Contract for a Healthy Future

The role of Europe's medical technology industry in steering healthcare systems onto a sustainable path

MedTech Europe
from diagnosis to cure

Contract for a Healthy Future

THE MEDICAL TECHNOLOGY INDUSTRY, ENCOMPASSING MEDICAL DEVICES AND IN VITRO DIAGNOSTICS, RECOGNISES THE NEED TO CHANGE HOW WE WORK in order to meet the challenges we all face in steering Europe's healthcare onto a sustainable path.

BUT WE CANNOT DO IT ALONE. All stakeholders will have to reconsider the role they play. However, if we all play our part, we can solve our shared problems together.

What industry will do

- Acknowledge the need for change
- Embrace, achieve and demonstrate cost-effectiveness, patient benefits, societal needs of patients, payers and policymakers
- Fulfil stakeholders' needs through value-based innovation
- Invest in knowledge transfer with healthcare professionals and institutions to optimise healthcare delivery and quality of care
- Provide medical technology innovations with socio-economic value that ensure sustainable, accessible healthcare and healthy ageing

What you can do

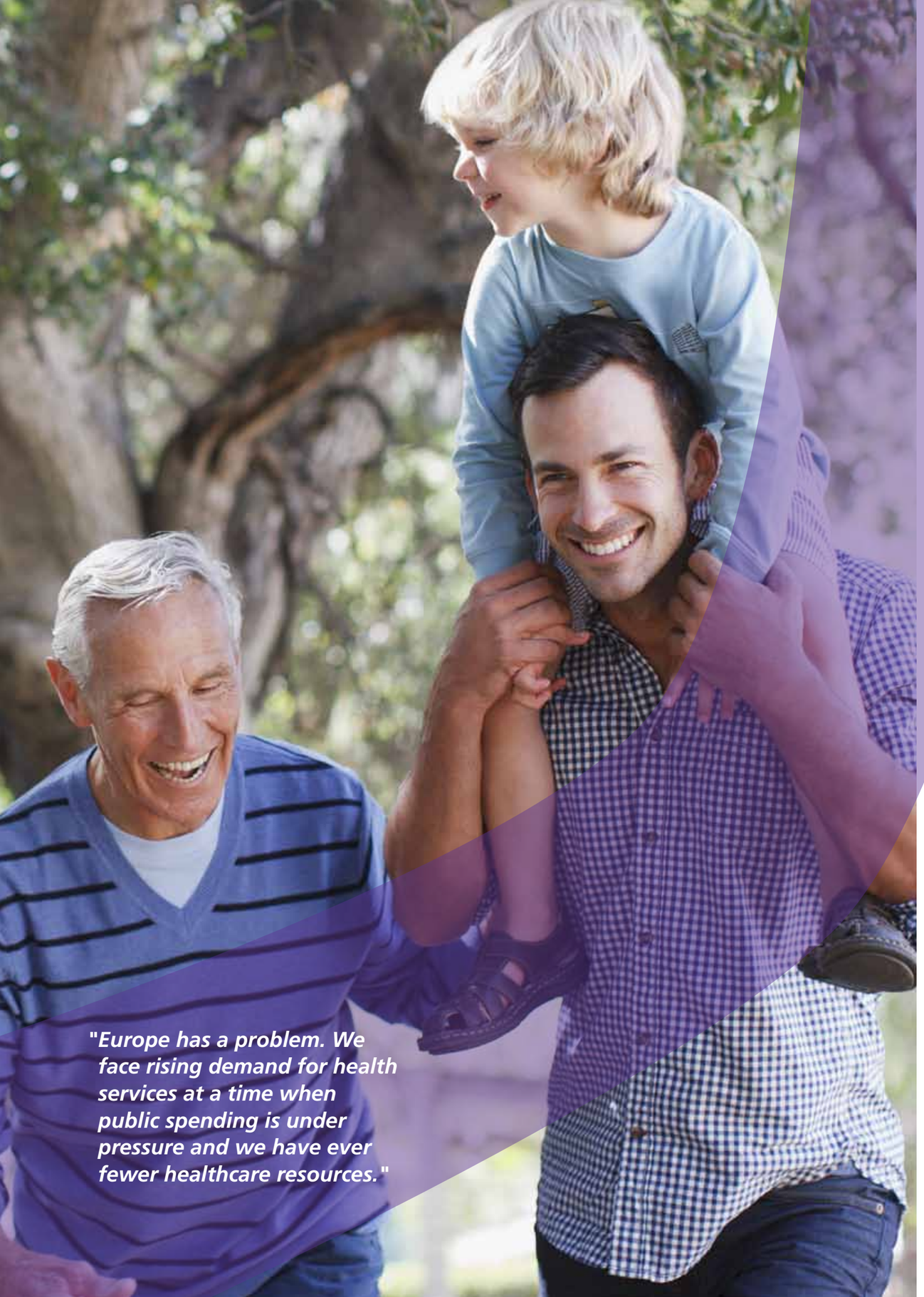
- **Policymakers:** Foster access to new technology; modernise healthcare and funding models and end silo-based budgeting to account for societal benefits
- **Payers:** Recognise the value of medical technology through optimised market access and timely appropriate funding
- **Healthcare professionals:** Treat technology as an enabler of change in efficiency and productivity; embrace the power of patients and other stakeholders in health decision-making
- **Healthcare institutions:** Work together for productivity and quality of care; embrace bold changes to how care is delivered
- **Patients:** Play a more active role in managing their own care, and be open to new care models and settings

Table of Contents

Executive Summary

Challenge to change

Europe has a problem. We face rising demand for health services at a time when public spending is under pressure and we have ever fewer healthcare resources. At the root of this problem is a demographic trend that will see an expanding aged population – in need of, and expecting, a high level of care – while the number of taxpayers contributing to the national treasury is shrinking.



We have to rethink our healthcare system and steer it back onto a sustainable path. The medical technology sector – including medical devices and in vitro diagnostics – recognises that the current business model is coming to the end of its lifecycle. It is now time to go to the next level – it is time to change.

As an industry, innovation has always been at the heart of what we do. But the future will demand a different kind of innovative thinking from all stakeholders in our economies. For the healthcare industry this means focusing on our common goal of designing a sustainable healthcare system.

In short, coming up with a slightly better way of doing what we do now and expecting to charge a premium price is no longer good enough. Our model of healthcare delivery is also coming to the end of the line. By 2030 our acute in-hospital care system will need to provide inpatient care for 40-50 % more patients[1]. Our hospitals will no longer be able to offer the beds nor the staff to meet these needs. Moreover, the chronic disease burden is also expected to double by that time. These challenges will require a significant increase in healthcare spending as a percentage of GDP.

This means patients, policymakers, payers, healthcare workers and hospital administrators, will need to do things differently. Indeed, the value of our contribution will only be realised if others recognise that it is a time of change and seek to collaborate to solve our common challenge. Together, we need to be courageous and smarter about how we use the resources we have and to direct them towards models of care that can deliver a demonstrable positive return on investment in healthy life years for citizens.

[1]The 2012 Ageing report: Economic and budgetary projections for the EU and Economic Calculations

"Change is never easy but it is imperative. EDMA and Eucomed have partnered in the MedTech Europe alliance to embrace this updated Contract and to chart the new way forward. The status quo has to go."

Contract for a Healthy Future

Bold thinking is required if we are to face this shared challenge: a grand bargain to steer our healthcare system back on a sustainable path. The medical technology industry is part of the solution. By concentrating on value-based innovation, we can marry prevention, diagnosis, treatment and management with cost-containment, efficiency, improved health outcomes and societal benefits.

In return, payers and policymakers must overcome silo budgeting in healthcare, and shift toward a holistic approach that considers the true value of medical technology for all healthcare actors.

New technologies which improve health productivity and efficiency should be funded timely and appropriately in an effort to help people age healthy and tackle the shortage of healthcare resources.

Industry ambitions: moving toward a value-based collaborative model

1 - Build and engage stakeholder networks to collectively establish the opportunity and value of medical technology and innovation

2 - Collect, develop and share, evidence-based cases of medical technology supporting effective personalised care, a sustainable healthcare system and healthy ageing

3 - Demonstrate the cost-effectiveness, potential cost-savings and the socio-economic value of medical technology, while improving healthcare outcomes and quality of care

4 - Innovate care processes to address labour shortages

5 - Increase the value of the industry to the European economy

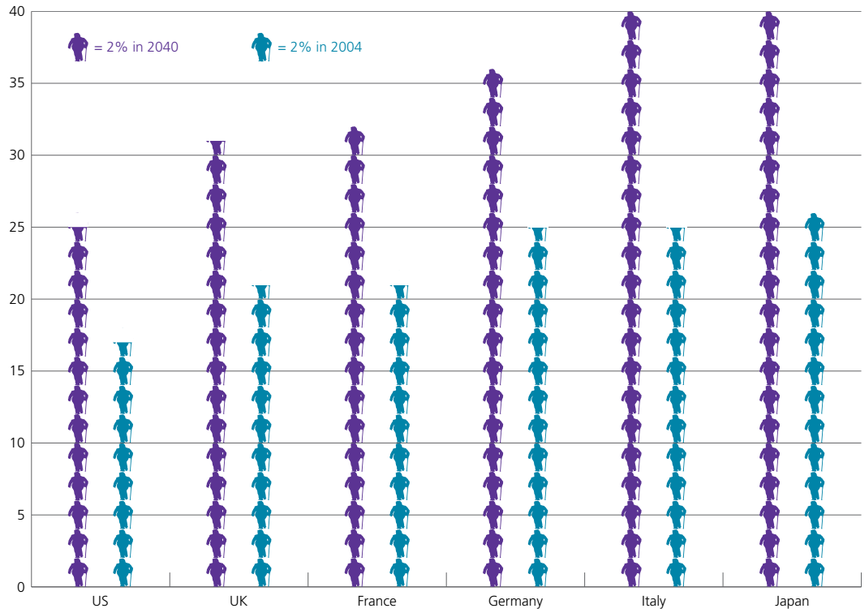
Demographics

The price of population change

The figures are stark. Today, the ratio of pensioners to people of working age is 1:4 –and healthcare systems are already under strain. By 2050, the ratio is expected to be just 1:2[2].

Graph 1: Demographics driving demand for healthcare

% of population over 65 years of age



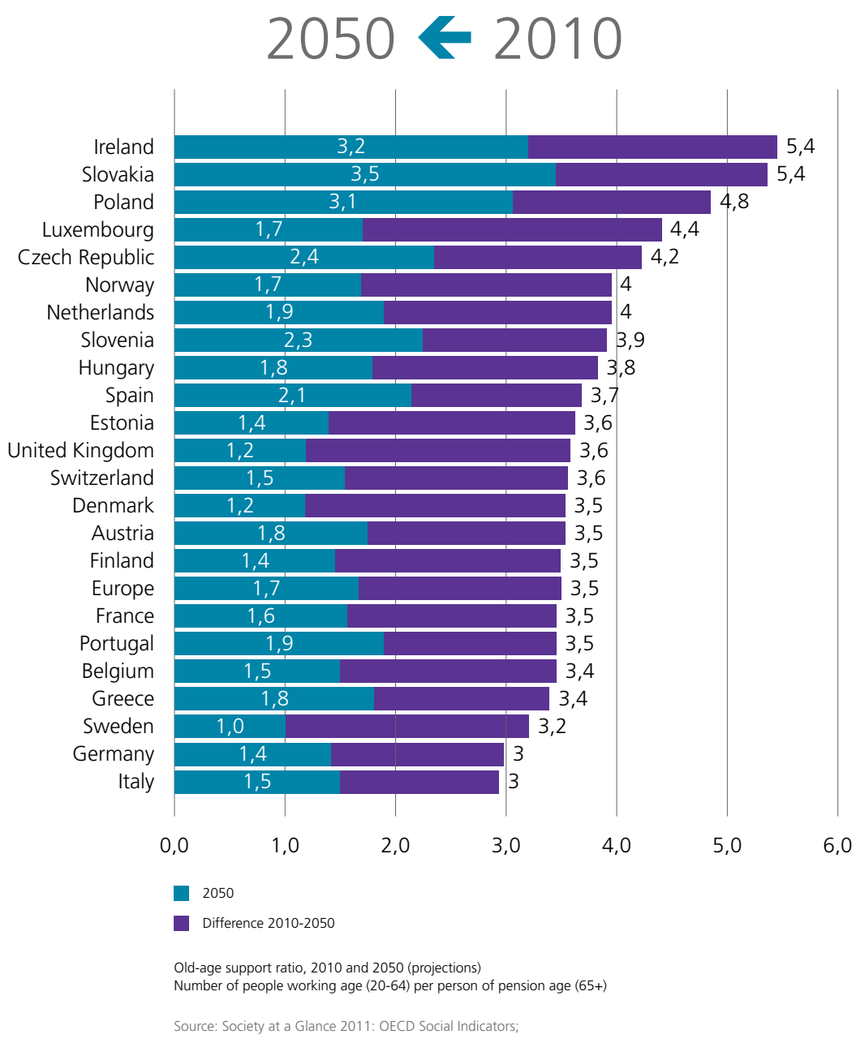
Source: The Silver Book: *Chronic Disease and medical Innovation in an Aging Nation* Partnership for Solutions 2004, *Chronic Conditions: Making the case for ongoing care*

We know that after the age of 55, the amount of healthcare resources we consume doubles every ten years. So, at a time when the absolute number of elderly people in need of care is rising fast, the proportion of taxpaying citizens is narrowing. A recipe for sustainability, it is not.

At the same time, the European Commission is warning that by 2020 the EU will have a shortage of one million health workers. This doubles to two million, if you include long-term care and ancillary health professionals, and means almost 15% of demand for care will go unmet[3].

[2]Guerzoni B. and Zuleeg F. (2011). *Working away at the cost of ageing*. Brussels: European Policy Centre.
[3]Testori Coggi, P., 2010. Health Trends and Challenges in the European Union. *Connaissance & Vie*. Antwerp 23 November 2010.

Graph 2: Working versus old population



Old-age support ratio, 2010 and 2050 (projections)
Number of people working age (20-64) per person of pension age (65+)

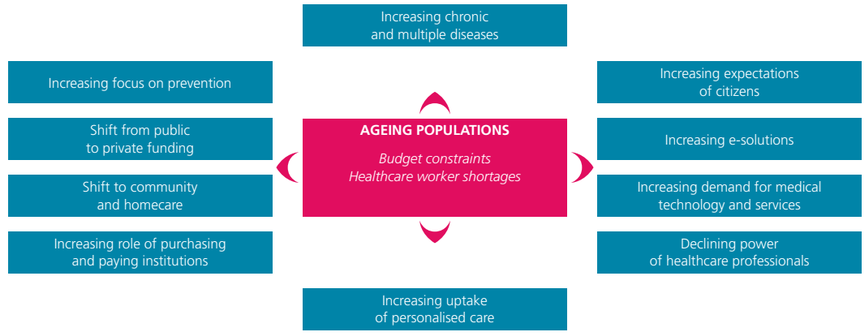
Source: Society at a Glance 2011: OECD Social Indicators;

The twin problems of increased demand and shortage of trained personnel require a solution. Under the current model of healthcare, having millions more elderly people leads to millions more hospital appointments, more days in hospital, more interventions, more medicines and more medical devices.

Other trends, such as the increase in chronic diseases and rising expectations of citizens, also feed into pressure on already-squeezed health budgets.

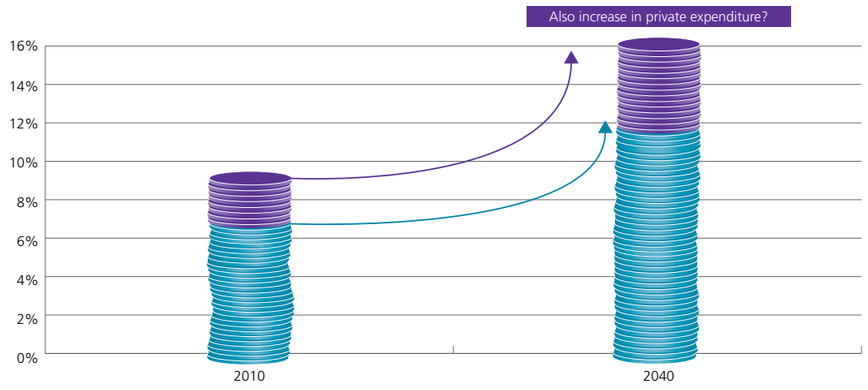
Shifting more activity away from hospital-based care towards community care will help make better use of limited resources. The value of technologies that facilitate this change, while preserving a high quality of care, must be recognised as being a central part of the fundamental changes that must be made. Programs, systems and therapies that support prevention of disease – including the critical contributions made by early diagnosis – are also crucial if we are serious about keeping people healthier for longer.

Graph 3: Ageing populations driving need for change in healthcare



The share of GDP spent on health (including private expenditure) could double in the coming decades if we fail to change course. Governments may turn to citizens to subsidise the shortfall via co-payments or top-up fees leading to reduced societal solidarity.

Graph 4: Public and private expenditure on healthcare in Europe as percentage of GDP in the EU27 2010-2040 (projections)



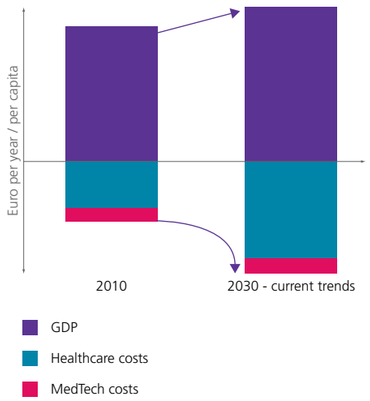
*Private expenditure for 2009, EU 27 (except Bulgaria, Cyprus, Latvia, Lithuania, Malta and Romania)
Source: European Commission, EPC, OECD, Eucomed calculations

Changing course

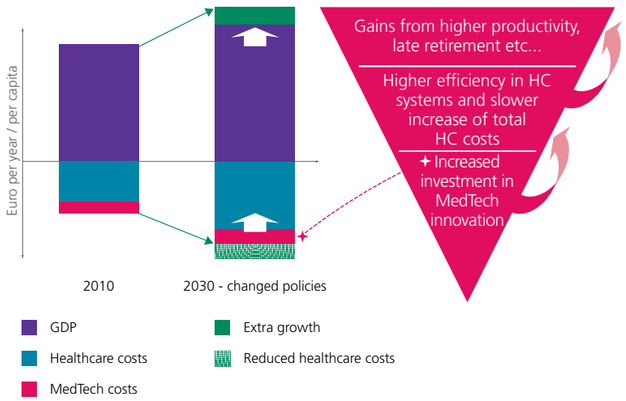
Less than 5% of healthcare spending goes on medical technologies (only 0.80% of healthcare spending goes to in vitro diagnostics[4]) whereas spending on medical care delivery - including hospital staff and internal processes – accounts for 70%[5]. Plotting a smarter course to healthcare delivery will mean radical changes and increasing investment in innovations proven to improve the productivity and efficiency of the healthcare system.

The right technologies can improve healthcare efficiency, reducing labour shortages, containing costs, and give citizens more healthy years in which to be economically active.

Graph 5: Current trends



Graph 6: Benefits of embracing innovation



[4]EDMA Annual Report, 2010. *European IVD Market Overview: Lights & Shadows at a Time of Economic Downturn*
[5]MedTap, the Value Group, 2004. *The Value of Investment in Health Care: Better Care, Better Lives.*

What is medical technology anyway?

Medical technology, which includes both medical devices and in vitro diagnostics, is used to prevent, diagnose, monitor or treat every disease or condition that affects us. Everyday examples include early-stage HIV testing, drug-eluting stents, MRI scanners, pacemakers, blood glucose testing kits, wound and incontinence management, and minimally-invasive surgical technology. It is the technology around us that maintains our health. To be clear, medical technology does not include medicines, biologics or vaccines.

Innovative technologies are improving the quality of healthcare delivered and patient outcomes through earlier diagnosis, less invasive treatment options and reductions in hospital stays and rehabilitation times.

Innovation is the lifeblood of our sector. As a research-based industry, we are leveraging advances in computers, communications, and genomics to deliver better outcomes at lower costs[6].

Meet Europe's medical technology industry

Europe is home to some of the biggest global names in the medical technology sector, which encompasses the medical devices and in vitro diagnostics industries. The continent also plays host to a burgeoning ecosystem of innovative small businesses producing both niche products and the innovations of tomorrow for local and global markets. The medical technology in Europe is serviced by several industry associations. Two of these associations, EDMA (the European Diagnostics Manufacturers Association) and Eucomed (the European Medical Technology Industry Association), are MedTech Europe's founding members. The companies represented by MedTech Europe provide high-end jobs in Europe by re-investing in R&D and employing thousands of people in advanced manufacturing facilities.

More than 500,000 people are employed medical technology companies in Europe. From small businesses to global corporations, the medical device and in vitro diagnostic industries in Europe represent a market worth over €95 billion.

The medical device and in vitro diagnostic industries contribute to innovation and technological progress by employing a fast-acting, holistic approach to providing essential solutions in response to emerging healthcare needs. Indeed, MedTech Europe's members work tirelessly towards improved diagnosis, treatment and monitoring of the conditions that most impact the lives of Europeans.

[6]Eucomed, 2011. *The Medical Technology Industry in Europe.*

New models

It's often said that prevention is better than cure. Yet our health services have traditionally been designed to focus on caring for sick patients, often devoting resources to the difficult task of undoing damage caused by a heart attack or diabetes.

If we are serious about rethinking our health system we need to steer our funding towards preventative, early diagnosis intervention and less-invasive treatment models. We must direct our creative energies towards innovation in this area. Remember: by the time the first signs of ill-health are obvious, the scope for intervention may be severely limited.

From a public policy perspective, getting more "bang for your buck" means more than finding the cheapest solution to today's ailment – it means reducing demand for cost-intensive services, satisfying demand more efficiently, helping carers care and giving people more time to be healthy and productive. Health technologies can help us intervene less often and, when we must intervene, to do so in a way that soaks up less costs overall.

Case Study:
Self-monitoring of blood glucose empowers patients

The incidence of Type 2 diabetes mellitus is on the rise throughout Europe and shows no signs of slowing down in the near future. The implications of the phenomenon are vast – from diminishing the quality of life to placing an additional burden on an already strained healthcare system. The anticipated greater cost and larger number of patients imply that the approach to health and treatment of the disease must change fundamentally if Europe is to avoid a spike in associated complications, such as blindness or cardiovascular disease.

To this end, self-monitoring of blood glucose (SMBG) in patients with all types of diabetes, but especially the growing group of Type 2 diabetes patients, carries great potential. SMBG can empower patients, allowing them to easily and conveniently maintain tight blood glucose control and avoid the development of hypoglycaemia. The tools are also of use for individuals with Type 2 diabetes receiving oral and not insulin-based treatment as SMBG lowers the rates of nonfatal micro- and macrovascular events when compared to patients who do not perform SMBG.

SMBG allows patients to develop a better understanding of the specificities of their illness, enabling them to take informed action without overreliance on physicians. With appropriate instruction, a well-informed diabetes patient can react quickly after the diagnostic test is performed. SMBG can help European healthcare systems cut their costs by minimising diabetes trauma cases, reducing incidence of related conditions and improve the quality of care for patients – all of which would be welcome changes.

Case Study:
Telemedicine – saving lives and money

Remote monitoring of implantable cardiac devices could help save Europeans billions of euros, according to research which looked at remote care applications for chronic heart disease.

Regular monitoring can help protect the patient from entering acute heart failure, leading to emergency admission to hospital. Traditionally, this required frequent visits to a doctor's office or an outpatient clinic. Now, thanks to our innovation, the patient can be monitored in their own home. This can be done by phone or by using information technology to transfer data collected via external monitors or from the patient's cardiovascular implant.

Analysis of 21 randomised-controlled trials comparing traditional management of heart failure with remote monitoring over a one year period found that 42% of patients in the first group were admitted to hospital compared with 29.5% in the second group.

Looking at the costs, it was found that over a one year period, a patient in the remote monitoring group saves an average of €450, with this figure rising as high as €1,000 in some countries.

The researchers concluded that the main barrier to widespread adoption of this more effective and efficient care option is the lack of appropriate reimbursement system to cover the costs.

Incentivising change

One common knee-jerk reaction when health budgets are squeezed is to cut back on medical technologies and that is short-sighted. 70% of health spending is consumed by personnel and hospital organisation costs. Compare that with medical technology which accounts for less than 5%[7]. It would be wiser to spend on the right technologies that bring better outcomes and allow smart resource reallocation through efficient hospital reorganisation.

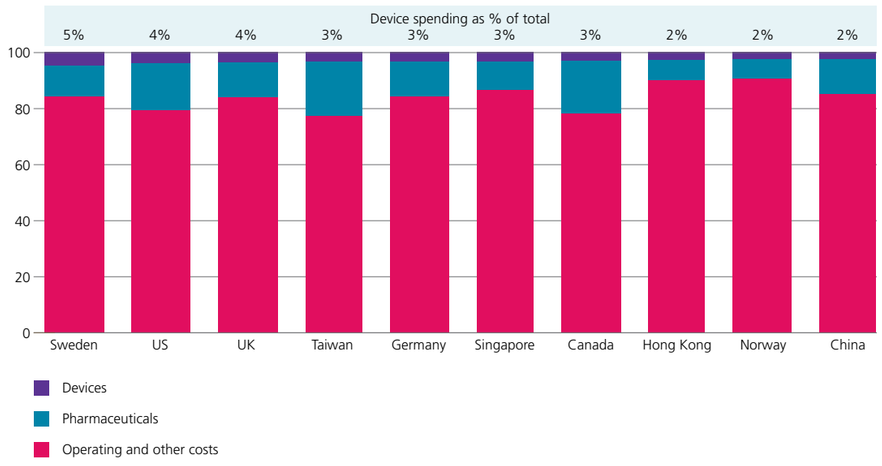
Price cuts have consequences. If profitability is down, investment in innovation suffers, which in turn reduces our scope for tackling the grand challenges posed by demographic shifts. Couple this with the new economic climate where sources of private venture capital have dried up, and an unappealing scenario of no new innovation to face mounting and impossible health challenges emerges.

Medical devices and in vitro diagnostics are enabling technologies: they are our best opportunity to improve efficiency, effectiveness and productivity, putting healthcare on a sustainable footing for the future. In our factories, on our farms, and in our own homes we all invest in technology. Why? Because technology and innovations help us do more things more efficiently and at lower overall costs. Why should we abandon this wisdom when it comes to our health systems?

Another force which undermines the potential of medical innovation is the rigid, silo-based structure of financing and funding healthcare, and more specifically the reimbursement of technologies. In our view, this obstacle to efficiency must be removed and replaced with value-based pricing that rewards long-term health-economic outcomes. If we agree that adding more healthy life years in a cost-effective way is our collective goal, then we must fund new technologies that can deliver.

However, we acknowledge that our innovations should reflect the needs of the 21st century and that adding value must be at the heart of what we do. We know too that more data is needed to illustrate the value of our technologies.

Graph 7: Healthcare spend by use of funds in 2008



Source: Espicom Health-care Intelligence. medical Market Forecasts to 2011. Chichester, UK.

"70% of health spending is consumed by personnel and hospital organisation costs. Compare that with medical technology which accounts for less than 5%."

Graph 8: Healthcare management models need to change

- Better health
- More people
- Constrained budgets
- Fewer carers

New approach in healthcare management models

1 - Integrating patients as active players to improve health and limit increase in demand

2 - Addressing the entire patient pathway to reduce treatment costs

3 - Overcoming silo-budgeting of healthcare to reward health outcomes

Increasing productivity and cost effectiveness of healthcare systems will become key focus for payers and policy makers

[7]MedTap, the Value Group, 2004. *The Value of Investment in Health Care: Better Care, Better Lives*

Fact Check:

Is medical technology driving up healthcare costs?

Thanks to advances in medical science, we can now expect to live longer but also healthier than ever before. This achievement has not come without cost, but on a fundamental level it is agreed that there is no going back. Since 1948, when the Universal Declaration of Human Rights established healthcare as a right, patient expectations have grown at the same time as the population has risen.

Running a modern healthcare system requires resources, but it would be a mistake to think that medical devices or in vitro diagnostics are the main driver of costs. In fact, innovative technologies are helping to slow the pace at which health spending is rising. There are hundreds of examples but here is a selection:

- Between 1980 and 2000, medical technology reduced hospital stays by 56% and dramatically cut costs[8];
- Technology to control blood glucose levels reduces diabetes-related complications, such as blindness, by up to 76%, and nerve disease by up to 69%[9];
- Hospital stays for minimally invasive treatment for aneurysms are nearly three days shorter than those for more invasive surgical interventions (4.5 days versus 7.4 days[10]);
- Inserting drug-eluting stents reduces the requirement for repeat revascularisation procedures and incurs lower average costs for follow-up[11].

Case Study:
Innovations save Germany €22bn

"We must not look at health expenses as a cost factor only, but we need an overall approach."

That's the view of Ernst Burgbacher, Parliamentary Secretary of State in the German Federal Ministry of Economics, when presenting a study which highlights the potential to save billions by investing in health technology.

The economic report, 'Innovation impulses of the healthcare industry', shows that increasing health spending by €101 billion between 2002 and 2008 was more than compensated for by a gross added value of €123 billion over the same period – a positive balance for the economy as a whole, according to the government's analysis.

The study shows that investing in medical innovation resulted in a decrease in lost working years, thus preserving productivity. Such is the belief that embracing cutting-edge technologies can have a positive effect on the economy that Germany's Federal Government is commissioning further work to highlight obstacles to innovation. Officials are looking at the creation of a dedicated innovation pool within the statutory health insurance system as part of its efforts to get the most out of technology.

[8]MedTap, the Value Group, 2004. *The Value of Investment in Health Care: Better Care, Better Lives*
[9]American Diabetes Association 2003 pp917-932; *Diabetes Care*, V26, #3
[10]Higashina, R. Treatment of unruptured intracranial aneurysms: a nationwide assessment of effectiveness. AJNR. 2007;28:146-151
[11]Bakhai A, Stone GQ, Mahoney E. Et al. 2006 Cost effectiveness of paclitaxel-eluting stents for patients undergoing percutaneous coronary revascularization: results from the TAXU-IV trial. *J Am Coll Cardiol*. 48(2), pp253-61

Case Study:
Finland's regular mass screening programme reduces cancer incidence

In the 1960s, the Finnish Government Decree on Screening mandated an implementation of a cervical cancer screening programme. Through the municipal health authorities, nurses and midwives were trained to perform a conventional gynaecological screening smear to be analysed by medical laboratory technicians using standard cytology. Intended for women between the ages of 30 and 60, who would each take part in the testing every five years, the programme has sent out approximately 250,000 invitations to citizens every year since its inception, of which 200,000 attend their appointment.

Thanks to the participation in the programme, over 600 cervical intraepithelial lesions are identified annually, contributing to the prevention of an estimated 200 deaths every year. The screenings have successfully reduced incidence to 4 in 100,000 women and mortality to 1 in 100,000. This constitutes an 80% decrease from the initial baseline making for a healthier Finland and decreasing the treatment burden on the country's national health system.

Value:

A common goal

For too long, stakeholders in healthcare have pulled in opposite directions – even though we all want a better, more sustainable system. If we are to deal with today's challenges, we all must make difficult – but *necessary* – changes, and begin to pull in the same direction.

"The old model of maximising volume and prices has run its course. The new game places value over volume."

People deserve to be healthy, active and productive for their entire life. We need to reduce the demand for human resource-intensive health services at a time of healthcare worker shortages. One answer to this challenge is to see technology as an essential part of the solution. It is in the interests of all stakeholders to support technologies and innovations which improve health of patients, economic productivity and efficiency of healthcare systems.

The medical devices and in vitro diagnostics industries know the game is changing. The old model of maximising volume and prices has run its course. The new game places **value over volume**.

We accept the need for a shift in mind-set right across the industry and we know this will not be painless. We know too that change for other stakeholders is not easy either – but we must embrace these challenges.

Industry Ambitions: Moving to a collaborative model

1 - Build and engage stakeholder networks to collectively establish the opportunity and value of medical technology and innovation

2 - Collect, develop and share, evidence-based cases of medical technology supporting effective personalised care, a sustainable healthcare system and healthy ageing

3 - Demonstrate the cost-effectiveness, potential cost-savings and the socio-economic value of medical technology, while improving healthcare outcomes and quality of care

4 - Innovate care processes to address labour shortages

5 - Increase the value of the industry to the European economy

We all need to change

To succeed we need to work together with all stakeholders.

Together we need to:

- commit to bold reforms
- abandon old fixed positions where evidence suggests a radical change is required.

If all stakeholders pull together, the future of Europe's healthcare system can be improved for everyone.

References

American Diabetes Association 2003 pp917-932; *Diabetes Care*, V26, #3

Bakhai A, Stone GQ, Mahoney E. Et al. 2006 Cost effectiveness of paclitaxel-eluting stents for patients undergoing percutaneous coronary revascularization: results from the TAXU-IV trial. *J Am Coll Cardiol*. 48(2), pp253-61

Christiansen C., 2008. *The Innovator's Prescription*. New York: McGraw-Hill

EDMA Annual Report, 2010. *European IVD Market Overview: Lights & Shadows at a Time of Economic Downturn*

Guerzoni B. and Zuleeg F. (2011). *Working away at the cost of ageing*. Brussels: European Policy Centre. (http://www.epc.eu/documents/uploads/pub_1265_working_away_at_the_cost_of_ageing.pdf, accessed 14 September 2011)

Higashina, R. *Treatment of unruptured intracranial aneurysms: a nationwide assessment of effectiveness*. AJNR. 2007;28:146-151

MedTap, the Value Group, 2004. *The Value of Investment in Health Care: Better Care, Better Lives* (http://www.advamed.org/MemberPortal/About/NewsRoom/MediaKits/vot_election.htm, accessed 3 August 2011)

Moylneuz, A, Kerr RS, Yu L, et al. 2005. International subarachnoid aneurysm trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2,134 patients with ruptured aneurysms: a randomized comparison of effects of survival, dependency, seizures, rebleeding, subgroups, and aneurysm occlusion. *Lancet* 366, pp 809-817

Suhrcke M. et al. 2006. Investment in health could be good for Europe's economies. *British Medical Journal* online. (http://www.bmj.com/content/333/7576/1017.full, accessed 5 August 2011)

Testori Coggi, P., 2010. Health Trends and Challenges in the European Union. *Connaissance & Vie*. Antwerp 23 November 2010. (http://ec.europa.eu/dgs/health_consumer/speeches/connaissance_vie_en.pdf, accessed 14 September 2011.)

United Nations, 1948. *Universal declaration of human rights*. (http://www.un.org/en/documents/udhr/index.shtml, accessed 3 August 2011).

Eucomed, 2011. *The Medical Technology Industry in Europe*. (http://www.eucomed.org/uploads/Modules/Publications/110527_the_medical_technology_industry_in_europe.pdf, accessed 15 September 2011)

World Health Organization, 2011. *Development of Medical Device Policies*. (http://whqlibdoc.who.int/publications/2011/9789241501637_eng.pdf, accessed 4 August 2011)

World Health Organization, 2001. *Health technology assessment of medical devices*. (http://whqlibdoc.who.int/publications/2011/9789241501361_eng.pdf, accessed 2 August 2011)

edma
DIAGNOSTICS FOR HEALTH

www.edma-ivd.eu

Eucomed
Medical Technology

www.eucomed.org

MedTech Europe
from diagnosis to cure

MedTech Europe is

an Alliance of European medical technology industry associations. The Alliance was founded by EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry. Other European medical technology associations are welcome to join the Alliance, established to represent the common policy interests of its members more effectively and efficiently.

Our mission is

to make value-based, innovative medical technology available to more people, while supporting the transformation of healthcare systems onto a sustainable path. We promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders. In addition, we demonstrate the value of medical technology by encouraging our members to execute the industry's 5-year strategy.

info@medtecheurope.org • www.medtecheurope.org • www.reforminghealthcare.eu

October 2012