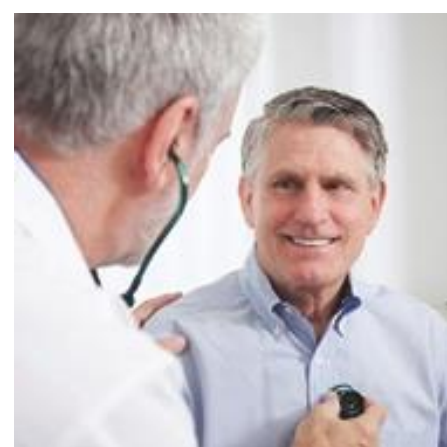




European Federation of Pharmaceutical
Industries and Associations

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

Author: **Marie-Claire PICKAERT** – EFPIA Deputy Director General



The EFPIA PRIZE
Parma, 7th April 2017



Declaration of Interest

- Marie-Claire Pickaert is a full-time employee of EFPIA, holding the position of **Deputy Director General** and is a member of its **General Management**.
- Since 2008, Marie-Claire is coordinating EFPIA's ethics and compliance activities. She is acting as the **Chief Ethics & Compliance Officer** at EFPIA.

In 2015, she was asked to take the role of **Ambassador to the Medical Communities**, coordinating EFPIA's relationships with medical & scientific societies, including learned societies, also through professional communities within the pharmaceutical companies that interact with medical communities.

- Marie-Claire Pickaert declares having **no direct / indirect financial interest** in any life science company.
- This slide deck includes **EFPIA public policy positions**, unless otherwise indicated.
- When expressing **personal opinions**, Marie-Claire will clearly indicate so.

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 15+ members.



Background to Public Policy that are relevant to Healthcare

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



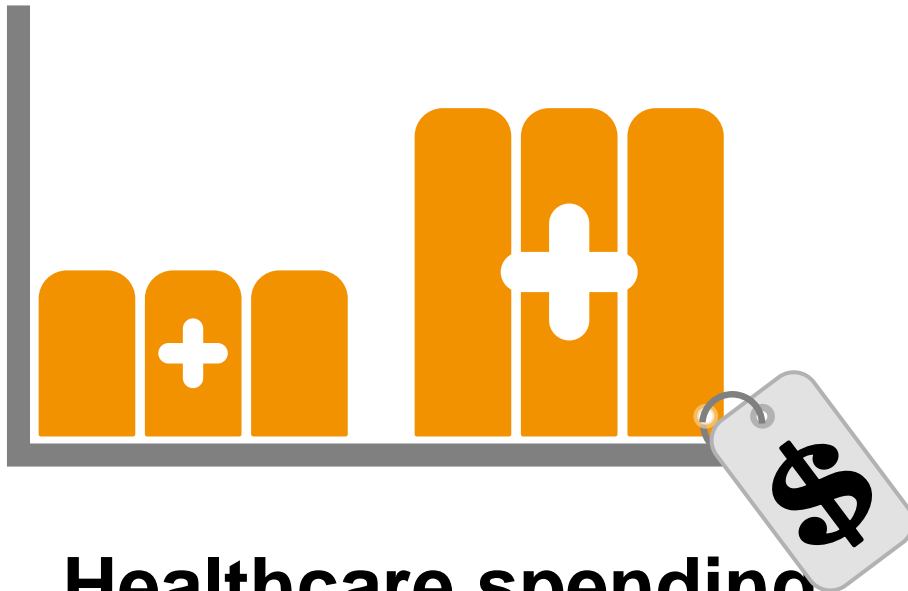
Additional 50+ year olds

>500
million



Chronic diseases

70%
of all illnesses



Healthcare spending to double

2x

2015 - 2025

2015 - 2025

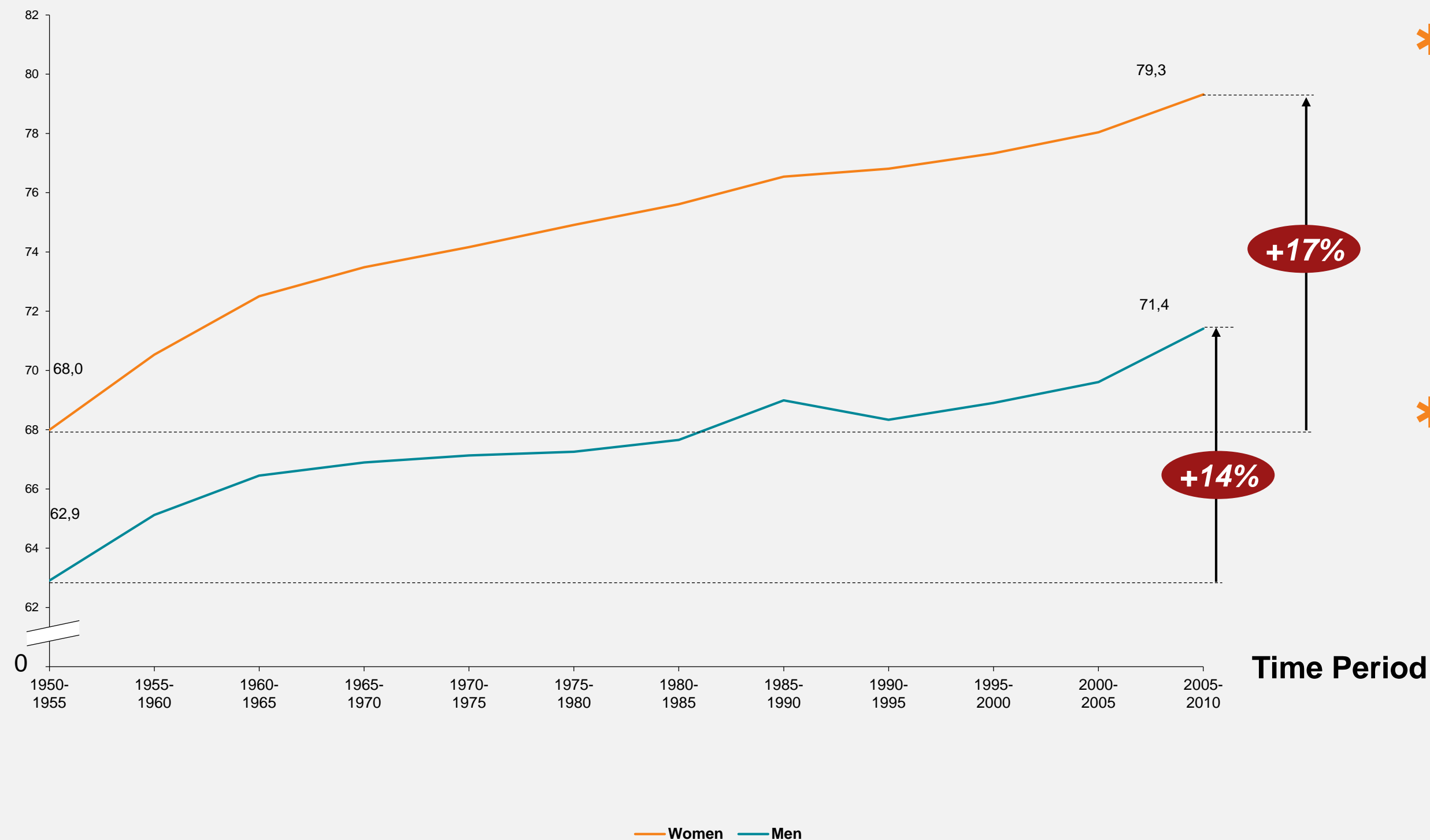
Source: Projections from UN; WHO; Projected Global Healthcare Spend, expressed in nominal terms | Source: Economist intelligence Unit, World Bank, Global Insights, BMI, OECD, McKinsey Strategy & Trend Analytic Center

Over the last 60 years, Europe has made great strides in improving life expectancy (increasing by 14-17 %)

Life expectancy at birth for EU27 countries (1950-2010)



Life Expectancy (years)



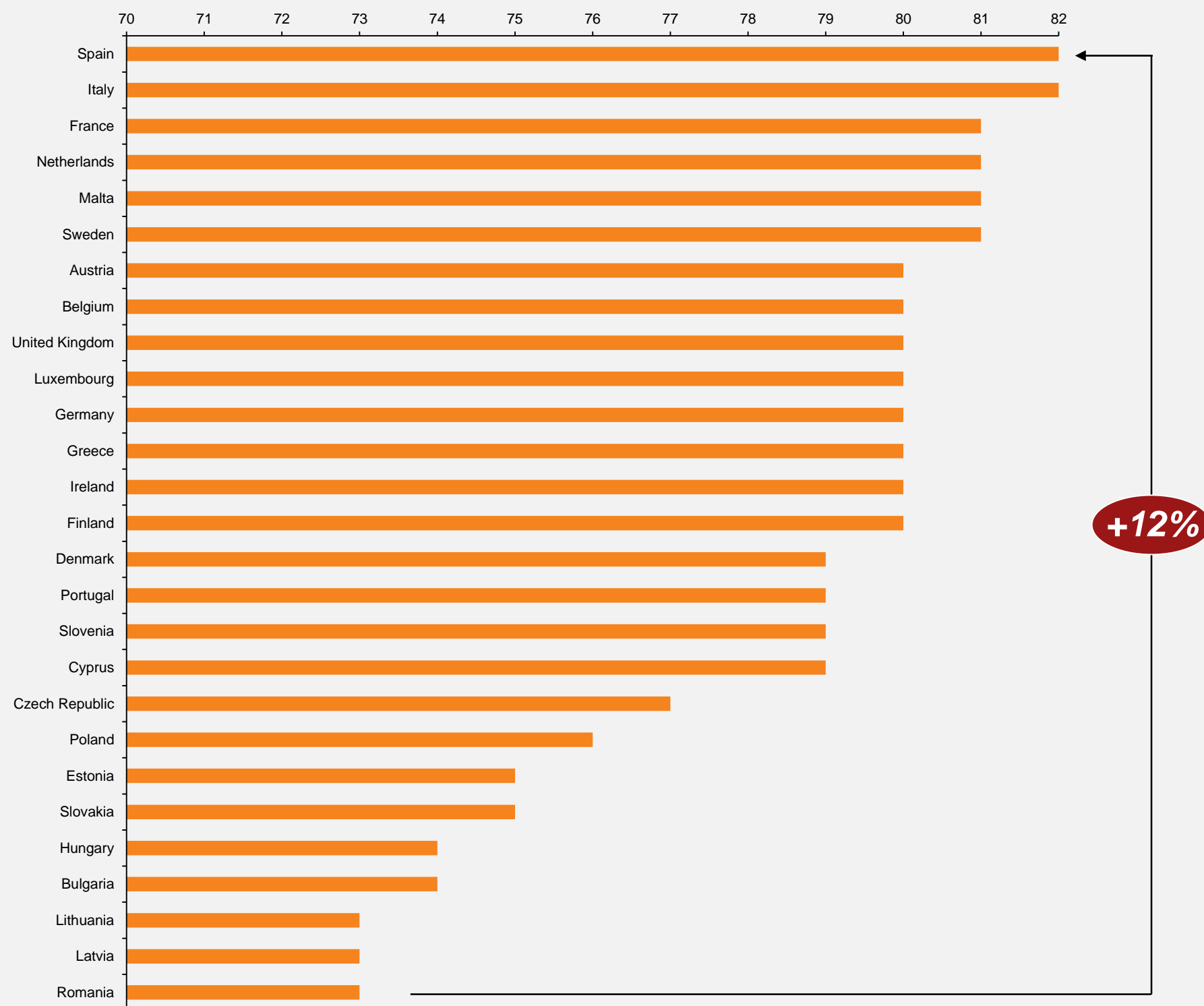
- * During the last 60 years, both male and female life expectancies have improved substantially across Europe.
- * Better health status resulting from improved care and prevention has its part in this improvement

However wide variations in health attainments remain across Europe, amounting to almost a decade of life expectancy

Life expectancy at birth – 2011



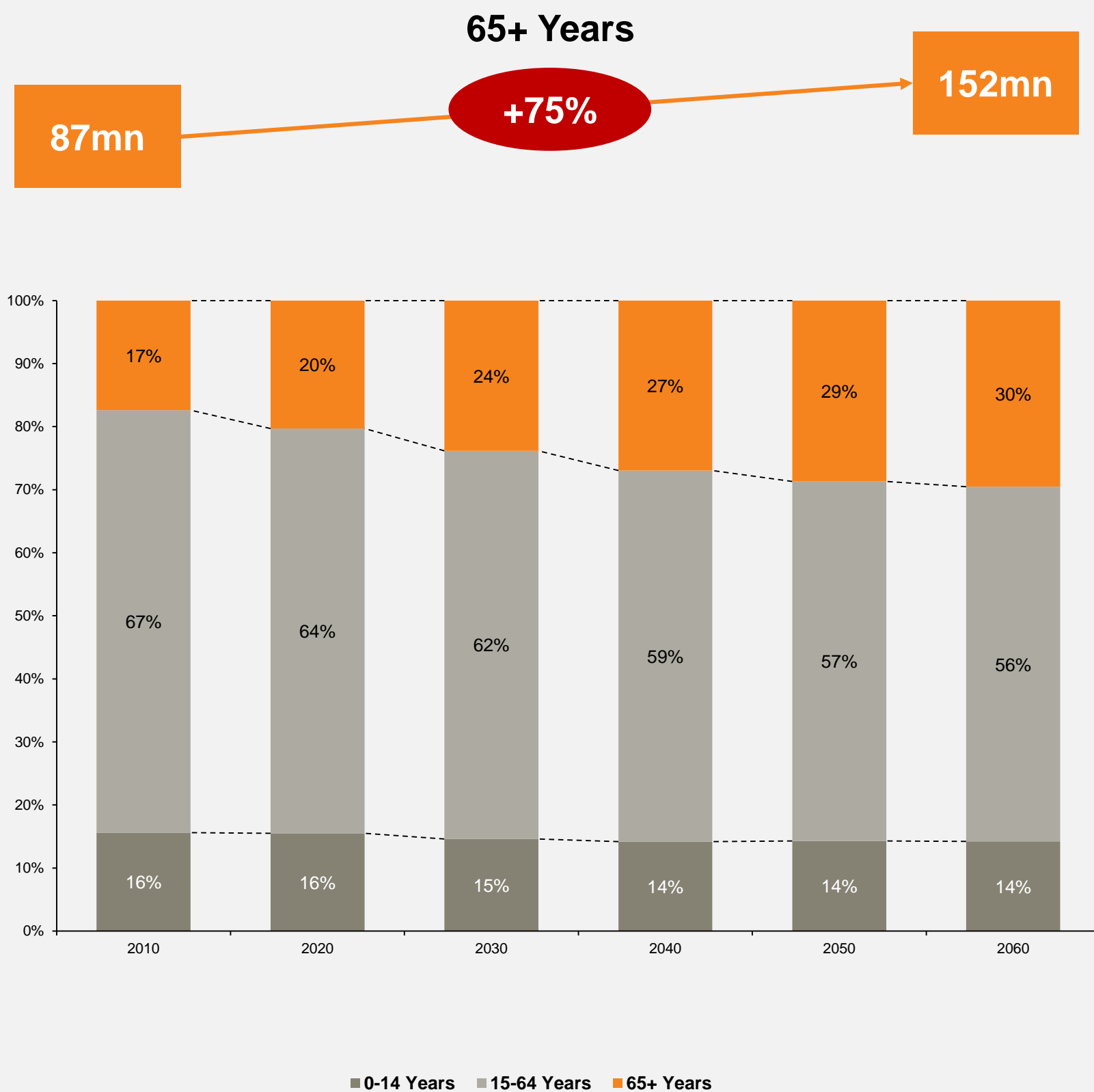
Life Expectancy at birth in 2011 (years))



- * While health outcomes have improved throughout Europe over the last 50 years, a 12% variation (equal to 9 years) in life expectancy exists between country with highest and lowest life expectancy.
- * Cumulative differences in life expectancy between each country and highest life expectancy amounts to over 1.22 billion life years.
- * While variations are most observable with countries that joined the EU just over 10 years, wide variations also exist between countries with highest life expectancy.

Looking to the future, Europe needs to find solutions to pressing demographic challenges that will impact health and social spending

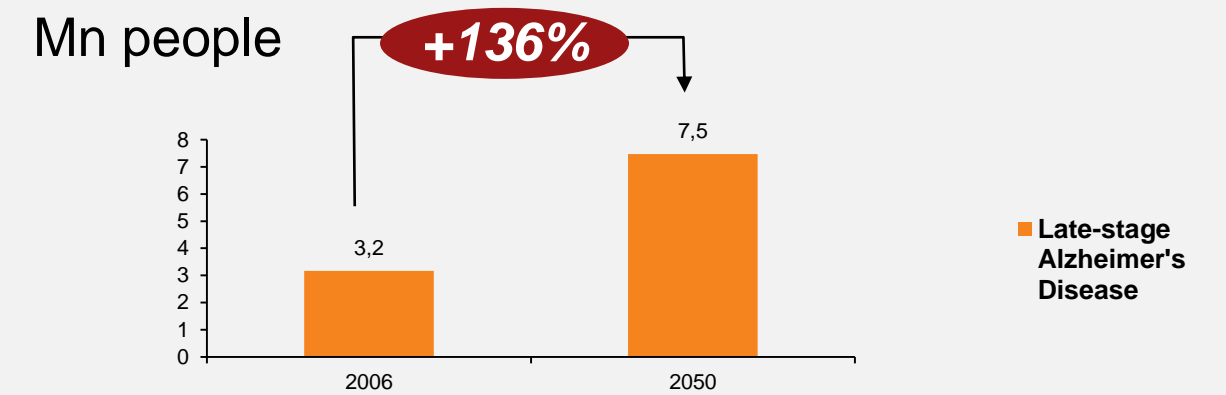
Demographic Development*



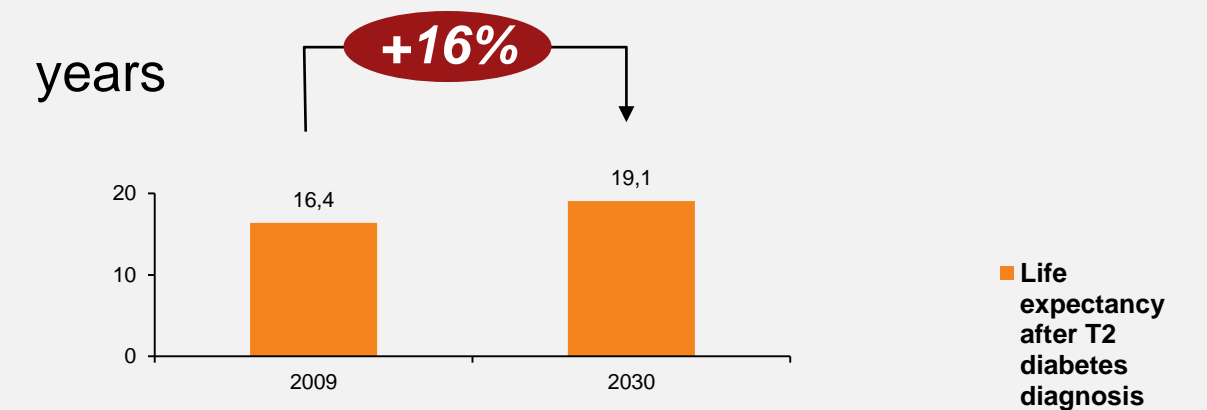
System Impact: Severity, length and increased incidence



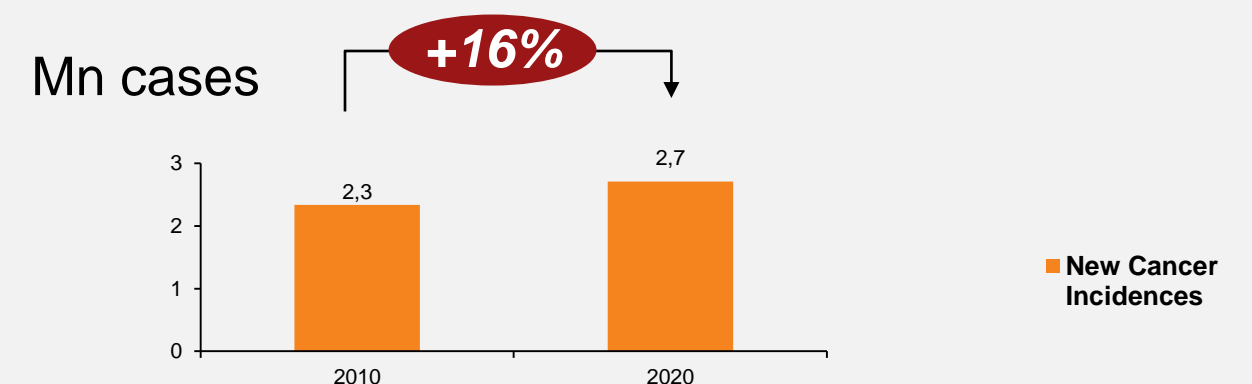
Increase in severity of Degenerative Diseases†



Extended impact of Chronic Diseases△



Increased incidence of Cancer#

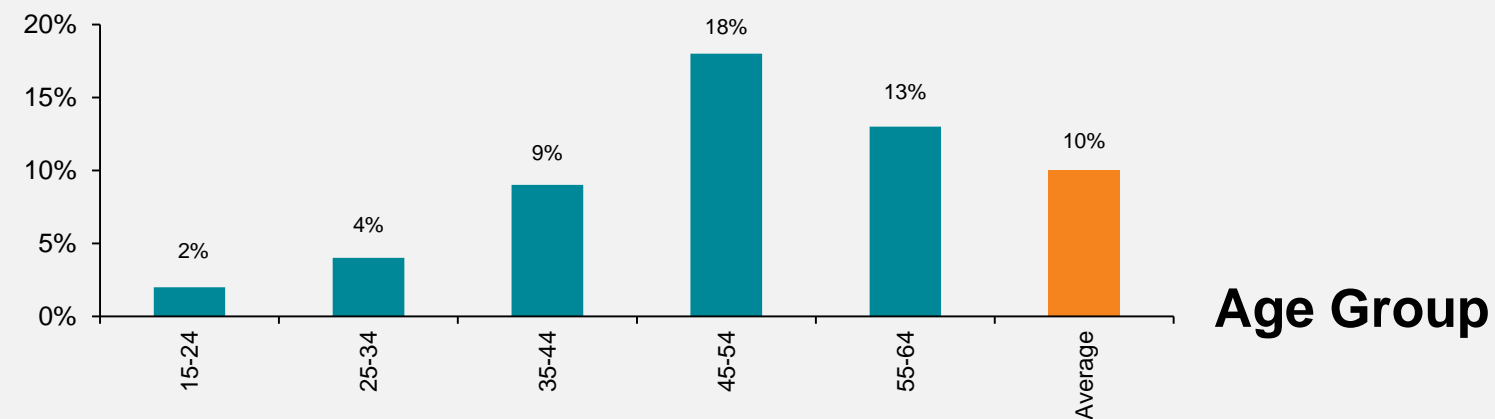


Health is a major cause of productivity loss and early labour market exit, with many causes being addressable

Health as a cause of leaving job



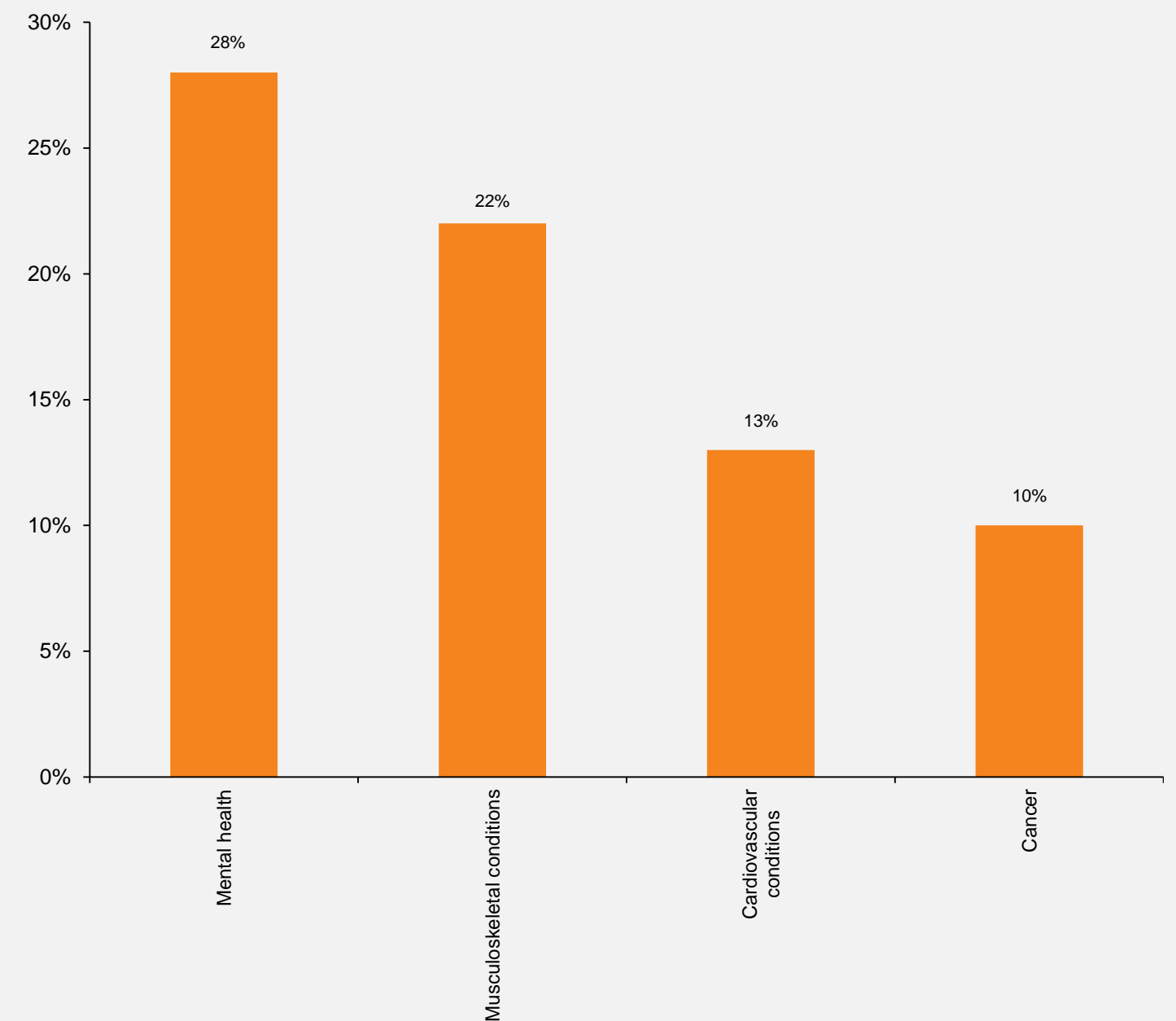
Left last job for reasons of health



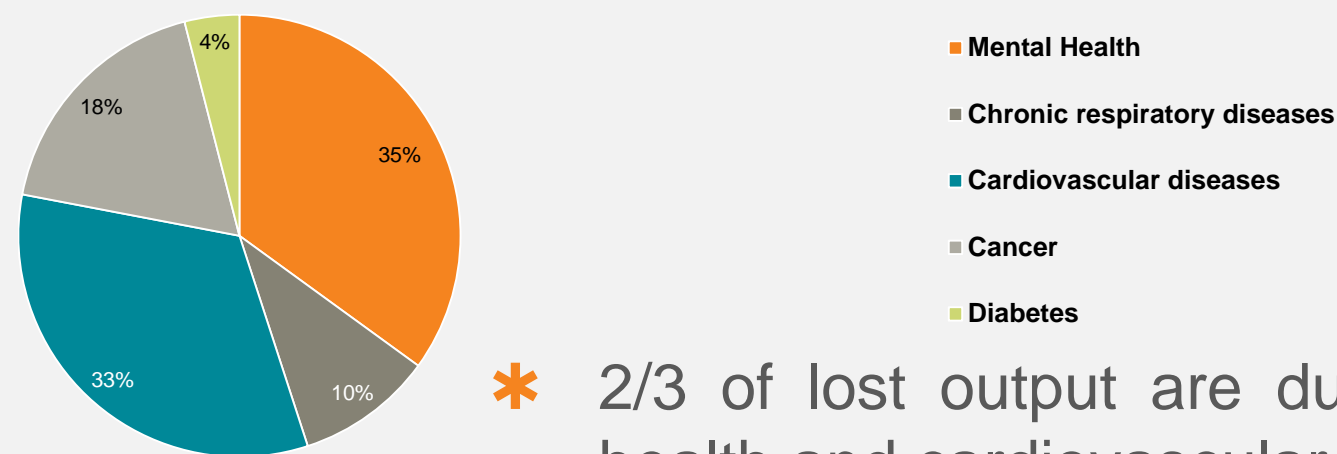
Determinants for health-related early labour market exits in Austria (% of exists)



% of market exists



Health related causes for loss of output

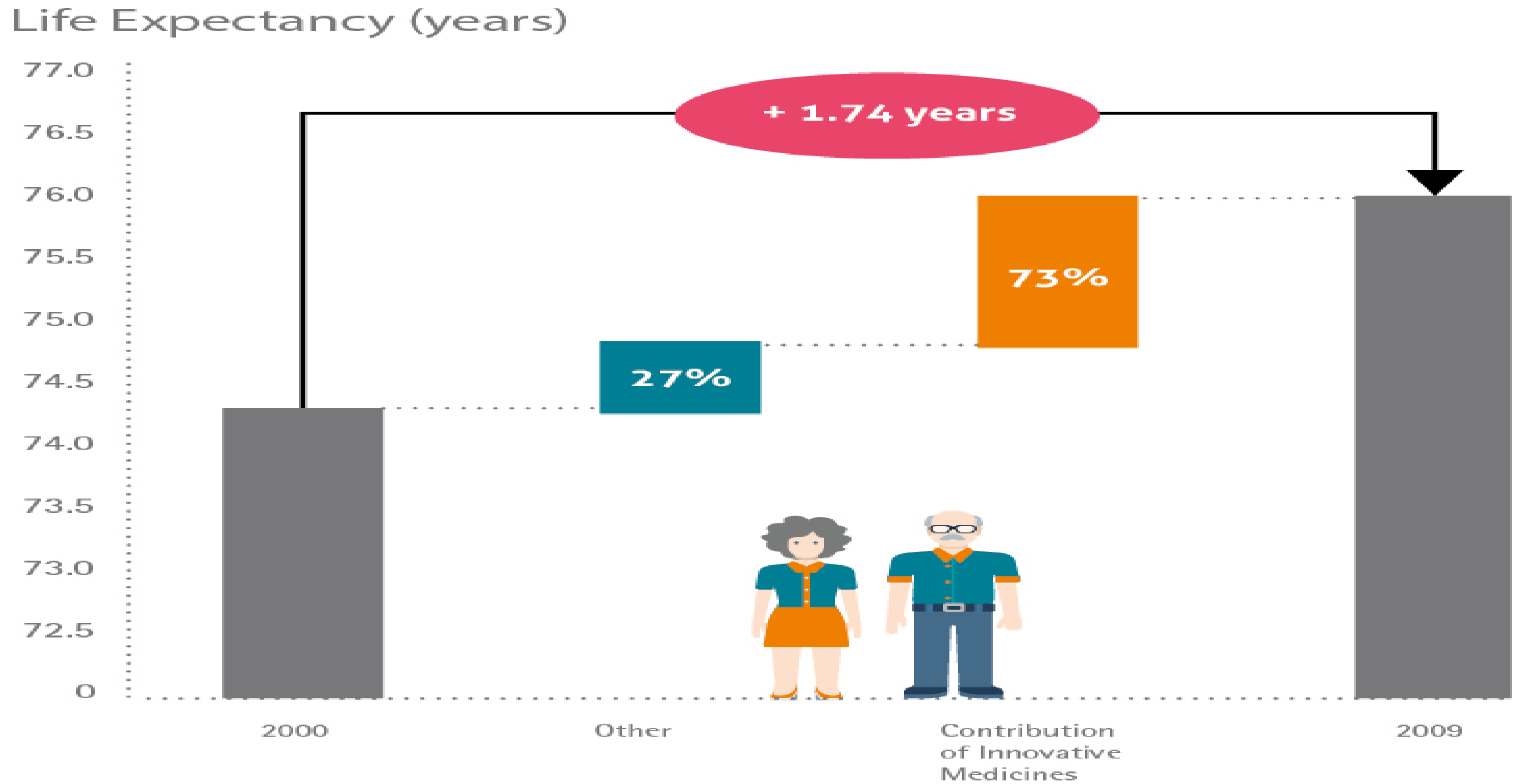


* 2/3 of lost output are due to mental health and cardiovascular diseases.

Note: Percentage of people that were previously employed and answered the main reason for leaving their job was 'Own illness or disability'

Source: European Commission: Health of People of Working Age(2011); European Commission: Health Systems and Health care in the EU (2012)

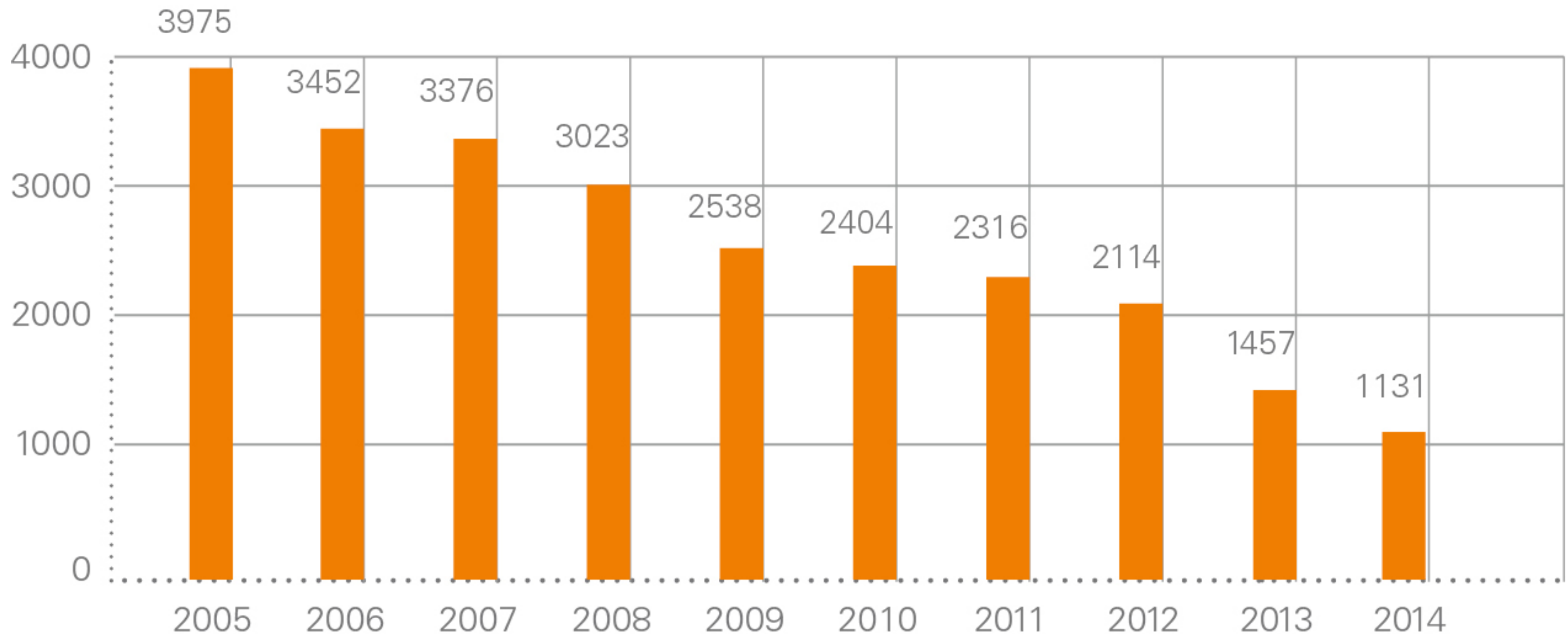
CONTRIBUTION OF INNOVATIVE MEDICINES TO INCREASE IN LIFE EXPECTANCY 2000-2009



Source: Lichtenberg, F: Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000-2009 (2012); in EFPIA in Figures, www.efpia.eu

TOTAL NUMBER OF DEATHS AMONG AIDS CASES IN EUROPE

HIV/AIDS Surveillance in Europe 2014



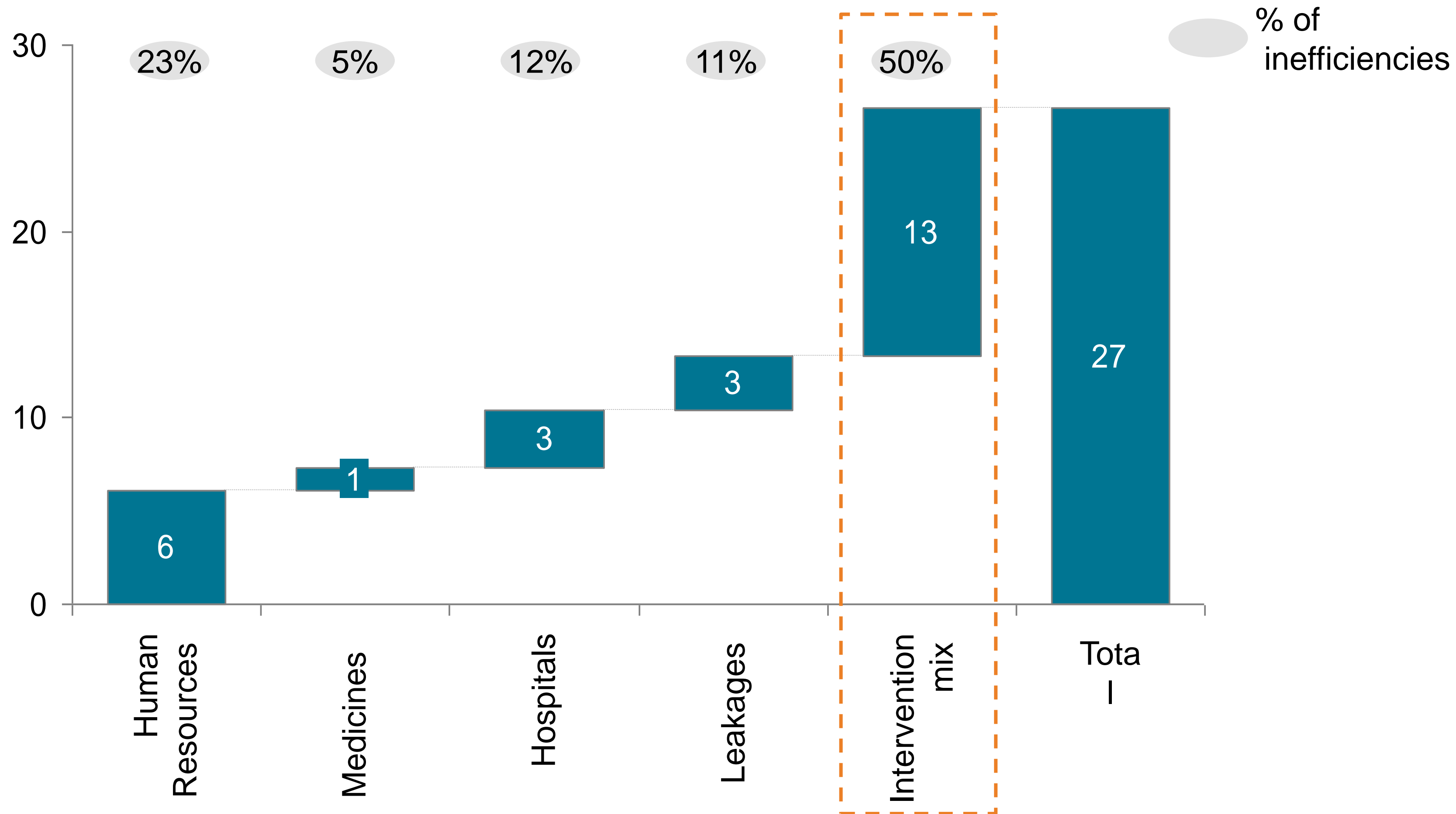
Europe = total European Union and European Economic Area

Source: WHO Regional Office for Europe and European Centre of Disease Prevention and Control (ECDC, December 2013; in EFPIA in Figures, www.efpia.eu)

Estimated 20-40% inefficiencies in health systems, with practice variation accounting for half of them

HC inefficiencies (%)

mean estimate for the different archetypes of countries combined





The Pharma Industry in Europe

PHARMA INDUSTRY IN EUROPE: Key Economic Indicators



INDUSTRY (EFPIA total)

2000

2010

2014

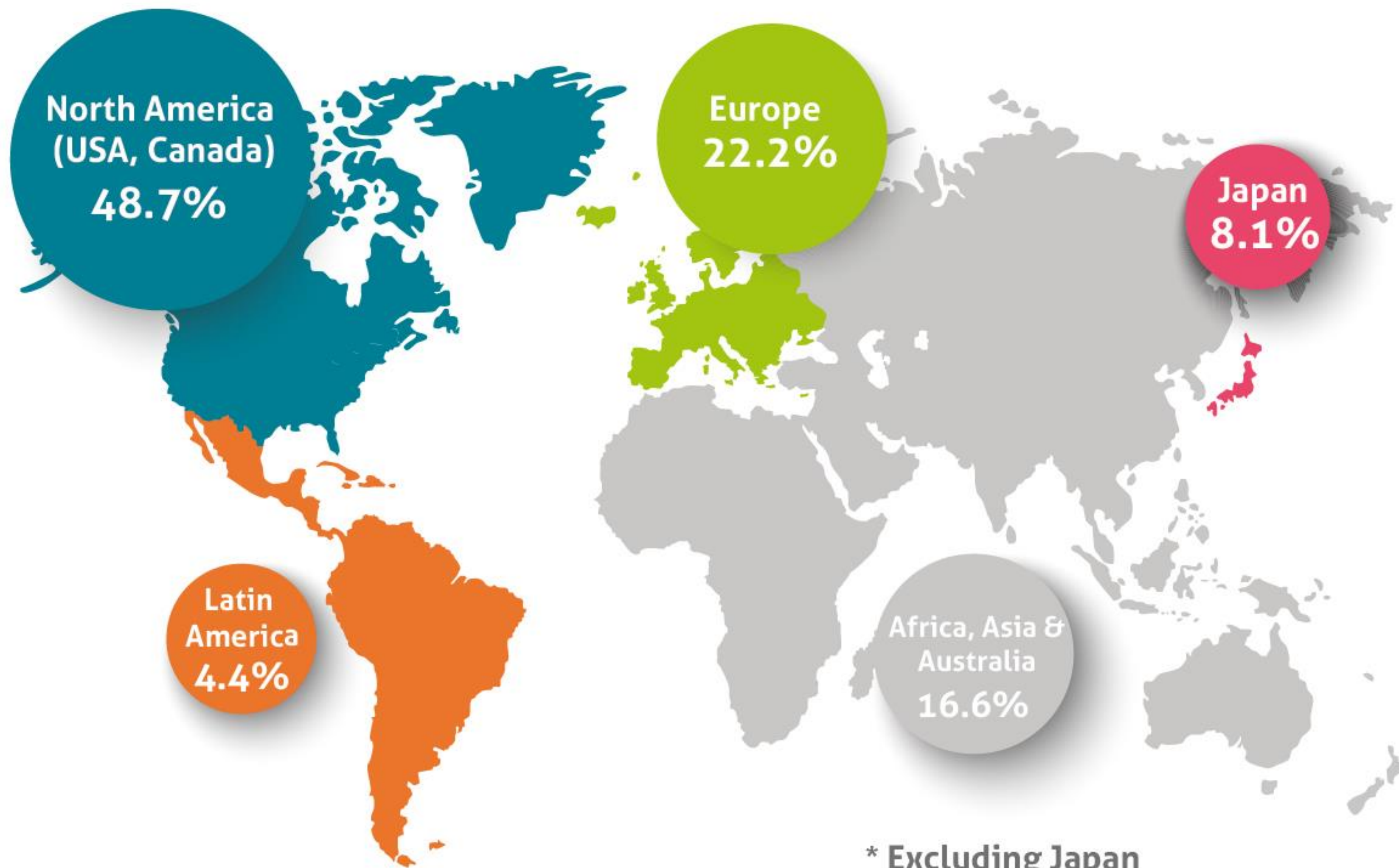
2015

	Production	125,316	199,400	221,088	225,000 (e)
	Exports (1) (2)	90,935	276,357	324,452	361,500 (e)
	Imports	68,841	204,824	251,427	275,000 (e)
	Trade balance	22,094	71,533	73,025	86,500 (e)
	R&D expenditure	17,849	27,920	30,887	31,500 (e)
	Employment (units)	534,882	670,088	723,448	725,000 (e)
	R&D employment (units)	88,397	117,035	118,052	118,000 (e)
	Total pharmaceutical market value at ex-factory prices	86,446	153,118	183,924	192,000 (e)
	Payment for pharmaceuticals by statutory health insurance systems (ambulatory care only)	76,909	129,464	124,273	126,000 (e)

Source: EFPIA in Figures, www.efpia.eu

BREAKDOWN OF THE WORLD PHARMACEUTICAL MARKET – 2015 sales

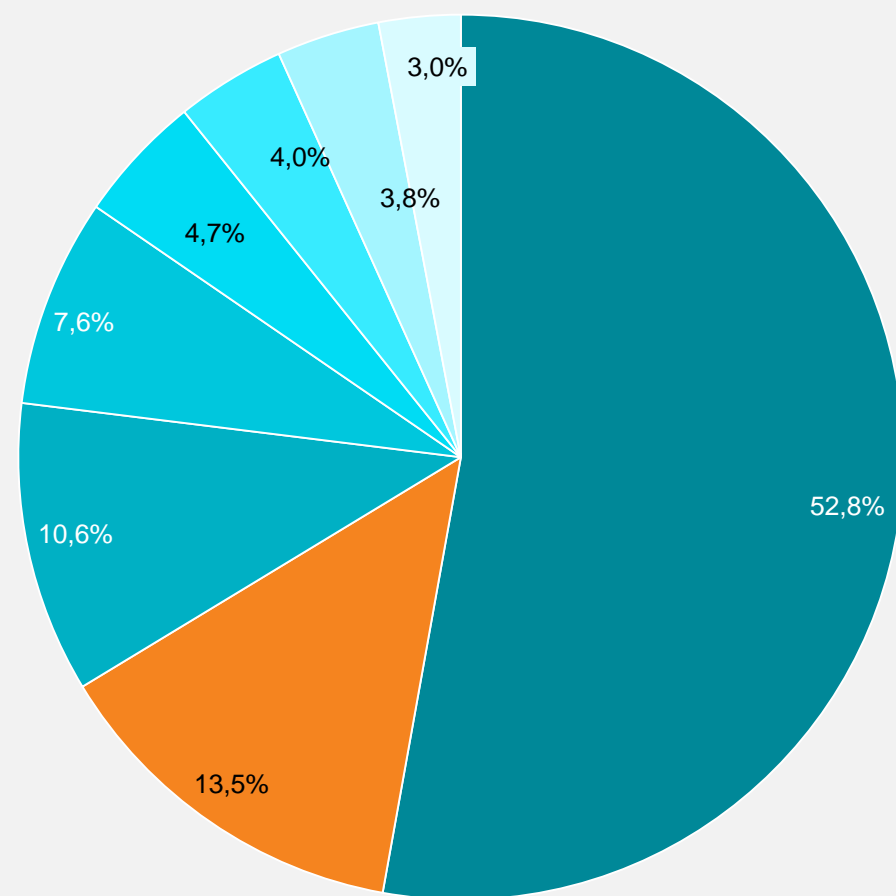
May 2016 (data related to the 2015 audited global retail and hospital pharmaceutical market at ex-factory prices)



* Excluding Japan

Overall medicines across Europe represent less than 15 % of total expenditure although variances exist between therapy areas

Total healthcare expenditure by function (2010, pop.-weighted, current prices, PPP, \$)*



- Curative and rehabilitative care
- Medicines
- Long-term nursing care
- Other Medical Goods
- Ancillary services
- Health administration and health insurance
- Other
- Prevention and public health services

Medicines contribution to disease cost (2011, various diseases)



Cost factor	COPD [†]	Diabetes [†]	CHF [†]	Alzheimers ^Δ	Prostate Cancer [#]
Care	21%	8%	6%	9%	34%
Hospitalisation	30%	22%	64%	11%	31%
Indirect Cost	22%	35%	18%	76%	N/A
Other Cost	14%	20%	6%	1%	2%
Medication	14%	15%	5%	3%	34%

BREAKDOWN OF THE RETAIL PRICE OF A MEDICINE

Non-weighted average for Europe



Manufacturer
65.9%



Wholesaler
4.8%



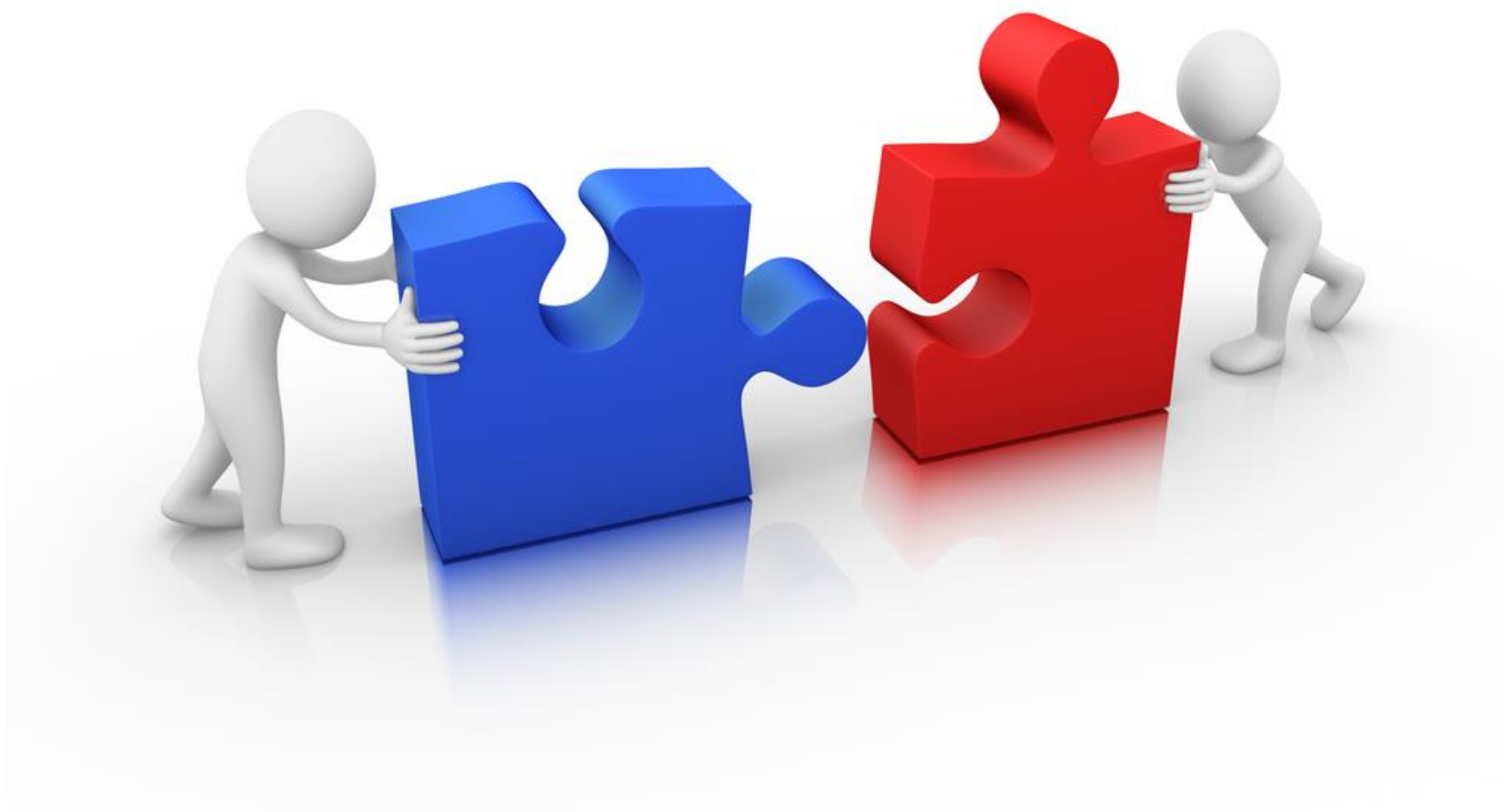
Pharmacist
19.8%



State (VAT and other taxes)
9.5%

Based on average estimate for 22 countries.

Source: EFPIA Member Associations; in EFPIA in Figures, www.efpia.eu



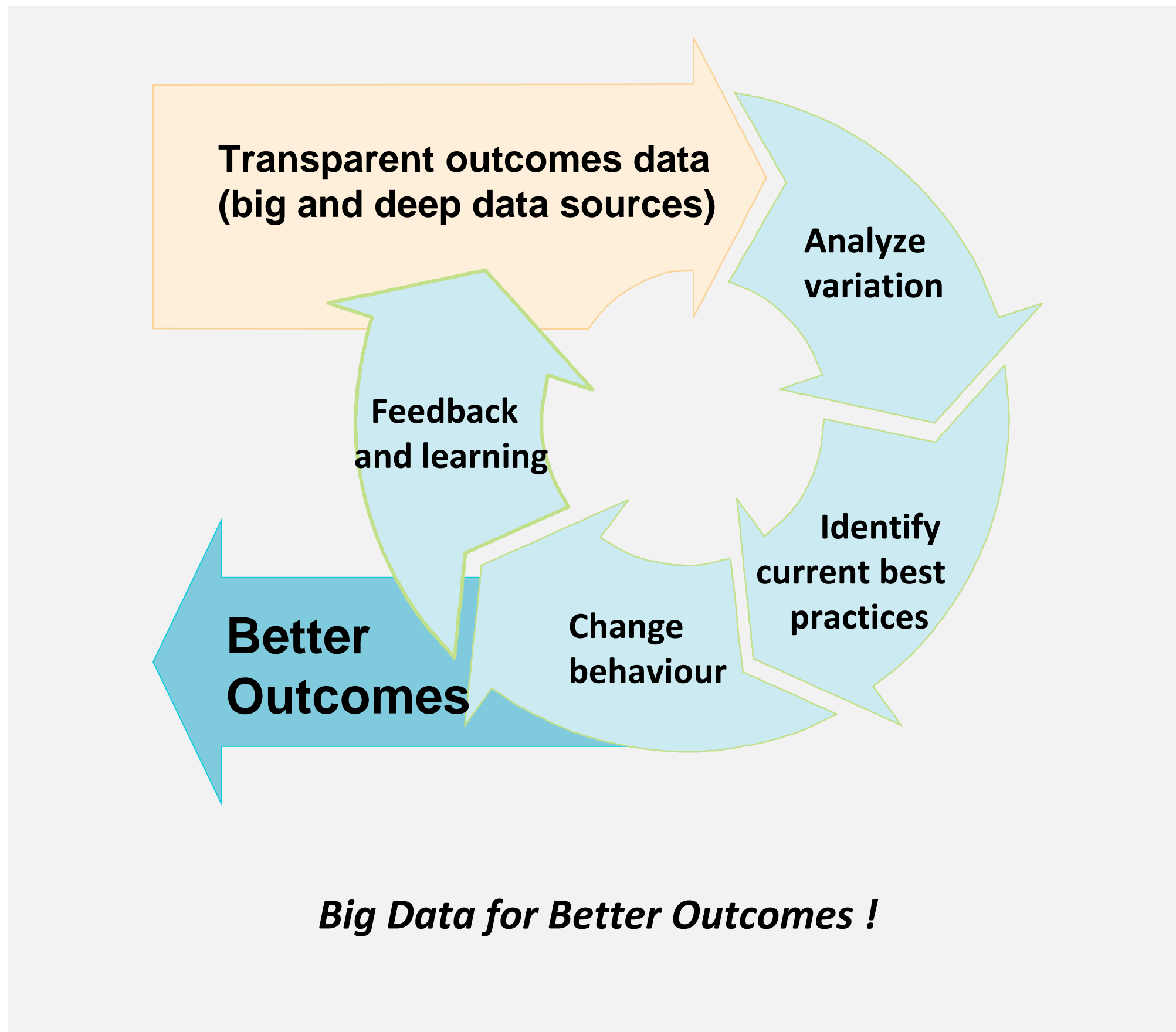
Consensus of Interest Models: Integrating policy thinking on elements that will result in win-wins



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

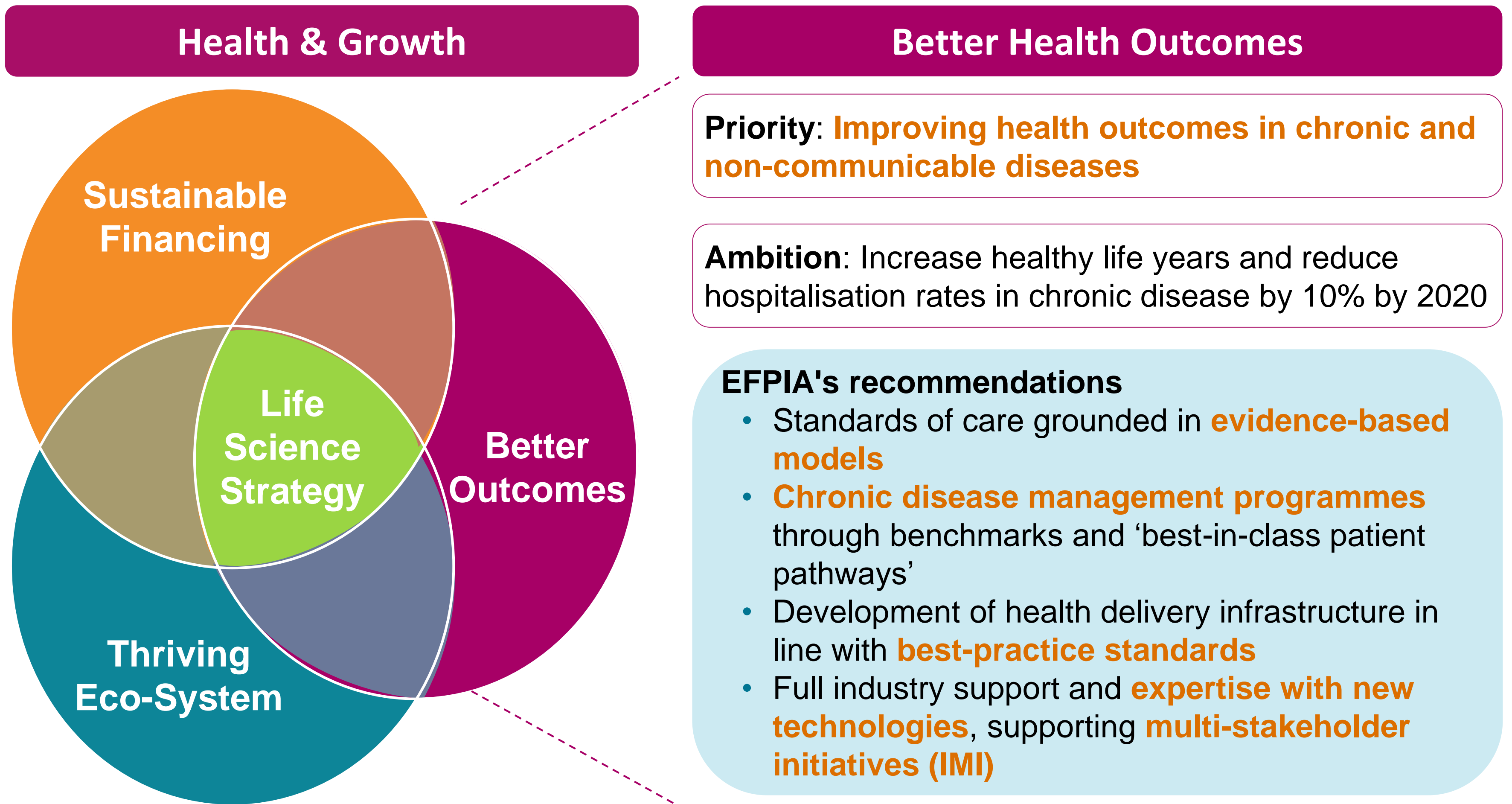


- ✓ Improved outcomes
- ✓ Reduced variation
- ✓ Reduced medical cost



**Improved
health care systems**

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



Member States joint initiatives: voluntary cooperation at EU level



- ❖ Benelux + Austria
 - *[Ireland, Italy and Portugal also interested]*
- ❖ Bulgaria/Romania CEE Cooperation (Sofia declaration)
 - Bulgaria (lead), Croatia, Latvia, Lithuania, Macedonia, Moldova, Poland, Romania, Serbia, Slovakia, Slovenia
 - *[Estonia and Hungary also interested]*
- ❖ Greece-led Mediterranean countries (Athens declaration)
 - Greece (lead), Italy, Malta, Portugal, Spain
- ❖ Visegrád Group (Poland, Hungary, Czech Republic and Slovakia) as well as Croatia, Slovenia, Lithuania and Latvia will come together early 2017 to discuss 'prices of very expensive drugs'



❖ **Baltic Partnership Agreement** (Estonia, Latvia, Lithuania)

- facilitate joint procurements of medicinal products and medical devices with the overall aim to reduce the expenditure regarding the State procurements of medicinal products and medical devices, as well as to ensure the continuity of the access.
- The Agreement was signed in 2012 and countries' legislation has been adapted to accommodate for it.

❖ **The Nordic Council Collaboration** (Denmark, Finland, Iceland, Norway, Sweden)

- focus on HTA methodologies
- joint purchase of pharmaceuticals and medical equipment

Outline of EFPIA's Vision & 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 WAIT indicator (e.g. EU weighted average)	●	<ul style="list-style-type: none"> Conduct benchmarking based on WAIT 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 (Patent WAIT + IMS 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 P&R 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 3 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 biobiosimilars markets (avoid policy treating biosimilars as generics) 	●

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	IMI-2 framework set-up (D1)	●	<ul style="list-style-type: none"> Complete IMI legislative package, ensuring flexibility and key IP features Agree IM2 project portfolio (incl. MAPPs programme) supported by companies science leadership 	●
Reduce time to market for new medications including new indications	% Enablers of MAPPs (development, financing & access) addressed in IMI Projects	●	<ul style="list-style-type: none"> Implementation of AI pilot project in line with MAPPs principles Launch IM2 MAPPs 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 Launch IM2 MAPPs programme 	●
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 negotiated 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 negotiated 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 an 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 stakeholder	% core transparency and P&R principles negotiated in TTIP	●	<ul style="list-style-type: none"> Ensure EFPIA, President, DG and IGMC 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

Ethics & Compliance

Enhance ethical behaviour within a self-regulation (industry) framework to increase reputation and credibility of the pharmaceutical sector

Working groups



EFPIA PRIZE



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.**

Procedure & Evaluation

- ❖ **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 – What does the Laureate get

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 can be agreed, such as contribution for accommodation in Brussels
- **Award Ceremony**

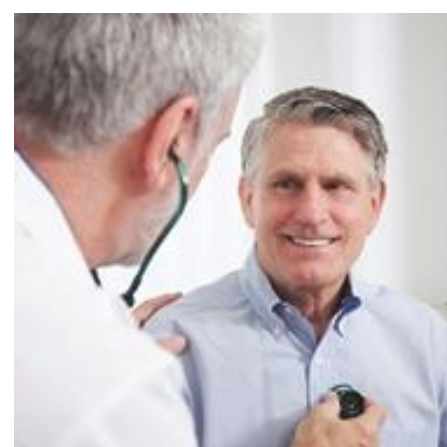


Year	Winner	Topic
2013	no submission	
2014	Maria PANTUROIU	From Orphan Drugs to Personalised Medicines
2015	Versina BREGU	Pharmaceuticals in the Environment
2016	no submission	
2017	One of you!	



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