European Federation of Pharmaceutical Industries and Associations

European Pharmaceutical Policy

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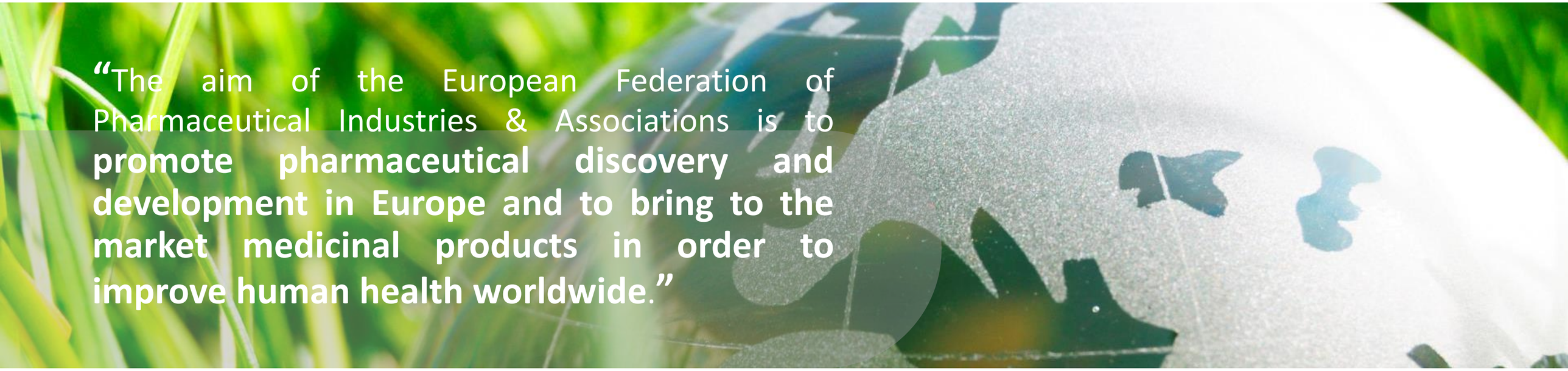
The EFPIA PRIZE

Parma, 9th April 2018

Declaration of Interest

- Nathalie Moll is a full-time employee of EFPIA, holding the position of **Director General** and is a member of its **General Management**.
- Nathalie Moll 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**, Nathalie 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 is relevant to Healthcare

The world population is growing larger and older with increasing morbidity and spending projected to double in just over 10 years

Population will increase by

1

billion

2015-2025

Additional 50+ year olds

>500

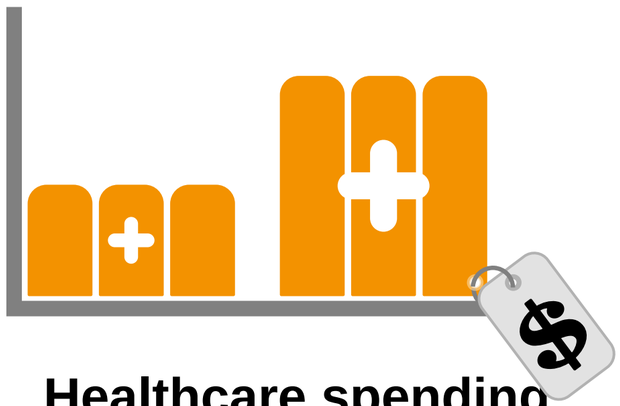
million

2015-2025

Chronic diseases

70%

of all illnesses



Healthcare spending to double

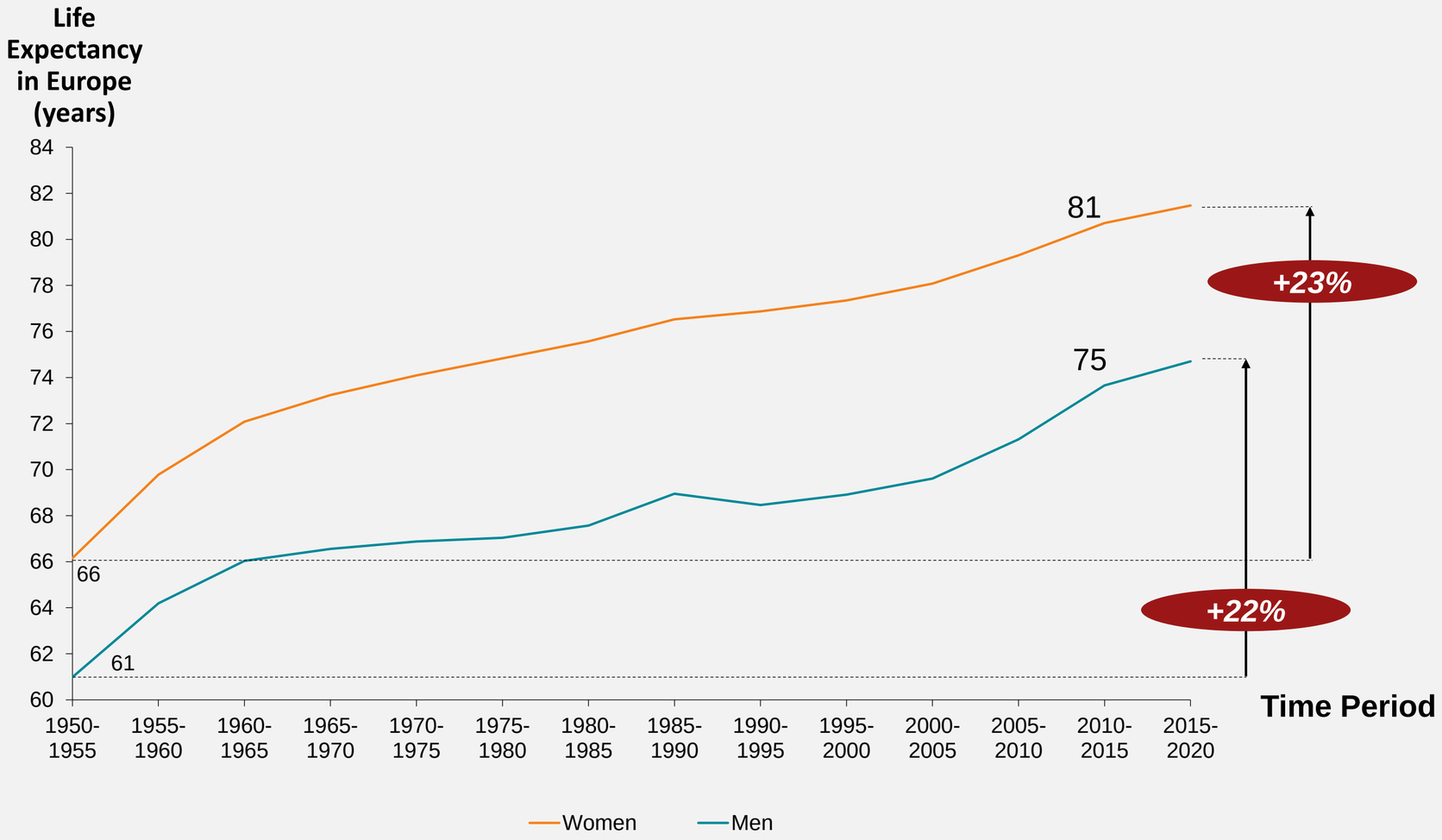
2x

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

Over the last 65 years, Europe has made great strides in improving life expectancy (+ 23-22 %)

Life expectancy at birth in Europe (1950-2020)

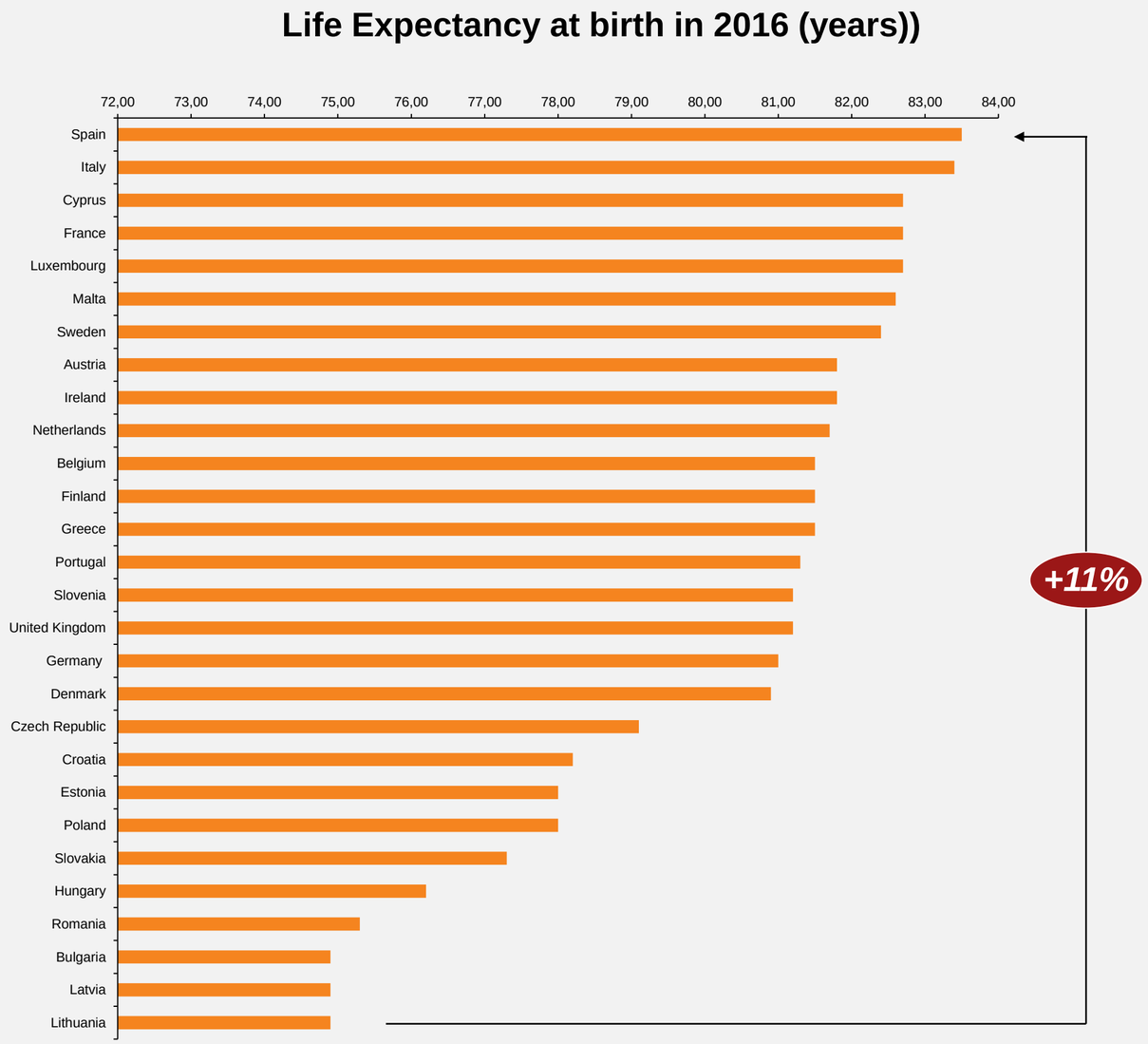


- During the last 65 years, both male and female life expectancies have improved substantially across Europe.
- Better health status resulting from improved care and prevention has its part in this improvement

Countries included are Belarus Channel, Islands, Albania Austria Bulgaria, Denmark, Andorra, Belgium, Czech Republic Estonia Bosnia and Herzegovina, France, Hungary, Faeroe Islands, Croatia Germany Poland Finland Gibraltar, Liechtenstein, Republic of Moldova, Iceland, Greece, Luxembourg, Romania, Ireland Russian Federation Italy, Netherlands, Slovakia, Latvia, Malta Switzerland Ukraine Lithuania Montenegro, Norway, Portugal, Sweden, San Marino, United Kingdom of Great Serbia, Britain and Northern Slovenia, Ireland, Spain, The former Yugoslav Republic of Macedonia.
Source: United Nations: World Population Prospects – The 2012 Revision (2014) accessed via the United Nation database on life expectancy at birth (accessed in August 2017);

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

Life expectancy at birth – 2016

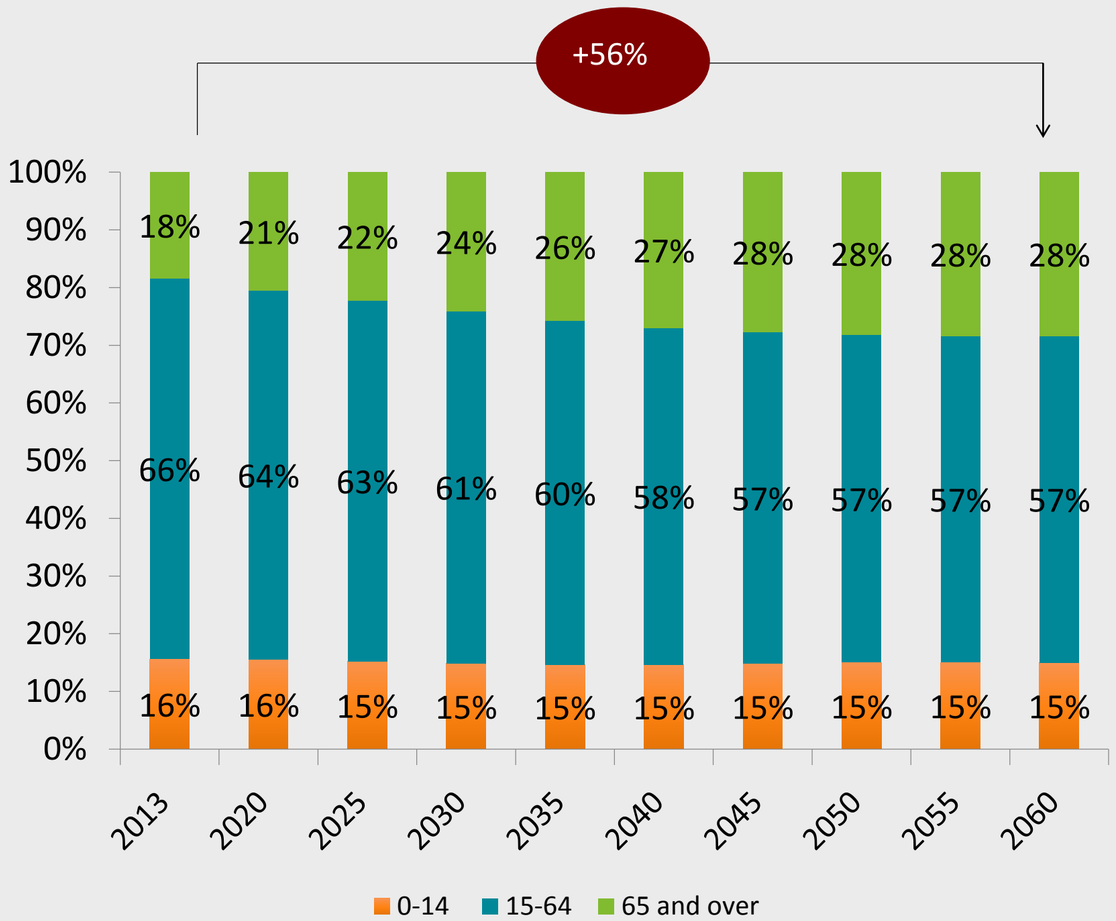


- While health outcomes have improved throughout Europe over the last 50 years, an 11% variation (equal to almost 9 years) in life expectancy exists between country with highest and lowest life expectancy.
- Cumulative differences in life expectancy between each country and highest life expectancy amounts to over 1.22 billion life years.
- While variations are most observable with countries that joint the EU 14 years ago, wide variations also exist between countries with highest life expectancy.

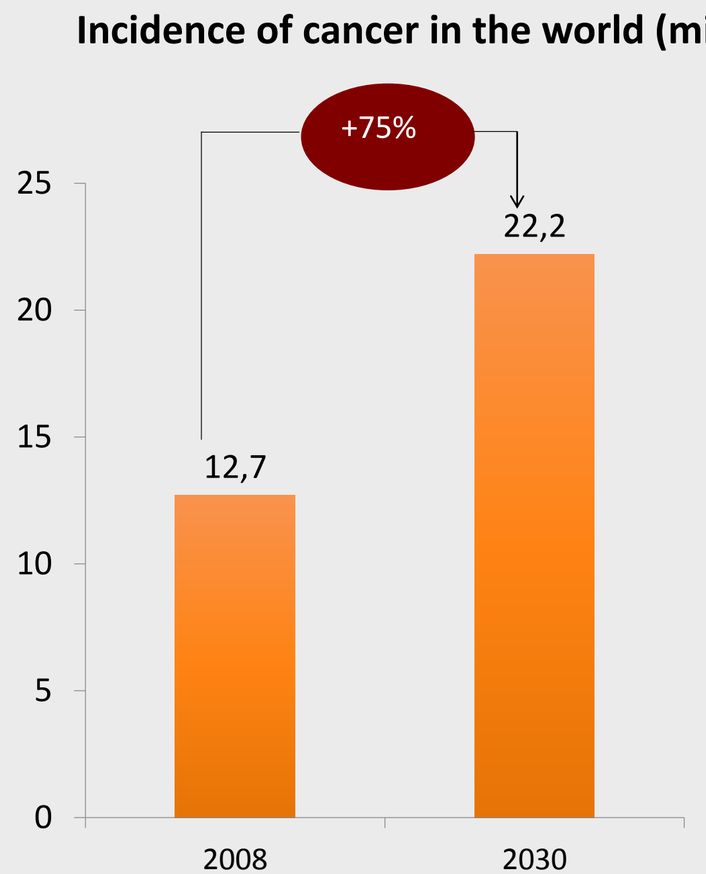
Source: World Health Organization (WHO): Database on life expectancy (accessed 2018); The World Bank: Database on life expectancy at birth (accessed 2016)

Demographic changes and higher longevity cause major health challenges for Europe

Demographic development in the EU-28*



Projected increase of cancer in the world†

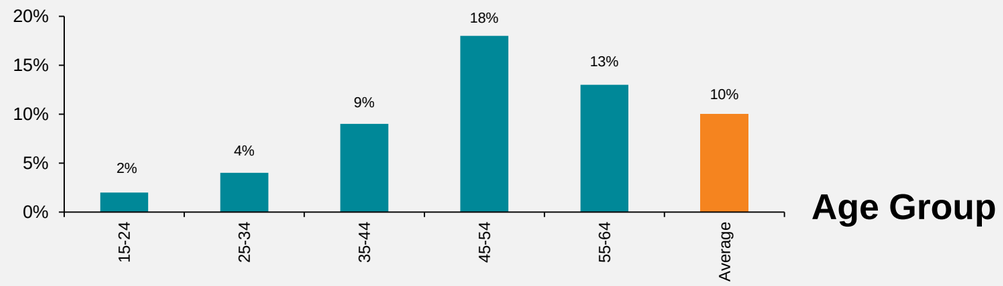


Sources: *European Commission (2015). The Aging report. †Freddie Bray et al (2012). "Global cancer transition according to human index a population based study". Lancet oncology. 13:8. Available at: http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(12)70211-5/abstract

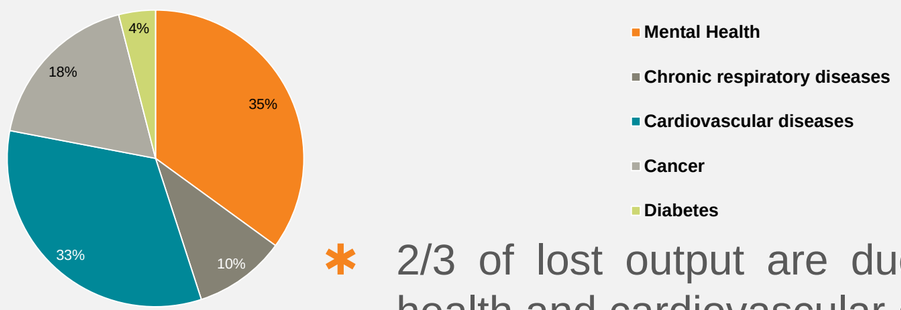
Ill-health is a major cause of productivity loss and early labour market exit, with many causes being addressable

Health as a cause of leaving job

Left last job for reasons of health



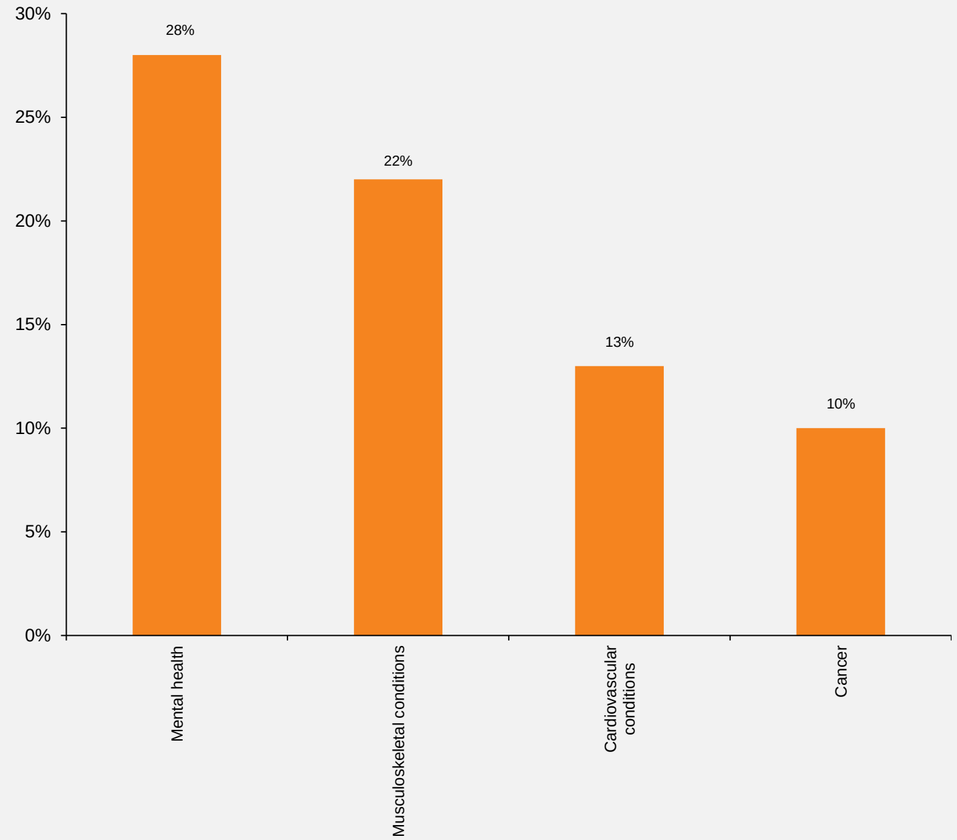
Health related causes for loss of output



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

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

% of market exists

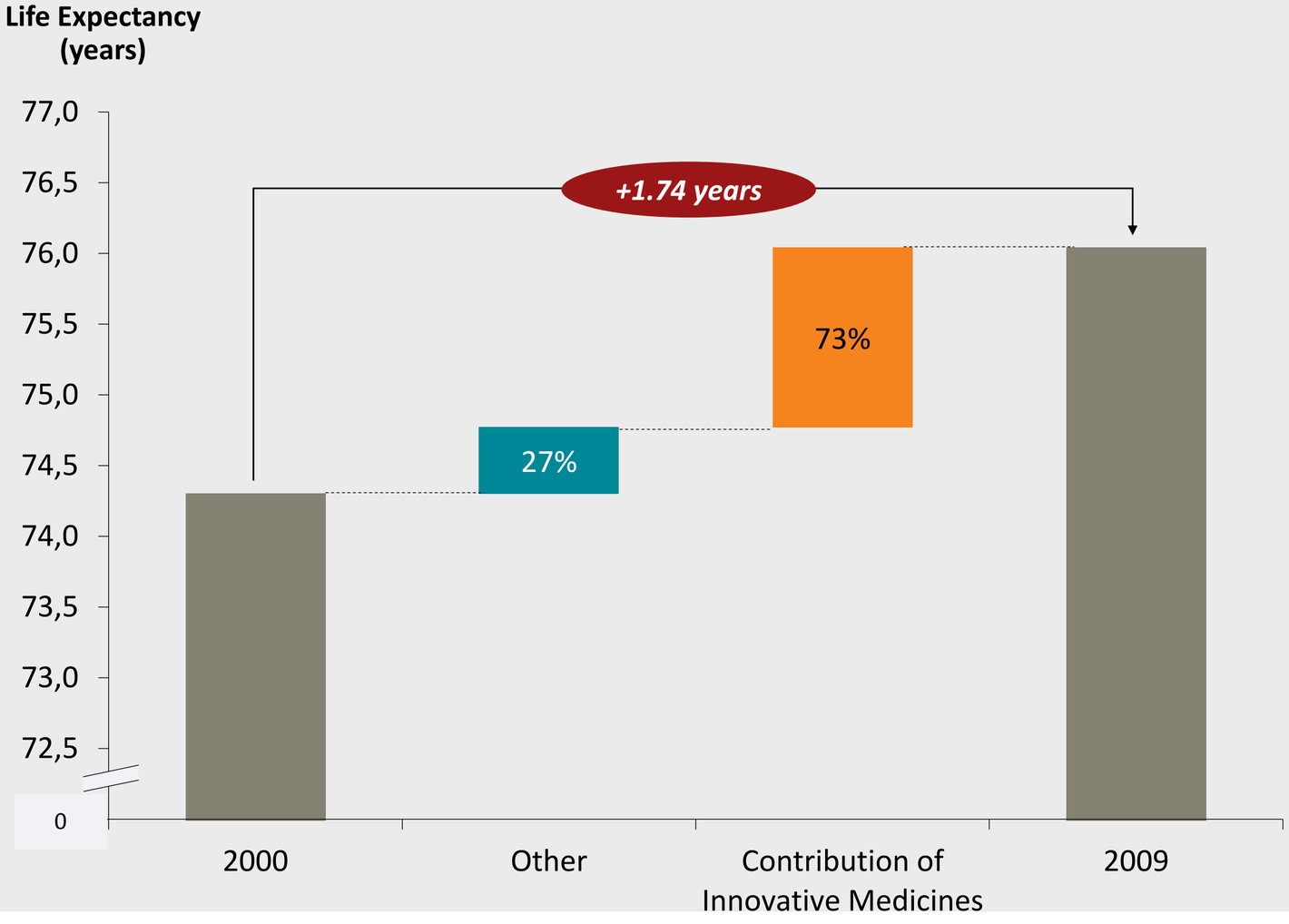


Note: Percentage of people that were previously employed and answered the main reason for leaving their job was ‘Own illness or disability”

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

Life expectancy continues to improve today and medicines usage has made major contribution to recent advances

Contribution of innovative medicines to increase in life expectancy (2004-2009)

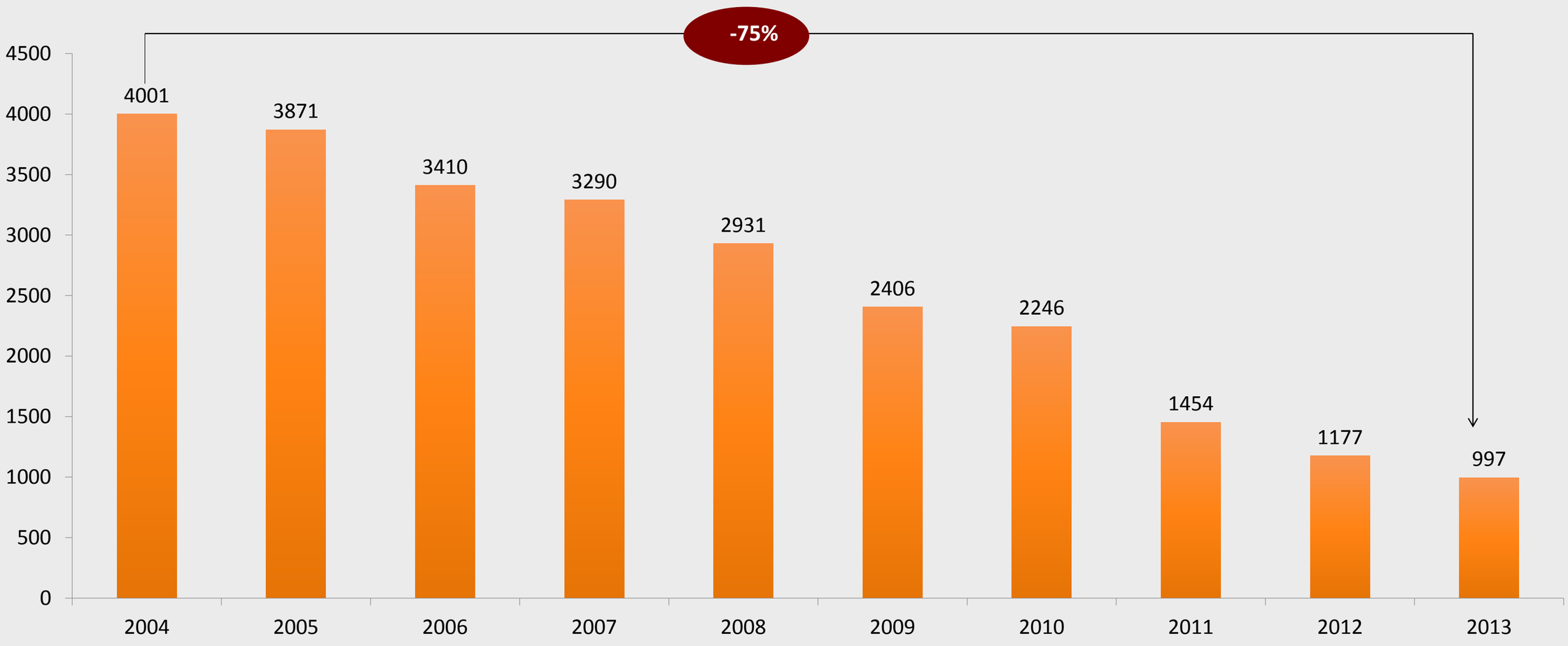


- From 2000 – 2009, an improvement in population weighted mean life expectancy at birth of 1.74 years was seen across 30 OECD countries.
- Innovative medicines are estimated to have contributed to 73% of this improvement once other factors are taken into account (e.g. income, education, immunization, reduction in risk factors, health system access).

Source: Lichtenberg, F: Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000 - 2009 (2012)

Progress in the treatment of HIV/AIDS has contributed to a significant decline in death rates

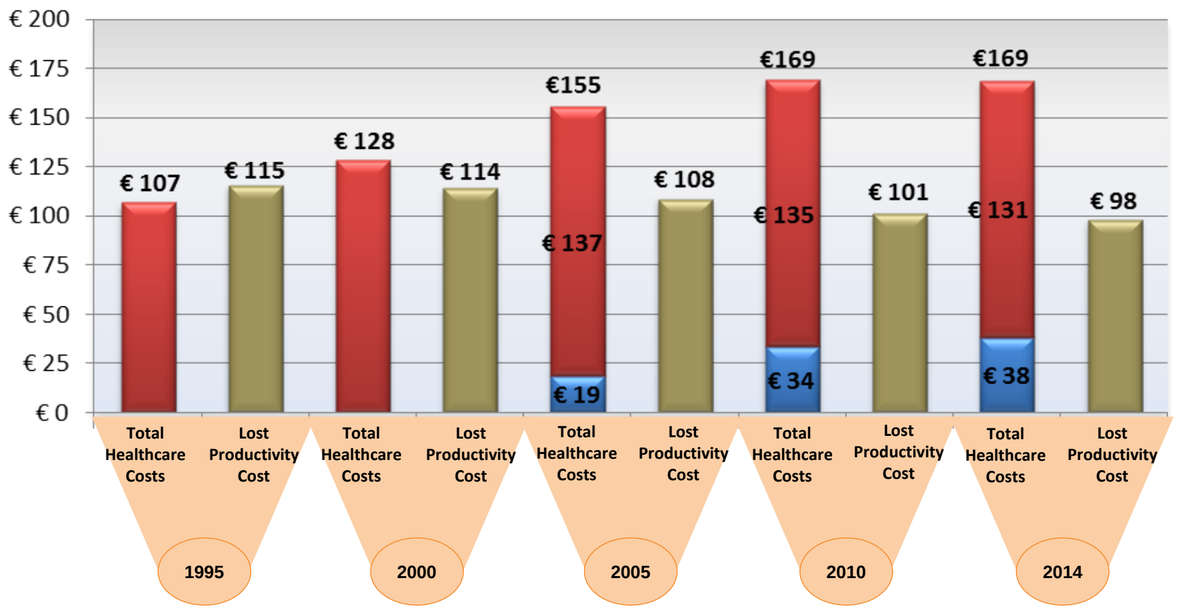
Number of deaths among Aids cases in Europe (Total EU/EEA)

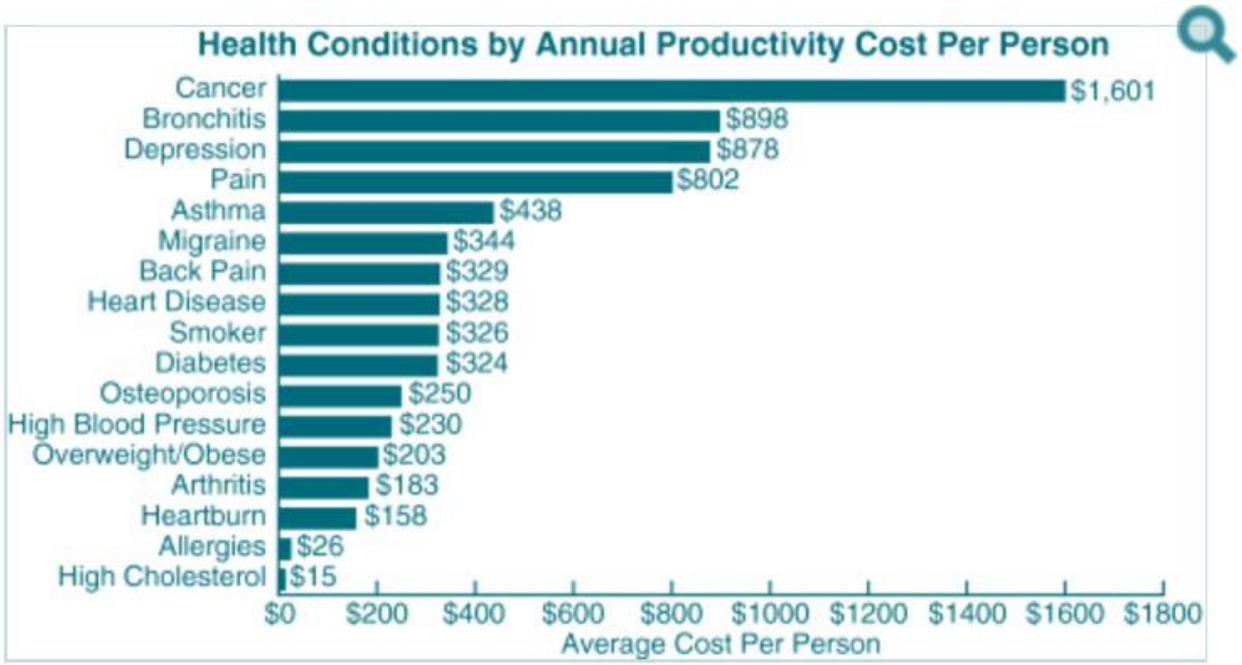


Source: HIV/AIDS surveillance in Europe 2013, WHO Regional Office for Europe & European Centre for Disease Prevention and Control (ECDC), November 2014 cited in EFPIA, the pharmaceutical industry in figures (2015).

Medicines offer an opportunity to reduce the cost of productivity loss and disability by improving workforce health

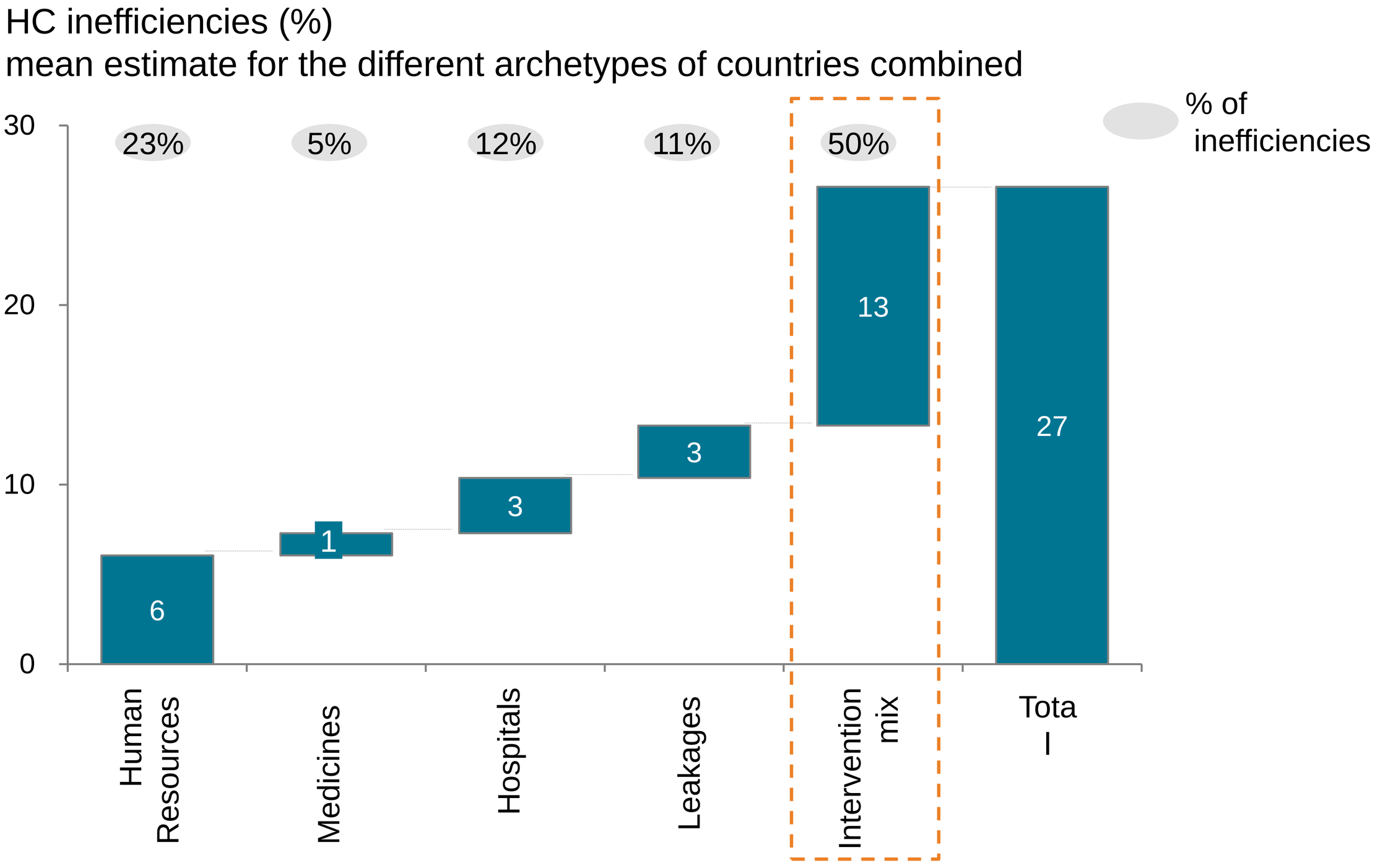
Economic burden of cancer per capita (in 2014 prices), 1995-2014 in Europe





Notes: “Total Healthcare Costs” = direct health cost of cancer; “Lost Productivity cost” = productivity loss due to premature mortality from cancer
Cancer is defined as ICD-10 C00-D48 for direct health costs, and C00-C97,B21 for productivity loss.
Source: graph left hand side: IHE comparator report ; graph right hand slide Mitchell, R & Bates, P. (2011) in *Population health management*, 14(2), 2011, 93-98.

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



Note: 10-15% of medicine costs resulting in 2-5% of total HC costs
Source: "The World Health Report: Health Systems Financing, The path to universal coverage," WHO, 2010 (`+Background paper 28)

Collecting standardised health outcomes data and learning from variation could improve healthcare value and reduce waste

	Description of the component	Contrib. to value
1 **Identify target population (e.g. disease groups)**	**Focus on disease groups and other relevant population sub-segments** • Identify patients based on their healthcare needs, behaviors, etc. to prevent and manage illness, rather than simply treat disease	**Identify patients with common needs and highest costs**
2 **Define target outcomes**	**Define target outcomes to improve care and reduce costs** • That matter to patients and clinicians, balanced along full cycle of care - prevention and cure, comparable, linked to population	**Identify which health outcomes are needed for a healthy population**
3 **Measure and learn from variation**	**Monitor outcomes and learn from variation to improve** • Establish registries, inter-operable data systems across providers, real-time measuring, transparency of outcomes, etc.	**Improve to achieve target outcomes at minimum cost**
4 **Define treatment pathway with coordinated delivery**	**Define treatment pathway around the patient vs. provider, enabling coordinated delivery across all stakeholders** • New models need to be based on the patient along the care chain, vs. single procedure or single episode of care	**Whole-person focus** • also reduce waste from coordination
5 **Align payments and incentives**	**Ensure reimbursement models enable value focus including outcomes along full cycle of care** • Payments aligned to providers' collective performance against target outcomes, instead of promoting price and volume. Ensure incentive design does not promote unwanted behaviors (e.g. hiding bad results...) • Gradual transfer of risk to providers	**Align stakeholders to achieve previous goals**

SOURCE: "ACCOUNTABLE CARE: FOCUSING ACCOUNTABILITY ON THE OUTCOMES THAT MATTER," WISH ACCOUNTABLE CARE REPORT, 2013; BCG

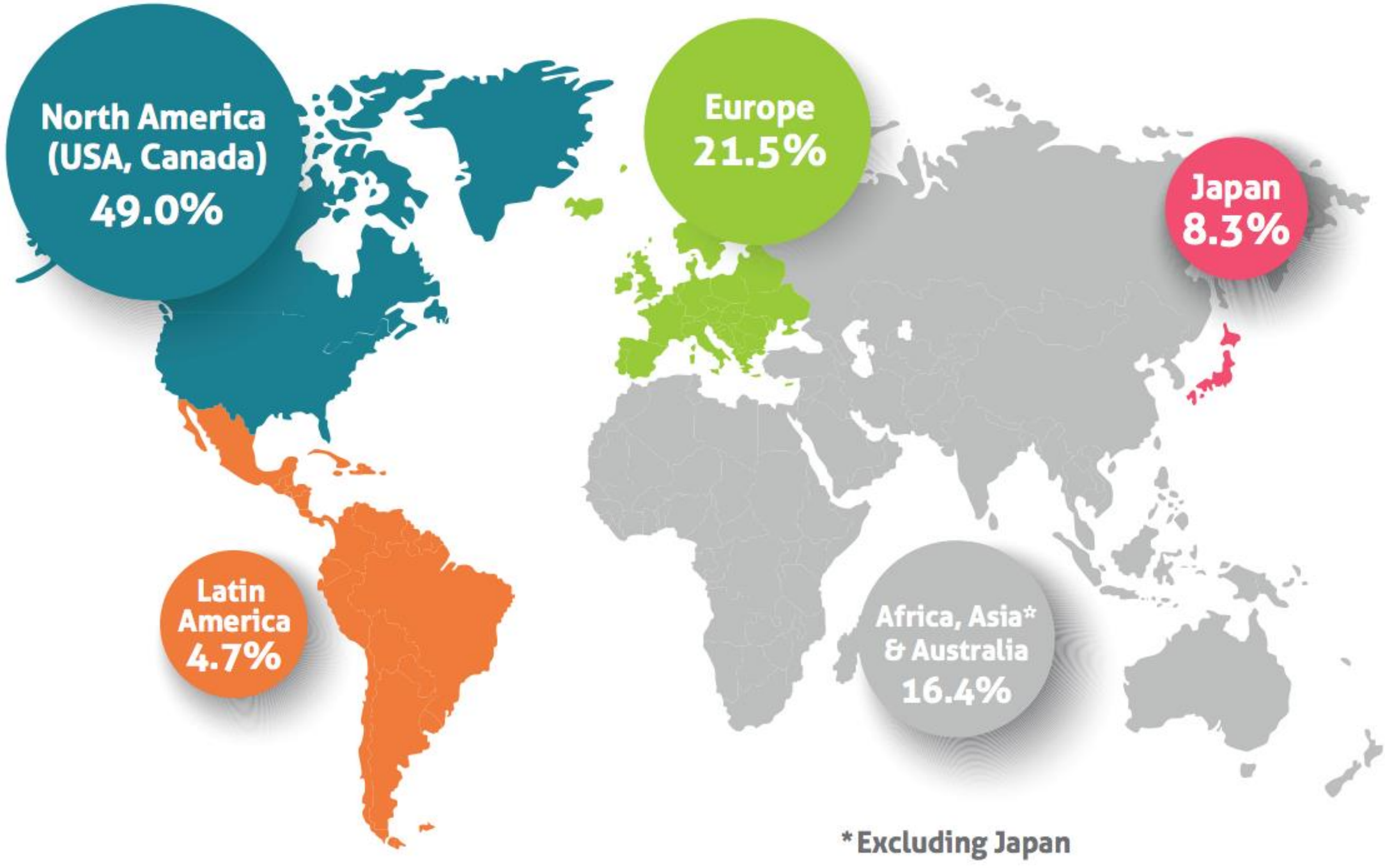
The Pharma Industry in Europe

PHARMA INDUSTRY IN EUROPE: Key Economic Indicators

INDUSTRY (EFPIA total)	2000	2010	2015	2016
Production	127,504	199,400	238,437	250,000 (e)
Exports (1) (2)	90,935	276,357	365,303	375,000 (e)
Imports	68,841	204,824	269,012	275,000 (e)
Trade balance	22,094	71,533	96,291	100,000 (e)
R&D expenditure	17,849	27,920	33,557	35,000 (e)
Employment (units)	554,186	670,088	739,499	745,000 (e)
R&D employment (units)	88,397	117,035	113,713	115,000 (e)
Total pharmaceutical market value at ex–factory prices	89,449	153,685	193,742	202,000 (e)
Payment for pharmaceuticals by statutory health insurance systems (ambulatory care only)	76,909	129,464	131,685	134,000 (e)

Source: EFPIA in Figures 2017, www.efpia.eu

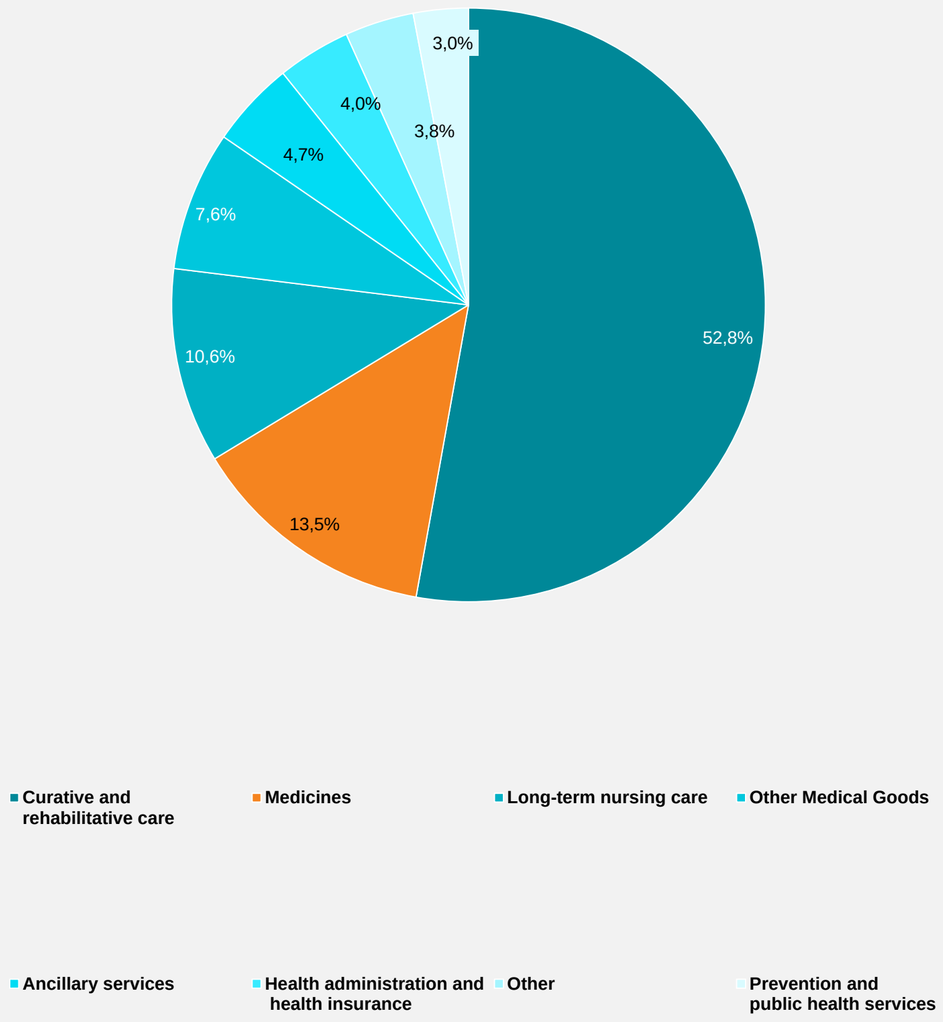
BREAKDOWN OF THE WORLD PHARMACEUTICAL MARKET – 2016 sales



Note: Europe includes Turkey, Russia and Ukraine; percentages might not add up due to rounding
Source: IMS Health (MIDAS), May 2017 (data relate to the 2016 audited global retail and hospital pharmaceutical market at ex-factory prices); in EFPIA in Figures 2017, www.efpia.eu

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, $)*



Medicines contribution to disease cost (2011, various diseases)

Cost factor	COPD†	Diabetes†	CHF†	Alzhei-mers△	Prostate Cancer#
Care	21%	8%	6%	9%	34%
Hospitali-sation	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%**

Source: * OECD Health Statistics Database (accessed 2013); † A.T. Kearney analysis (2012); △ Schwarzkop et al. (2010); # Damm el al. (2012)

BREAKDOWN OF THE RETAIL PRICE OF A MEDICINE

Non-weighted average for Europe

Manufacturer
66.0%

Wholesaler
4.8%

Pharmacist
19.2%

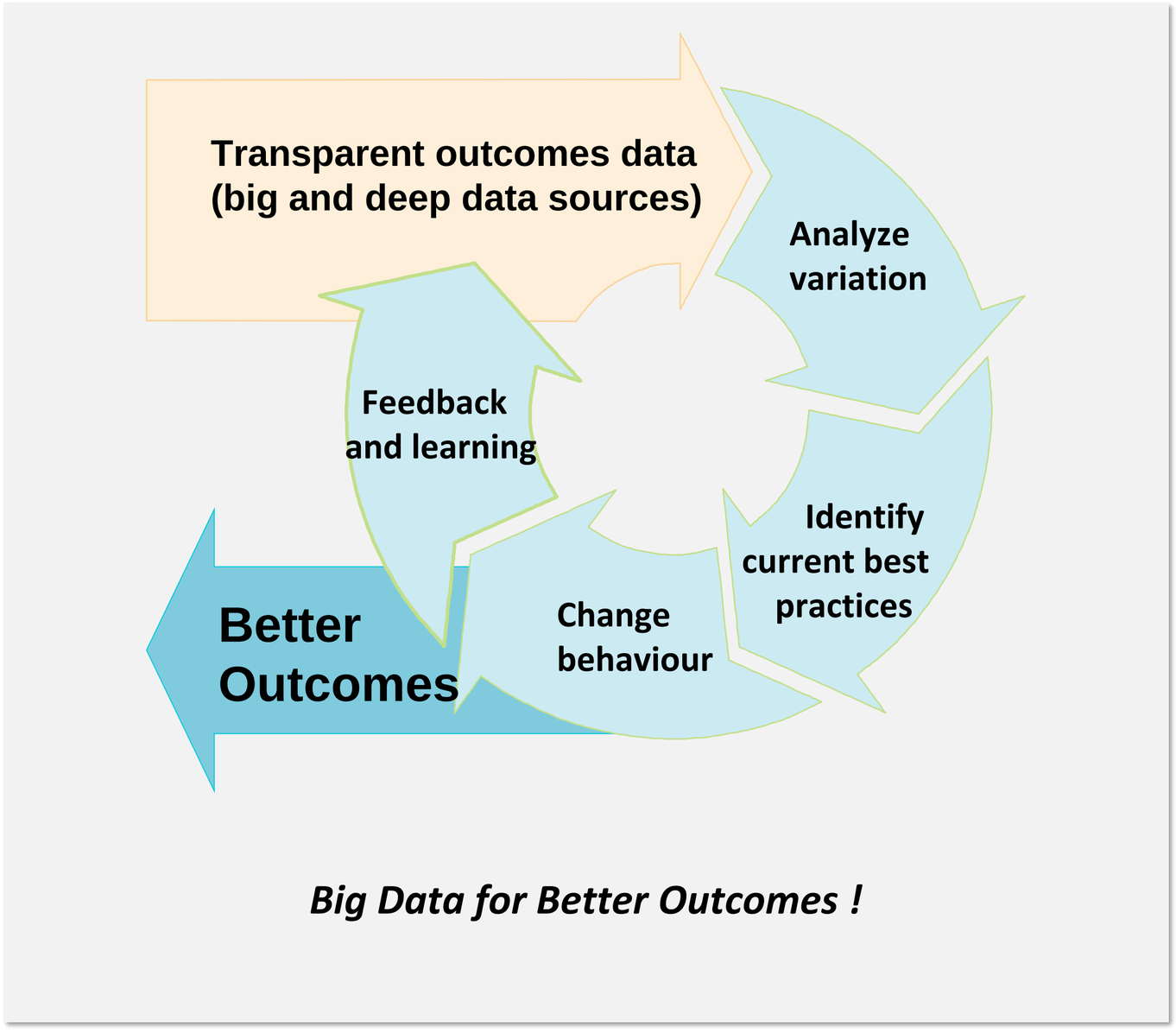
State (VAT and other taxes)
10.0%

Note: Based on non-weighted average for Europe (average estimate for 23 countries)
Source: EFPIA Member Associations; in EFPIA in Figures 2017, 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...



Big Data for Better Outcomes !

... while contributing to system sustainability

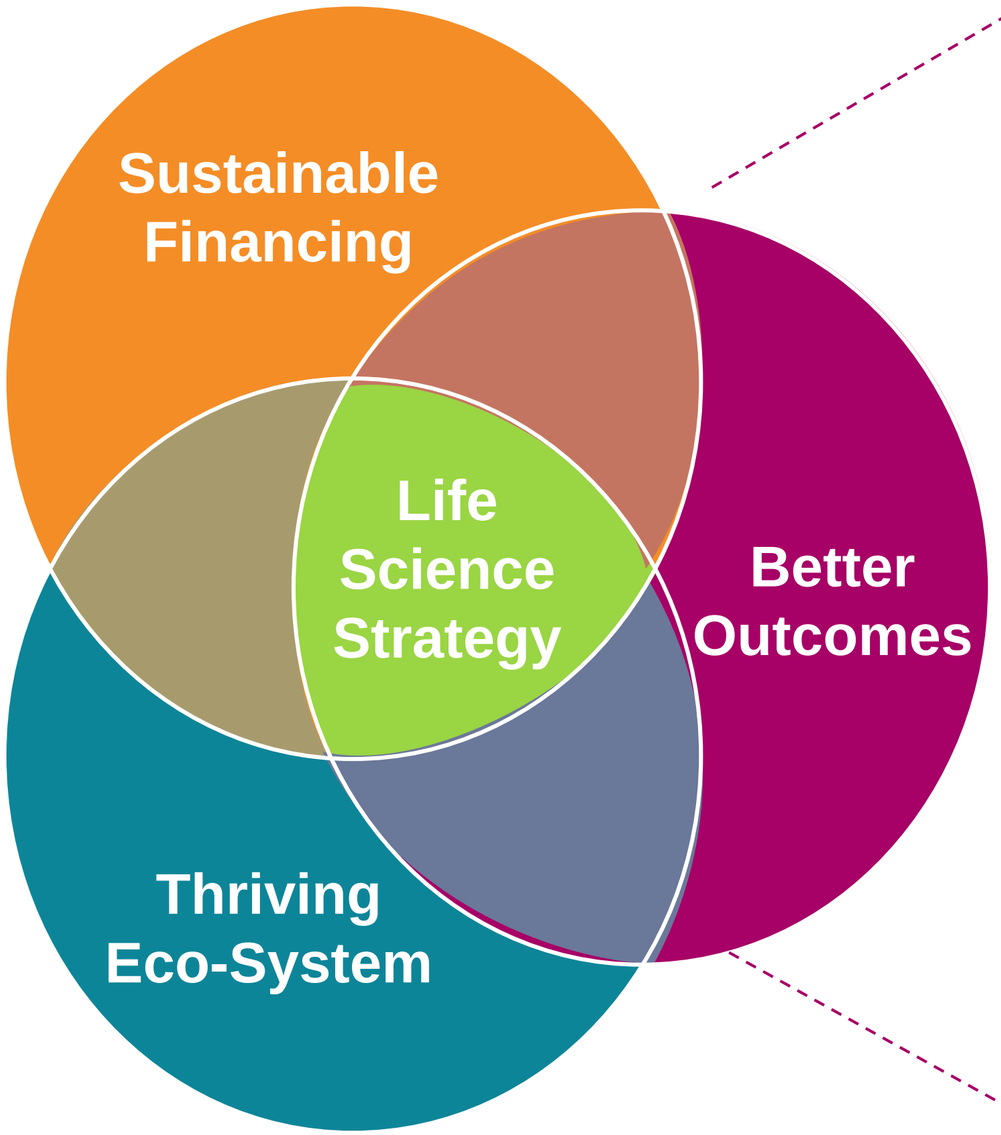
- ✓ Improved outcomes
- ✓ Reduced variation
- ✓ Reduced medical cost

Improved health care systems

Source: BCG experience

Improving outcomes is core to EFPIA's overall strategy

Health & Growth



Better Health Outcomes

Priority: **Improving health outcomes in chronic and non-communicable diseases**

Ambition: Increase healthy life years and reduce hospitalisation rates in chronic disease by 10% by 2020

EFPIA's recommendations

- Standards of care grounded in **evidence-based models** derived from comparable **data on health outcomes**
- **Chronic disease management programmes** through benchmarks and ‘best-in-class patient pathways’
- Development of health delivery infrastructure in line with **best-practice standards**
- Full industry support and **expertise with new technologies**, supporting **multi-stakeholder initiatives (IMI)**

Source: EFPIA.eu, "A vision towards a life sciences strategy for Europe" (2014)

Member States joint initiatives: voluntary cooperation at EU level

- **BeNeLuxA** (42.3 M citizens)
  - Start date: September 2015
  - Countries involved: Belgium, Netherlands, Luxembourg, Austria, [Ireland is also also interested]
  - Collaboration facilitates various activities such as horizon scanning, REA/HTA, joint market research
  - The focus is currently on joint pricing negotiations.

- **Valletta Declaration** (156 M citizens)
  - Start date: May 2017
  - Countries involved: Italy, Cyprus, Greece, Malta, Portugal, Spain, Ireland, Romania, Slovenia, [Croatia also interested]
  - The aim is to jointly act on topics such as horizon scanning, REA/HTA, joint pricing negotiations, joint public procurement and contracting
  - The focus is currently on joint pricing negotiations.

- **Visegrad+ Collaboration** (70.9 M citizens)
  - Start date: March 2017
  - Countries involved: Poland, Slovakia, Hungary, Lithuania
  - Objectives for collaboration include horizon scanning, informed purchasing, joint public procurement and contracting.
  - The focus is currently on joint pricing negotiations.

- **Baltic Partnership** (6.2 M citizens)
  - Start date: May 2012
  - Countries involved: Estonia, Latvia, Lithuania
  - The main coordinated initiative is related to joint procurement and contracting

- **Nordic Council** (26.6 M citizens)
  - Start date: March 2017
  - Countries involved: Denmark, Finland, Iceland, Norway, Sweden
  - The main coordinated initiative is related to joint procurement and contracting

Source: EFPIA analysis

Member States joint initiatives: voluntary cooperation at EU level

Potential Opportunities

- Broaden overall access to therapies for patients
- Commercial opportunity by increasing market size and volume
- Harmonisation and streamlining of REA, HTA, pricing negotiations, purchasing and contracting processes – particularly beneficial for smaller companies
- Workload sharing among authorities of participating Member States
- Support for better budgetary forecasts through horizon scanning

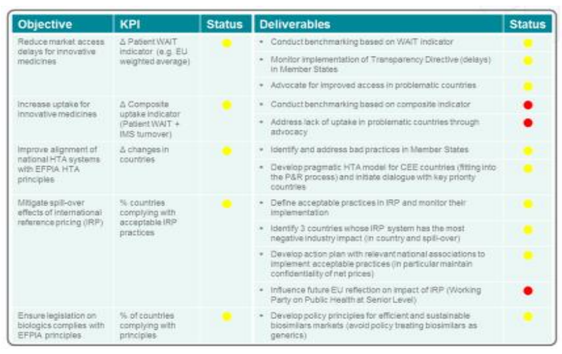
Potential Challenges

- Unclear process:
  - Lack of governance and methodology to initiate, conduct and conclude pilot projects
  - No obligation for participating Member States to adopt the outcomes of joint reports
- Unclear legal basis and framework in particular interactions with current EU (e.g. Transparency directive, public procurement legislation) and national legislations
- Duplication and /or no consideration for existing pan-European initiatives (e.g. EUnetHTA, REA)
- Limited of (successful) real-life experience (two pilots in BeNeLuxA, one expected pilot in Nordic Council)
- Lack of clear impact of horizon scanning activities on budget forecasts
- Risks of distortion in supply, trade and competition if no appropriate conditions for purchasing and contracting (e.g. sound tender criteria)
- Larger Member States increasingly interested in participating to cross-border collaborations
- Spill-over to innovative medicines

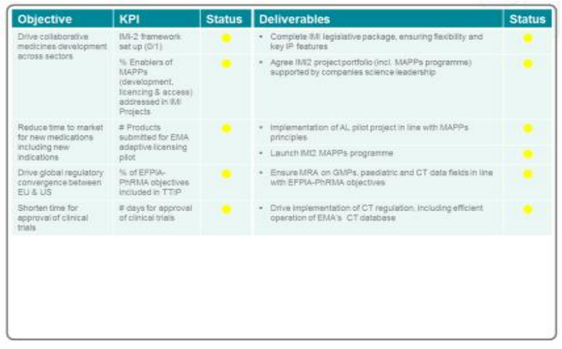
Outline of EFPIA's Vision & Key Priorities

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

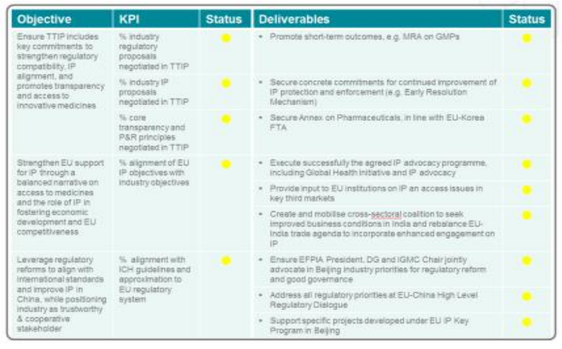
Patient Access	Innovation	International	Ethics & Compliance



Objective	KPI	Status	Deliverables	Status
Reduce market access delays for innovative medicines	Δ Patient WAIT indicator (e.g. EU weighted average)		• 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 (Patient WAIT + IMS turnover)		• 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		• 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		• 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		• Develop policy principles for efficient and sustainable biosimilars markets (avoid policy treating biosimilars as generics)	



Objective	KPI	Status	Deliverables	Status
Drive collaborative medicines development across sectors	IMI-2 framework set up (0/1)		• Complete IMI legislative package, ensuring flexibility and key IP features	
	% Enablers of MAPPs (development, licencing & access) addressed in IMI Projects		• Agree IMI2 project portfolio (incl. MAPPs programme) supported by companies science leadership	
Reduce time to market for new medications including new indications	# Products submitted for EMA adaptive licensing pilot		• Implementation of AL pilot project in line with MAPPs principles	
			• Launch IMI2 MAPPs programme	
Drive global regulatory convergence between EU & US	% of EFPIA-PhRMA objectives included in TTIP		• Ensure MRA on GMPs, paediatric and CT data fields in line with EFPIA-PhRMA objectives	
Shorten time for approval of clinical trials	# days for approval of clinical trials		• Drive implementation of CT regulation, including efficient operation of EMA's CT database	



Objective	KPI	Status	Deliverables	Status
Ensure TTIP includes key commitments to strengthen regulatory compatibility, IP alignment, and promotes transparency and access to innovative medicines	% industry regulatory proposals negotiated in TTIP		• Promote short-term outcomes, e.g. MRA on GMPs	
	% industry IP proposals negotiated in TTIP		• Secure concrete commitments for continued improvement of IP protection and enforcement (e.g. Early Resolution Mechanism)	
	% core transparency and P&R principles negotiated in TTIP		• 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	% alignment of EU IP objectives with industry objectives		• 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	% alignment with ICH guidelines and approximation to EU regulatory system		• 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	

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

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

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

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

- **<u>Subject of the Thesis</u>** – an area of particular interest to the pharmaceutical industry, chosen by the student – EN / FR
- **<u>Guidance & support</u>** – 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
- **<u>Academic evaluation</u>** – 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)
- **<u>Evaluation criteria:</u>**
  - Comprehensiveness
  - Coherence of argumentation
  - Understanding of fundamental issues
  - <u>Introduction of new dimensions (innovative solutions)</u>

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**

European Federation of Pharmaceutical Industries and Associations

Thank you for your time and attention!



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