

Innovation in Healthcare: from Research to Market

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.

The urgency in removing roadblocks on the journey from research to market prompted the European Commission to engage with stakeholders to identify concrete solutions. Two Innovation in Healthcare conferences were held in Brussels, in 2010 and 2011, 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 two events and the solutions proposed by participants.

To address these twin challenges, boosting innovation in healthcare can be the answer.

The challenge

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.

Solutions:

- *EU funding programmes should help remove bottlenecks*
- *Research funds should support applied innovation projects*
- *Private sector investment 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.

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. VCs have concerns on unintended effects of current financial regulatory tightening on their activities.

The funds which we have are struggling to attract sufficient money and some of our talented VC fund managers work in United States.

Solutions:

- *More direct public investment into 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*
- *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*

“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.

In terms of seeing concrete results reaching patients, only 5-10% of FP projects lead to a product or service making it to 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, when temporary partnerships are cobbled together for the sake of ticking the ‘collaboration’ box on the application form, it can prove inefficient; 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*

“Perhaps 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. 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*
- *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

Innovation market

Companies in the healthcare sector seeking to bring their bright ideas to patients must clear a series of demanding regulatory hurdles. 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.

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 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. SMEs in particular view the regulatory system as a major turn-off. Requirements for clinical trial design are ill-suited to developing personalised medicine.

Another cause for concern 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 access and innovation. Since the latter is a matter of national competence, a possible solution would be greater coordination of health technology assessment at European level.

Anyhow, a need for the improvement of the European context was stressed.

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 technology will suffer, with consequent loss of innovation in promising fields like 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*
- *More evidence-based decision-making is required, such as the use of 'mini-HTAs'*

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.

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.

Delivering on the promise of innovation in healthcare requires public support, patient engagement and flexibility.

Solutions:

- *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*

“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).

*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.”