Innovation in Healthcare
From Research to Market to Health-systems to Patient
Main conclusions from 2010, 2011, 2012 conferences

Patients’ expectations are increasing while Europe’s population is growing older. This puts pressure on our health systems at a time when public finances are under considerable strain and our companies are fighting for survival.

Our demographic and competitiveness challenges can be tackled, at least in part, by boosting innovation in healthcare.
We know finding better medicines, smarter medical devices, and new telemedicine systems can help us to live longer, healthier, more independent lives. This cannot be achieved without the direct involvement of innovative research intensive small and medium-sized enterprises (SMEs) and Europe’s excellent researchers. Those key actors will have to be enabled in playing pivotal roles for future research and innovation.

The trouble is that while Europe has several fundamental strengths in this sector, many of our brightest ideas do not make it to market due to obstacles which healthcare innovators face.
A number of these problems – bureaucracy, access to finance, lack of capacity in technology transfer, intellectual property protection – have been with us for some time. Some have been made worse by the economic crisis and others are the result of rising global competition. But all can be tackled.

European prosperity is dependent on sustained and coherent investments in research and innovation and on intelligent policies that foster their success responding to specific realities. It is pivotal to connect different investments, policies and decision making processes across sectors. In new member states, where health inequalities are a particular problem, transformational changes that enhance innovation in the health systems building more effective, accessible and less unequal systems are required. Better use of structural funds could be the driver for improvement in competitiveness and for addressing health inequalities.

Health problems are of course not only European. The global health challenges that we face are immense – but through effective co-operation with developing countries we can bring benefits to all parties enhancing Health Innovation.

The urgency in removing roadblocks on the journey from research to market to health systems to patient prompted the European Commission to engage with stakeholders to identify concrete solutions. Three Innovation in Healthcare conferences were held in Brussels in 2010, 2011 and 2012, bringing together high-level policymakers, industry representatives, patient groups, researchers and regulators, along with experts in the fields of venture capital, technology transfer and academia.

This report sets out a summary of the challenges highlighted during these three events and the solutions proposed by participants.
The challenges
Getting a new medicine from bench to bedside can take anything from ten to 20 years and cost more than €1 billion. For every new drug or medical device that hits the market, hundreds of potential medicines or fledgling technologies fall by the wayside. It’s little wonder that some innovators and investors view healthcare innovation as being more trouble than it’s worth. Nor is it surprising that SMEs find it hard to compete in such a costly and heavily-regulated environment. Industry believes EU research priorities have focused too much on fundamental research at the expense of projects which have greater potential to result in new products. In addition, too many ideas fail to make the leap from basic science to commercialisation. To enhance innovation in healthcare, there is need for more coherence in planning and for connecting the different policies and decision making processes, enforcing integrated programming.

Solutions:
- EU funding programmes should help remove bottlenecks in a coherent manner.
- Research funds should support applied innovation projects.
- Private sector investment and new approaches should be encouraged.
- Europe needs to accelerate market access for new medical products.

“Innovations can be realised with a more value-driven and market-oriented focus, so that regulations and costs are less important as barriers to change.”
Guy Lebeau, chairman of the European Medical Technology Industry Association, EUCOMED

Finance
One of the biggest challenges for innovative researchers and companies in the healthcare sector is in finding finance. Healthcare innovation is expensive and, although the rewards can be great, the risks are similarly high.
The key ingredients for venture capital (VC) investment are available: we develop good science in Europe and there has been a culture shift about patenting. Now filing a patent is well perceived by scientists and it has become more a routine. We are starting to find repeat entrepreneurs in Europe. We have VCs who operate across borders, although VCs have concerns on unintended effects of current financial regulatory tightening on their activities. We have big European pharma companies in Europe and they collaborate with VCs. The problem for VC is more downstream: the big "pharma" companies are the only exit option for VCs in Europe since there is no NASDAQ and the different European stock exchanges do not have critical mass.
In terms of the availability of venture capital, European healthcare faces a unique challenge. Europe simply does not have enough VC funds geared towards investing in life sciences. The “big money” is with the institutional investors: limited partners (LPs). We need to have more funds of funds, reactivate the process of LPs and fuel this money to VC.
There are new good financial models emerging in some countries. The classic VC model will endure, but new VC-like models are already emerging: philanthropic foundations and crowdsourcing are ways to address and bridge the early-stage funding gap. European funding schemes do not address properly co-investment with venture philanthropy associations, and Europe lags behind in this regard. Patient’s groups should be more involved in the financing process.
Solutions:
- More direct public investment in life science VC funds is needed.
- Alternatively a new life sciences ‘fund of funds’ could be created with European support.
- This could include expanding the role of the European Investment Fund.
- The European Investment Bank could help to leverage the investment of the LPs with specific financial instruments (e.g. guaranties).
- Europe’s institutional investors could be encouraged to allocate a percentage of their investments to life sciences VC along with measures to remove disincentives to investing in European healthcare VC.
- Alternative sources of funding, like venture philanthropy or public private partnerships should be encouraged.
- The profile of the health sector needs to be raised further, with increased awareness and advocacy to bring more sources and types of investors into the sector.

“Investment in public sector R&D matters, if anything, more than it did 10 or 20 years ago, and further investment is needed.”
Iain Gillespie, Head of the Science and Technology Policy Division, Organisation for Economic Cooperation and Development (OECD)

EU Funds
The Framework Programmes (FP) have improved significantly in recent years. However, there is still an urgent need for reforms that would foster innovation in healthcare, and barriers to SME participation must be addressed, allowing for example single entities funding (especially SMEs) in particular for the SBIR-like instrument.
In terms of concrete results reaching patients, only 5-10% of FP projects lead to a product or a service, making it to the market. Industry and SME stakeholders complain that those evaluating projects often take an academic view of the value of their proposals, rather than assessing the prospects of commercial success.
European researchers have a strong track record for cross-border collaboration – something the FPs have encouraged. However, avoiding “cosmetic” inefficient collaborations, consortia shall be built around the project goals.
Small is beautiful, as a general rule, greater levels of partners adds exponentially to the complexity of the negotiations needed to advance a programme, reducing the prospects for ultimate commercialisation.

Solutions:
- Further simplification of framework programmes to encourage SME involvement.
- End the ‘silo-thinking’ in how research is funded, enhancing discipline oriented scientific activities.
- More experts evaluating project proposals should have industry experience.
- More funding for ‘applied innovation’ small projects.
- Increased focus on funding proof of concept projects, pre-commercial development, and clinical trials. This can bridge the ‘Valley of Death’ where promising ideas fail to make the leap to the next stage of development due to funding constraints.
- Some funding lines should be available to single companies or universities.
- Funds for unsuccessful projects should be cut and redirected towards what works.
- Collaborative projects should further enforce, making it compulsory, exchanges and integration throughout the whole value chain, in order to magnify knowledge and
skills transfer
- Enforce/improve/broaden public-private partnerships like the innovative medicine initiative (IMI), as they leverage industrial investment in fields where big pharma and VC money is not available but where there is a clear medical need.

“We need thematic programmes that are more market-oriented, more bottom-up approaches relevant to SMEs, and themes closer to the grand challenges.”
MEP Maria Da Graça Carvalho, ITRE member and Rapporteur for simplifying the implementation of framework programmes

Technology Transfer
Europe has excellent researchers pushing the boundaries of science. But exploiting this knowledge to develop new products, processes and services is an art we are struggling to master. The problem, at least in part, boils down to a human resources issue.
Europe has too few technology transfer officers with the scientific and business expertise required to bring new healthcare products to market. Academia and technology transfer offices (TTO) often fail to recognize downstream risks, lacking hands-on experience. It is fundamental to have professionals with expertise and understanding of the healthcare sector, market and of key stakeholders' needs. Those with the right combination of skills are in high demand, forcing universities and institutes to compete with pharmaceutical and biotech companies at home and abroad. Finding high-quality technology transfer officers is tough; keeping them is even tougher.

Solutions:
- Training and capacity-building of Europe’s current technology transfer officers.
- Recruiting and retaining professionals with the right mix of expertise.
- Secondments and exchanges between industry and technology transfer offices.
- Development of networks within the life sciences sector and sustain/promote incubators.
- Funding of IP funds to protect European universities’ and institutes’ intellectual property.
- Building on, and increasing, current European Investment Fund technology transfer funds.

“Technology transfer is not just about licensing, it requires a strong understanding of the sector, the market, and who the eventual customers will be.”
Christian Suojanen, Head of Life Sciences, Valor Management S.A. and Co-Chairman Tech-Transfer Summit

Marketing Innovation
Companies in the healthcare sector seeking to bring their bright ideas to patients must clear a series of demanding regulatory hurdles and SMEs in particular view the regulatory system as a major turn-off. On top of the burden of meeting Europe’s excellent standards in patient safety, innovators are faced with expensive, complex and fragmented systems for approving new products. A need for the improvement of the European context was stressed.
One long-standing problem has been the lack of a unified European patent system. This has made protecting intellectual property expensive and unpredictable, often discouraging smaller
companies from exploiting the potential of the internal market. While recent developments at the European Council are cause for optimism, progress on the unified patent has been in the making for far too long and cannot come quickly enough for healthcare innovators. Another cause for concerns is the level of fragmentation between EU Member States in the area of health technology assessment (HTA). The coexistence of a centralised procedure for marketing authorisation together with a great number of national (sometimes regional) pricing and reimbursement systems was seen by many as an obstacle to market innovation. Since the latter is a matter of national competence, a possible solution would be greater coordination of health technology assessment at European level. With governments reining in public spending in an effort to balance budgets, there is growing concern that expenditure on new medicines and investment in state-of-the-art diagnostic and other medical technologies will suffer, with consequent loss of innovation in promising fields like personalised medicine. In particular, requirements for clinical trial design are ill-suited to developing personalised medicine.

Solutions:
- **Regulatory clinical trial design should be better tailored to personalised medicines.**
- **Reform finance support systems to better suit life-sciences and healthcare SMEs.** The current market-based risk-management standards are not appropriate to healthcare innovation companies with long-product development cycles and generally no products on the market.
- **Take advantage of scientific progress (e.g. in diagnostics) to rationalise healthcare spending.** Provide loans to hospitals to allow them invest in new technologies and uptake innovation.
- **More evidence-based decision-making is required, such as the use of ‘mini-HTAs’.**

“National Healthcare Systems are one of the most important welfare achievements in the European social model. However, their financial foundations are under stress and innovative technologies will be subjected to increased scrutiny...While health technology assessment is a valuable and necessary instrument for decision making, it is important that it does not represent an unnecessary burden for companies facing a diversity of national requirements for HTA and approval mechanisms.”

MEP António CORREIA DE CAMPOS, Vice-President of the panel for the Assessment of Scientific and Technological Policy Options for the European Parliament (STOA)

**What about the patient?**
While the focus is often on the structural and technical reforms needed to boost the competitiveness of this vital European industry, the ultimate inspiration for innovation in healthcare is the patient. "Big pharma" is starting to recognize the value available outside of its own structure, namely in academia and SMEs, as well as the importance of involving the patient as early as possible in the product development process. Ensuring that innovation is directed towards objectives that are valued by society, it is essential that patients are part of the conversation. Ultimately, citizens’ money is invested in the R&D that develops products, and in buying the fruits of that research. Patients' needs are at the very core of healthcare innovation. Delivering on the promise of innovation in healthcare requires public support, patient engagement and flexibility.
Solutions:
- Involve patients more effectively in research, creating patient’s academies for health literacy and empowerment on the model of the 'European Patients' Academy on Therapeutic Innovation (EUPATI), funded by IMI.
- Multi-stakeholder engagement to answer the needs of patients.
- Good products should be approved, but incremental innovation can improve them.
- Examine new models for approving products.

“How healthcare innovations that do not reach patients are a waste of time, expertise, and resources.”
Alastair Kent, Chairman, European Platform for Patients’ Organizations, Science and Industry (EPPOSI)

How to overcome barriers to equality and solidarity in developing countries (Africa as case study)?
Scientists and innovators in Africa, and other developing regions of the world, comprise an immense and largely untapped resource that need to be unleashed. We should focus less on the obstacles and more on opportunities in Africa, and must improve our ways of collaborating, learning how to complement each other in a more effective way. Cooperation with Africa is of strategic importance for Europe. Innovation should be stimulated by developing human capital, but also by the way in which partnerships are developed and above all in a paradigm shift in product development. Many of the weaknesses relate to lack of coordination across sectors and current use of limited public initiatives where new models of partnerships may be more effective.
In this context, new models of partnerships have been developed for reseach. The largest and most important is the European and Developing Countries Clinical Trials Partnership (EDCTP). This partnership between Europe and sub-Saharan Africa aims to establish a research and development programme for the development of new or improved clinical interventions to combat poverty related diseases through a long-term partnership.
The European Commission has – together with the WHO – been instrumental in establishing ANDI, the African Network for Drugs and Diagnostics Innovation. ANDI will promote and sustain African-led product R&D innovation through the discovery, development and delivery of affordable new tools.

Solutions:
- Keep political momentum, with a focus on priorities and quick gains.
- Coherent programs that link funding to global healthcare objectives and strengthen capacity in partnership countries are required.
- Increase focus on training and local capacity building through local and regional networks.
- More should be done to ensure that research is translated into product development and taken up in the healthcare system. EU could consider to finance co-operation between scientists from Europe and low/middle-income countries on the whole innovation chain, from ideas and proof of concept to final prototype and market introduction, including regulatory aspects as well as health technology assessment.
- EDCTP winning model should be renewed and its mandate extended.
"The burden of diseases in developing countries offers an “opportunity” by way of necessity. For example, South Africa has now the biggest antiretroviral program in the world…"
Derek HANEKOM, Deputy Minister of Science and Technology Dept of South Africa

Commissioner’s views

Maire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science
“In Europe, we have excellent researchers, but we need to remove the barriers that prevent bright discoveries from reaching the market in the form of innovative products and services. This means fostering knowledge transfer, entrepreneurship and academia-industry partnerships.”

John Dalli, European Commissioner for Health and Consumer Policy
“The health sector has tremendous potential for innovation – both as a creator of new jobs and as a provider of better care for generations to come. This is the time to create more efficient models of healthcare and find innovative solutions.”

Antonio Tajani, European Commission Vice-President, responsible for Industry and Entrepreneurship
“The new 2020 Strategy aims at turning the EU into a smart, sustainable and inclusive economy delivering high levels of employment, productivity and social cohesion. To reach these objectives, the healthcare sector is a key area.”