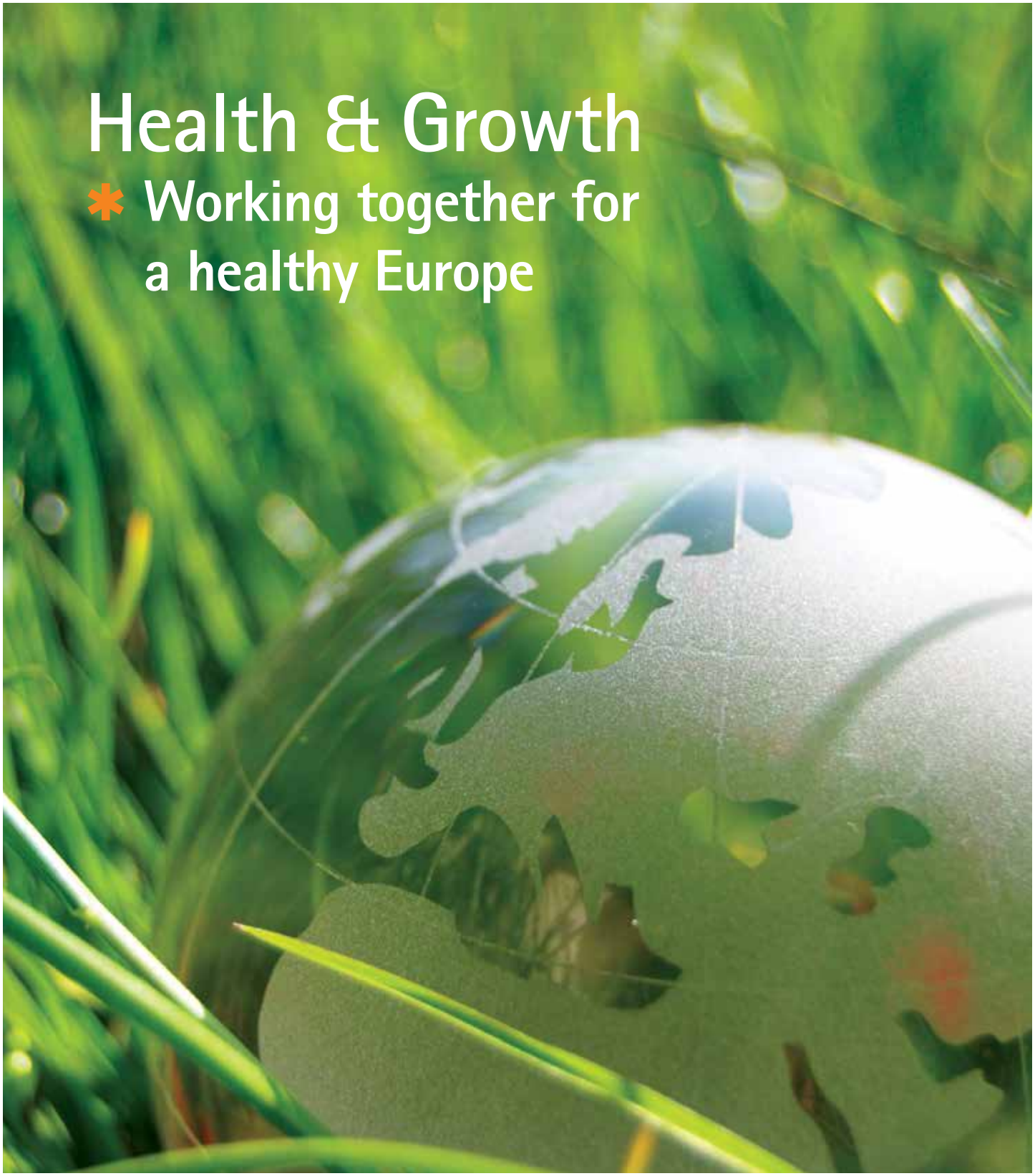

Health & Growth

Working together for a healthy Europe

A vision towards a life sciences strategy for Europe

Brussels, 2014

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European Federation of Pharmaceutical Industries and Associations

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1 Foreword

European healthcare systems are at a tipping point, driven by the increasing burden of providing world-class care for populations that are living longer – often with one or more chronic diseases – at a time when austerity measures are putting pressure on healthcare spending generally, and medicines expenditure in particular.

As Europe begins to emerge from the financial crisis and sets out its plans for a return to growth, the time is right to fundamentally review how Europe addresses the inter-connected challenges of improving the health prospects and productivity of its citizens, within an affordable financial framework, while ensuring that the pharmaceutical and life sciences industries – jewels in Europe's economy – continue to thrive. These challenges cannot be separated and addressed in isolation.

Europe cannot take the future competitiveness of its pharmaceutical industry for granted. Competition is now truly global. While the sector continues to grow in value terms, Europe's share is declining across many important indicators, such as share of global pharmaceutical R&D expenditure, New Chemical Entities discovered and employment. Being world class, rather than second best, matters.

Now is the time to look ahead. To return to prosperity and preserve its identity, Europe must emerge from the crisis as a highly competitive economy, grounded in a skilled workforce, a healthy population, and a sustainable social model. Any challenges that stand in the way can surely be overcome.

To ensure that the industry contributes to Europe's future success, we must all endeavour

to break down barriers and silos, and work together across Finance, Health and Social Care, Science and Industry to deliver improved health outcomes, within a sustainable financial framework and thriving healthcare and industrial ecosystem.

The biopharmaceutical industry is eager to strengthen its partnership with European institutions and governments to make innovation-led growth happen. We believe that now is the right time to open a new dialogue with Government and Society on how best to do that, so that we may collectively move in the right direction.

Richard Bergström
Director General of EFPIA

2 Introduction

'Health & Growth: Working together for a healthy Europe' sets out our vision for an integrated European life sciences strategy aiming to balance the need to manage rising healthcare costs with the need for an environment where industry can thrive and patients continue to benefit from innovative life-saving and life-enhancing treatments.

This strategy calls for a new generation of multi-stakeholder partnerships, joint direction-setting with industry, and co-created solutions to target Europe's key health and competitiveness challenges. We firmly believe that a new European Life Sciences Strategy will be vital to achieve the objectives of Europe 2020 and beyond.

Europe has made huge strides in improving life expectancy and health outcomes over the past 60 years. Innovative medicines have been a major contributor to these recent advances, accounting for 73 per cent of the improvements in life expectancy - which now extends to 100 years for one half of the children born today in the developed world.[1,2]

Healthcare advances have shifted the public debate from delaying death or increasing life expectancy at birth to reducing the prevalence of disease and improving quality of life. As we survive long enough to face the increased risk of degenerative diseases of the mind and body, people are living for many years with some form of medical disability or illness, which diminishes the quality of their existence, raises healthcare costs and undermines economic productivity. For the benefit of society and of the economy, we need new approaches to accelerate the translation of scientific progress and innovation into patient benefits in a safe and effective way.

The challenges we face could not have come at a more difficult time. The financial crisis, and the fiscal stabilisers it has triggered, has placed

a European-wide burden on public finances that is unprecedented since the era of post-war reconstruction. Healthcare in particular, has been strongly impacted with flat or negative budget settlements against rising volumes. The Organisation for Economic Co-operation and Development itself recognises that Governments in Europe have gone too far, and that the health prospects of European citizens have been compromised.[3]

The European Commission's Europe 2020 strategy addresses some of the key challenges ahead, focussing on delivering growth that is smart, sustainable, and inclusive – with a strong emphasis on quality job creation and poverty reduction.[4] The strategy sets out a vision for more effective investments in education, research, and innovation; demand-side policies to create 'pull' for innovative products and services; and the fostering of a high-quality employment economy that delivers social and territorial cohesion.

Through its contributions to innovation and growth and its focus on improving health outcomes, tackling inequalities in access to medicines, and reducing the productivity impairments caused by ill health, the research-based pharmaceutical industry is heavily invested in making the Europe 2020 strategy a success. In Europe alone, the research-based pharmaceutical industry invests around €30 billion in R&D each year.[5] It directly employs 700,000 people and generates three to four times that number of indirect jobs.[6] With almost 110,000 employees in R&D, the sector contributes in excess of 5% of the value added in the European economy.[7] Compared to other industries, the pharmaceutical industry has also proven more resilient to macroeconomic cycles,[8] providing vital economic stability. The pharmaceutical industry has broadly held its employment levels.[9] Continued growth in export performance has led to positive net trade balances comparable to the auto industry.[10]

Short-term resilience, though, is not the same as long-term invulnerability. The long-term viability of the pharmaceutical industry in Europe depends on Europe being a thriving centre for innovation. Even in a globally networked economy, where science happens is often where innovation happens. Where innovation happens is often where high technology manufacturing happens, particularly in the field of bio-pharmaceuticals. Only where new innovations are actively used, can their on-going potential for further development be actively explored – a key feature of the most recent advances in cancer innovation. For instance in colorectal cancer, median overall survival has increased from 8.0 months to 25.1 months through eight incremental innovation steps that combined clinical and pharmacological innovation.[11] The ability to bring all of these aspects of the bio-science ecosystem together explains why, since the US Government dramatically increased the funding of the National Institutes of Health in the 1960s and 1970s,[12] the US share of new chemical entities discovered has grown from 30% to 57%, while Europe's share has fallen from 58% to 34%.[13] As Europeans, we have to accept that we have to use innovation in order to have innovation.

3 Health and Growth:
A new life sciences strategy for Europe

Europe requires a new, sustainable, and holistic life sciences strategy to deliver innovative solutions to its citizens' pressing health needs and increase the region's global competitiveness. At the core of this new life sciences strategy is a new form of multi-stakeholder partnerships and joint direction-setting to effectively address the key health challenges of the future.

The research-based pharmaceutical industry can play a unique role, not only by investing in science and bringing innovative treatments to the market, but also by contributing more generally to Europe's economic recovery by generating quality employment and a positive balance of trade.

The new European life sciences strategy is built around three interlocking themes:

* **Health Outcomes** – improving health outcomes in Europe and removing the barriers that lead to inequalities in access
* **Sustainable Financing** – ensuring appropriate investments in medicines and exploring new, more affordable approaches to medicines pricing
* **Thriving Ecosystem** – committing to strengthen Europe's scientific base and creating an environment that will attract high quality innovation investment

European Life Science Strategy

Improving **HEALTH OUTCOMES** and removing inequalities in Europe

Supporting **SUSTAINABLE FINANCING** approaches to funding healthcare and medicines

Building a **THRIVING ECOSYSTEM** for healthcare innovation in Europe

Figure 1: European Life Science Strategy

Better outcomes

Europe has made significant advances in health outcomes over the past 60 years. Life expectancy has increased by nearly a decade,[14] and effective treatments have become available for many of the most common infectious and chronic diseases. Against this positive overall picture, access to healthcare and health outcomes can differ significantly across EU member states – and even within the different geographies of a single country.

Tackling health inequalities through more flexible and innovative approaches to medicines pricing and value recognition will be essential elements to continue to improve health outcomes and ensure they reach all citizens, regardless of where they work or live, or their personal wealth. It will also be an important signal that Europe takes access to innovation seriously.

Sustainable financing

Increased longevity has brought an increase in the number of years Europeans live with some form of disability or illness, with the attendant costs in terms of healthcare spending and lost productivity. The European Commission (EC) has estimated that, without new approaches, average healthcare spending could rise from 7 to 9 per cent of GDP by 2060,[15] placing a strain on national finances. Halting and reversing the progression of chronic diseases is the best investment that health systems can make to ensure over all expenditure stays in control, and medicines have a key role to play. Sustainable financing means ensuring that the right investment gets made, ensuring that all patients can get access to the best treatment options, whilst at the same time ensuring a stable and predictable funding environment. Achieving this will require better-coordinated, more agile medicines assessment processes across EU member states and the widespread signing of Growth and Stability agreements among, governments, payers, and industry to stabilise spending policies and reduce their volatility. This greater predictability will give the research-based pharmaceutical industry the confidence it needs to continue to invest in the research and development in Europe that translates into ground-breaking innovation.

Thriving ecosystem

The research and development that is conducted today will lead to the discovery of tomorrow's life-changing and life-saving medicines. Around the world today, more than 16 000 compounds targeting over 100 diseases are currently in development.[16] Yet, over the past ten years, the number of active substances launched in Europe has consistently been lower than in the United States and Europe's share of new chemical and molecular entities discovered is at its lowest ever.[17,18] A coordinated, pan-EU R&D agenda in life sciences is needed to create a thriving ecosystem that ensures that the European pharmaceutical industry remains globally relevant and that our citizens obtain swift access to the innovative treatments they need and deserve. Another critical factor required to sustain the ecosystem is a revised incentives scheme adapted to the next generation of biomedical research and to Europeans' most critical unmet health needs.

The new life sciences strategy outlined in this chapter aims to balance the need to manage rising healthcare costs with the need to create an environment where industry can thrive and patients continue to benefit from innovative, life-saving and life-enhancing treatments. In short, 'Health & Growth' proposes a policy framework to drive **better health outcomes for European citizens**, **more sustainable funding approaches**, and **a flourishing healthcare ecosystem in a pro-innovation environment** – while ensuring that the pharmaceutical sector remains a key source of growth and competitive advantage for Europe and society as a whole.

3.1 Improving health outcomes and reducing inequalities in Europe

Health is a value in its own right. As a society, it is our duty to look out for our weakest members and ensure that everyone has access to what they need to realise their full potential and to lead a happy and successful life. Without health, much else becomes impossible, including economic prosperity.

While Europe has come a far way in delivering improved health outcomes to its citizens, an ageing population, sedentary lifestyles, and the growing burden of chronic diseases is changing how healthcare is organised and delivered. Moreover, health outcomes can differ significantly depending on where a patient lives, among other reasons because of unequal access to innovative medicines. Within Europe there is almost a 10 year difference in life expectancy between the citizens of Spain and Italy at one end, and Romania and Latvia at the other.[19]

Although health and healthcare are largely a national matter, European institutions cannot afford to sit idly by, as our region's prosperity and well-being hang in the balance. Nor can we accept that patients across Europe do not have the same level of access to innovative medicines, when our institutional framework is built on the foundations of solidarity and cohesiveness.

3.1.1 Chronic diseases and increasing disability are the biggest threat to a healthy and productive Europe

Longer life expectancy and urban lifestyles in Europe have given rise to a new set of challenges. As more citizens live more years with some form of disability or illness, societies must devote less attention to prolonging lifespans and more to reducing the prevalence of disease and increasing patients' functioning.

According to the European Chronic Disease Alliance,[20] more than 100 million European citizens – or 40 per cent of the population above the age of 15 – suffer from chronic disease. That proportion rises progressively with age, and nearly all Europeans are likely to suffer from at least one chronic condition before retirement. A European adult can now expect to live between 12 and 16 per cent of their life with some form of medically related disability or illness, equivalent to almost 1.5 additional years with a disability or illness compared to 20 years ago.[21] Chronic diseases, now including cancer, are responsible for €700 billion in annual healthcare spend in Europe (more than 70 per cent of the total), and they continue to rise with no end in sight.[22]

The prevalence of chronic disease and associated disabilities – currently affecting 14 per cent of Europe's working-age population – not only drives up healthcare costs, it also undermines economic productivity. In some European countries, as much as 7 per cent of GDP may be lost due to the impact of non-communicable diseases.[24] With the European workforce expected to decline by 10 per cent over the next 40 years due to demographic factors.[25] Europe can simply not afford to ignore this issue.

The reality is that health systems across Europe have struggled to halt the progression of chronic diseases. Experts have long recognised that new approaches are required to raise awareness among 'at risk' populations to take action, proactive risk profiling and end-to-end approaches to pathway management are needed, requiring re-alignment of system incentives. Unfortunately, initial experience with disease management programmes has been largely disappointing. Many of them have produced, at best, only modest improvements in health outcomes, and few have actually led to lower health care

Male Disability life years in % of total life expectancy

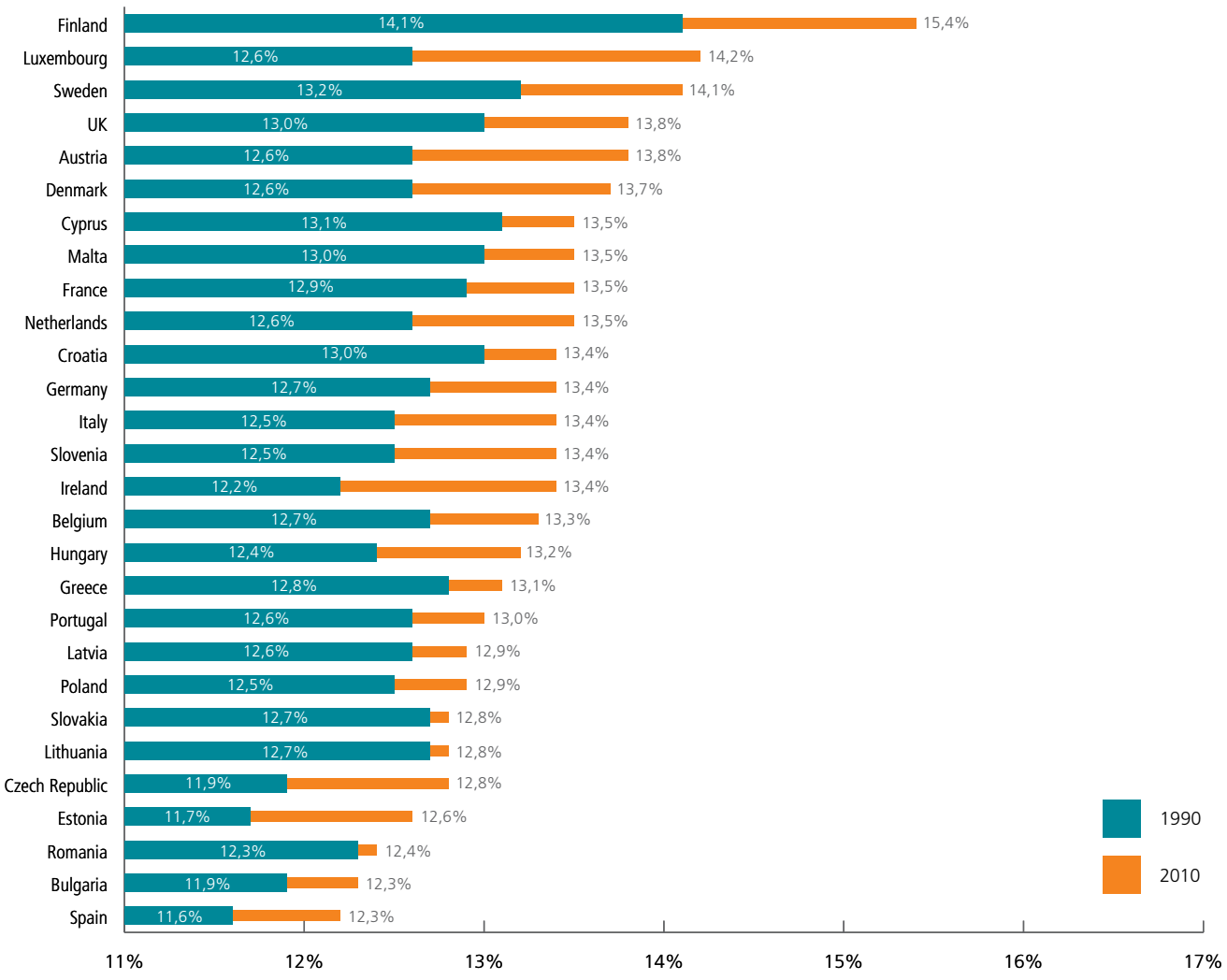

Figure 2: Male and Female Disability Life Years as a percentage of total life expectancy in 1990 and 2010 (first part)

spending. In fact, an analysis of more than 300 early disease management programmes found that while many had improved the quality of care, there was little conclusive evidence of better long-term outcomes or significant savings.[26]

From an economic perspective, Europe may be on the verge of a vicious cycle in which the combination of healthcare costs, changing demographics, and illness-related productivity losses put the sustainability of European universal healthcare models at risk. Many countries have already restricted access to healthcare by, for example, making it difficult to obtain innovative medicines, increasing user charges, or delisting services from the benefits catalogue – measures that, while seemingly necessary in the short term, risk creating greater costs over the long run.

Female Disability life years in % of total life expectancy

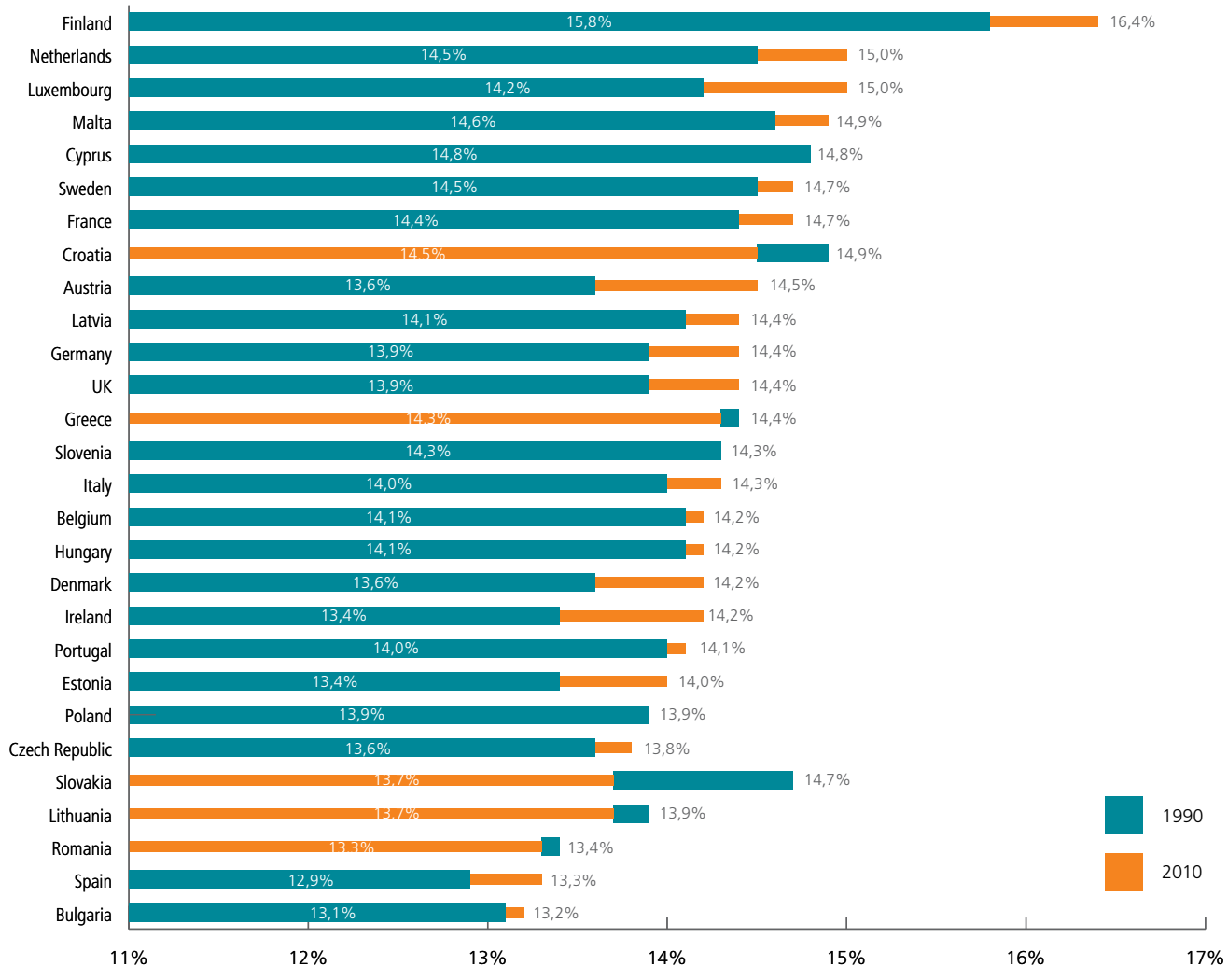

Figure 2: Male and Female Disability Life Years as a percentage of total life expectancy in 1990 and 2010 (second part)

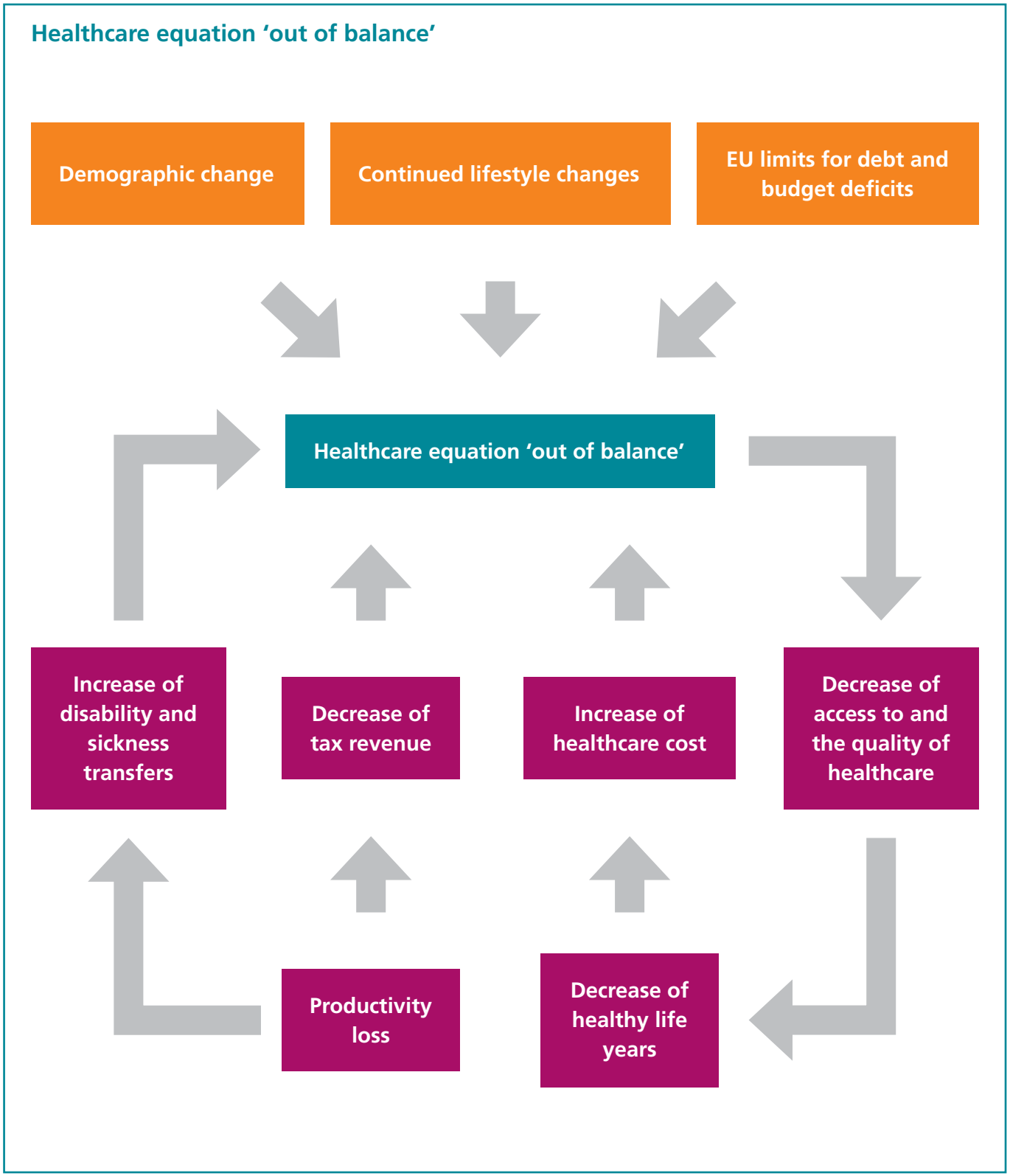

Figure 3: Healthcare equation 'out of balance'

> Healthcare stakeholders must act on the increasing burden of disability if Europe is to remain healthy and productive.

Both the health and social sectors need to develop more responsive and sustainable approaches. Given the often complex causes leading to the onset of many chronic diseases, a coalition should be formed among public policymakers, the health community, patient advocacy groups, and civil society in general to take action at many levels and across multiple policy areas. Currently, initiatives such as the 'European Innovation Partnership on Active and Healthy Ageing' promote a good example how a multi-stakeholder initiative from governments, academia, health care providers, industry and other stakeholders combine their forces.[27] However, Europe should raise its ambitions for the future and act on the increasing burden of disability, moving the focus from extending life expectancy to preventing disability where possible – and improving patients' ability to function where not. Without a continuing improvement in health outcomes, healthcare in Europe will be unaffordable in the future.

RECOMMENDATIONS & PROPOSALS

* In the short term, the research-based pharmaceutical industry calls for investments in developing European-wide norms for data capture and data registries to define standards of care grounded in evidence-based models.
* A European framework to evaluate chronic disease management programmes by defining benchmarks and 'best-in-class patient pathways' should be established to ensure the continuity and sustainability of improved patient care. This could be developed through a pilot in one of the six key areas of chronic disease (cardiovascular, metabolic, oncological, respiratory, musculoskeletal, or mental health), before rolling it out to the other five by 2020. The initiative should set European standards for pathway management, based on harmonised measurements of clinical outcomes and cost-effectiveness.
* Investment of EU structural funds should be explored over the medium term (where local funding is not available) to encourage the development of health delivery infrastructure in line with best-practice standards, with a focus on intermediate-care capabilities, risk profiling, and performance and outcomes data management.
* The research-based pharmaceutical industry will offer its full support and provide its expertise with new technologies in patient care (e.g., e-health), disease awareness, and compliance programs, supporting multi-stakeholder initiatives to address this pressing need. Through the Innovative Medicines Initiative (IMI) platform, it will also co-invest in public private partnership initiatives aligned with this policy goal.

3.1.2 Patients across Europe should have equal access to innovative medicines, and medicines pricing should better reflect each country's ability to pay

Huge inequalities persist across Europe, both among and within countries. For example, life expectancy at birth in Romania is nine years less than in Spain,[28] while in the UK, a 20-year difference in life expectancy can be found between London underground stations.[29] Current differences in health outcomes are a result of numerous factors including availability of healthcare infrastructure, access to and quality of healthcare, early and appropriate use of best available medicines and medical technologies, and specific social context.

Despite studies indicating that the use of innovative medicines accounted for nearly 75 per cent of the improvement in life expectancy over a five-year period in several OECD countries, there is abundant evidence that innovative medicines do not reach all European citizens, let alone at the same speed. A study in 2010 for the European Council demonstrated large differences in the uptake of new medicines, while a more recent analysis reveals significant differences in the adoption of innovative medicines within different therapeutic areas.[31] These different rates of uptake cannot be solely explained by differences in GDP per capita, although this is clearly a factor for lower income economies.

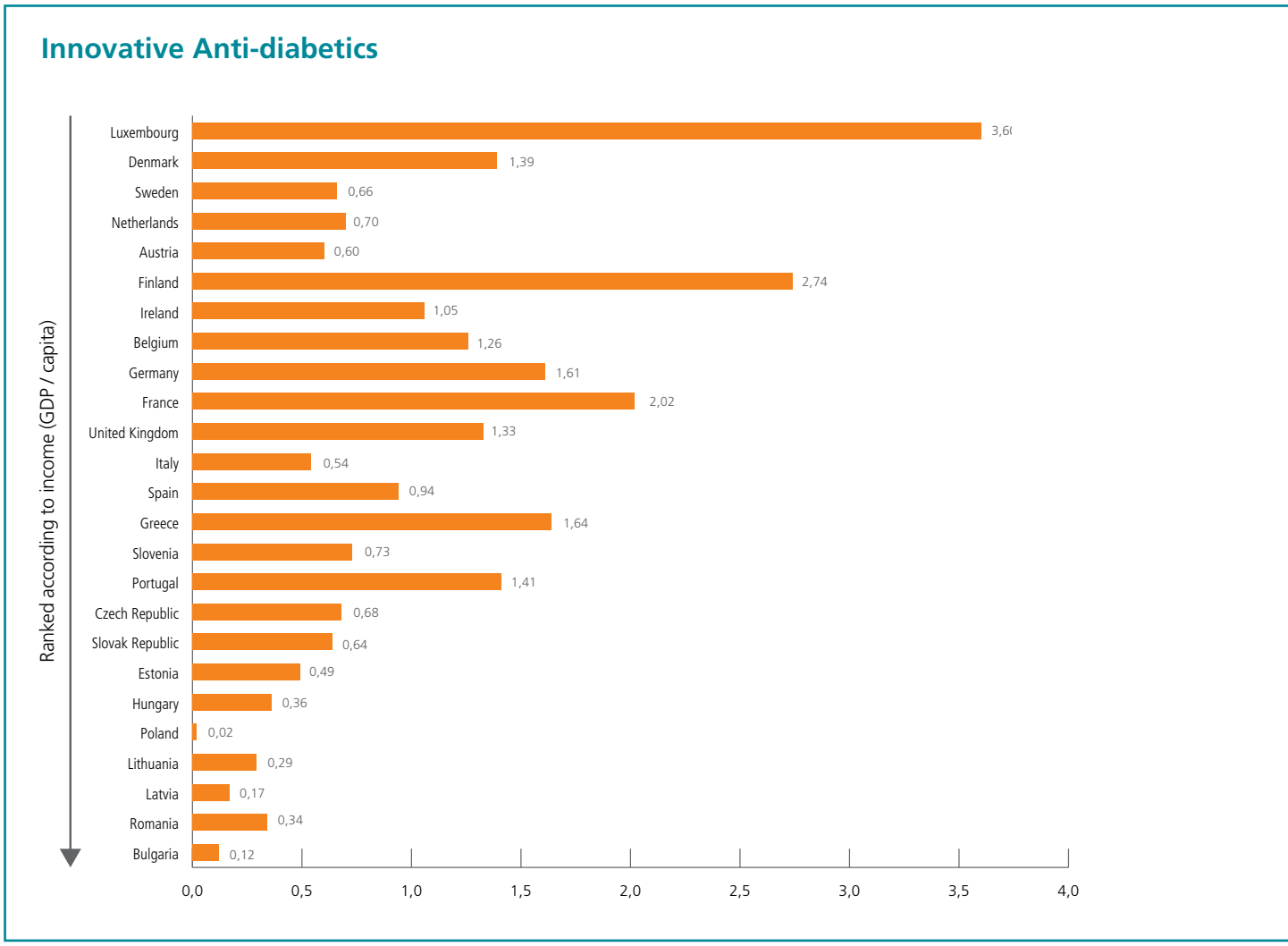

Figure 4: Volume consumption of innovative therapies / 100 000 people indexed to European Average (2012)[32] (first part)

In a perfect world, pharmaceutical companies would have an incentive to adjust prices according to different demand conditions, which include not only the ability to pay but also disease prevalence, clinical practice, and other factors affecting the volume of consumption. In practice, the presence of international reference pricing and the practice of intra-European trade in medicines distort incentives for true price discrimination. A company lowering its price in one country would find a significant portion of the medicines available for that country exported to higher price countries, contributing to supply shortages in the lower priced countries and lost earnings – largely to the benefit of traders not healthcare systems – from higher priced countries.[33] In addition, the practice of reference pricing means that other markets could then reference the lower price, either directly (where pricing baskets are formally used) or indirectly through comparison of purchase prices.

These factors combine to create distortions in the European market for medicines. Medicines are unlike any other good insofar as society expects everyone to have access to what they need. Ability to price discriminate, then, is a critical factor for ensuring such access for patients.

Innovative Anti-Coagulants

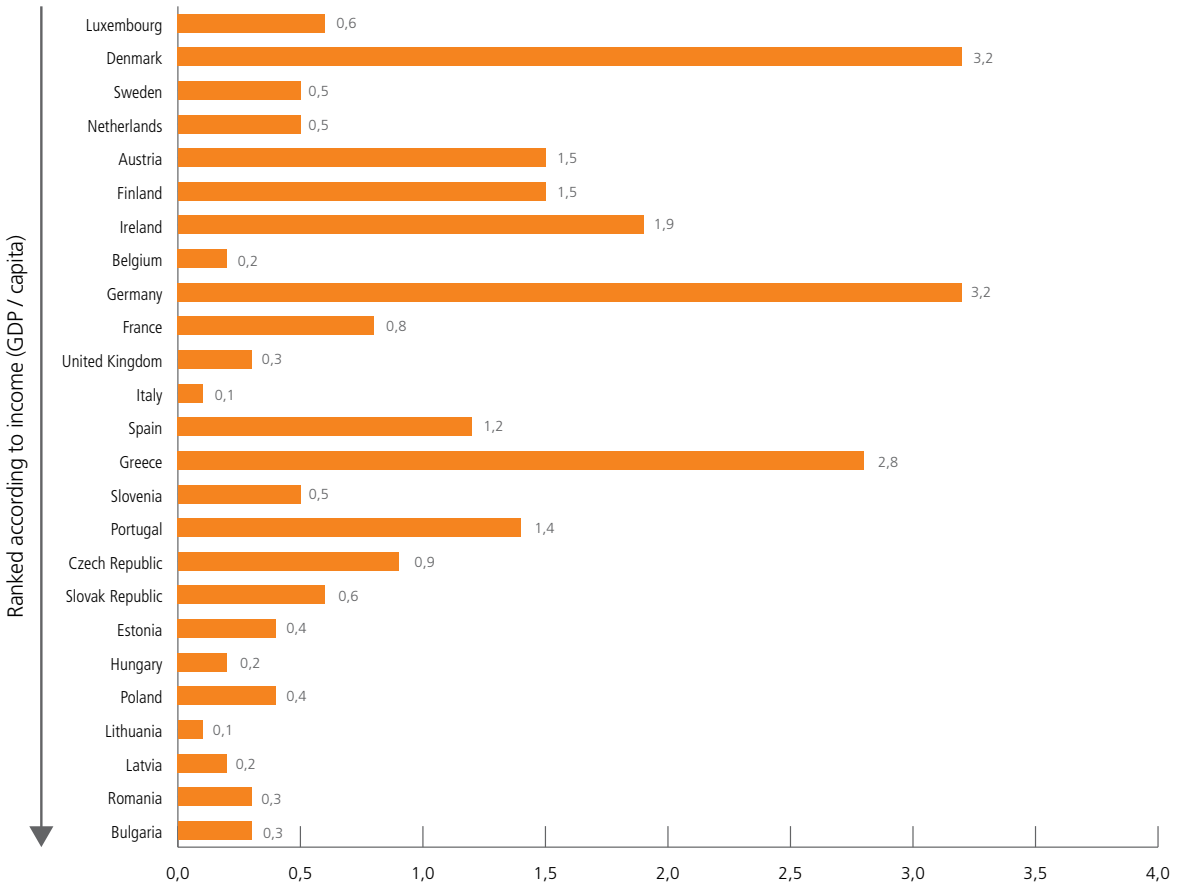

Figure 4: Volume consumption of innovative therapies / 100 000 people indexed to European Average (2012)[32] (second part)

Innovative “wet” AMD therapies

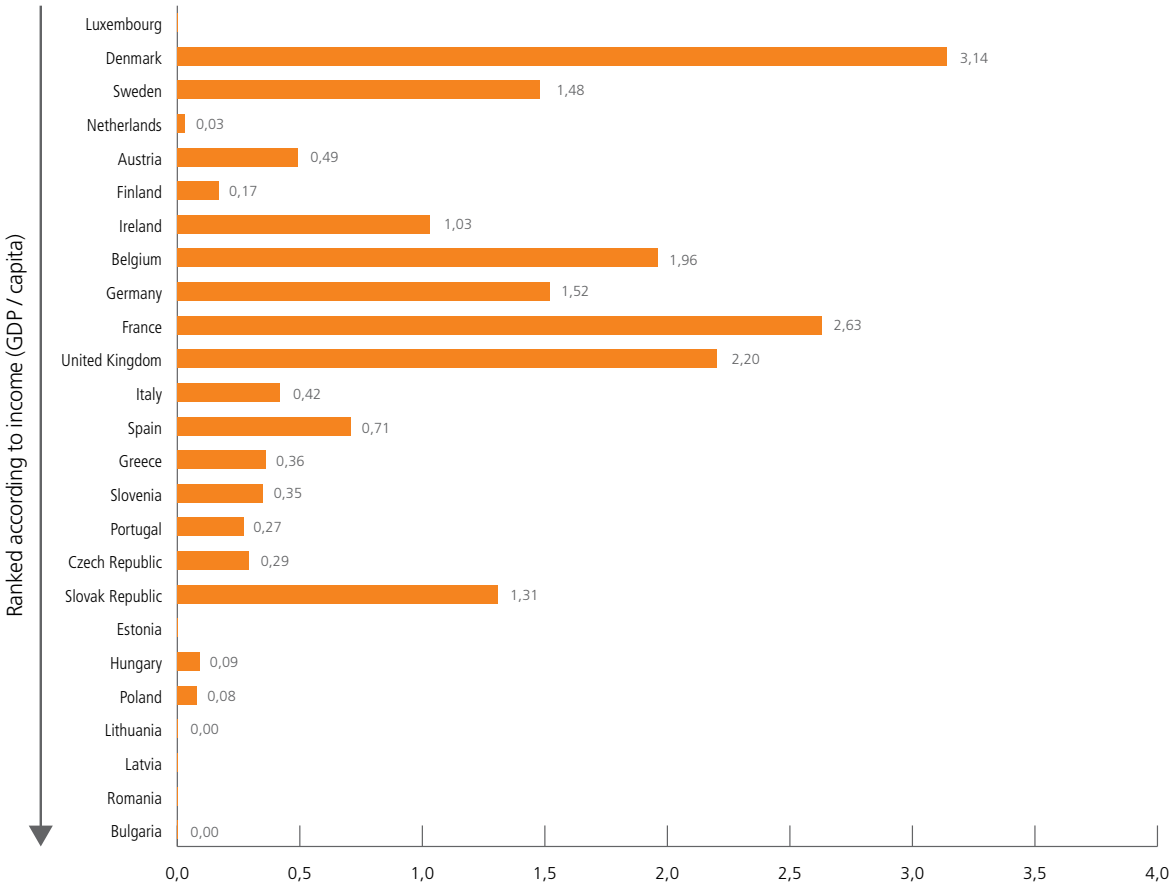

Figure 4: Volume consumption of innovative therapies / 100 000 people indexed to European Average (2012)[32] (third part)

> Stakeholders need to minimise health inequalities by joining forces to overcome institutional barriers to access.

Over the last decade, these issues have been discussed on European and national level, to limited effect. In 2003 the European Commission, based on recommendations by the G10 group, promoted differential pricing as a means to enhance patient access to medicines.[34] In that same year, the Commission also advocated a differential pricing model as a potential means to control national pharmaceutical-related expenditure, followed by an acknowledgement in 2008 of the need for more action to improve the availability and affordability of medicines within the EU.[35] Despite these developments and the positive dialogue with the Commission on how access to medicines can be improved, over a decade has passed since the G10 recommendations without real progress.

Europe needs to ensure that the practical operation of the single market maximises patient access to treatments across the whole of Europe.

RECOMMENDATIONS & PROPOSALS

* The research-based pharmaceutical industry calls on the EU to urgently review the practical operation of the free movement of goods principle in medicines to ensure that market distortions do not hinder patient access.
* The EU should encourage the adoption of new voluntary measures to improve medicines access in Europe to ensure that the single market results in fair prices, based on ability to pay, and equal access for all. The EU should encourage member states to take reasonable measures to ensure security of medicines supply and encourage differentiated price competition, while minimising the impact on price referencing.
* The research-based pharmaceutical industry proposes the piloting of such differential pricing measures in a selection of countries where access to medicines is currently poor. Any measures taken should be properly evaluated in line with EU principles. The overarching objective should be to allow patients in all EU countries to achieve a similar level of access to medicines.

3.2 Supporting sustainable funding approaches to healthcare and medicines

Financing healthcare is and will continue to be a fundamental challenge for policymakers. It is important that governments manage their overall healthcare spend in a fiscally responsible manner as the overall demand for healthcare will rise due to the increase in chronic disease prevalence associated with ageing population. European society needs to ensure that the best possible use is being made of the public money available. A realistic view on how much Europe and the Member States want to spend on healthcare and whether or not such spending can be sustained from the tax payer is a critical step for the future. This equation should reflect all factors of the healthcare process – not only medicines – to create an integrated value-based system for the future that can support rational decisions.

A value-based system relies on a thorough analysis of costs, savings and efficiency drivers. Currently, such an analysis is rarely available in an ideal form. Nevertheless, genuine efficiency often requires spending money upfront, in order to reduce cost either later or elsewhere in the system. When seeking efficiencies in practice, short-term solutions are often preferred over the challenge of tackling long-term problems. However, policymakers should nevertheless resist this urge and instead move towards planning for the long term.

Medicines should be part of an integrated assessment approach to understand the real value of money spent in healthcare management. Where an integrated approach to healthcare management is not practical, it is important that the industry is engaged in discussions with policy makers to ensure stability in the medicines market.

Currently, many believe that medicines are the chief culprit behind rising healthcare costs in Europe. They are not. Medicines account for less than 15 per cent of total healthcare expenditure across Europe – significantly less than other healthcare interventions, including inpatient care and long-term nursing care.[36,37] In addition, only 15 per cent of increased healthcare spend across OECD countries between 2004 and 2010 can be attributed to medicines.[38] In fact, the average unit cost of medicines has declined by 16 per cent since 2000, against a 25 per cent increase in general consumer prices.[39] This does not mean that further efficiencies in medicines expenditure cannot continue to be generated: they can and should. But such efficiencies should neither compensate for, nor subsidise, the failure of other parts of the system to drive out efficiencies.

3.2.1 Sustainable healthcare financing in Europe needs to be based on a mutually-agreed definition of medicines' value and provide, when appropriate, for early access to medicines

Early and appropriate use of medicines is one of the most effective interventions that can be made to control costs in the health system overall. However, inconsistent healthcare policies, reimbursement processes, and health technology assessments across Europe delay early access to medicines for many citizens. Medicines prices and expenditure is an easy target for policy makers in search of quick savings. However, this also impacts global perceptions of whether countries truly value innovation and is therefore a factor in creating an environment that fosters economic stability for the pharmaceutical industry in Europe.

Most EU member states are formally introducing some form of health technology assessment (HTA) to assist in access decisions including pricing, and reimbursement processes for medicines. Appropriately designed HTA processes can help encourage rational decisions. However, the current patchwork of valuation and assessment criteria across Europe may be leading to wasteful and costly duplication of effort in both public and private sectors. This means more cost and delay for everyone.

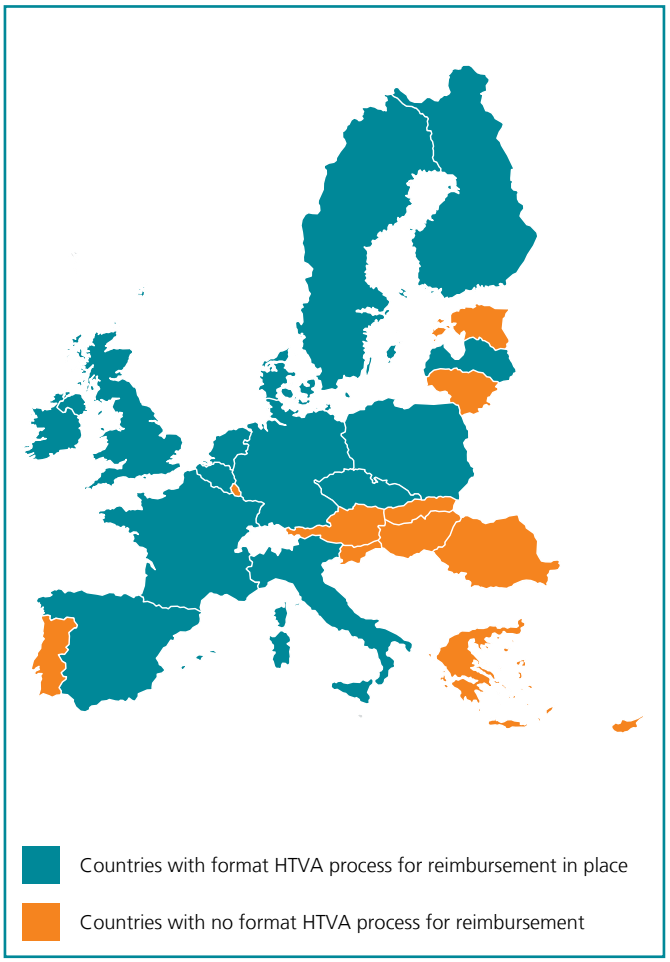

Figure 5: Countries with formal HTA system in place [41]

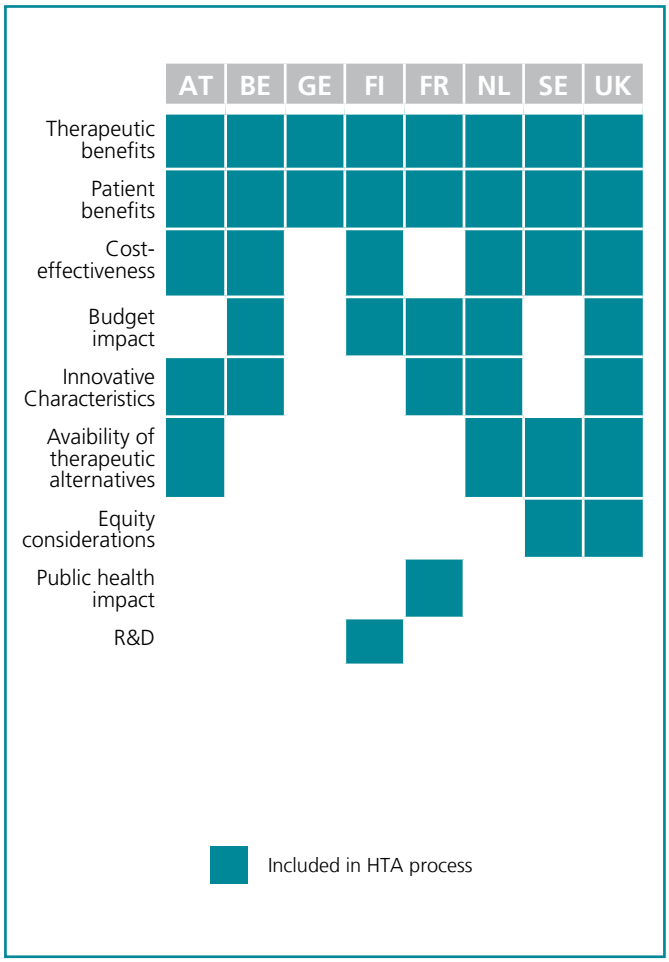

Figure 6: Reimbursement criteria across countries [42]

A recent review of assessments conducted by authorities in Germany and France on the same nine medicines, clearly underlines the lack of alignment on key ratings such as the degree of innovation, inexcusable in an environment where clinical standards are increasingly global.[40] Far from being empirical, HTA processes can often be arbitrary and politicised according to the experience of our members. Processes and timelines also pose an issue. While in some countries, such as Germany, medicines are immediately available to patients after marketing authorisation (and before the HTA is performed), in other countries HTA and reimbursement processes delay access to innovative medicines up to several years.

We support the proposition that the medicines assessment process and HTA agencies should be tailored to each country's healthcare system. We also agree that each country's decision processes should reflect its unique legal conditions and cultural understanding. But they should not be an excuse to postpone patients' timely access to the medicines they require, or to challenge or re-interpret basic decisions on clinical efficacy already taken by the European Medicines Agency. Citizens in Europe are entitled to some consistency in decision making in matters that affect their entitlement to better health.

In 2004, the European Commission and Council of Ministers recognised the urgent need to establish a coordinated network of European HTA organisations. This led to the creation of the EUnetHTA, charged with developing a general strategy, principles, and implementation proposal for sustainable European HTA collaboration. Its more immediate task was to strengthen the practical application of tools and approaches to cross-border HTA collaboration. Several promising pilots have been conducted to tighten cooperation between regulatory and HTA agencies to facilitate development plans and align evidence requirements both pre- and post-approval. In November 2013 the EMA and EUnetHTA published a three-year work plan that formalises the cooperation started in 2010 and covers collaboration in the following areas: (i) scientific advice and early dialogue with sponsors, (ii) exchange on the development of scientific and methodological guidelines to facilitate clinical-trial design and to generate data relevant for benefit-risk and relative effectiveness assessments, (iii) approaches for collection of post-authorisation data, and (iv) orphan medicinal products.

Emphasising the pressing need for optimisation in this area, a new initiative, 'The HTA Network', began in October 2013 to develop a vision on the long-term provisions for HTA cooperation in the EU.Under a harmonised HTA landscape, assessments should recognise the value medicines deliver to the wider system and quality of life, not just cost, and provide appropriate incentives for on-going innovation in areas of high priority for Europe.

In serious conditions with high unmet medical needs, the regulatory assessment process should be flexible enough to provide patients with early access to new treatments – before full marketing authorisation – if compelling clinical evidence suggests they offer a substantial improvement over existing therapies. Article 83 (1) of Regulation (EC) No. 726/2004 introduces the legal framework of compassionate use in the European Union.[43] Compassionate use programmes allow medicinal products that do not yet have full market authorisation, but are in the development process, to be made available to patients with a severe disease who have no other satisfactory treatment available to them. Currently, compassionate use programmes, such as the French ATU, are co-ordinated and implemented by the EU Member States, which decide independently how and when to open such programmes according to national rules and legislation.[44] We would encourage a more systematic implementation of such programmes across Europe.

More needs to be done in Europe to signal the urgency of accelerating patient access to the most beneficial new medicines. Through the FDA's breakthrough designation, the US has made progress in this area. Europe however is more complicated because patient access is determined not only by regulatory authorities, but by an increasingly complex array of health technology assessment and other market access processes. We recommend as a first step that a clear designation be established at the EMA to identify those products where accelerated market access is important. Such a 'Priority Medicines Designation' could, for instance, indicate a strong alignment with the objectives outlined in the Priority Medicines for Europe and the World 2013 update report, co-ordinated by the World Health organisation.[45] The designation should be a signal to HTA and other market access agencies around Europe to appropriately prioritise those products identified.

> Europe should establish a harmonised approach to assess the value of medicines delivered to the wider system and foster early access to medicines through compassionate use programmes.

RECOMMENDATIONS & PROPOSALS

* The research-based pharmaceutical industry calls for immediate action to intensify and institutionalise the dialogue between regulators, HTA agencies, and industry. The current initiatives for joint scientific advice involving regulators and payers – and specifically, the three-year work plan by EMA and EUnetHTA – provide an excellent foundation on which to build. We ask the European Commission, Member States, and all relevant policymakers and stakeholders to grant their full support and attention to achieve sustainable and substantial results.
* We ask that compassionate use programmes should be implemented more widely across Europe to foster early access to medicines in life-threating diseases. Best-practice examples in early medicines access should be rolled out across Europe to build on the existing experience such as the ATU in France. Further, Europe should establish a way to indicate the most beneficial new medicines with a clear urgency of accelerating patient access. This should serve as a signal to HTA and other market access agencies around Europe to appropriately prioritise those products.
* Over the longer term, the research-based pharmaceutical industry calls for the harmonisation of HTA approaches across Europe, by establishing a more consistent definition of value and approach to the evaluation of relative effectiveness, while retaining the independence of national HTA authorities on the pricing and reimbursement of medicines. Working collaboratively with the pharmaceutical industry, member states are asked to deepen their collaboration and foster convergence in key assessment criteria such as comparators, end-points, and levels of evidence considered in clinical trial activities and value dossiers.
* The research-based pharmaceutical industry has developed substantial capabilities in the HTA and regulatory field and insights into approaches used across the world. We are committed to providing this expertise and to working jointly with stakeholders to develop a more homogeneous and sustainable approach and provide candidate products to test new approaches.

3.2.2 Arbitrary financial policies to slow medicines expenditures are jeopardising health outcomes and inhibiting investment in R&D

Many observers, among them the World Health Organisation,[46] believe that the dramatic slowdown in the growth of healthcare expenditure and real decreases in medicines budgets place many of the health gains achieved in Europe over the past 30 years at risk. If this trend continues, it could endanger the vision of a healthy and productive European population, which is required to meet the continent's future challenges. Within constrained healthcare budgets, there is no consensus on the appropriate share that should be devoted to medicines, but studies in many countries bear out that a significant reduction in medicines expenditure – or a shift of their cost from a third-party payer to individuals – causes an immediate deterioration of health outcomes and increases demand for more expensive forms of healthcare delivery. Recent experience has shown that reducing medicines coverage and increasing the financial participation on the part of patients, has led to postponement of treatment and greater demand for more expensive, but free at the point of use, services elsewhere in the system, like emergency departments.[47]

In most countries, medicines have shouldered a disproportionate burden of the savings in healthcare expenditure, despite being extensively value-assessed in many jurisdictions and proving the delivery of value throughout their lifecycle. This creates an unpredictable environment for industry, sends a confusing signal

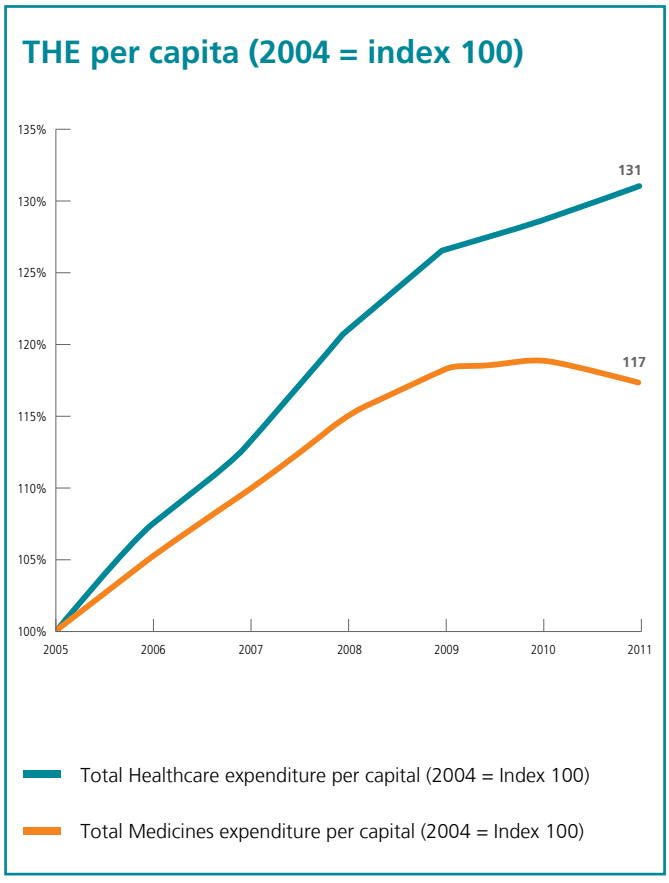

Figure 7: Total healthcare expenditure per capita and total medicines expenditure per capita[51]

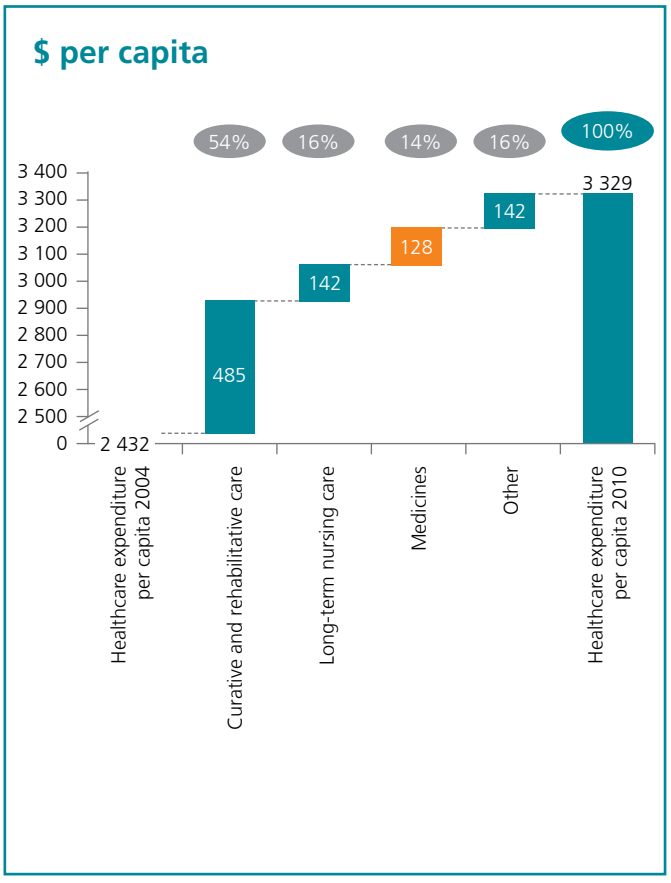

Figure 8: Share of growth per healthcare category[50]

about Europe's commitment to innovation, and potentially risks member states' ability to achieve further efficiency in healthcare through the appropriate use of medicines and other technologies.

A recent OECD report shows that growth in medicines expenditure per capita across Europe has lagged that of healthcare expenditure since 2007.[48] In addition, the growth rate of medicines from 2004 to 2010 – at 14 per cent – is slightly below that of long-term nursing (16 per cent) and significantly below that of curative and rehabilitative care (54 per cent).[49]

Europe cannot afford to risk an increase in disability and ill health by adopting the wrong measures. Disabilities and sickness transfers already account for more than one of every three euros Europe spends on social protection.[52] This issue heavily affects all regions – a US study of 50 000 employees found that health-related productivity costs were, on average, 2.3 times greater than medical and medicines costs combined.[53] Policymakers and regulators alike would do well to look beyond short-term cost containment, seeking instead system efficiency to keep citizens healthy, minimise absenteeism, and prevent early health-related exits from the labour market.

Improved and appropriate usage of cost-effective medicines continues to be an opportunity in several countries to achieve better returns from existing medicines expenditure and create headroom to improve usage of clinically cost-effective new medicines. Currently, there is a significant difference in cost per treatment across Europe.[54]

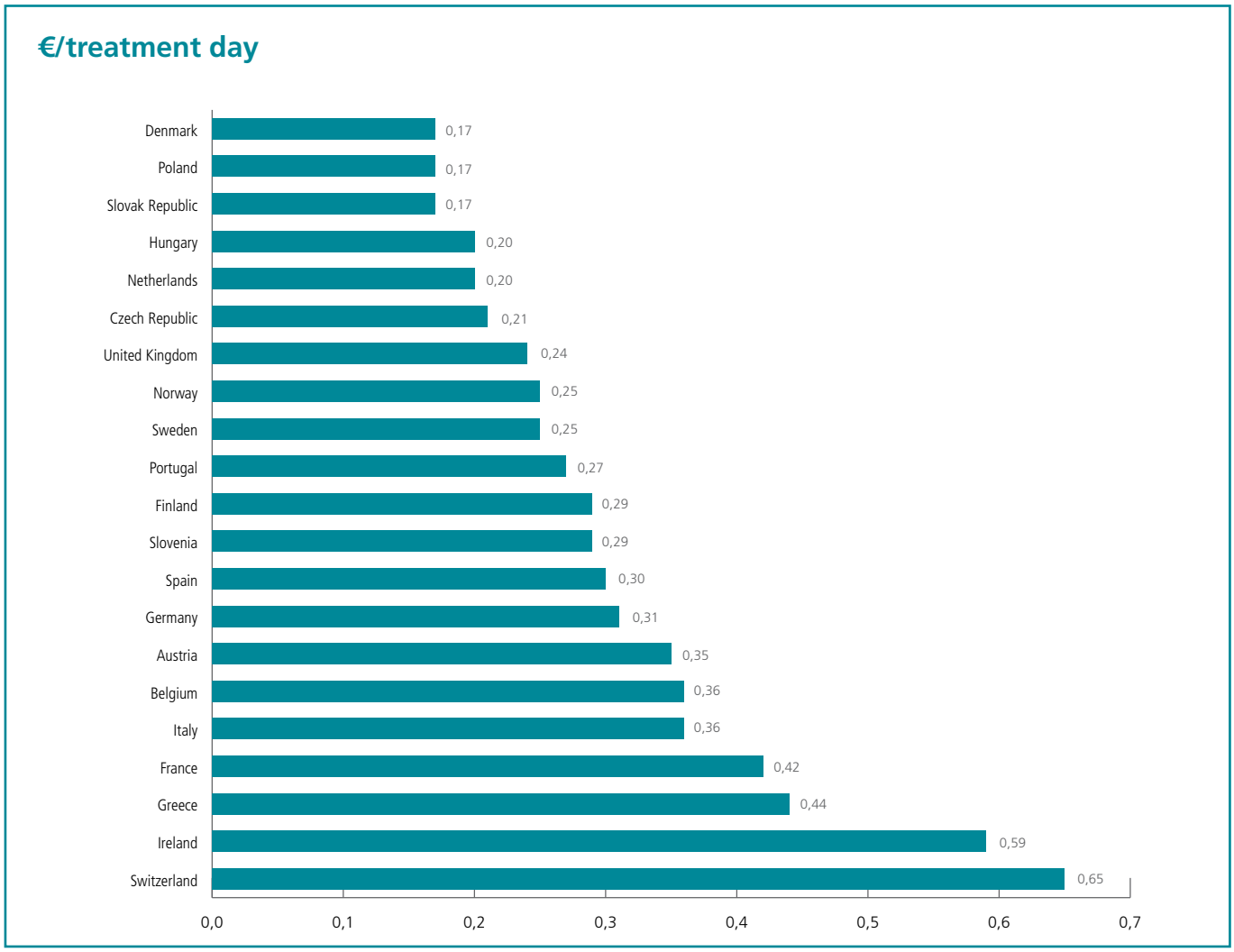

Figure 9: Cost per treatment day for 7 therapeutic areas, based on daily defined dose (DDD), Q3 2013 (Europe weighted); Selected therapy areas: Angiotensin II antagonists, anti-depressants, anti-epileptics, anti-psychotics, anti-ulcerants, cholestrol regulators and oral anti-diabetics[55]

> The signing of "Growth and Stability Framework" agreements will stabilise spending, reduce volatility, and increase confidence to invest in innovation in Europe.

RECOMMENDATIONS & PROPOSALS

* The research-based pharmaceutical industry calls for governments, payers, and industry to develop Growth and Stability agreements, where they are not in place already, for medicines expenditure across Europe to improve predictability for all parties in the healthcare ecosystem. The development of best-practice frameworks could be facilitated by the European Commission, but implemented at member state level to take into account differences in demographic development, real demand, inflation, technological advancements, and other nationally relevant circumstances.
* The research-based pharmaceutical industry would commit to supporting the sustainability and viability of such a framework through industrywide agreements and by using new commercial models and tools such as managed entry agreements, the opportunity to price medicines according to the ability to pay, or the facilitation of the appropriate use of lower cost medicines. At the same time, industry would work collaboratively with Government sponsors to improve access and appropriate use of all medicines in the population, and accelerate adoption of innovation.

Moving beyond non-price efficiencies that can be achieved, we believe that in several countries more use could be made of "Growth and Stability Frameworks", agreements between industry and government, of the sort signed in several countries such as the UK, France, Sweden, Denmark – that help manage the medicines bill whilst ensuring predictability to both sides. Such agreements take different forms in different countries, but they have common elements and are usually a sign of a mature collaborative approach from which all sides benefit.

3.3 Building a thriving European healthcare ecosystem

The pharmaceutical industry is increasingly seen as one of the most important and strategic industrial sectors for a region's future.[56] Pharmaceutical industry research helps the scientific community to better understand the aetiology of diseases, develop new treatment approaches, and design preventive measures. Industry-sponsored research is also breaking ground in understanding patients' specific genetic characteristics, which will pave the way to targeted, more effective therapies following the principle of personalised healthcare. More broadly, the pharmaceutical industry makes an important contribution to Europe's overall balance sheet, offering among the highest net trade balances and accounting for over 5% of Europe's value added.[57]

There is no innovation without research and development. Europe has a deep research heritage and many centres of academic excellence. Its scientists and clinicians make major contributions to advancement of medicine and medical practice. Yet steeply rising development costs, concerns about the affordability of treatments, and access to treatments have become the most challenging issues facing the healthcare ecosystem today. Our future health care problems will not be solved simply by reducing costs. New models are needed if we are to meet these challenges.

Coordinating nationally fragmented policies under a world class, pan-European R&D agenda is one of the keys to creating critical mass and competitiveness in the field of innovation and ensuring a viable, vibrant European healthcare ecosystem. At the same time, biopharmaceutical intellectual property (IP) protection, such as patents, data protection, and competitive investment incentives can allow Europe to improve its attractiveness as a destination for R&D investment, ensuring that important discoveries are made in Europe and that Europe gains from their global adoption.

3.3.1 Medical research and innovation are key to Europe's future, but Europe needs to regain scientific leadership

Over the past decade, the global R&D model for pharmaceutical products has changed profoundly. The trend is towards closer collaboration and clustering, a greater exploitation of the links between foundational and translational research, and the creation of innovation development partners. Despite this, Europe has developed few bioscience networks that can compare to those centred on world-class academic centres in the US. There, the National Institutes of Health (NIH) have played a pivotal role in both fostering excellence in academic research and in shaping the innovation agenda around key health priorities. In order to remain competitive, and in the context of the Lisbon Treaty's ambition to invest 3 per cent of GDP in R&D, Europe must champion excellence in academic research, encouraging an open and collaborative R&D model, and the further development of scientific skills.

As Europe has consistently missed the 3 per cent R&D target, a renewed focus on basic science and education is required. It is time for Europe to recommit to excellence and create an environment that encourages innovation and attracts high quality investment. In the field of pharmaceuticals the choice is stark – either Europe invents the solutions of the future, or it will have to import them.

At present, the organisation, governance, and funding of basic biomedical research across Europe is being managed through a range of independent, fragmented, and broad-based programmes at both national and European levels. Despite some excellent European initiatives, the reality is that there is too much competition between member states, sub critical mass investment and not enough effort devoted to achieving a coherent strategy for Europe. This results in different quality assessment criteria, duplication of efforts, waste of financial resources, and diminished incentives to create broad-based public-private partnerships. Critically, Europe is falling behind the US in many areas of biomedical research, leading to a loss of competitiveness. In 2010, European governments invested just 0.07 per cent of GDP in health research against 0.24 per cent in the US end.[58]

Strengthening foundational and translational research, and creating world class centres of excellence in Europe, is vital to ensuring that the region remains attractive for R&D investors. Although Europe has much of what is needed to lead in this arena, including the greatest number of research scientists and a large proportion of biotechnology patents, it faces tough competition. When it comes to medical and pharmaceutical research, Europe has to compete on a global scale with the very best. Out of the top 100 centres for medical research, 56 are American and only 37 are European. In fact, eight of the top ten academic centres are American and Asia is catching up quickly. Europe has consistently lagged behind the US as the place where innovators want to test and launch their products first. In an increasingly competitive climate this does not send a supportive message to potential investors.

Launches of new active substance

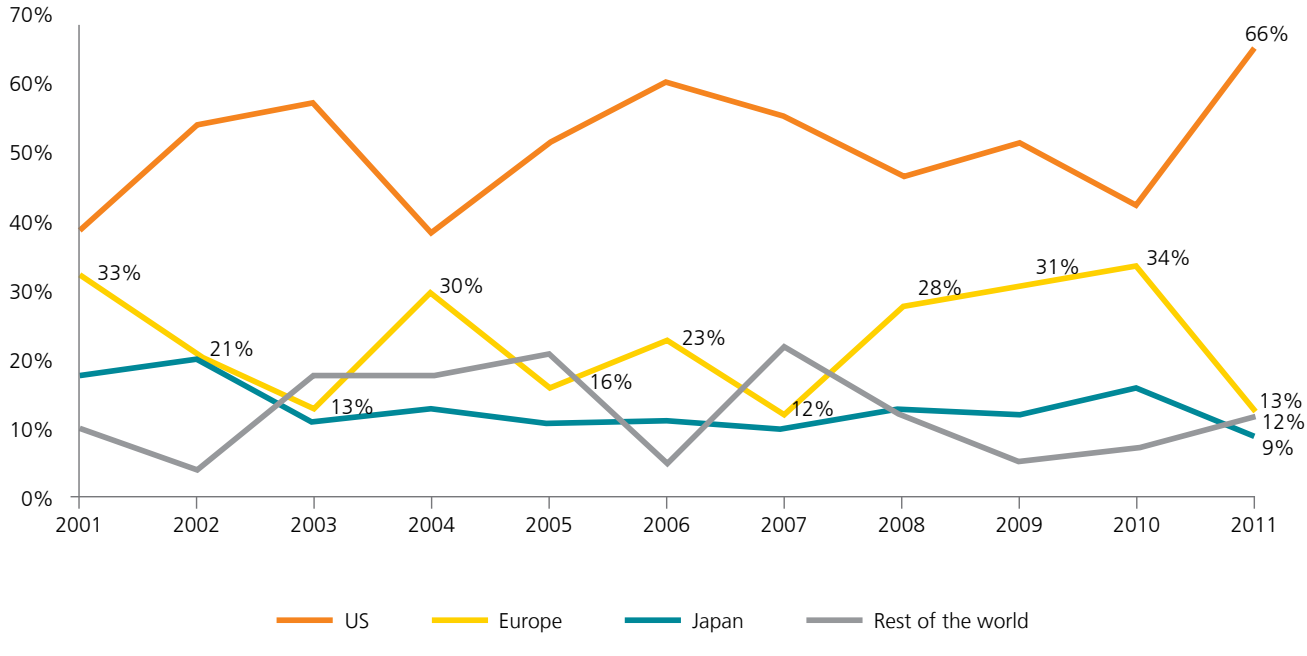

Figure 10: Launches of new active substance by region, 2001 – 2011[59]

> Europe needs to combine its forces to develop a long-term, coherent European research leadership and innovation agenda for life sciences and biopharmaceuticals.

To ensure that future innovations are generated in Europe and a sustainable research environment persists in general, there are several initiatives that Europe can build on.

The Innovative Medicines Initiative (IMI) is an essential starting point. A joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), IMI aims to support a collaborative pharmaceutical R&D ecosystem in Europe that will lead to quicker, more efficient discovery and development of better and safer medicines for patients. With a €2 billion budget, IMI acts as a catalyst for partnership working, bringing together competing pharmaceutical companies to work with each other and with academia, regulatory agencies, and patients' organisations to tackle the major challenges in drug development.

On 10 July 2013, the European Commission released its proposal for the Innovative Medicines Initiative 2 (IMI 2), which will focus on developing next-generation vaccines, medicines, and treatments, such as new antibiotics. The strategic component of IMI 2 centres on personalised healthcare by delivering the right prevention and treatment for the right patient at the right time. Like IMI, it will bring together companies, universities, public laboratories, innovative small and medium-sized enterprises (SMEs), patient groups, and regulators in collaborative projects that will pave the way to tackle Europe's growing health challenges and secure the future international competitiveness of Europe's pharmaceutical industry. IMI 2 is expected to start in 2014 and will run for 10 years.

RECOMMENDATIONS & PROPOSALS

* IMI is a great example of how industry can work with EU and academia to advance science. But we need to go further. Europe requires a coordinated strategy for medical and bioscience research, together with an increased focus on excellence in basic biomedical research and education to achieve scientific leadership in support of the Europe 2020 strategy and to foster competitiveness on a global level.
* In the near term, building on IMI and IMI 2 will foster public-private partnerships on open innovation in the life sciences field. As a first step of a long journey to research leadership, a network of European Institutes of Health Research Excellence should be established as a point of coordination for biomedical research and innovation. The network should adopt a holistic and long-term perspective on the health challenges facing Europe, foster public-private partnerships on open innovation within biomedical research, and champion regulatory reform to enable and reward innovation. It should achieve this through both European-level initiatives and by acting as a hub for national research funders. The network of European Institutes of Health Research Excellence should benefit from more increased public funding for basic health research. As a benchmark, US public health funding through the NIH is more than $30 billion (~€22 billion) annually.

3.3.2 An appropriate intellectual property system is the cornerstone of medicines innovation

The intellectual property (IP) system is a key enabling factor of pharmaceutical innovation, as it provides the necessary incentives to research and development focussed on addressing global health needs and improving health outcomes. The IP system and, especially, patent protection are intended to allow innovators to recoup their investment and earn a fair return for a limited and legally defined period of time.

Overall, the development of new medicines have covered a range of different therapies and contributed greatly to improved health outcomes across the world. A comprehensive review of the industry's R&D pipelines clearly shows that the industry is already aligning its efforts to address the areas of greatest unmet need today and in the future. Of more than 16000 compounds currently in development, over 80 per cent are focussed on degenerative diseases, cancer, and other non-communicable diseases – particularly, those therapeutic areas where patient pathways lack effective pharmacological solutions.

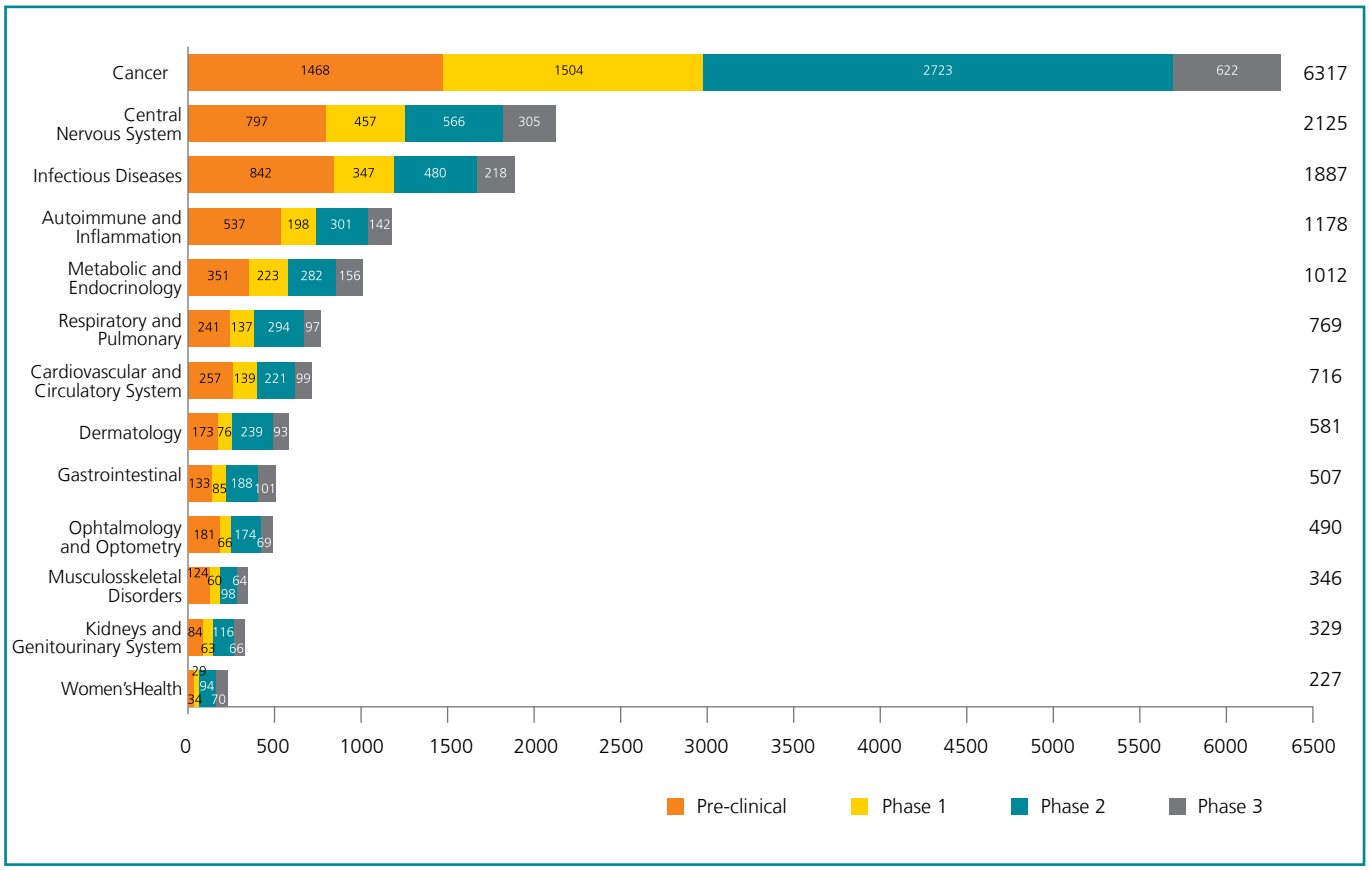

Figure 11: Registered Pipeline Compounds end of year 2011[60]

> Europe needs to evolve IP and incentive systems to address the challenges of biomedical research, in line with Europe's key unmet health needs and competitiveness agenda.

Combined with targeted investment incentives, the IP system in Europe can be used to drive innovation in the region and 'capture' it for the benefit of patients and the region's economy.

Over the last decade several major changes have led to additional challenges in the pharmaceutical business model that support the development of new technologies. Products are becoming more complex with an uncontested shift from small molecules towards more complex and multi-indication, biologicals. Consequently, the complexity of R&D processes and programmes has increased. Many of these products have evolving research programs that explore the application of the molecules in different disease states over a period of time.

To keep pace with the inexorable trend of personalised healthcare and targeted treatments, innovative medicines development is confronted with a large number of small patient (sub-) populations. To realise the medical benefit to patients who exhibit certain diseases specific diagnostic criteria, research on all sub-classifications of a disease is needed. These trends lead to increased complexity and cost of development and, potentially, a lower return on investment. Such capital outflows, in times of fiscal uncertainty, require an acknowledgement of the risks involved, and the development of appropriate incentives that stimulate risk-taking and encourage research-based companies and institutions to invest in the development of innovative targeted therapies for unmet needs.

The overriding ambition for Europe is not to subsidise the risk that industry faces, rather to make sure that Europe has the most competitive environment for attracting and retaining R&D investment.

RECOMMENDATIONS & PROPOSALS

* It is time for a wide-ranging debate among all stakeholders – patients, providers, suppliers, regulators, and policymakers – on how the IP regime for medicines can be tailored to this new generation and how those protections should play out over the course of a product's lifecycle.
* We believe that medicines that are consecutively approved for new indications over their lifecycle should be granted prolonged exclusivity to justify the additional investment in research and clinical development. This will increase the attractiveness of continually exploring and investigating the full potential of existing medicines as treatment options in different therapy areas and, ultimately, create alternative treatment options for patients.
* Further, an IP scheme adapted to the next generation of biomedical research should foment R&D models consistent with the development of innovative pharmacological solutions for diseases with key unmet needs such as neurodegenerative diseases, psychiatric disorders, antibiotic-resistant organisms, pandemic viruses, rare cancers, and genetic diseases.
* With new incentives, intellectual property frameworks and regulatory pathways, European society is more likely to benefit from breakthrough clinical advantages aligned with European health priorities.

4 Summary and vision

Healthcare is likely to be at the top of the European political agenda in the coming decades. An ageing population will inevitably focus attention on what healthcare systems are able to deliver, in an affordable way, to improve the quality of life for European citizens and to finally address health inequalities that have persisted for many years, while keeping people physically and economically active for as long as possible.

At the same time, Europe's economic prosperity – and consequently its ability to afford the healthcare it needs – will depend on whether we are able to maintain and grow the sort of high value-added, knowledge-based industries that can compete in a global marketplace.

These twin-challenges of ensuring health into the future, and ensuring world-class industry in Europe, are intrinsically linked. In this document we have set out our vision for three policy goals, which we believe we share with society: better health outcomes, sustainable finance and a thriving life sciences ecosystem. These can be – and must be – mutually reinforcing objectives.

There are no quick wins in this agenda. Whether we are talking about a fundamental shift to the sort of data infrastructure in healthcare systems that would drive genuine value-based approach to management or whether we are redesigning an intellectual property regime that is fit for future science, a sustained collaborative effort is required by all actors in the system.

This document is intended to be a starting point for a conversation with society, not a blueprint for what needs to happen. We, the pharmaceutical industry, do not have all the answers. But we have something to bring to the table. Our track record as a high quality employer, investor, and most importantly innovator that has helped improve the health of countless millions though our medicines means that we are part of the solution.

In the coming months and years to come, we will be further exploring the ideas set out in this strategy. We will be taking the conversation across Europe through and hope to develop new partnerships that can help drive this agenda forward. Better health outcomes, financial sustainability and a thriving ecosystem in Europe is in everyone's interests and we want to help make it happen.

5 EFPIA Governance

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 34 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and quality of life around the world.

EFPIA members are committed to delivering innovative medicines to address unmet needs of patients and reducing the burden of chronic diseases for Europe's ageing population. EFPIA believes in close cooperation with its stakeholders to help create sustainable healthcare systems and to develop prompt responses to health threats in Europe.

The EFPIA General Assembly comprises all full members and meets once a year to define the Association's general policy. The Board comprises representatives from 25 corporate members (full member companies only); the Executive Committee is composed of delegates from member companies and associations, elected for a period of two years. The Board/Executive Committee carries out the tasks and duties determined by the General Assembly and ensures that these are implemented by the General Management.

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efpia

European Federation of Pharmaceutical Industries and Associations

Where we need to work together:

Health is at the heart of Europe's economic and social prosperity for the future and the bio-pharmaceutical industry is one of our best growth prospects in Europe.

The European Parliament should provide leadership for a more ambitious and integrated life science strategy for the EU.

Our industry is committed to partnering with all stakeholders to:

* deliver better health outcomes across Europe
* support financially sustainable healthcare systems across Europe
* achieve economic growth in Europe

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