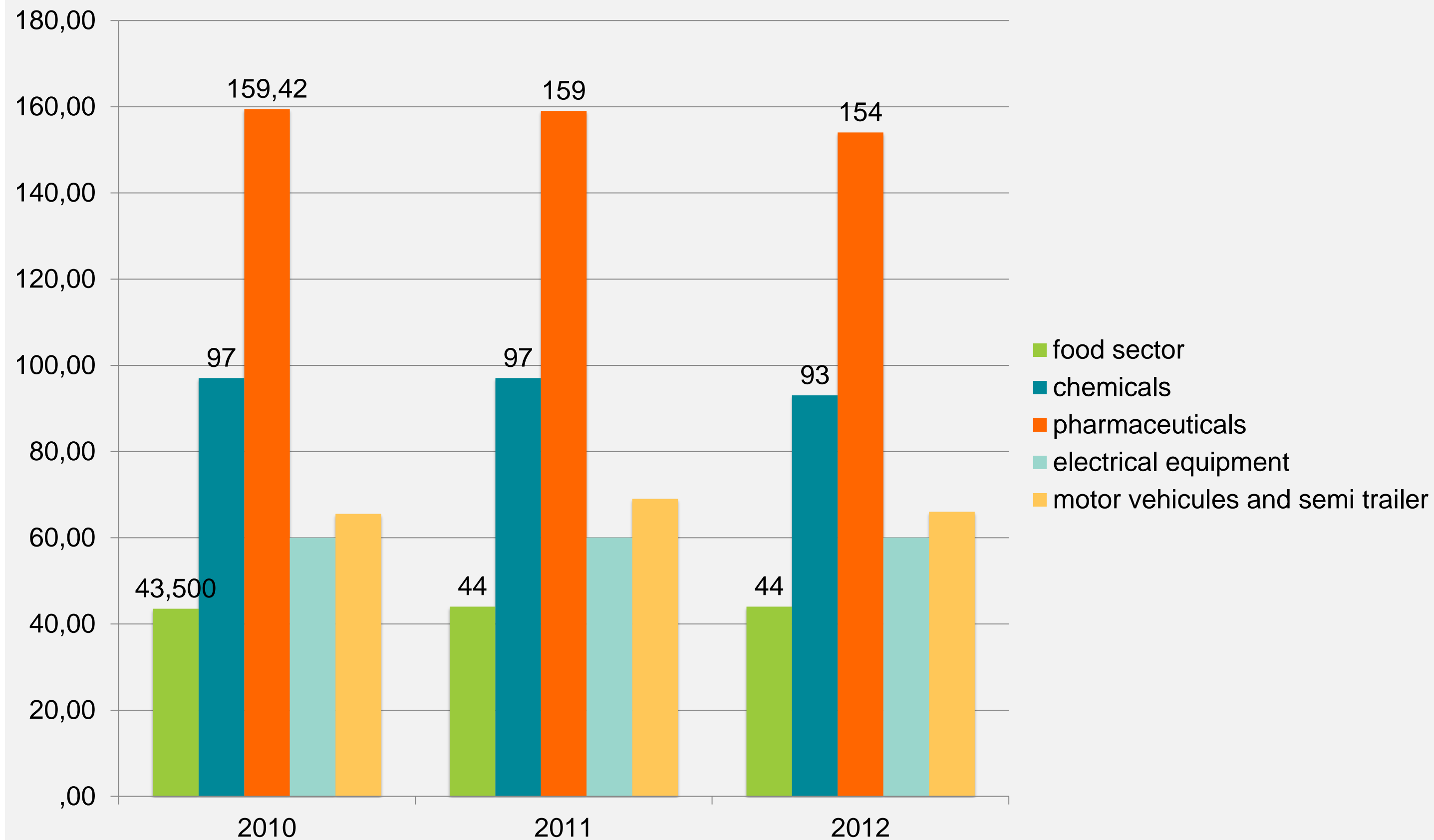
■ percentage change between 2008 and 2012 ■ percentage change in employment between 2011 and 2012

Note: the graph measures change in employment for the EU27 (2008-2012) and for the EU28 (2011-12). The chemical industry could not be included in the graph because of the absence of statistics for the year 2012.

Source: Eurostat database on employment by NACE2 sectors.

Economic value added per employee in the pharmaceutical sector is higher than comparable industries

Gross value added per employee (2010-2012) (1000 EUR)



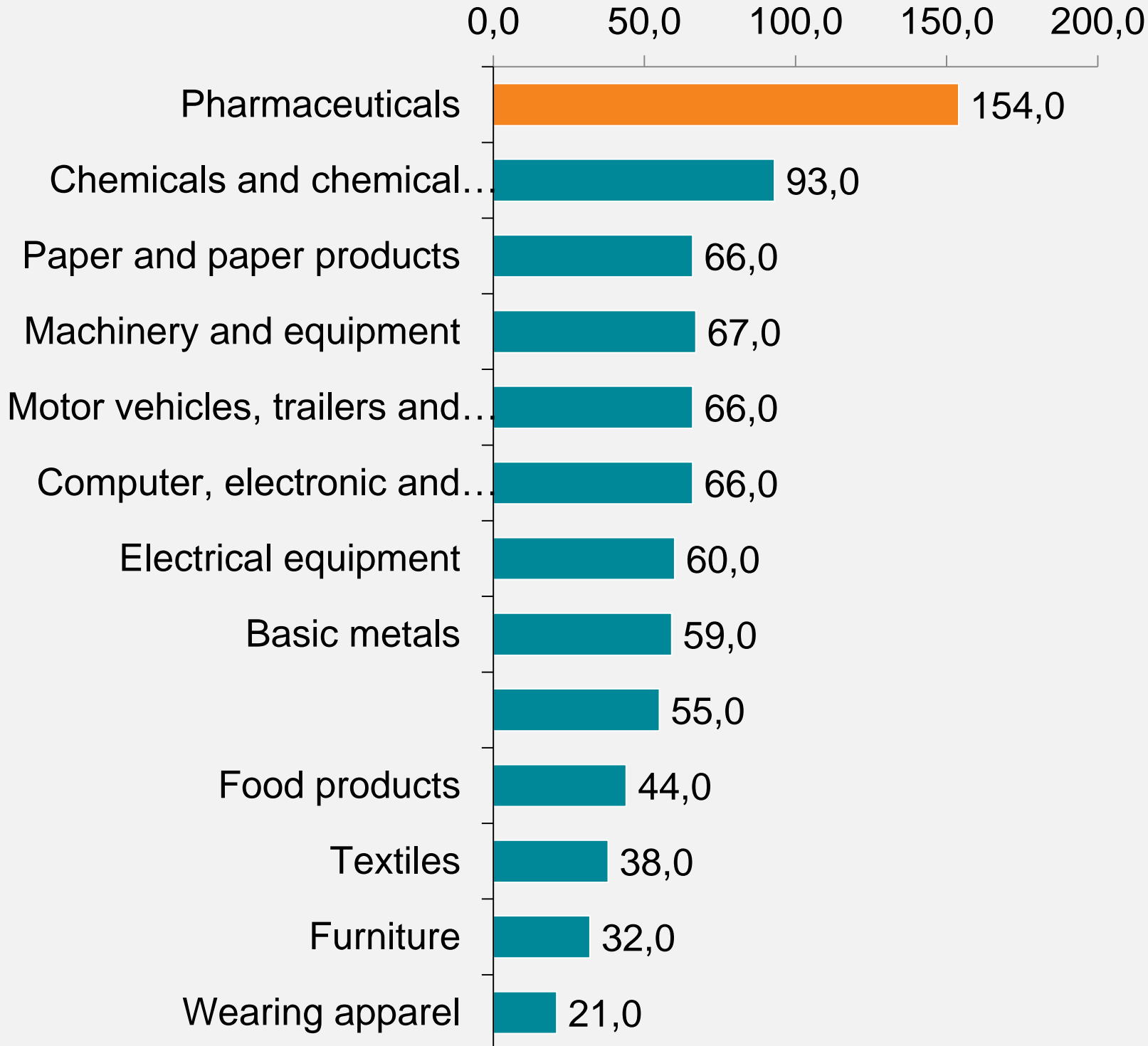
Note: Gross Value Added is defined as the difference between Production and Intermediate inputs.

Employment within the pharmaceutical sector generates one of the highest returns compared to other industries

Gross value added per employee



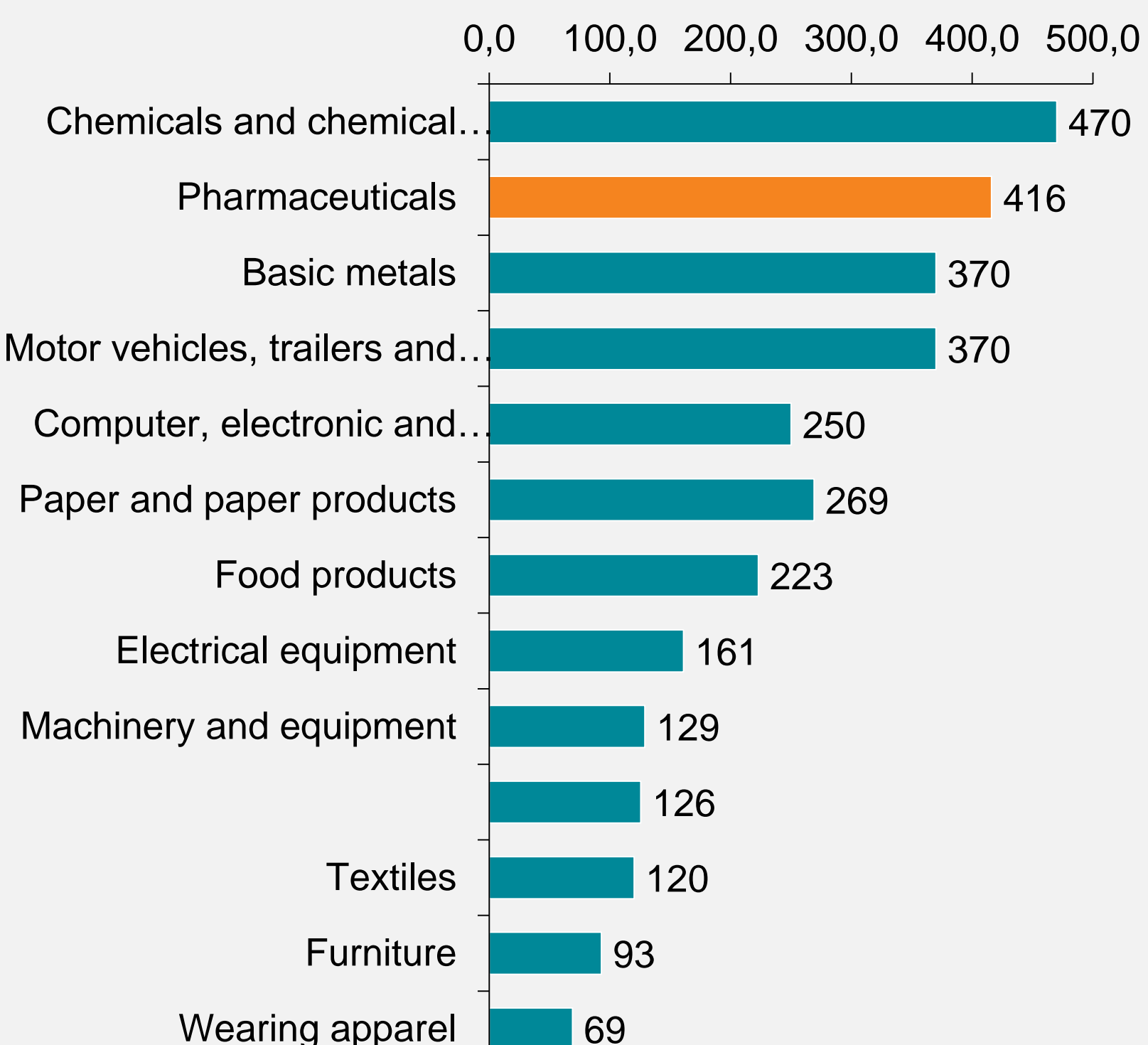
Value added/employee (1000 EUR)



Turnover generated per employee



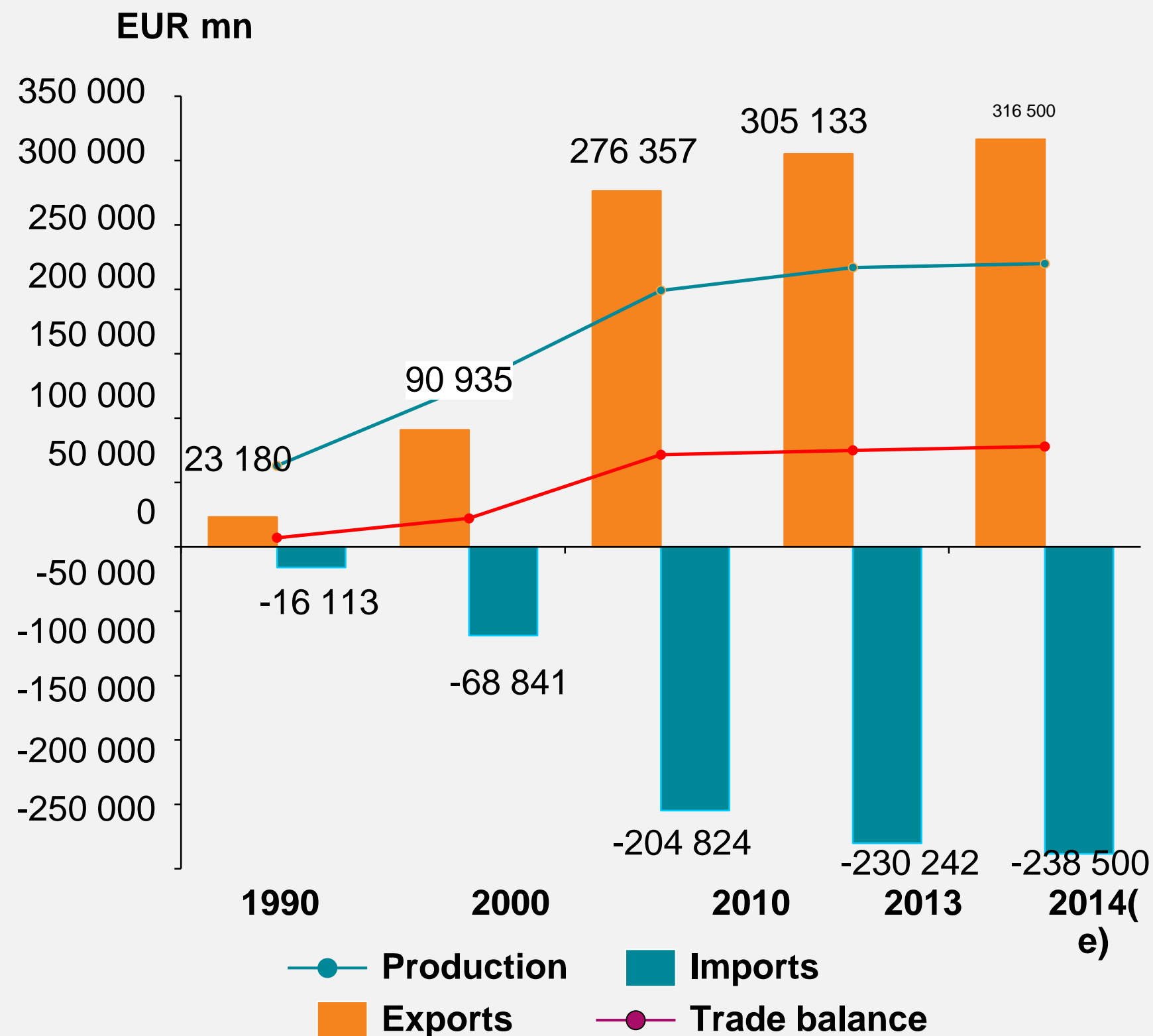
Turnover generated per employee (1 000 EUR)



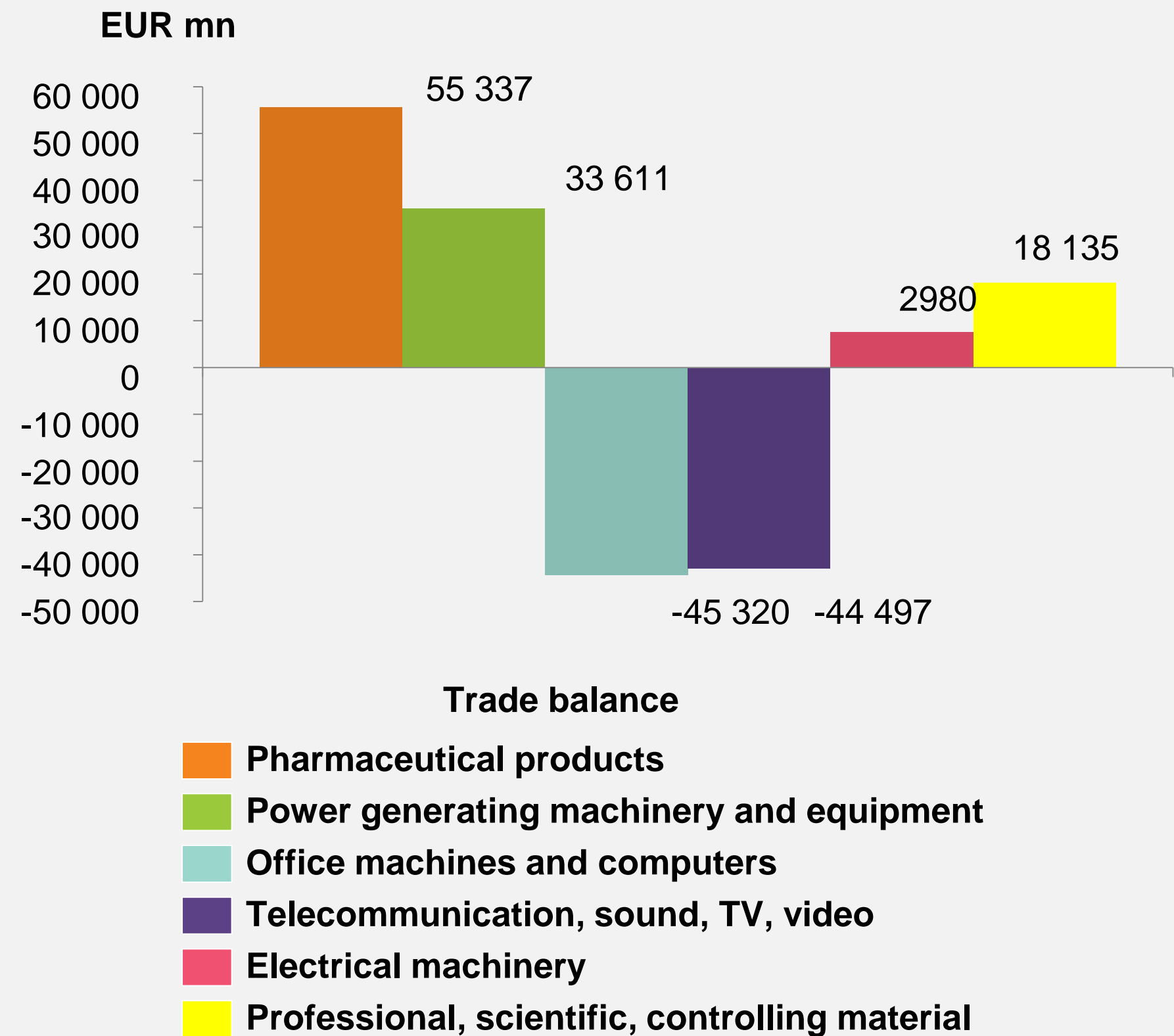
Source: Eurostat (online data code: sbs_na_ind_r2): 2012 figures (accessed in March 2015)

The pharmaceutical industry continues to drive a positive trade balance for Europe

Trade Balance for Europe (2010-2014)



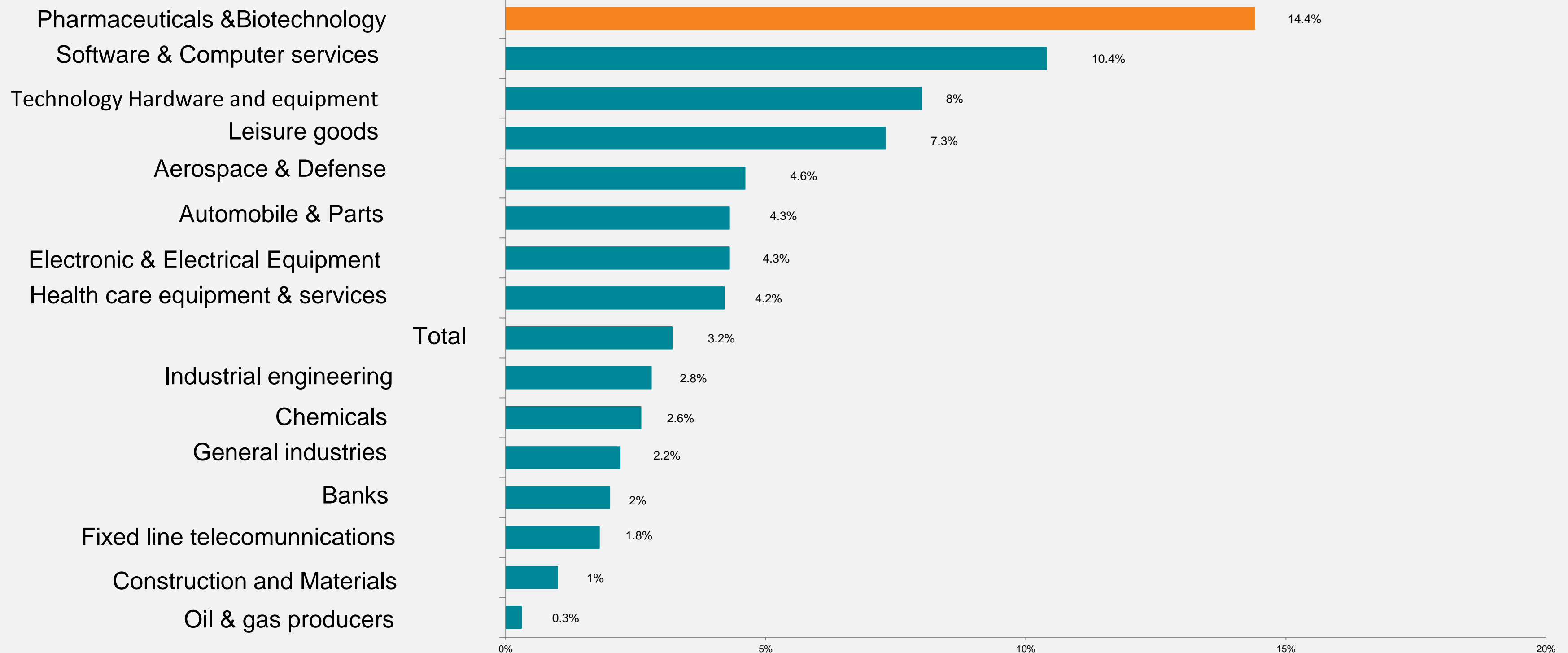
EU-28 Trade balance for high technology sectors (2013)



Note: the graph on the left hand side was based on EfPIA member associations (official figures) - (e): EfPIA estimate; Eurostat (Eu-28 trade data 1995-2014)

The pharmaceutical industry is the largest investor in R&D

Ranking of industrial sectors by overall R&D intensity (as percentage of net sales, 2013)



Note: data relate to the top 2,500 companies with registered offices in the EU (633), Japan (387), the USA (804) and the Rest of the World (676), ranked by total worldwide R&D investment (with R&D investment above €15.5M)

A key asset to healthcare

HEALTH OUTCOMES & SUSTAINABLE FUNDING

The world population is getting larger and older, but morbidity also increases, with spending projected to double in just over 10 years



Population will increase by

1
billion

2015 - 2025



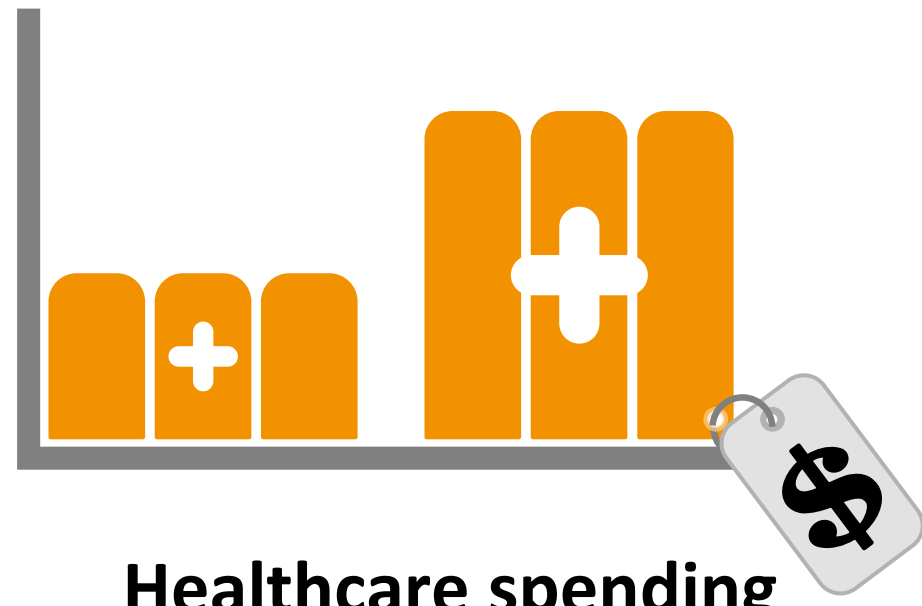
Additional 50+ year olds

>500
million



Chronic diseases

70%
of all illnesses



Healthcare spending to double

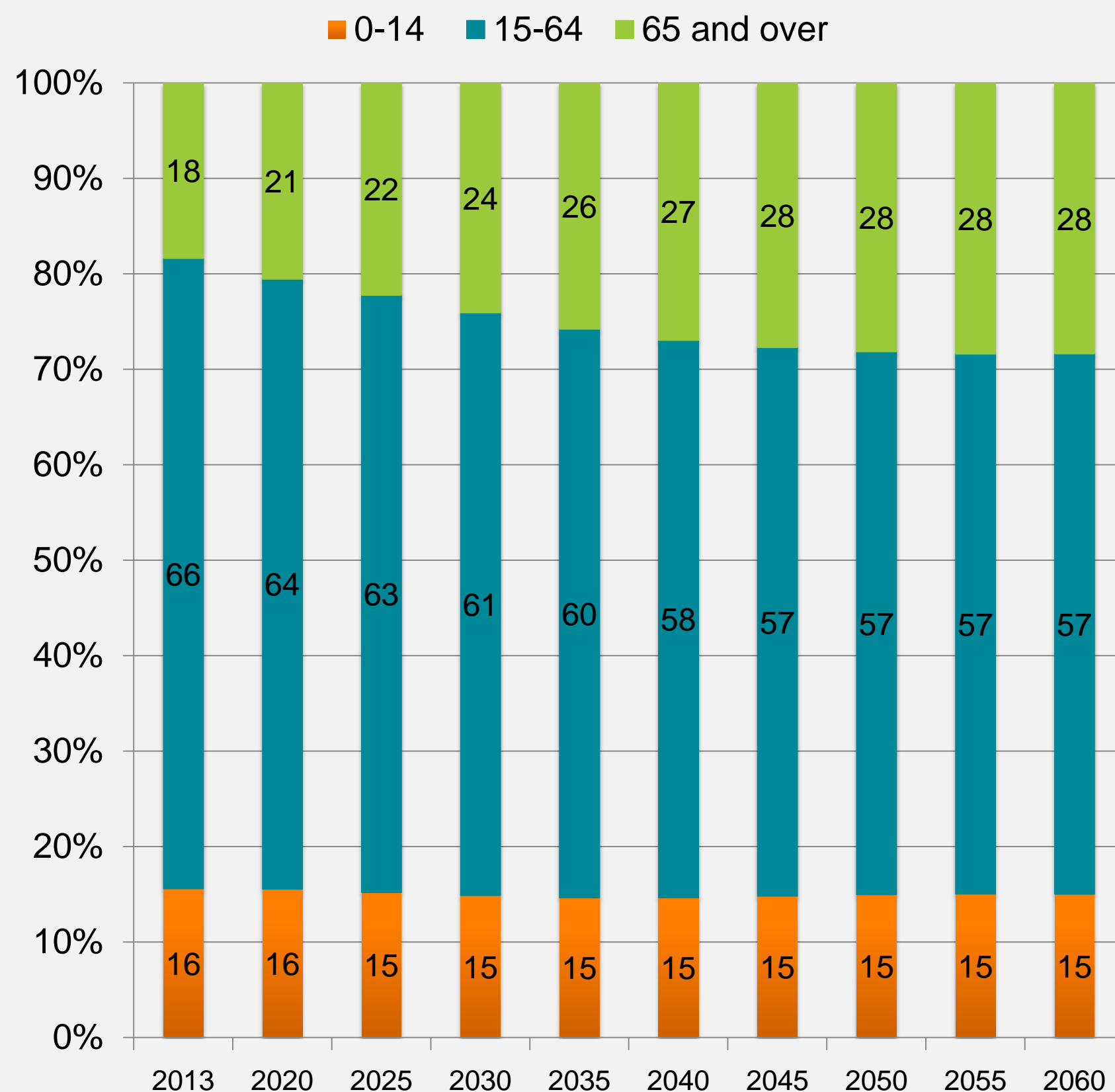
2x

2015 - 2025

Source: Projections from UN; WHO; Projected Global Healthcare Spend, expressed in nominal terms | Source: Economist intelligence Unit, World Bank, Global Insights, BMI, OECD, McKinsey Strategy & Trend Analytic Center

Demographic changes and higher longevity cause major health challenges for Europe

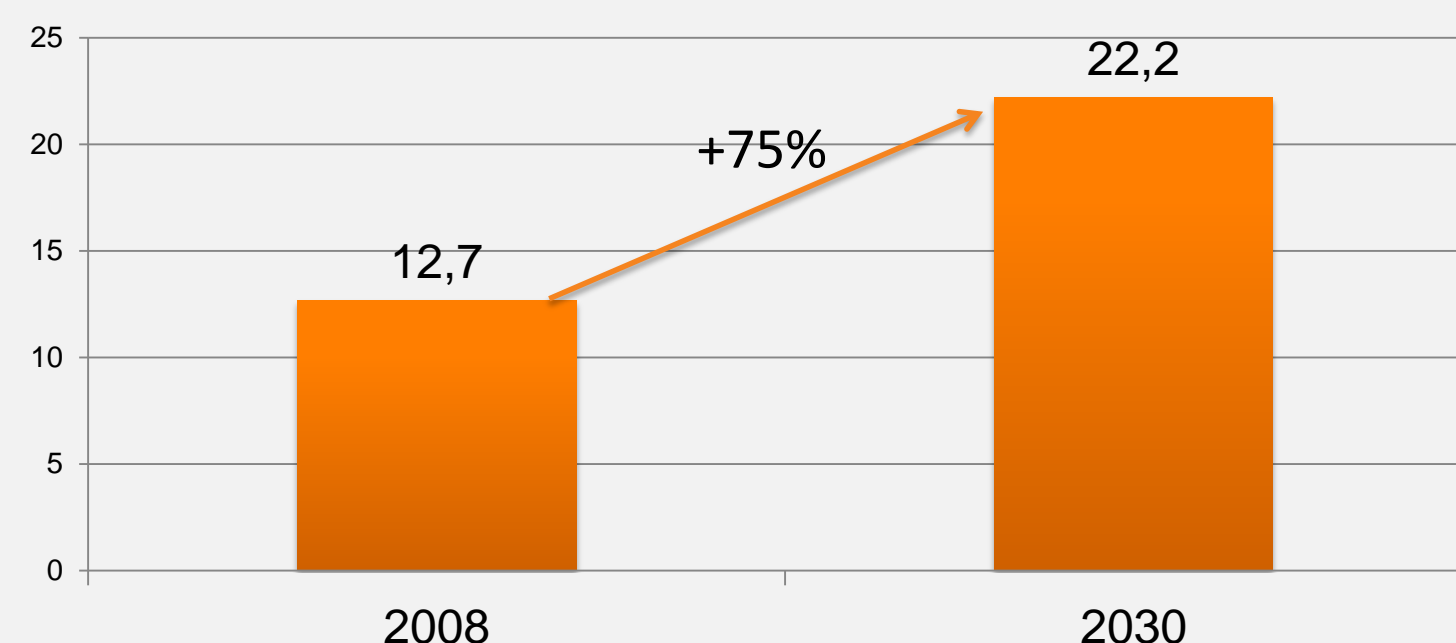
Demographic development in the EU-28*



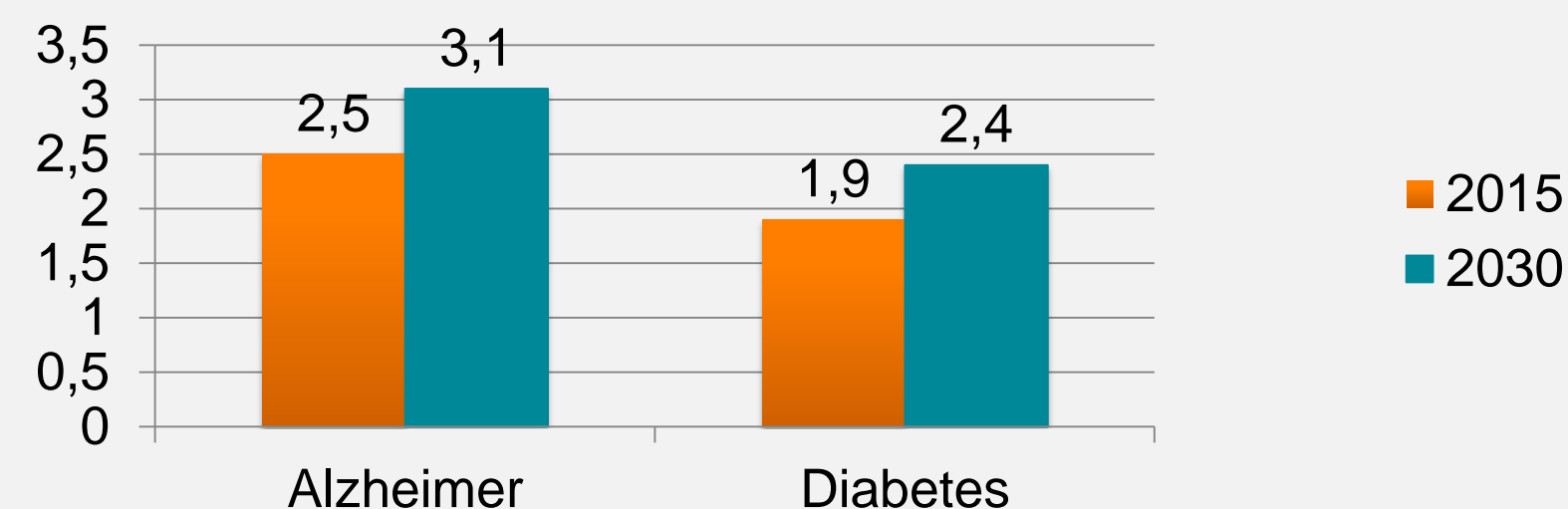
Projected increase of cancer, degenerative and chronic diseases in Europe.



Incidence of cancer in the world (million) †



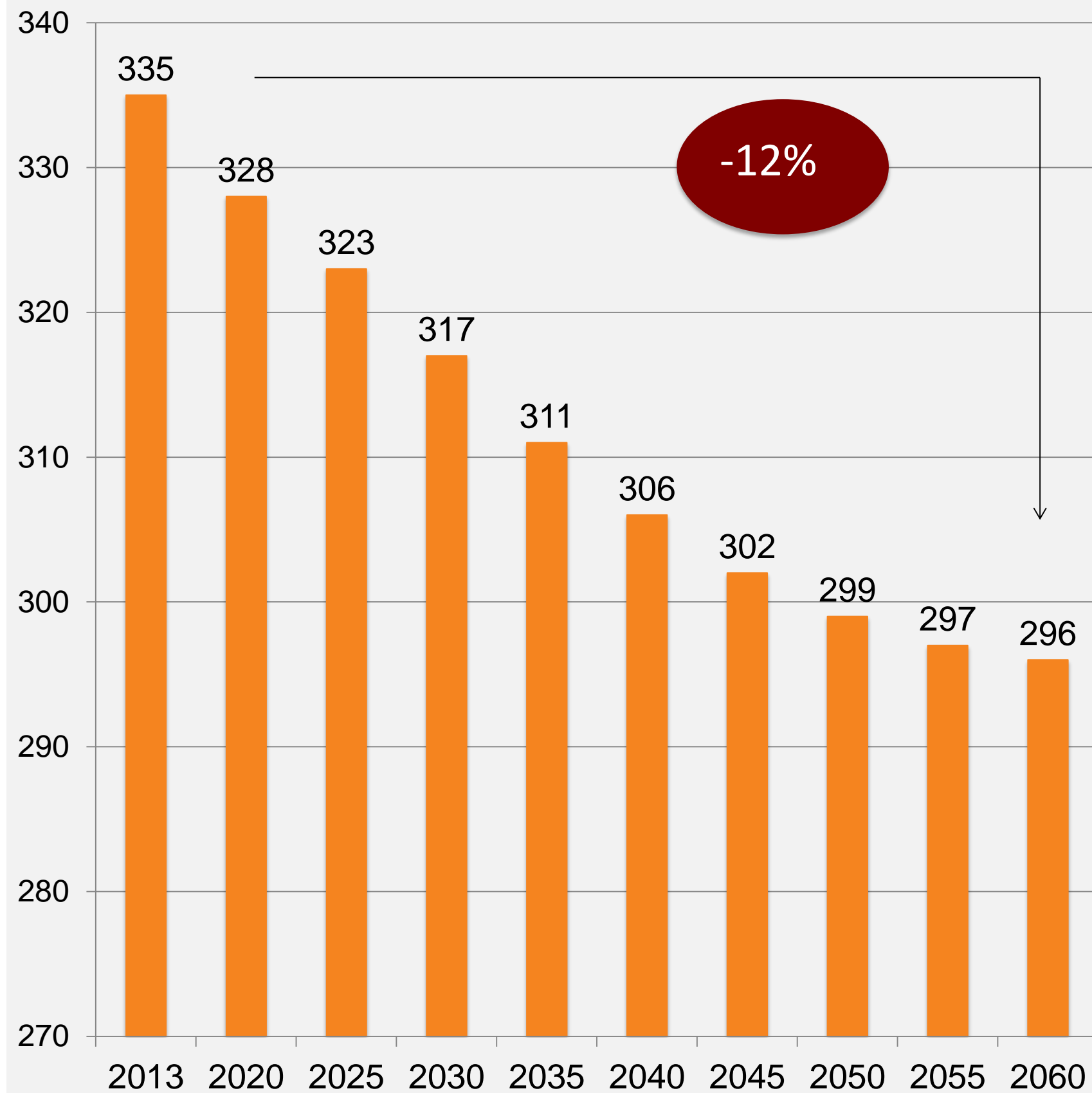
Deaths by cause in Europe (2015-2030, % of total)



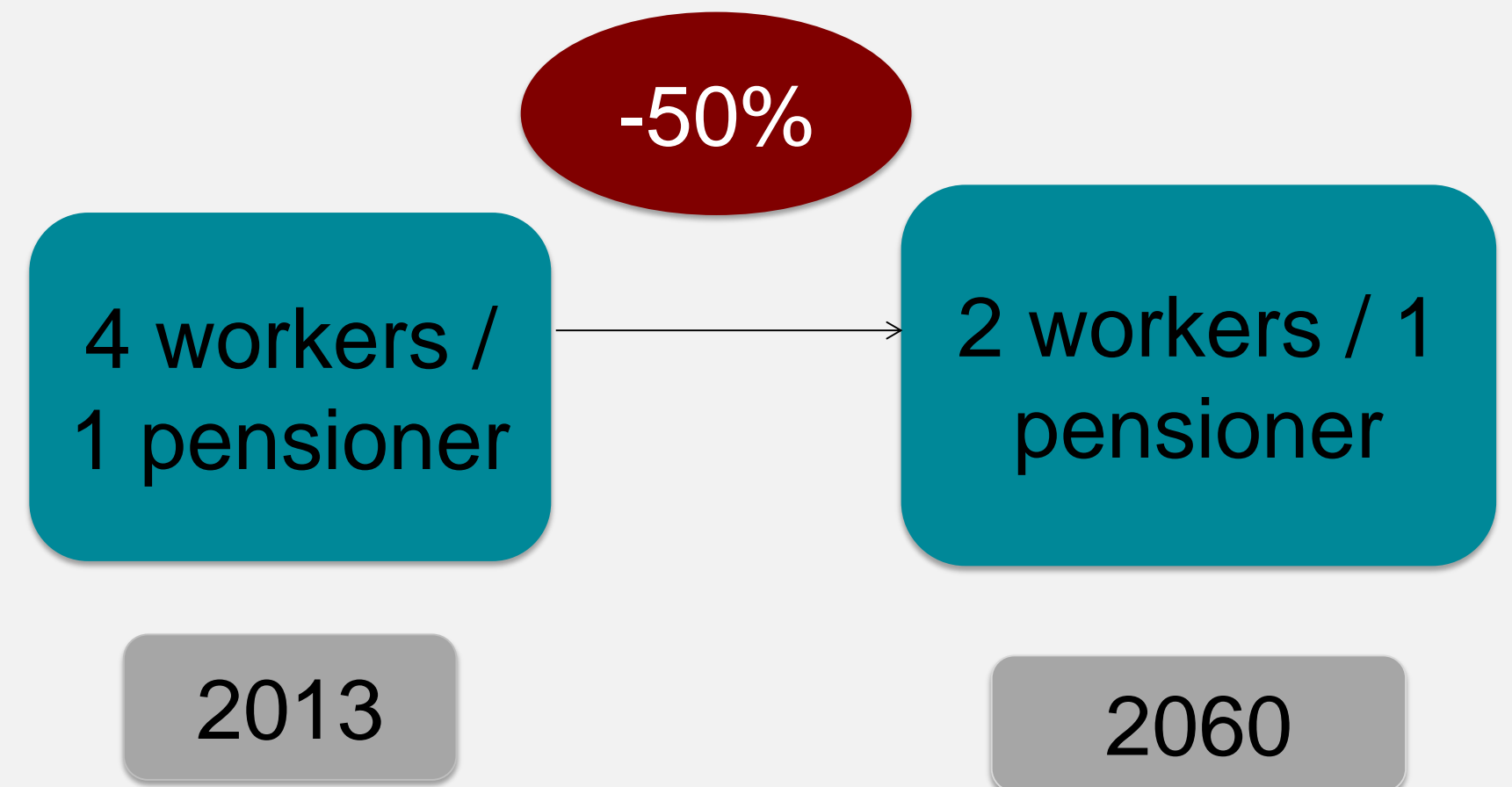
* European Commission (2015). The Aging report. Freddie Bray et al (2012). "Global cancer transition according to human index a population based study". Lancet oncology. Available at: [http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(12\)70211-5/abstract](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(12)70211-5/abstract) and the World Health Organization, projected mortality (2015-2030) (accessed in 2015)

Workforce reduction and increasing dependency ratio put increased pressure on society's healthcare financing

Social Impact: Decline in workforce due to demographic changes (mn people)*

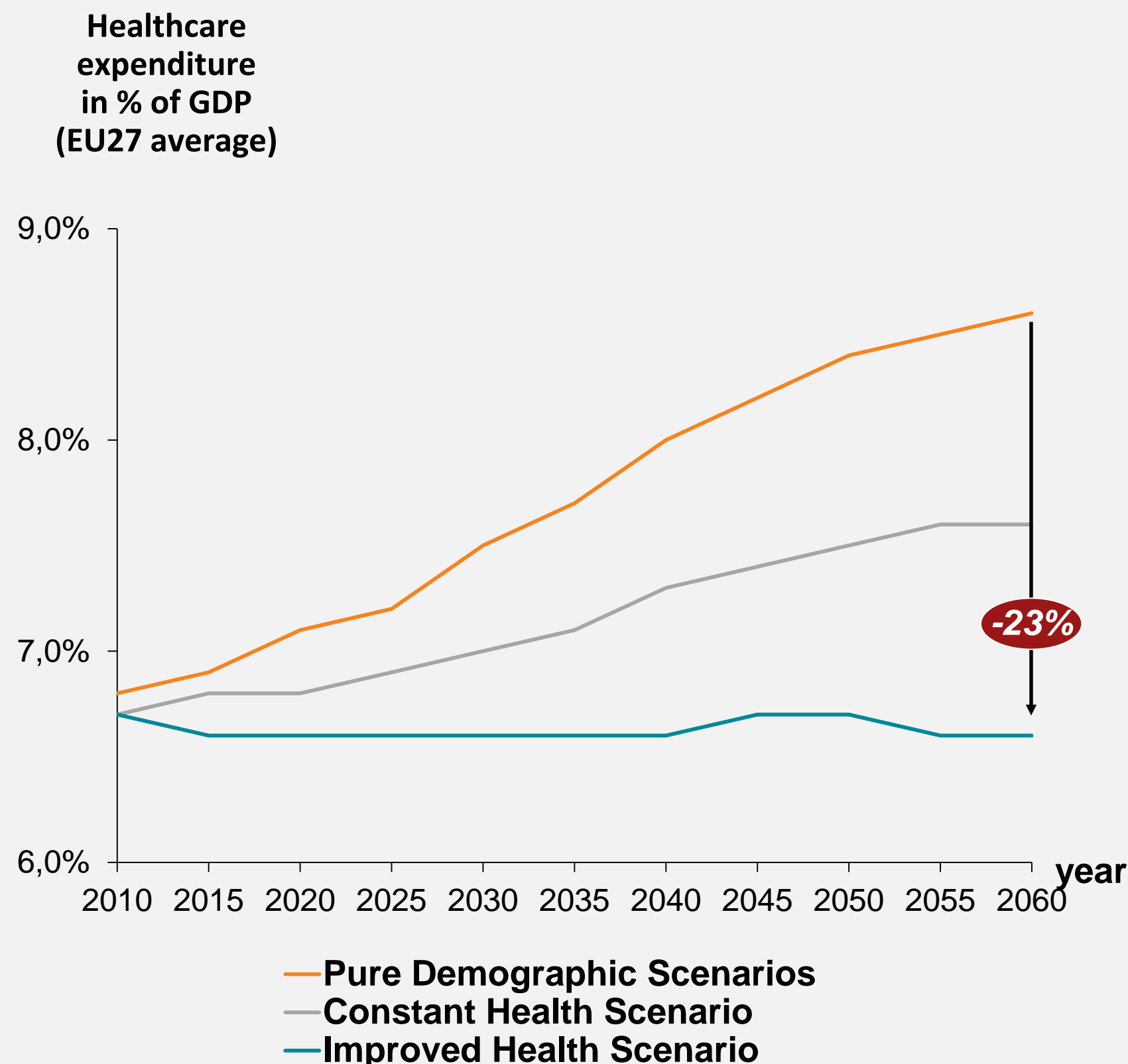


Ratio of workers to pensioners will decrease



Without new approaches the EU itself acknowledges that demographic challenge will render healthcare systems unsustainable

Healthcare Expenditure (% of GDP, EU27 average) under different scenarios



* Pure Demographic scenario:

Gains in life expectancy are assumed to be spent in disabled health while the number of years spent in good health remains constant. In this, the assumption is that health care cost per capita for each year of age remains constant in GDP per capita-adjusted terms over the whole projection period.

* Constant Health scenario:

For each year and for each age/gender, the age-related expenditure profile is shifted outwards – i.e. providing modified values of cost per capita, which are then applied in the same manner as the pure demographic scenario. For the constant health scenario, the scale of the outward shift in the age-related expenditure profile is directly proportional to the increase in life expectancy for each cohort.

* Improved Health scenario:

Similar to the constant health scenario, only the same outward shift is assumed to be multiplied by a factor of 2.

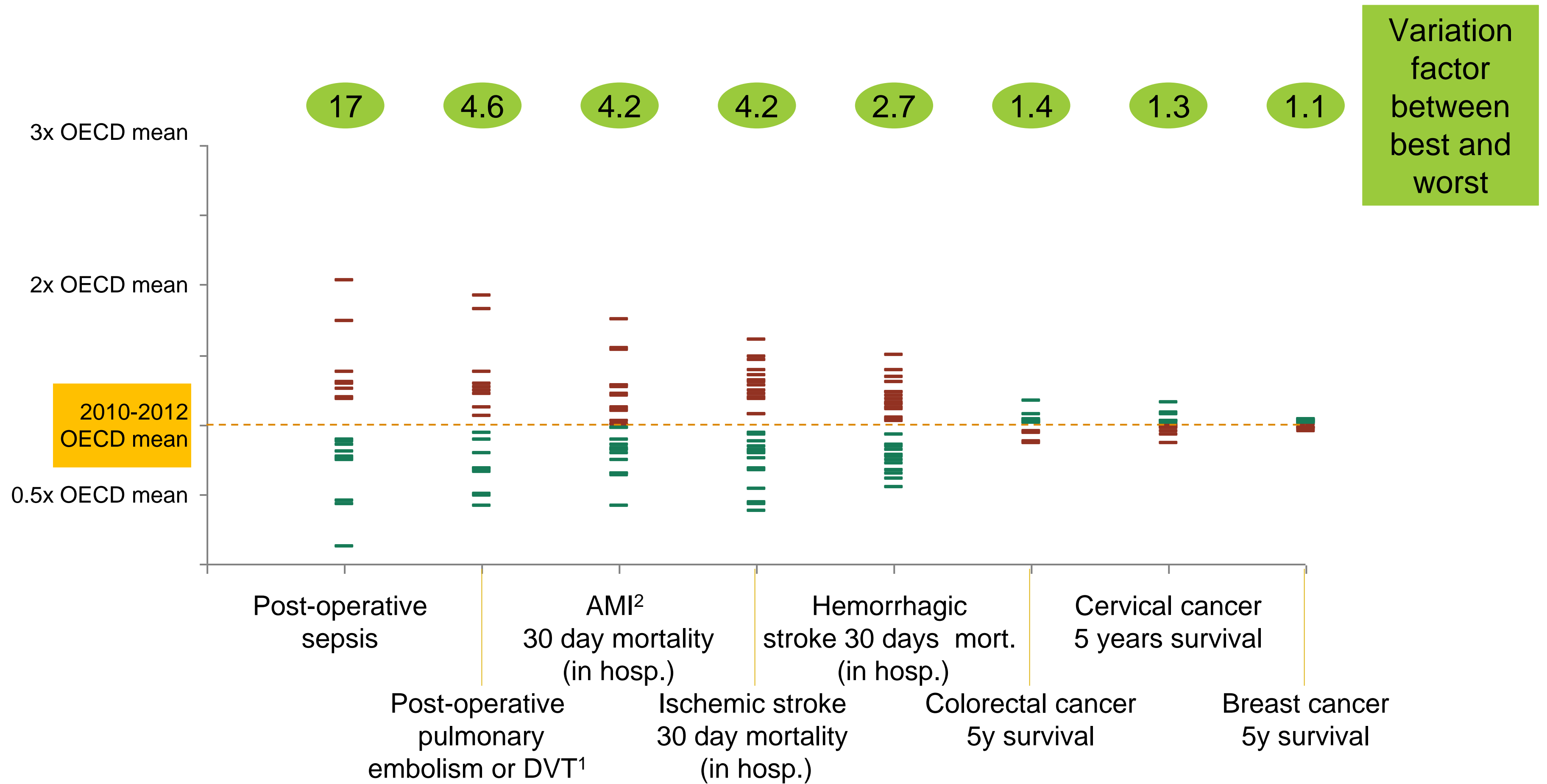
Source: European Commission: Projecting future healthcare expenditure at European level (2010)

Developing solutions for the future

VISION & RETHINKING INCENTIVES

Outcomes vary widely among developed countries

2010-2012 OECD Health outcomes indicators



1. Deep Vein Thrombosis
2. Acute Myocardial Infarction

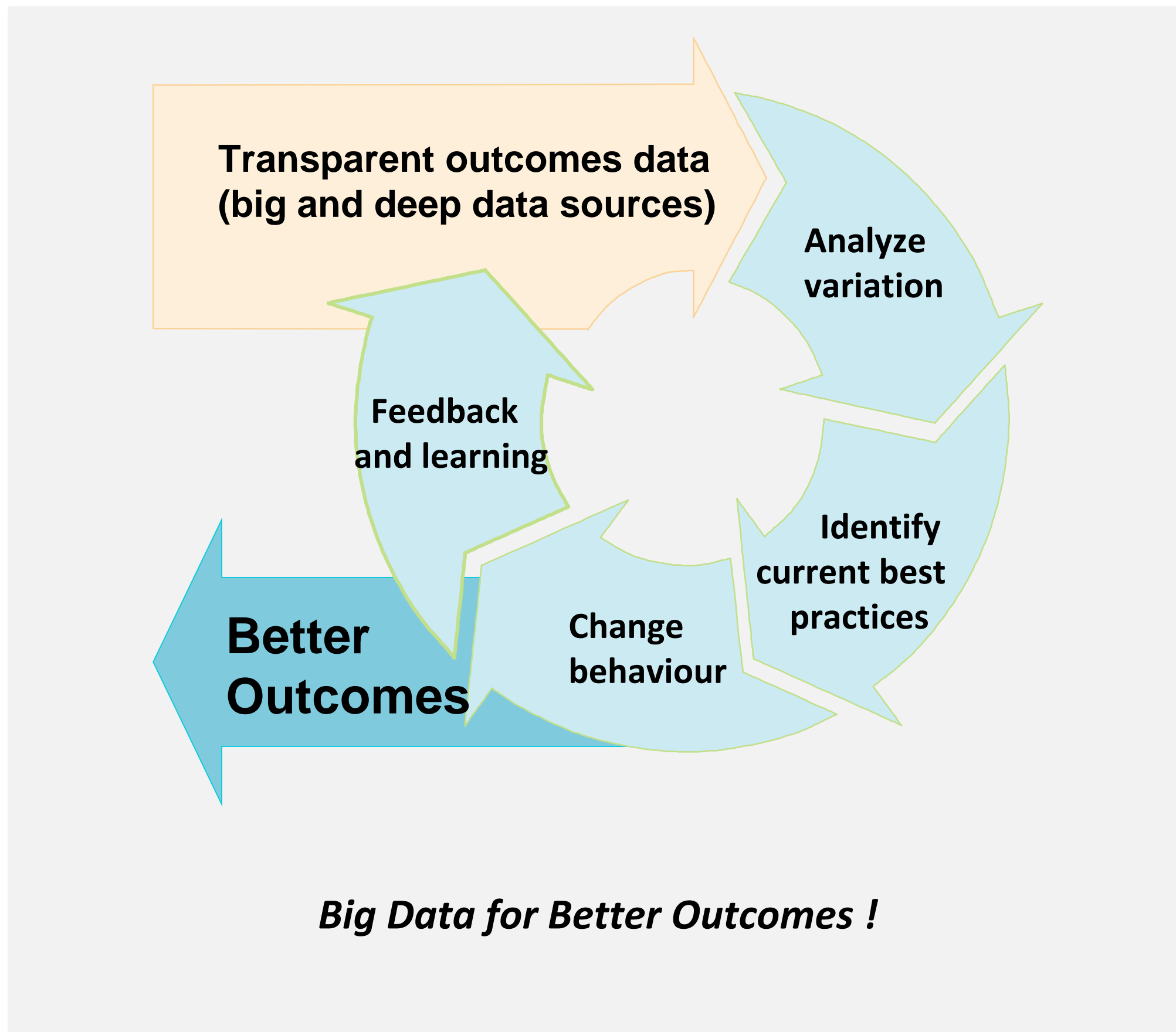
Note: Latest available data for 2012, 2011 or 2010. Mexico not included



Health data is a key driver to improve patient outcomes and health systems quality

Big Data opportunities exist to improve health outcomes...

... while contributing to system sustainability

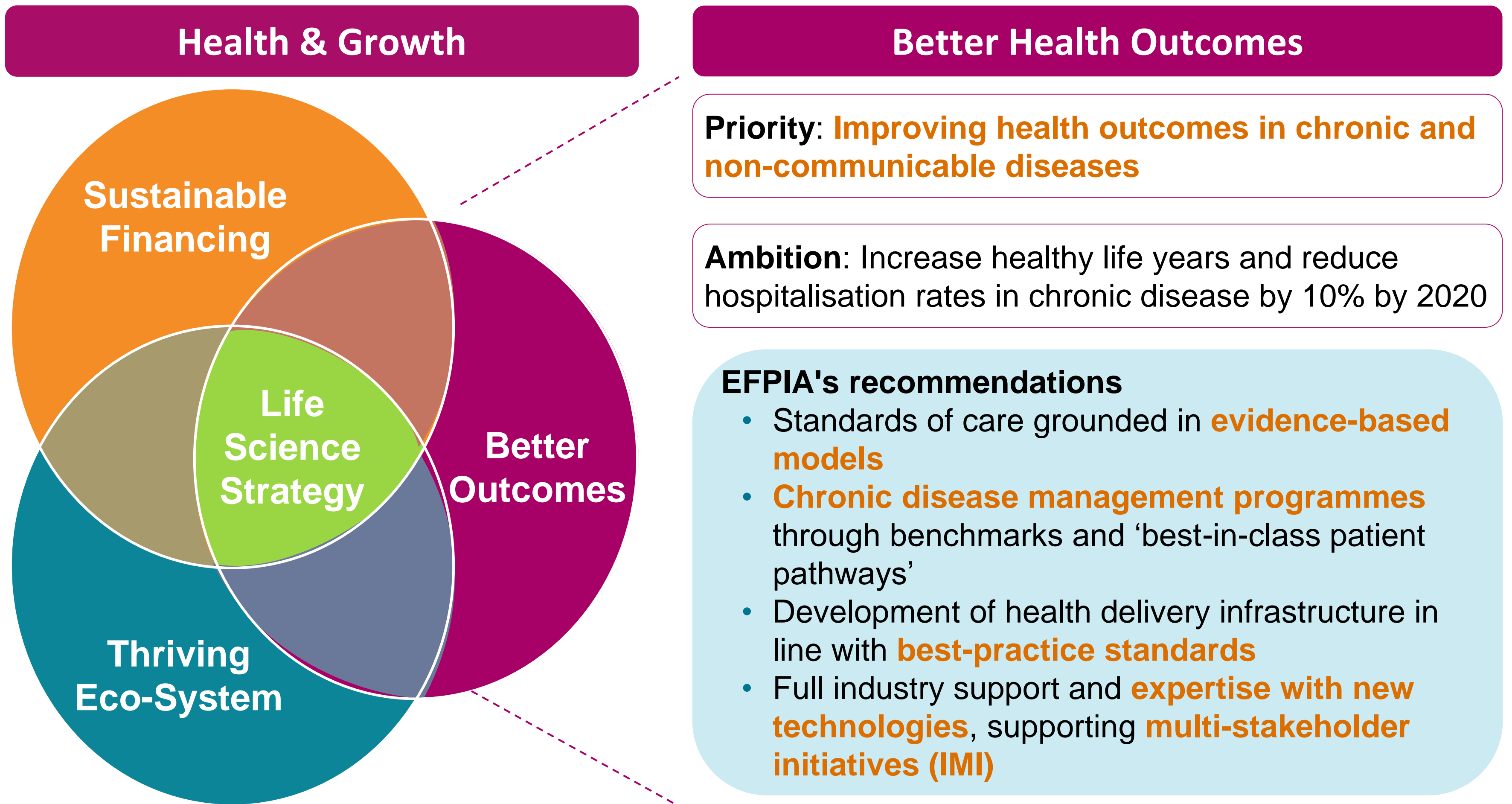


- ✓ Improved outcomes
- ✓ Reduced variation
- ✓ Reduced medical cost



**Improved
health care systems**

Improving outcomes is core to EFPIA's Health & Growth strategy



EFPIA's Collaboration with the College of European Studies

EFPIA'S PHARMA AWARDS

The EFPIA AWARD will be given to a student of the European College of Parma Foundation for a DASE Thesis covering an area of particular interest to the pharmaceutical industry.

This Award will be open to students who have followed the Seminar on “EU Pharmaceutical Policy”, and who will submit their Thesis for evaluation within 6 months following the Academic year.

- ❖ **Subject of the Thesis** – an area of particular interest to the pharmaceutical industry, chosen by the student – EN / FR
- ❖ **Guidance & support** – the Thesis will be written under the supervision of (a) Professor(s) of the College
 - Within admissible boundaries, EFPIA will offer access to information, including organisation of contacts, where appropriate
- ❖ **Academic evaluation** – the Thesis will be evaluated under the general rules applicable at the College, without intervention of EFPIA
 - Minimum mark for participation: 15/20 or higher
- ❖ **Following the pre-selection at academic level, EFPIA evaluation process,** involving the EFPIA Award Jury (including relevant expertise)
- ❖ **Evaluation criteria:**
 - Comprehensiveness
 - Coherence of argumentation
 - Understanding of fundamental issues
 - Introduction of new dimensions (innovative solutions)

The Prize for the winning Thesis includes:

- **Distribution of the Thesis** – communication of the Thesis to all EFPIA members and posting on the EFPIA website
- **A remunerated stage** – a 12-month employment contract with EFPIA (which could partly be at one of EFPIA's member associations or companies)
 - Including a net monthly remuneration of € 1,750 (*net*) + basic package (including group insurance)
 - Where appropriate, other allocations could be agreed, such as contribution for accommodation in Brussels
- **Award Ceremony**

- Website
www.efpia.eu
- By phone
+ 32.2.626 25 55 (General)
- By e-mail
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Versina.bregu@efpia.eu
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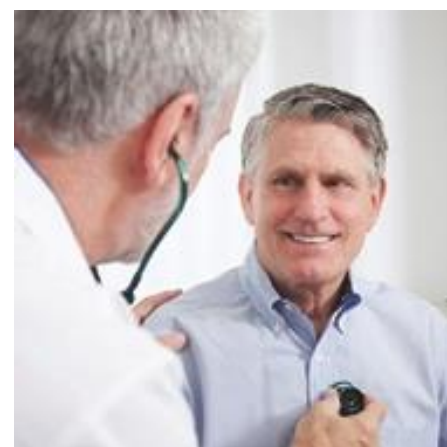
Laureates of the EFPIA Prize

Year	Winner	Topic
2013	No submission	
2014	Maria PANTUROIU	From Orphan Drugs to Personalised Medicines
2015	Versina BREGU	Pharmaceuticals in the Environment
2016	One of you!	



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