

INVESTING IN UK HEALTH AND LIFE SCIENCES



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Government is putting all its efforts into rebalancing the UK economy, and with this the life sciences industry has come sharply into focus. In the last decade the UK pharmaceuticals industry has grown faster than any other sector of the economy, excepting the finance and insurance sector, with an annual turnover of over £50 billion.

Of course with 34 Nobel Prizes in medicine under its belt, the UK has a proven track record of being at the forefront of life sciences discoveries with fantastic health benefits – from Alexander Fleming discovering penicillin in 1928, to James D. Watson and Francis Crick identifying DNA in 1953; from Sir Alec Jeffreys' discovery of DNA finger-printing in 1984 to the first cloning of a mammal at the Roslin Institute (Dolly the sheep) in 1997; from Sir James Whyte Black finding the first clinically significant use of beta blockers in 1962, to the birth of the first 'test tube baby' in 1978.

Now we find ourselves at a crossroads. Global pharmaceutical sales are predicted to grow by up to 6 per cent a year in the coming years, painting an optimistic picture. Emerging markets are creating exciting investment opportunities and western countries such as the US and Germany have developed simpler regulatory processes to approve new therapies. We acknowledge that we have under-utilised our

strengths. To remain competitive we need to up our game in the UK because the challenges facing the industry are real and growing.

Added to this is the changing shape of the industry: the old 'big pharma' model of having thousands of highly-paid researchers working on a pipeline of blockbuster drugs is declining and a new model of collaboration, outsourcing of research and early clinical trials on patients is emerging. But does the UK 'ecosystem' currently support this? And how does innovation fare in the UK regulatory landscape?

The UK has significant areas of excellence, not least its science base, and industry tells us that, yes, the NHS is world-renowned, but it could tempt a lot more investment if we made more of our greatest assets: our talent for discovery and our NHS.

Government recognises that this is the key to ensuring that UK life sciences continue to contribute to sustainable UK

growth. On 5 December 2011 we delivered a radical set of measures in a *Strategy for UK Life Sciences*, alongside the NHS Chief Executive's review, *Innovation health and wealth, accelerating adoption and diffusion in the NHS*.

NHS data is more comprehensive than any other comparable health system in the world, but neither the NHS nor scientists developing new drugs and treatments have been able consistently to make good use of the data to drive further scientific breakthroughs. In the UK we are investing to make it easier for industry to partner with our world-leading scientists and clinicians, and to unlock the power of our unique patient data. That is why the National Institute for Health Research (NIHR) has committed a record investment of £800m over five years to the creation of Biomedical Research Centres and Units within the UK's leading teaching hospital-university partnerships, and the establishment of two new NIHR Translational Research Partnerships. The National Institute for Health Research Office for Clinical Research Infrastructure (NOCRI) provides a single point of entry to these centres for life sciences companies. We are also launching a new secure service to link primary and secondary care data at an unidentifiable

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patient level, and investing £60m in a secure Clinical Practice Research Datalink (CPRD) to provide researchers with access to patient data for clinical trials recruitment and observational studies.

Government will support patients to have access to novel treatments, and be part of wider patient benefits, by consulting on an amendment to the NHS constitution. Whilst protecting the right of an individual to opt out, this would assume that data collected as part of NHS care could be used for approved research, with appropriate protection for patient confidentiality. It would also assume that patients are content to be approached about research studies for which they may be eligible, to enable them to decide whether they want a discussion about consenting to be involved.

To complement this, we will invest £75 million to our ELIXIR programme to expand our ability to assemble and manage biological and genetic information generated by research. This will include the provision of a new facility within the existing European Bioinformatics Institute in Cambridge for biological data-storage to support life sciences research and its translation. Furthermore, the NIHR is investing £2.5m pump-priming this year in a new national NIHR Bioresource. This Bioresource will provide a national cohort of healthy volunteers, patients and their relatives who wish to participate in experimental medicine research, and are willing to provide clinical information and samples that will enable them to be recalled for specific studies. It will support companies and researchers in recruiting healthy participants to undertake stratified studies. These studies

will have the potential to rapidly advance the understanding of disease mechanisms, identify potential drug targets, and improve insight into the therapeutic potential and limitations of existing and emerging therapies.

Of course many of the UK's discoveries - potentially the most innovative medicines - will never reach the translation stage from the lab into a commercial venture, falling into the so-called 'valley of death' because small and medium-sized enterprises (SMEs) cannot secure financing in the early years of their R&D.

Building on current investments, we will invest £310 million to support the discovery, development and commercialisation of research into stratified medicine and mechanisms of diseases in people. This will include a £180 million biomedical catalyst fund to tackle the 'valley of death', nurturing the most promising medical treatments from the academic or commercial sector through to companies with products or technology platforms in order to attract private equity. It also includes a £10 million investment by the Medical Research Council (MRC) for collaboration with AstraZeneca to provide academic researchers with unprecedented access to 22 high quality AstraZeneca clinical and pre-clinical compounds which are the building blocks of new medicine. But that is not all. We will make a further investment of up to £50 million over the next 5 years in a Cell Therapy Technology Innovation Centre to focus on the development and commercialisation of cell therapies and advanced therapeutics.

For these investments to have their greatest impact,

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industry needs to support new businesses to understand the commercial environment. SMEs are often strong on scientific and research skills but may lack business and management skills. Through Cogent, we will develop and implement a tailored mentoring programme that will provide SMEs with the management skills they need to enhance their competitiveness.

Innovation in life sciences proceeds at an astonishing pace; however, we recognise that this pace is not always mirrored through the regulatory system. Through the MHRA therefore, we will work with industry and other international regulators to develop a progressive regulatory environment that not only supports innovation, but openly promotes it. Furthermore, as part of a major drive to improve innovation and access to medicines in the NHS, Government has announced proposals to consult on a new early access scheme that could allow thousands of the most seriously ill patients to access new cutting-edge drugs up to a year earlier than they can now.

As important as this suite of measures, which includes a raft of tax changes to incentivise R&D, is getting the UK 'house' in order. Granted we have an impressive set of life sciences clusters in the UK but in these global climes we need the UK to be, at the very least, on a par

with the likes of Boston, and the San Francisco Bay area. To ensure that researchers, clinicians, businesses and investors see the UK as the location of choice for life sciences, we are taking steps to build a fully integrated life sciences ecosystem from our world-class research and clinical infrastructure. Building on the Academic Health Science Centre model of adoption and diffusion, the NHS Chief Executive and the Chief Medical Officer will establish a number of Academic Health Science Networks (AHSNs) across the country, with the first going live during 2012/13. The AHSNs will align clinical research, informatics innovation, training and education and healthcare delivery, and will provide industry with clear points of access to the NHS.

We are genuinely committed to this impressive industry and excited by what these comprehensive and far-reaching proposals can offer it. But the proof, so they say, is in the pudding. In our determination to see early results and to ensure these measures deliver to their greatest potential, we have appointed two independent life sciences champions to support delivery against the strategy and we look forward to seeing what we can achieve together in 2012 and beyond.

