efp*****a



COLLEGE OF EUROPEAN STUDIES PHARMACEUTICAL MARKETS & ECONOMICS

Marie-Claire PICKAERT EFPIA, Deputy Director General Parma, 24 April 2015

European Federation of Pharmaceutical Industries and Associations

What is EFPIA **EFPIA'S MANDATE**

EFPIA – Mandate

The aim of the European Federation of Pharmaceutical Industries & Associations, which has no profit-making purpose, 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 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 **42 leading companies**. Two specialised groups within EFPIA represent vaccine manufacturers – **Vaccines Europe**, with **12 member companies**) and **European / emerging biopharmaceutical companies** – **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 6 members.



A leading economic sector in Europe

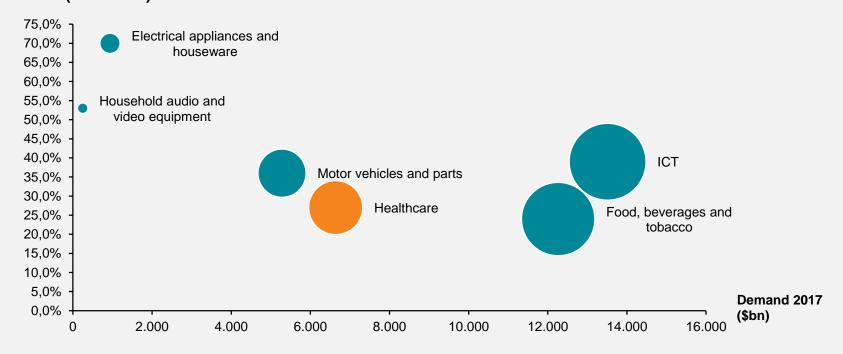
WEALTH CREATION & GROWTH

Over the next few decades, healthcare will be amongst the key growth sectors

Projected global demand for healthcare and other comparable industries



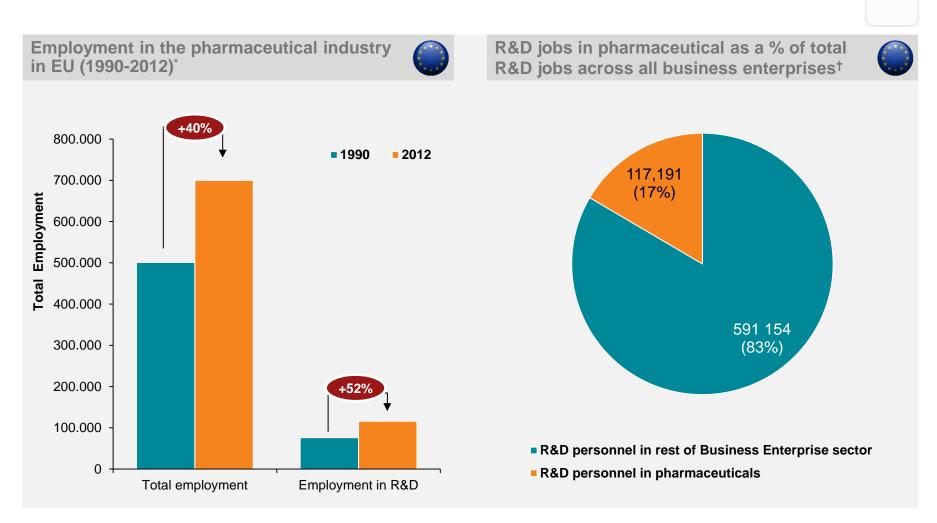
Growth rate (2011-2017)



Note: ICT = Information and Communication Technology

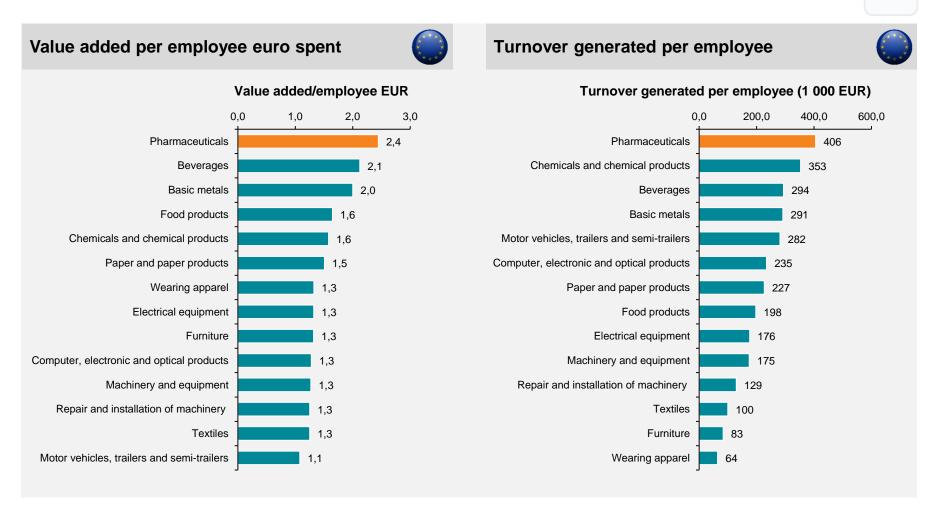


The industry employs over 700 000 people in Europe, accounting for 17% of total business enterprise R&D employment





Employment within the pharmaceutical sector generates the highest returns among comparable industries



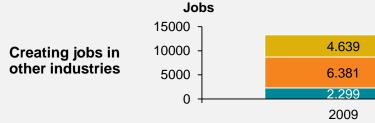


The impact of the industry can be seen even outside of the EU5 and the multipliers observed are in line with those seen in the US

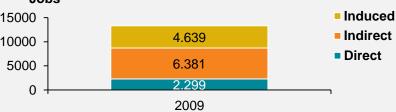
Example: Czech Republic

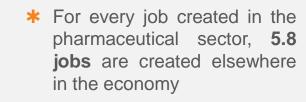
Spillover effects of pharmaceutical industry in 2009



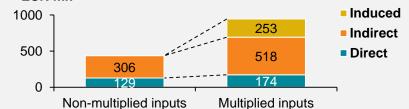


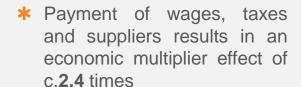
EUR mn



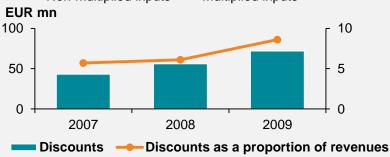








Lowering the cost of access to medicine



Through discounts, Czech pharmaceutical patients' medicines bill was reduced by EUR 72m in 2009



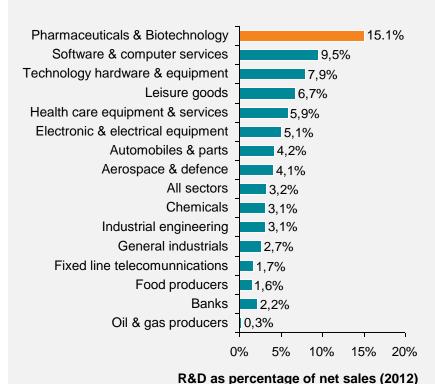
Industry continues to invest significantly in R&D, driving one of the highest value added relative to other industries...

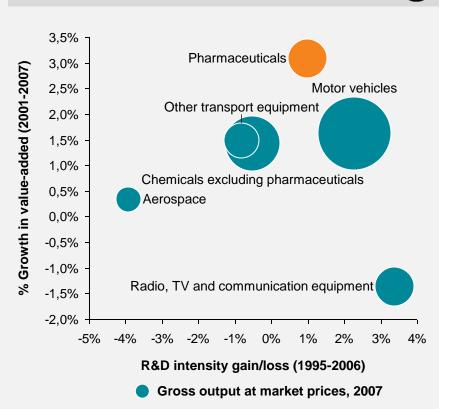
Ranking of industrial sectors by overall R&D intensity*



Value added vs. changes in R&D intensity[†]







Note: R&D intensity gain/loss calculated as difference between average R&D intensity in 1995-2000 and 2001-2006



| COLLEGE PARMA | 24 APRIL 2015 *9

EU is also one of the foremost suppliers of pharmaceutical products worldwide and to the fastest growing markets

EU share of imports in the world's fastest growing markets 60% 70% 80% 30% 40% 50% EU share of Europe's pharmaceutical 59% China imports sector accounted for almost 44% **Brazil** half of the pharmaceutical Venezuela 30% 73% Turkey of the world's imports India 39% growing markets, fastest 53% Rep. Korea with a total absolute value **Russian Federation** 76% of \$15.8bn. 71% Ukraine 66% UAE 64% **South Africa** 56% **Pakistan** 55% Indonesia 53% **Thailand** 51% Malaysia 48% **Argentina** 46% **Hong Kong SAR** 42% Chile 41% Vietnam 27% Peru 21% Nigeria 17% Ecuador EU share of imports R.O.W. share 48% 52% Note: China, Brazil, Venezuela, Turkey, India, S.Korea, and Russia are projected to be in Top 20 countries worldwide by size of pharmaceutical market in 2013e



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



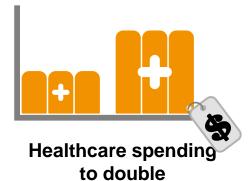
Population will increase by



Additional 50+ year olds



Chronic diseases



1 billion >500 million

70% of all illnesses

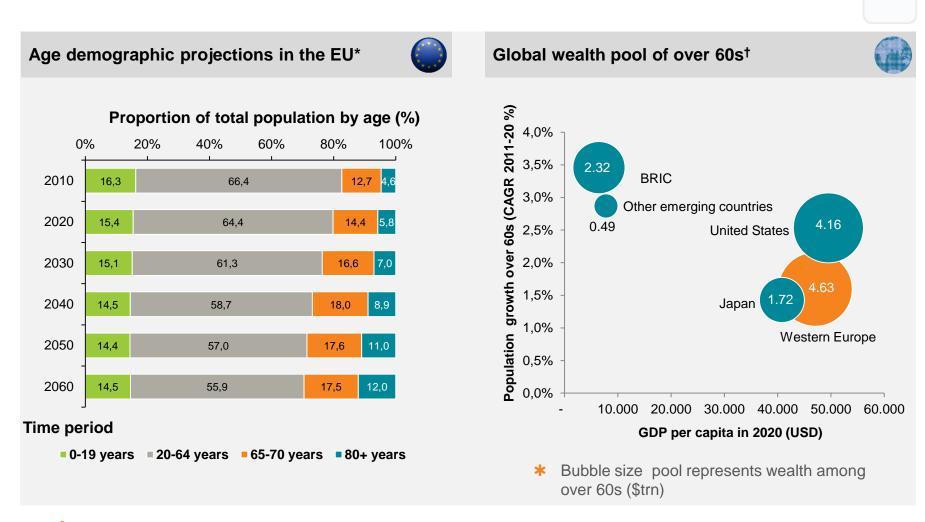
2X

2015-2025

2 0 1 5 - 2 0 2 5

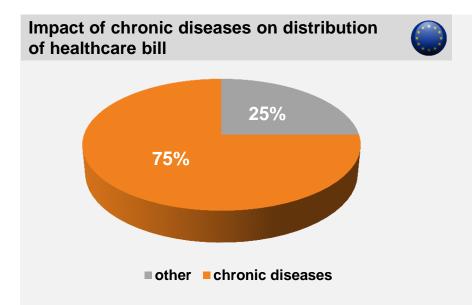
Source: Projections from UN; WHO; Projected Global Healthcare Spend, expressed in nominal terms | Source: Economist intelligence Unit, World Bank, Global Insights, BMI, OECD, McKinsey Strategy & Trend Analytic Center

With a high wealth pool, Europe's ageing population represents the fastest growing consumer segment in Europe

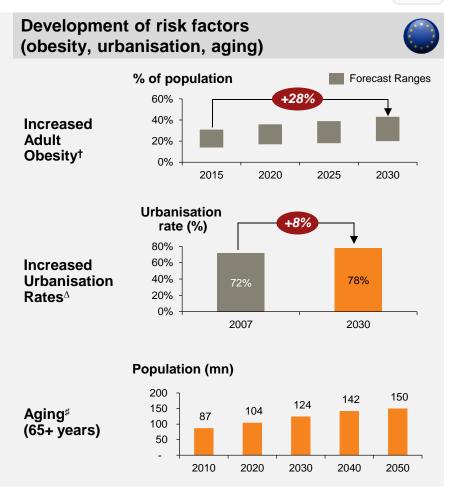




Chronic diseases are already a major part of the healthcare bill and, unmanaged, risk factors indicate it will keep rising

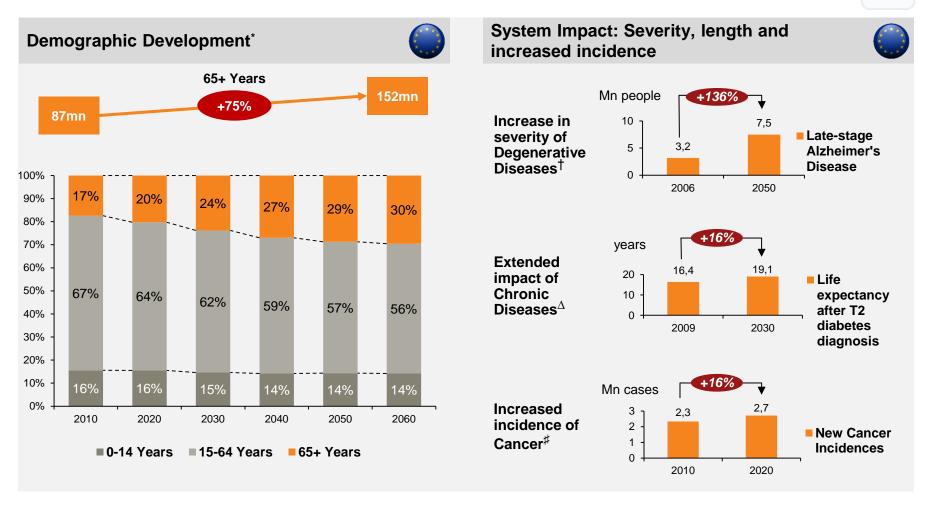


- * ~75% of Europe's healthcare bill is spent on chronic diseases amounting to €700 bn*.
- * Chronic diseases like heart disease, diabetes, lung disease, and Alzheimer's Disease are overwhelming healthcare with soaring annual costs.





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

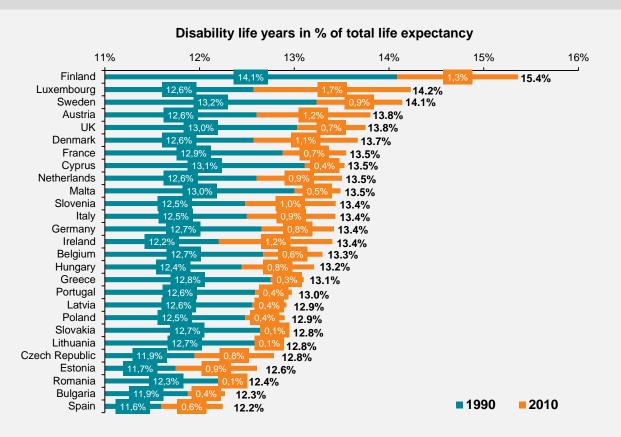




With an ageing population living with disabilities focus needs to shift from preventing mortality to improving quality of life and function

Male Disability Life Years as a % of total life expectancy in 1990 and 2010





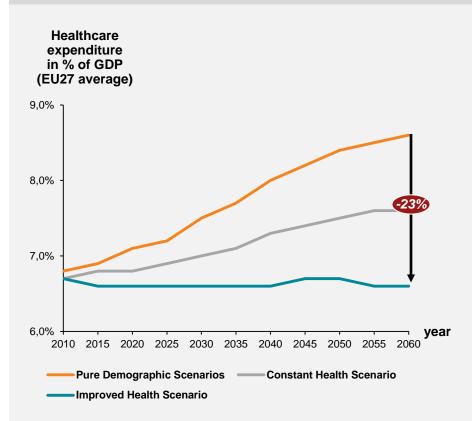
- In all 27 EU countries, disability life years as % of life expectancy has increased in the period 1990 – 2010.
- Going forward the oldage dependency ratio the impact and chronic diseases on disability could result in additional increases going forward with productivity losses and increases in incapacity benefits as outcomes.



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.



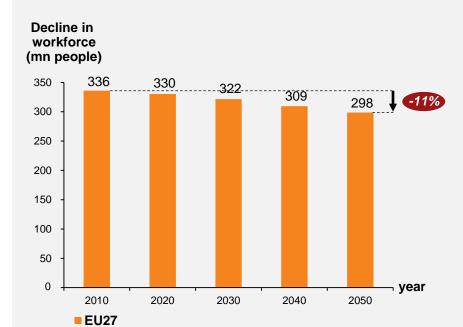
Workforce reduction and increasing dependency ratio put increased pressure of society's healthcare financing

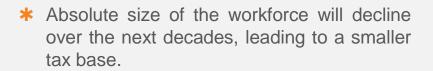
Social Impact: Decline in workforce due to demographic changes*

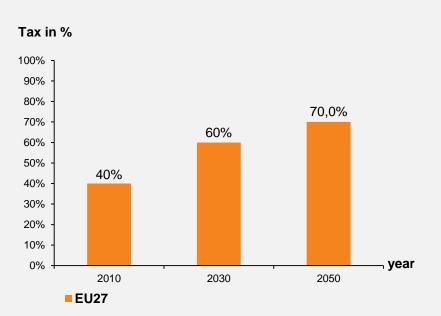


Social Impact: If no alternative financing is identified, taxes will rise to unseen levels[†]





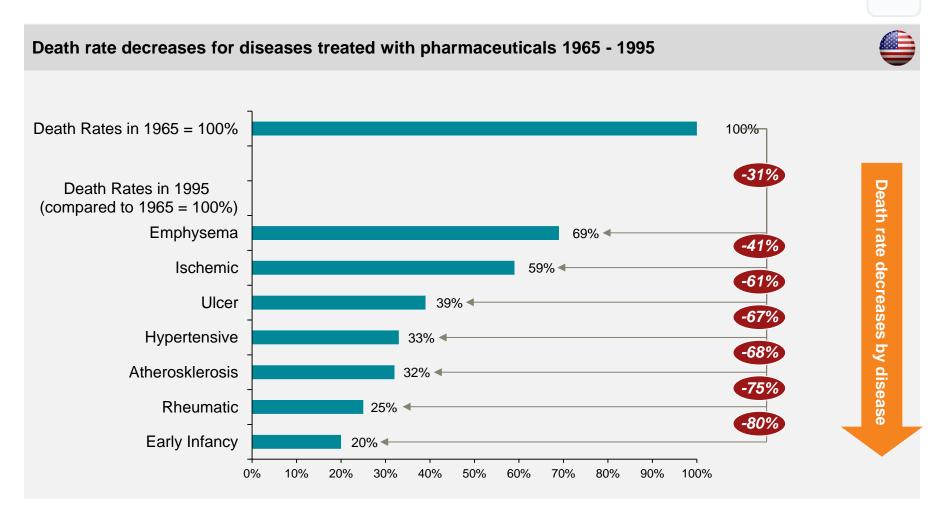




* Tax burden in Europe is rising (per cent on wages).

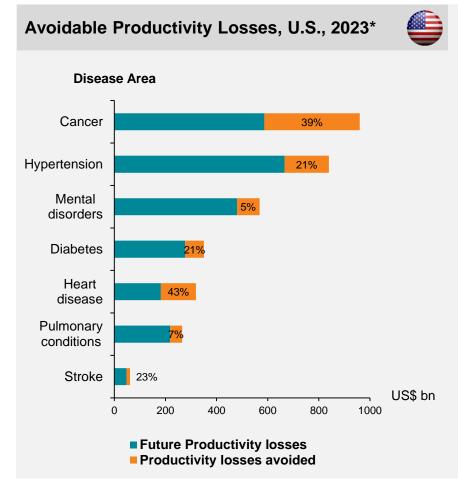


Medicines innovation has made major contribution to reducing mortality rates in many priority conditions



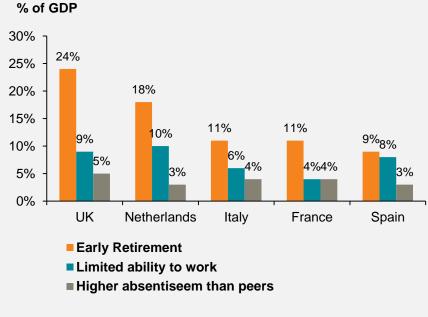


Medicines offer an opportunity to reduce the cost of productivity loss and disability by improving workforce health



COPD in selected European countries: % of GDP lost due to chronic disease[†]





* Across Europe, a significant amount of people with chronic diseases had either gone into early retirement or were contributing less than productive peers.

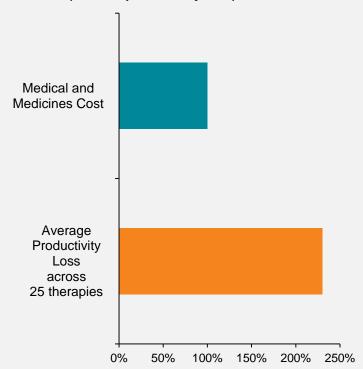


Relative to the economic cost of lost productivity, medicine and healthcare are very cost effective

Cost of Medical and Medicines cost vs. Productivity Loss



Parameter (cost vs. productivity loss)



* Study objective:

To assess business implications of a full-cost approach to managing health.

* Methodology:

Questionnaire study with more than 50.000 employees participating combined with medical claims data. Regression analysis were used to estimate impact of health-related absenteeism and presenteeism.

* Results:

Health-related productivity cost are significantly greater than medical and medicines cost combined (on average 2.3 times across 25 therapy areas).



Patent expiries will continue to create headroom for innovation in Europe, while ensuring the medicines bill stays in control

Net effect of new launches, core sales and patent expiries 2010 – 2016*



160

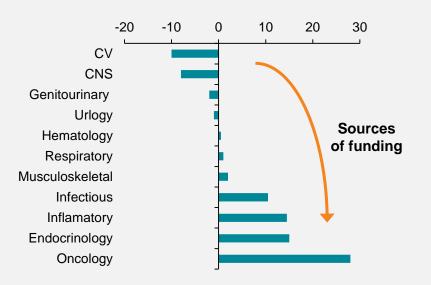
150

140

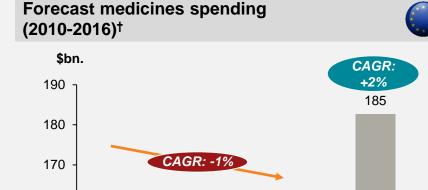
130

163

2010



- Net spending growth (selected therapy areas)
- The current generation of generic expiries in community care is funding headroom for new technologies



8

2010 - 2016

155

2016

* If governments continued to fund medicines at the same rate as health expenditure, \$30bn extra funding for medicines would be available for medicines investment

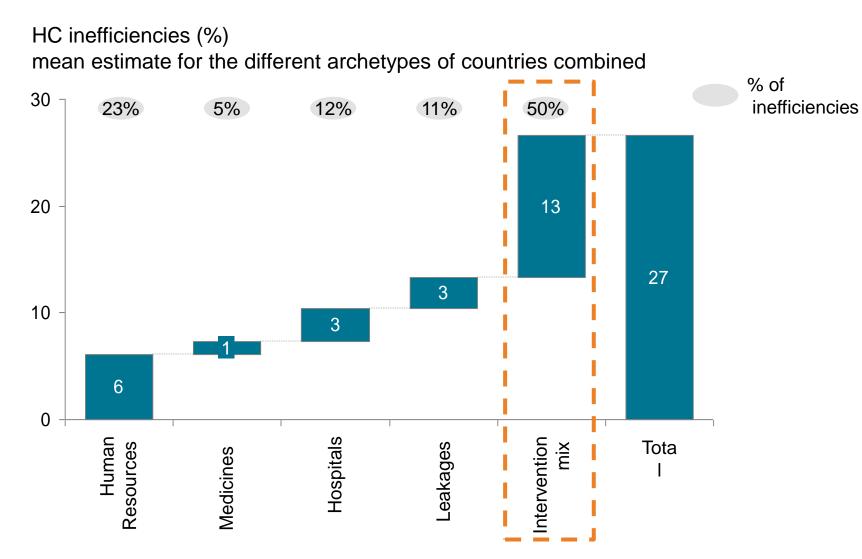


2016 at health

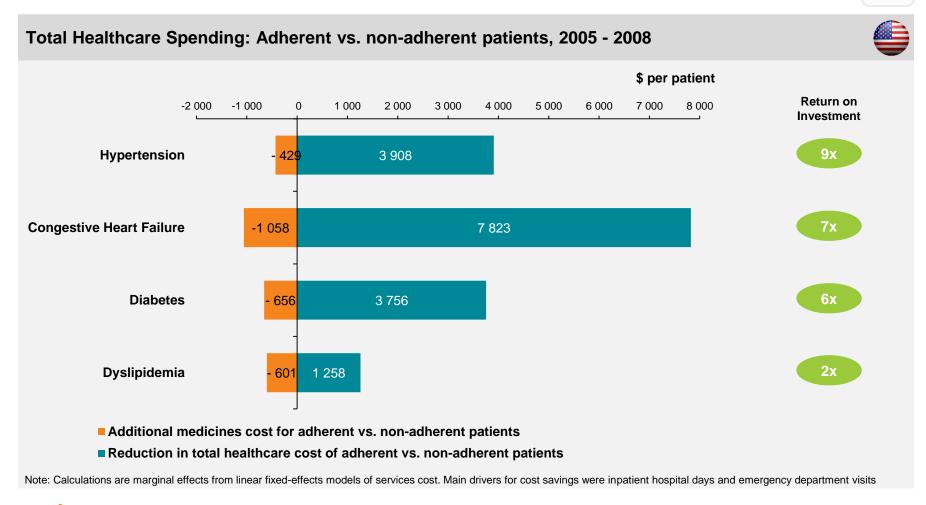
expenditure

growth rate

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



Analysis of compliance data clearly shows substantial returns that can be achieved through appropriate medicines usage





Developing solutions for the future

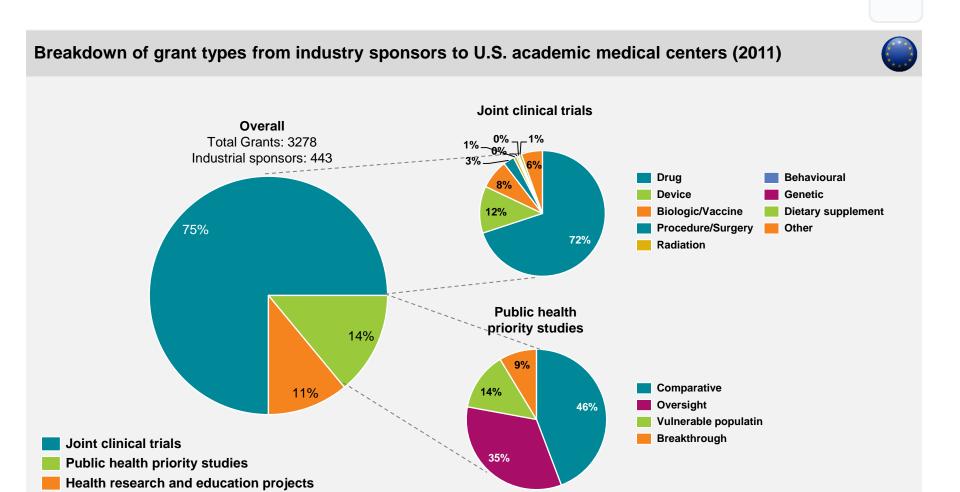
VISION & RETHINKING INCENTIVES

Integrating policy thinking on three elements that will result in win-wins



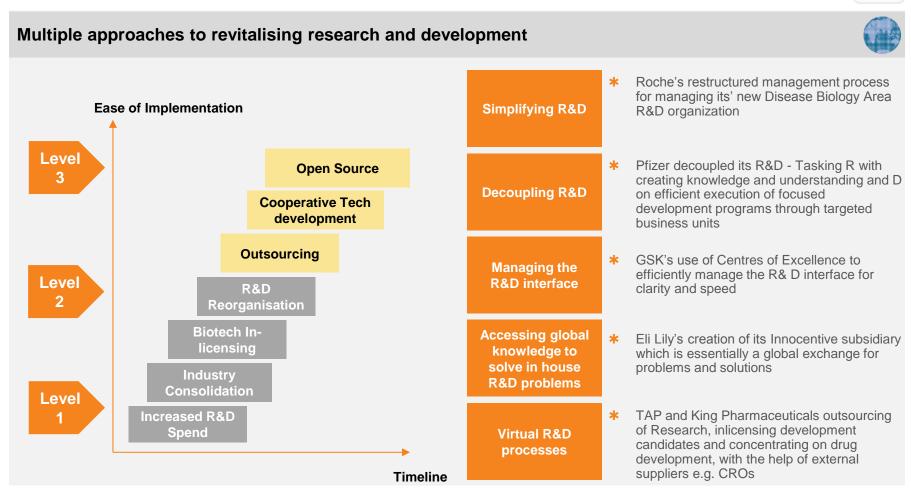


A large portion of healthcare research studies are driven by the biopharmaceutical industry and medicines research





The pharmaceutical industry is exploring more open and collaborative R&D approaches with wider ecosystem impacts





The advent of social media and more connected patients are opening up new opportunities to support patients and physicians

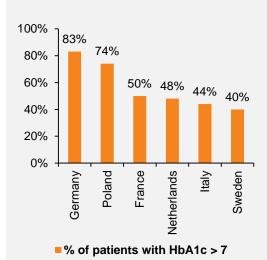
Case Study

Development of mobile disease management tools



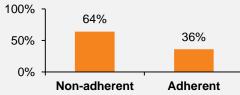
Situation

★ Diabetes patients across Europe are not in good glycemic control resulting in elevated risks for severe macro- and microvascular complications*.

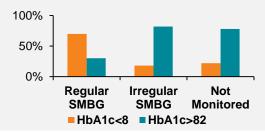


Situation

★ Diabetes relies heavily on selfmanagement[†], but the majority of patients are not adhering to their recommended SMBG therapy[△].



★ Regular SMBG increases the proportion of individuals achieving their glycemic targets[#]



Industry's Response

- The pharmaceutical industry has responded to the need for a more integrated way of blood glucose monitoring by establishing new paradigms around mobile and seamless disease management.
- ★ Example: 'iBGStar system' an integrated system of blood glucose monitoring, data capture, -storage, and –transmitting and management tool as integrated into an iPhone





Outcomes orientation allows creation of greater value in healthcare systems

Sustainable and valuable = Health Care

Health outcomes

Cost of delivering the outcomes

Population-specific

Improve outcomes

Starting point is to focus on improving patient outcomes

Reduce overall costs

Better quality of care is often less expensive over the long-term

Increase value and financial sustainability

Better quality care at equal or lower cost leads to higher value in the system

What can be done to achieve outcomes-focused health care systems?

Spread the word and knowledge

 Make sure decision makers understand not only the concept but also the key challenges and enablers towards on outcomefocused system

Collect outcomes data

- Secure standard-set of metrics
- Fund registries, securing infrastructure for data collection

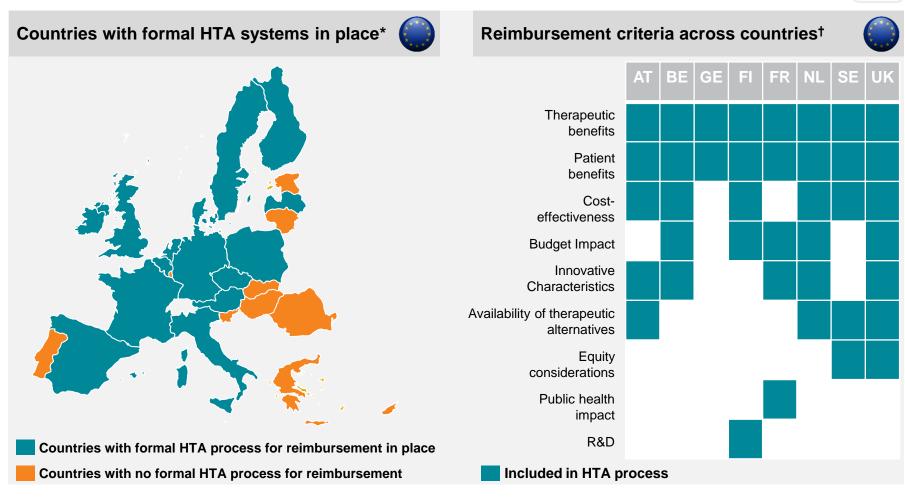
Use data to improve clinical practice

- Make data transparent and easily available for all stakeholders from physicians to patients and payers
- Introduce processes for data analysis, best practice identification and implementation

Re-design HC system structure to facilitate an outcomes focus

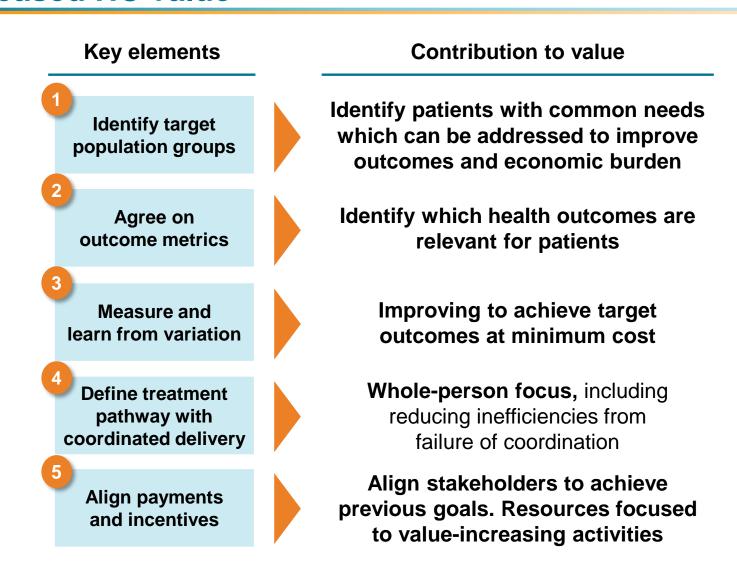
- Modify reimbursement models to eliminate barriers to outcomes measurement and value focus. Consider aligning economic incentives through value-based payments
- Organize health care around patients and patient pathways

Throughout Europe medicines are only reimbursed if value can be comprehensively proven across multiple dimensions





5 key elements in models that have successfully increased HC value

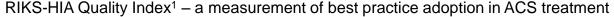


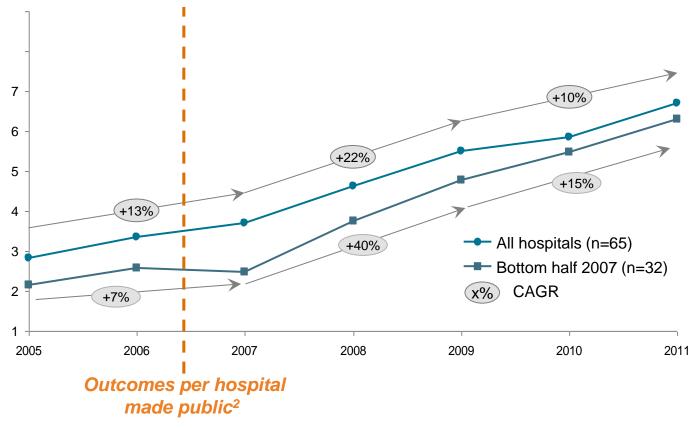


Data collection and transparency is a driver of quality improvement through best practices adoption



Decreased variation when low performers catch up with high performers





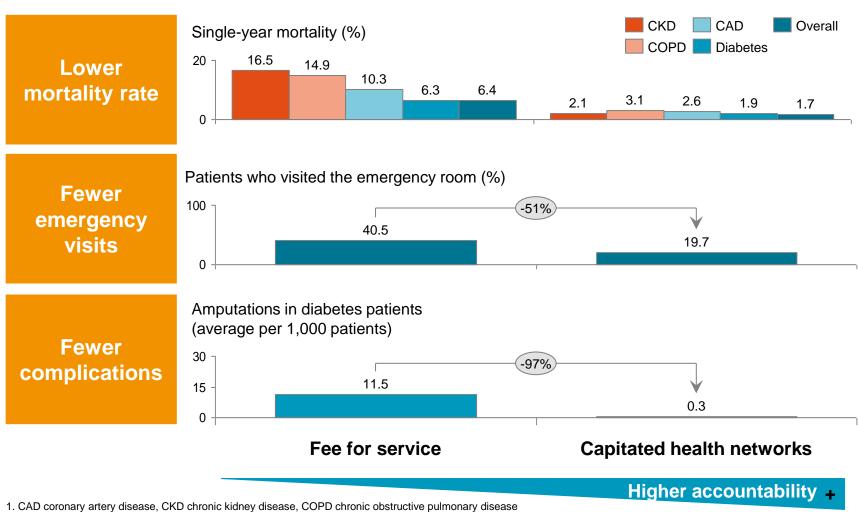
^{1.} The quality index from Riks-HIA measures Swedish hospitals adherence to national guidelines (best practice) regarding Acute coronary syndrome (ACS). The index is based on nine different process metrics which are described in the appendix. 2. Data on individual hospital performance was first published in the 2006 RIKS-HIA annual report. From 2006 onwards the public and the media could easily access the data and compare individual hospital performance. Source: RIKS – HIA Annual Reports 2005 – 2009, BCG Analysis



Payments tied to accountability show better outcomes & less resource usage than fee for service schemes



Based on Medicare data from patients in different programs



Note: Based on an analysis of glaims data and demographic information from 2011 for ~3M Medicare patients Source: Alternative Payer Models Show Improved Health-Care Value, BCG, 2013

Currently significant activity is developed at EU level, but there is too often a disjointed link between existing EU initiatives and outcomes agenda

Key elements	Contribution to value	Activity level
Identify target population groups	Identify and define measures of health outcomes the are needed for health quality and a healthy population	
Agree on outcome metrics	Significant efforts aligning measures working with other international bodies	1
Measure and learn from variation	Collects, compares and disseminates information o variation in health outcomes	n 🛑
Define treatment pathway with coordinated delivery	Existing focus on integrated case including reducir inefficiencies from failure of coordination (Europea Innovation Partnership on Active and Healthy Agein but currently not linked to outcomes	an 🕕
Align payments and incentives	Past project in DRG based funding, 1 out of 45 EuroREACH studies looking at how financing mod affect outcomes	el

Recap

CONCLUSIONS & WAY FORWARD

Healthcare eco-system is amongst the best growth opportunities for Europe

Key Headlines

- * Over the next few decades, healthcare will be amongst the key growth sectors
- * Health industries are responsible for the amelioration of pressing unmet global needs
- * Within healthcare, medicines are among the most exciting growth opportunities, primarily driven by demand from emerging markets
- * Positioned properly, pharmaceuticals should be able to continue to drive a positive trade balance for Europe
- ★ EU is also one of the foremost suppliers of pharmaceutical products worldwide and to the fastest growing markets
- * With a high wealth pool, Europe's ageing population represents the fastest growing consumer segment in Europe
- Growth in out of pocket expenditure, albeit modest, demonstrates an increasing willingness to fund healthcare consumption
- * In Europe, growth in demand for healthcare is forecast to outstrip that of other major industries
- Underlying demand will preserve and strengthen healthcare industry's status as Europe's foremost employer



Healthcare eco-system is amongst the best growth opportunities for Europe

Key Headlines

- ★ In addition, through joint funding of initiatives like IMI, further training and education are made available across Europe
- * Time between approval of first and second drug in a TA is decreasing over time, commercial success is more elusive than before
- * The pharmaceutical industry is exploring more open and collaborative R&D approaches with wider ecosystem impacts
- Sustained investment in R&D drives wealth across the economy and stimulates the next wave of innovation and entrepreneurship
- Evolving from a transaction-based models to outcomes-focused healthcare systems will deliver better health and contribute to sustainability of the social model in Europe



EFPIA's Collaboration with the College of European Studies
EFPIA'S PHARMA AWARDS



EFPIA Pharma Award

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 new 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

- ❖ <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)

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 € 1,650 (net) + basic package (including group insurance)
 - Where appropriate, other allocations could be agreed, such as contribution for accommodation in Brussels
- Award Ceremony





- Websitewww.efpia.eu
- By phone+ 32.2.626 25 55 (General)
- By e-mail firstname.familyname@efpia.eu amelia.kossi@efpia.eu

info@efpia.eu