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Connecting the dots

Towards a coherent, comprehensive strategy for health sector innovation in Europe

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On 8 November 2017, the Science|Business Network of 61 universities, companies and public-sector organisations met to discuss a vital question for Europe's future: How to maintain a strong, productive pipeline of healthcare innovations across Europe in the years ahead, despite mounting pressures of budget, politics and demographics?

This report draws upon the expertise offered at that meeting. Science|Business intends to organise similar strategic discussions during 2018 about the prospects for innovation in energy, ICT and other sectors.

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The context...

Health is one of those topics that dominates political discussions. It's an area where the public can be very vocal, especially when they perceive injustices in how they or their loved ones are treated. The supply and demand of treatments, medicines and medical technologies is subject to a complex web of regulation, economics, and behavioural sciences alongside the research chain from basic to applied research and its translation into marketable products. In Europe, this is all set in the context of a field where many regulatory and research decisions are made at European level, but the provision of healthcare itself – and health spending – is controlled at the national level.

Yet never has there been more need for direction and action at a European and even global level. Our aging populations are living for longer. Total antimicrobial resistance is possible if new antibiotics are not available within the next five years. There is a global shortage of doctors, nurses and midwives, and the enduring wealth gap, which for many countries is growing, is also intrinsically linked to a gap in access to healthcare. If we are to tackle these challenges head on we need a healthcare sector that is supported by coherent policies and practices at every stage of the system, from the training of researchers and healthcare professionals, to the development and marketing of new treatments, to the adoption and usage of those treatments and protocols by practitioners and patients. International collaboration in this area seems obvious and essential, yet fears abound that the European Commission sees this as an area that could be removed from their portfolio in coming years[i]; and the ramifications of Brexit could compound the problem.

Discussions on the future of health are surrounded by other political and location-based issues. Member-state investment in health varies widely, and even more so for healthcare research and innovation. From basic biomedical research, clinical drug trials and medical-product development right through to health budgets, administration and clinical practice – all are cogs in a machine exquisitely sensitive to political, demographic or economic perturbations. The Trump Administration has instigated restrictions on international mobility that affect researchers around the world, disrupting the international flow of ideas and talent. The Brexit negotiations herald additional changes, causing uncertainty about budgets, collaborations and trade as well as potential loss of access to a pool of talent and flourishing life sciences scene. Changes have already started; Amsterdam has just been named as the new host city for the European Medicines Agency, a move that will force this regulatory agency to focus only on performing its core functions while it relocates, creating uncertainty and limiting its ability to shape the future.

Strategy matters: The Science|Business network is clear that a coherent European vision in the health sector is vital if we are to get the most from it. There needs to be a longer-term view of innovation issues if our health sector is to flourish, with policies and processes that better reflect the timescales of research and development. This strategy needs to transcend national level politics, championing increased healthcare system effectiveness across Europe. Importantly, this strategy needs to be employed across the different silos of the Commission that are active in health.

> *"It is to my mind one of the beauties of the EU; we have these long-term programmes and it does give stability. In member-states, where governments come and go, strategies come and go. Within the European Union we have a strategy for seven years, with plans and frameworks. These can evolve in this time, ideally learn from themselves, but you have that longer-term perspective."*
>
> *Clare Moody, Member of the European Parliament (Labour – UK), at the conference*

But it doesn't end there. If the EU is going to have a robust and dynamic health sector then this strategy needs to be pervasive, working coherently across all the EU member-states. If we are to most effectively support the needs of every element of the sector - the patient, healthcare professionals, policymakers, research, and industry - then this needs to include the UK, too, no matter what the outcomes of Brexit. Only through this collaborative action can the EU truly reap the rewards of national investment in health.

The following pages outline our understanding of the key issues and actions needed to support an innovative and effective health sector across Europe, based on a high-level dinner debate of the Science|Business network.

Clare Moody, MEP

In brief...

Key actions needed for an innovative and effective health sector in Europe

Europe needs a coherent, 'whole value chain' strategy for health research and innovation, to drive forward progress in healthcare. While national politicians control the delivery of healthcare to their own citizens, when it comes to research and innovation progress can be faster and cheaper if there is an over-arching, European-wide agreement towards common goals. That should start with a more coherent, more effective EU-level strategy for healthcare innovation than has been possible hitherto. To implement this, it needs actions, including, but not limited to, the following:

- The skills and attitudes required for innovation need to be built into education as early as possible, looking beyond post- and undergraduate studies, back into schools, and included in the training of world-class doctors, nurses and other health-sector workers.

- European policies and legislation for health need to reflect the disparate healthcare systems across the continent and differences in national legislation. If the burden of localisation can be tempered through European-level strategies and collaboration, then companies operating in this sector will be able to invest more easily in European innovation. For example:

  > *Authorisation of new treatments and technologies*. For pharmaceuticals, the European Medicines Agency plays a vital role in ensuring new treatments can be easily rolled out across all EU member states through effective networking of member-state agencies. Other EU-level mechanisms help make an effective single market for medical devices and other essential tools of healthcare.

  > *Data protection*. Member-state implementation of European directives for data protection is at the moment uncoordinated, with uncertain consequences for how patient and public data is used in research. Compatibility of data usage throughout Europe is essential for development and testing of treatments and technologies.

  > *Intellectual property*. To keep innovations flowing from lab to clinic, we need to maintain a steady system of intellectual property protection, responsive to the long timescales, intense collaborations and complex processes of health R&D. This is at least as important for small start-ups as it is for big companies.

- Innovation in the health sector needs incentives, to drive progress beyond being just reaction to new legislation. Critical areas include:

  > *Collaboration incentives*. Academia, industry and healthcare delivery organisations need to be rewarded for working together, enabled through financial benefits for collaborative research, development and deployment.

  > *IP incentives*. The timescales of developing many treatments are not compatible with those for patenting, which makes innovation in new ideas a risky investment for the companies active in this area.

  > *Reform incentives*. If healthcare systems are to take up new treatments, technologies and approaches then they need money and time to do so. Most healthcare workers are at capacity with their normal workload, unable to take the time to strategise, network or collaborate.

  > *Involvement incentives*. To ensure healthcare and innovation systems are able to deliver the outcomes that matter most to patients and society there needs to be a culture of involvement, including financial and professional rewards available to researchers, industry and healthcare workers for addressing societal issues and involving public and patient perspectives.

- To properly test new treatments - definitively establishing their suitability, viability and market readiness - needs larger pots of funding to be made available. The current funding programmes for innovation release small amounts of funding on short timescales, which is ineffective in a health environment. These larger pots should be supplied through EU mechanisms, perhaps like the proposed European Innovation Council; but investment banks, venture capitalists and innovation angels should also be counselled to consider new approaches to the way they invest in healthcare innovation.

- To ensure that the potential negative impacts of Brexit are mitigated, Europe needs to retain after Brexit the current good working relationships with the UK in the health sector, including collaboration within research and development, regulatory alignment and join-coordination mechanisms, as well as shoring up its own activities in the health sector.

- Europe should build an identity as a global leader in the life sciences. By coherently supporting the health sector across policies in research and innovation, regional development, data protection, IP, the economy, growth and digitalisation, at both the European and member state level, Europe has the potential to be world-leading in this area. The building blocks are all there; now we need to put them together on a firm foundation.

Annemarie Haverhals, of Dutch hospital group Santeon

Connecting the dots

A summary of the policy elements required for a comprehensive, well coordinated European strategy for healthcare innovation

Topic	Examples
Getting to the lab: Robust research, training and education	
EU Framework Programmes	European Research Council, Innovative Medicines Initiative, pre-clinical innovation actions
International research cooperation	Horizon 2020, bilateral Science & Technology Agreements and multi-lateral research cooperation
Professional training	Doctoral programmes, medical schools, teaching hospitals
Researcher mobility	Erasmus+, Marie Curie, visa regimes
R&D regulation	Data protection regulation, animal testing
Getting to the clinic: clinical trials, authorisation, finance, manufacturing	
Finance	SME Instrument, European Innovation Council, angel and VC investment for clinical trials and beyond
Product authorisation	Clinical trial regulation, European Medicines Agency and harmonisation of Member-State authorisations
Intellectual property	IP protection, Unitary Patent & Court
State Aid	Exceptions regime (by sector or size)
Technology convergence	Legal frameworks for e-Health, m-Health
Manufacturing technologies	New process technologies for biologics and immuno-therapies
Getting to the patient: Budgets, administration, outcomes, market structure	
Innovation procurement	Pre-commercial procurement, uptake of innovations in personalised healthcare, mobile health, etc.
System management	Budget efficiency, outcomes management, integrated care and system sustainability
Patient and staff mobility	Cross-border care, health record transfers and e-prescription, doctor and nurse mobility
Competition	Generics, biosimilars, IP protection
Finance	Securities & pension fund regulation, stock market liquidity, merger reviews
Trade	Cross-border supply chains (Brexit disruption?), gray market, North/South pricing, Falsified Trade Directive, patent box, taxation

Towards an effective and innovative healthcare sector

In a sector as diverse as healthcare, with so many stakeholders - from individuals to large, established organisations - adopting innovation has traditionally been a challenge. Change can come slowly, hampered by bureaucracy, fear of the unknown or stagnant organisational cultures. Yet there is a desire for change on all sides; the public are vocal in their demands for improved access and new, better treatments, whilst researchers continue to push the boundaries of what is known about healthcare science and management. But these new discoveries are of no use if they are not able to be employed or practiced in the field. Improving the whole value-chain of innovation in healthcare, from basic research to translation to patient access, is essential if Europe is to benefit from the investments made by member-states, the European Union and industry in this area.

So, what's needed is one, over-arching strategy for healthcare innovation across Europe. Of course, the EU member-states control their own health systems; but when it comes to biomedical research and innovation, special economies of scale and network effects predominate. That requires trans-national thinking and collaboration with a specific innovation focus – and that has been inadequate so far. What follows is a discussion of the policy elements that any such strategy would require.

Creating a fertile environment for new approaches and ideas

Training new healthcare workers - the doctors, nurses, clinicians and technicians who deliver healthcare to the public - remains a significant challenge. Medical degrees across Europe are considered equivalent, yet the environments in which health workers operate differ widely. New treatments and technologies can only be adopted if practitioners have the knowledge, skills and confidence needed.

Clare Moody, MEP, and
Richard L. Hudson of Science|Business, discuss Brexit with Network members

Science|Business Network dinner debate

However, this isn't a problem if there are no new treatments to roll out. The entrepreneurship needed to take ideas from basic research and into the markets requires a level of risk-awareness, technical know-how and business skills that are not yet built into the education systems across Europe. There is still significant work needed to ensure Europe's young people value STEM subjects as part of their learning paths, as well as the skills they'll need to capitalise on their bright ideas.

The European Commission's Horizon 2020 research and innovation programme has spent about €2 billion in the last two years on health initiatives. But this is a small part of EU spending compared to budgets in the member-states. There's money in the system at a national level, but it is not being deployed in a cohesive fashion. Advocates need to speak up now if health is to receive the focus required in the next funding framework and Commission budgeting.

The aforementioned fledgling entrepreneurs need an environment that supports their idea generation and fundamental research, but also nurtures the partnerships that they will need to follow their ideas through to the market, or as Anna Sandström, science relations director of AstraZeneca put it, "breakthrough science doesn't lead to a paradigm shift in how we treat patients unless it is implemented. A foundation of implementation is cross-sector collaboration. We need both the collaborative climate, and the breakthrough science." This collaborative climate might well include the financial incentivisation of innovation and industry, but it must also reach back into the academic world and form part of the reward, recognition and performance criteria of universities, and forward into ensuring that innovative practices and products are really adopted – in short, shape a culture of innovation across the many different actors in the health ecosystem.

The public attitude towards healthcare innovation must also be taken into account, in trying to reinforce this collaborative culture. For instance, when it comes to the use of animals in research, public understanding and trust are weak, with policymakers repeatedly running into conflict over genuine issues with mistreatment of animals and the consequent public misconceptions over the use of animals in research more widely. Yet this is an area in which Europe excels, with world leading regulation that protects both animals and the ability to do research. Better communication and monitoring of legislation in this area would support more treatments to be successfully tested.

From trial to treatments

Regulation of health products is important, but at the moment the funding for getting ideas from the lab-bench through to market isn't available on useful timescales or in useful amounts. Current European funds for research translation are drip-feeding innovation at a rate of €1 million to €2 million per project; larger amounts must to be made available – on a scale of €20 million - to allow products to successfully move through pre-clinical research and into the truly mega-budgets of large-scale clinical trials.

Collaboration is critical to innovation, but the nature of ownership and how to profit from translated research means that IP protection is something that must be navigated within any potential partnership. Pascale Augé, CEO of Inserm Transfert, highlighted the need to "be able to talk about assets in a protected way", recognising the issues faced by academic teams that have to break out of the normal publish-or-perish mentality of academia if they are to protect the intellectual assets they are generating, and work with industry on a profitable product. We also need to find ways to value access to patients, patient data and the analysis of this data as assets when assessing the contributions made to a translation project.

The role of patients within trials also stands further examination. The cooperation of patients and access to public health data are valuable assets during the development and testing of new treatments. European -wide data protection legislation, soon to be implemented at the national level, has significant consequences for the way personal data is used, stored and shared; and the ways in which individuals give consent for the taking and use of this data have ethical implications and affect whether the final product can go to market. What consent looks like within the new data protection legislation, how this fits within ethical frameworks, and what boundaries these set for any data collected, are key issues.

Large-scale cohort trials don't just take money, but also time. At the moment, the funding schemes available are not aligned with the time needed for big clinical trials, let alone to develop the collaborations needed to make them work. Innovation takes time, and needs multidisciplinary approaches. And this time needs to be reflected in the systems that support intellectual property.

Pascale Augé
of INSERM Transfert

Line Matthiesen of DG Research and Innovation, European Commission

The current issues in support for large-scale cohort trials are obviously a problem for EU funding, but could also be considered to be part of a wider European mind-set around innovation. Countries like the USA or China are currently investing in the right amounts and time-frames, so it is time for Europe to catch up. As well as finding EU mechanisms to supply better innovation funding, such as the EIC or the capital markets union, investment banks, venture capitalists and innovation angels should also be counselled to consider new approaches to the way they invest in healthcare innovation.

Delivering innovation for all

Addressing the big issues of our day, such as widespread antimicrobial resistance, or the dramatic impact of rare diseases, is where innovative healthcare systems really come into their own. But this means joining up research, policy and patients in ways that have never been done before. Personalised medicine, and the digitalisation of health care will be game-changers in this field.

Strong networks are one way that implementation of new technologies and treatments can be more easily adopted, but this needs for there to be implementation and adoption teams within healthcare structures, taking an objective viewpoint across the system or at least clusters of hospitals.

> *Two big areas where we really try to move Europe are personalised medicine and digitalisation of healthcare. These are interlinked, because you can't have the personalisation of medicine without the digitalisation of healthcare. Work on rare diseases is something we see as a model for this work. We reinforce our collaboration with member-states, and not least with regions, because a lot of the European regions are investing in personalised medicines.*
>
> *Line Matthiessen, Director for Health, DG Research and Innovation*

As well as being an issue at the research stage, patient data has massive potential for the renovation of healthcare delivery; one thing that the healthcare networks mentioned above would benefit from is the sharing of patient data. Yet data sharing even within one country can be difficult, let alone across borders. The jury is out on how widespread personal objections to data sharing really are across Europe; some surveys suggest that, at least when it comes to health data, most people are willing to allow regulated access to researchers who could develop new cures. But one thing is for certain; the public would like more control over their treatments and how their information is used. The inability to drive such sharing forward hampers progress limiting the potential for improving healthcare based on patient data.

Once the sharing issues have been worked out there are methodological issues too; health is an area where Big Data approaches could be revolutionary, if the various stakeholders could be convinced to collaborate. If we really want to understand the take-up of new treatments, then collaborations with the behavioural and social sciences will be essential, as will a holistic, system-wide approach to evaluation. Yet at the moment this work is non-essential to the researchers developing treatments, the entrepreneurs turning those ideas into viable products, and the patients benefitting from the results. Incentives will be needed, financially, professionally and in policy, if significant change is to be made.

With that in mind it makes sense that the final, and most important, point raised was that European-level leadership within the health sector and life sciences needs a sense of strategic direction. If we are to put the patient at the heart of the system, then health sector policies need to transcend local issues, geographical borders and policy silos:

> *"Think of all the innovative medicines that are in the pipeline - developing the new schemes to incentivise AMR research, adopting personalised medicine… All of these issues need to be taken care of on behalf of all of Europe. This is something that member-states need to think about in these [Brexit] negotiations; it's not about nation, it's about patients."*
>
> *Anna Sandström, Science Relations Director, AstraZeneca*

Anna Sandström of AstraZeneca

Jan Palmowski of the Guild of European Research-Intensive Universities with Anne Borge of the University of Oslo

Potential Implications of Brexit

The full implications of Brexit on the health sector promise to be painful, at least in the short-term. Currently the UK receives about 15 per cent of Horizon 2020 funding, and produces about 16 percent of the most highly cited publications in the world[ii]. The research strengths of the UK are an asset for the EU; conversely, many UK researchers are now looking towards Europe for their next career move. As changes take place, the position of the EU and UK within research rankings will be at risk[iii].

There's been a significant reduction of EU healthcare workers into the UK since the Brexit vote. For nurses, where there is already a shortage of 30,000 in England alone, the number of EU nurses entering the UK fell from 1,304 in July 2016 down to 46 in April 2017[iv]. This doesn't just leave the UK short-staffed; EU nurses now have their career options limited, with the promise of long-term well rewarded contracts in the UK removed. This issue highlights the perils of not joining up the thinking, both across policy areas and across borders.

The UK has a strong strategic identity for the life sciences. Inability to partner with the UK for work in the health sector means the loss of access to:

- Research institutions known for their excellence in this area
- A large population within a single health system, suitable for large scale testing of new treatments and technologies
- The NHS infrastructure, the access it provides to patients and healthcare workers, and its ability to implement change

A lack of coordination is a significant worry, particularly when considering how the UK and EU deal with health threats such as pandemics. Until a new EU-UK joint coordination mechanism is worked out, something that is many years away, the UK will need to liaise directly with individual member states in emergency situations, something that carries a huge administrative burden for both parties.

The relocation of the EMA has the potential to disrupt drug licensing and standard setting for the EU. Whilst contingency plans are in place to ensure the transition is as smooth as possible, staff losses have the potential to impact on specific services depending on who leaves. The pressure is on the pharmaceutical industry now to be proactive, developing and deploying contingency plans to ensure that patients do not see disruption in their supply of medicines.

The risk is that pharmaceutical manufacturing sites in the UK have to retest their products in other EU member-states before use, instead of the current process of products tested in the UK being approved for wide deployment. Double testing is costly and takes time, and lack of certainty in the complex regulatory environment leaves the pharmaceutical industry in a difficult position; whilst some companies will be prepared, and are already taking steps to deal with the consequences of a “hard-Brexit”, there will be those who do not have the expertise, time or money to respond to the changing environment. This has the potential to stop hundreds of medicines from becoming available to EU member states, leaving hundreds of thousands of patients without the drugs they need. This also has the potential to drive these companies not just out of the UK, but out of Europe completely, as they look for more efficient and lucrative ways to develop their products.

Of course, some hope that such dire warnings, particularly the explicit example of loss of access to drugs, might be used to gain public support for a softer Brexit or abandoning the split completely. But that may be wishful thinking, and more sober planning is needed for sector-by-sector agreements.

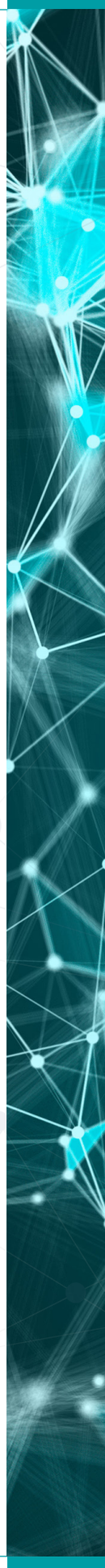
A strategic solution

When you examine the needs of the stakeholders in health, and the problems in this sector being raised by Brexit, one thing becomes clear: more collaboration and joined-up thinking is what is wanted, not less. All of the major issues faced by patients, policymakers, healthcare workers, researchers and industry - whether it be about access to funding, access to data, or implementation of new ideas - could be addressed through better coordination, communication and collaboration.

As such the best way forward now is not a reduction of EU-level interest in health, but a renewal of purpose, and a strong, cross-sector and cross-border European strategy for innovation in the life sciences. This will require leadership from the Commission – across all relevant departments, from research to health to information technology to industry. Hitherto, too much of the programming in Brussels – as in the member-states – has happened in policy silos. A coherent, over-arching strategy for healthcare innovation is needed now to fend off the worst political, economic and demographic challenges of our age.

References:

[i] https://sciencebusiness.net/healthy-measures/news/dont-kill-eus-role-health-implores-senior-austrian-official
[ii] https://en.unesco.org/unesco_science_report
[iii] https://ec.europa.eu/unitedkingdom/tags/horizon-2020_en
[iv] https://www.nmc.org.uk/news/press-releases/nmc-releases-new-data-on-eu-nurses-and-midwives/



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