

From the President
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Wednesday 28 September 2011

Ms Christine Bloor
Director
The Office for Life Sciences
Department for Business, Innovation and Skills
1 Victoria Street
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Dear Christine,

Office for Life Sciences Review

Following my meeting with colleagues representing the Office for Life Sciences on Wednesday 21 September, please find below the Academy of Medical Sciences response to the current consultation.

The UK has historically enjoyed a vibrant pharmaceutical and biotechnology sector that is the largest in Europe and second in size only to the USA. The benefits of this strong commercial presence are well established: the sectors support over 250,000 high-value UK-based jobs and account for the largest share of industrial R&D spend.

An unprecedented phase of scientific discovery has generated opportunities to develop novel medicines and build on UK strengths across the medical science industries. However, the sector is experiencing challenging times and faces difficult issues with regard to its R&D pipeline. Despite increasing commercial expenditure on R&D, the number of new molecules approved for clinical use continues to fall. Challenges around the development of new medicines are compounded by the impending expiration of patents on many older medicines, leading to loss of profits and increased generic competition.

To address these challenges and boost innovation and productivity, much of the pharmaceutical industry has adopted a new business model. Companies are now investing in flexible partnerships with biotechnology firms and universities to access specialist expertise and share skills and resources. No other country is as well placed as the UK to benefit from the opportunities of this new model and the rearrangement of assets, people and investment.

The landscape of UK medical research has been enhanced in recent years by several initiatives aimed at increasing the economic benefits of publicly funded medical research. The creation of the Office for the Strategic Coordination of Health Research (OSCHR) has made the UK more coherent by coordinating the strategies of the Medical Research Council (MRC) and National Institute for Health Research (NIHR). The NIHR has created a sustainable and strong base for research within the NHS and the Technology Strategy Board has begun to play an increasingly important role in driving innovation.

By building on these steps, maintaining public sector support for biomedical sciences and enacting the measures outlined below, the Government can ensure that the UK profits from future growth in the life sciences sector. We would be happy to expand on any of the points in this response.

1. *Fueling the pipeline*

Our universities are a unique strength and an important source of compounds and technologies that have commercial potential. Universities need more support in thinking strategically and incubating a portfolio of products for longer to increase the potential for investment from venture capital and the pharmaceutical industry. Strong and coherent public programmes to support early phase innovation in universities will leverage further inward investment in the UK and bridge the gap between idea generation and commercial financing. A number of schemes already exist to facilitate technology transfer and fund the space between academia and industry, including the MRC's Developmental Pathway Funding Scheme. However, there are significant opportunities for enhancement of such schemes, and funds available for translation should be

used to support the best translational activities, regardless of whether private, public sector, or cross-sector collaboration.

2. Supporting a 'life science ecosystem'.

In the UK's world class universities, hospitals and companies we have the individual building blocks for a flourishing 'life science ecosystem'. The future of this sector lies in putting these elements together and collaborating to share expertise, skills and resources. In other countries, hubs for biotechnology and innovation have developed largely in clusters where a critical mass of academic scientists and institutions fuel a small company sector that ultimately supports the large pharmaceutical companies. The best international examples include the Bay Area in California, the San Diego cluster and the cluster around Boston. Successful clusters are characterised by a critical mass of academic and commercial scientific activity, a high percentage of the local population being degree-qualified, an exchange of personnel across the academic and industry sectors and a supportive legal, financial and capital infrastructure.

In the UK, a Scottish cluster based around four major universities has delivered commercial collaborations with a number of large pharmaceutical companies and resulted in the growth of a number of biotechnology prospects. The biotechnology sectors around Oxford (Thames Valley) and Cambridge are the largest in the UK and present opportunities to develop internationally competitive clusters. In short, enhancing the performance of UK geographical clusters and establishing better shared programmes and facilities between the commercial and academic sectors must be a priority for economic growth.

In addition to geographical clusters, networks which join expertise in specific disease areas, and bring together enabling technologies and cohorts of well characterised patients are powerful hubs for commercial interaction and inward investment. Translational Research Partnerships in the areas of 'joint and related inflammatory diseases' and 'inflammatory respiratory disease' are the first attempt to do this in the UK.¹

Early phase translational studies of novel therapeutics represent one of the greatest challenges of biomedical research. Engaging the university sector more effectively in these activities, either in collaboration with industry or alone, will be crucial to enhancing the environment for biomedicine in the UK. Academics must be supported in undertaking early stage clinical studies, and incentive mechanisms such as the Research Excellence Framework should recognise the value of entrepreneurial and translational science activities.

3. Supporting a vibrant small company sector

Reducing the time period that innovations require private investment, and allowing hubs for biotechnology and innovation to evolve in areas of world leading academic and commercial activity, will have a significant impact on the small company sector. A strong UK biotechnology sector is increasingly important, both in the creation of clusters and to attract a significant share of international investment to the UK.

The UK currently lacks medium sized life science companies that can function efficiently with a portfolio of products and programmes, maximising experienced scientific and managerial staff and enabling improved decision-making on commercial opportunities. Consideration should be given to how assets from across academia, large pharmaceutical companies and small biotechnology firms could potentially be combined to facilitate the growth of medium sized companies, following the examples of Gilead, Amylin or Cephalon, which currently operate largely outside of the UK.

4. Fiscal incentives

In a global market, it is vital that fiscal incentives are in place to support UK biotechnology firms and ensure they attract a significant share of pharmaceutical and risk capital investment. Consortium relief is an important way of encouraging investment by large, established companies in small and innovative businesses, as it allows a consortium of corporate investors to offset the losses of the small business against their taxable profits. Consortium relief in the UK would encourage earlier interactions between biotech and pharma companies and would provide a significant fiscal incentive to encourage this sector to thrive. Measures that promote investment from 'high-value' individuals and the corporate venture funds of 'big pharma' are crucial and would increase risk capital flow into this crucial sector of the economy.

¹ http://www.nihr.ac.uk/industry/Pages/translational_research_partnerships.aspx

5. *Engaging the NHS*

NIHR has led the way in creating effective clinical and academic partnerships, including the NIHR Biomedical Research Centres and Units (BRCs and BRUs) and Academic Health Science Centres (AHSCs). The BRCs/BRUs and AHSCs provide a locus for world-class translational research within the health service and have the potential to position the UK as a preferred site for clinical development by the pharmaceutical and biotechnology industries. As well as providing an engine for research, consideration could be given to expanding the role of the BRUs/BRCs and AHSCs in driving innovation and the evaluation of new interventions in the NHS. This could include embarking on joint development programmes with industry – particularly in diagnostics and devices – which share both risk and reward, optimise the use of data for clinical studies and healthcare applications.

Efforts should also be made to ensure the wider health care system supports and recognises the importance of research and innovation to improved patient care. The Academy has long championed the opportunities for health research available through the NHS, and there are now important examples of what can be achieved when the right framework and culture are put in place, for example the Northwest Exemplar programme.² However, cultural change is required to ensure health research and the uptake of innovation is formally embedded within NHS leadership and governance processes.

As previously recommended by the Academy, cultural change needs to be accompanied by a new streamlined and proportionate regulatory and governance pathway.³ The Government's support for the Academy's recommendations to create a single health research regulator and to link funding and metrics to efficient sign-off of research approvals by NHS Trusts is welcomed. However, these changes must be delivered in a coordinated fashion that delivers the required efficiency gains and increases the attractiveness of the UK as a site for commercial and non-commercial research.

6. *Innovation: the uptake and adoption of new interventions*

Our strengths in basic and translational research have resulted in the UK creating a quarter of the world's top 100 medicines. However, this expertise in advancing knowledge and developing new treatments has not been routinely matched by an ability to quickly deliver the benefits to patients.

A national health system that supports and adopts innovation is a crucial component in fostering an environment where companies look to invest in the UK. However, a number of obstacles exist that currently hinder innovation in the NHS including: a tendency for the cost of new innovations to be loaded on top of existing technologies, adding cost rather than achieving significant cost benefit; an approach that fails to utilise procurement as a mechanism to resource innovative technologies; and variation and delay in national and local level commissioning.

The NHS Chief Executive's ongoing review of innovation provides an important opportunity to address these obstacles and put in place a set of national and local incentives to accelerate the adoption and diffusion of innovations in the health service. The cultural obstacles to innovation must be removed by ensuring appropriate responsibility for innovation across new NHS structures, raising the profile of the NHS as a centre for innovation, and linking the performance of NHS Trusts and Clinical Commissioning Groups to the adoption and diffusion of innovation. Measures are needed to streamline decision-making regarding the value of new medicines, removing national and local level duplication and re-interpretation, and introducing strict deadlines for local commissioning decisions.

7. *Training and workforce*

Highly skilled individuals are UK medical science's most valuable resource and play a significant role in attracting commercial activity and investment. We must nurture and develop a pool of talented bioscience professionals – across the healthcare, academic and private sectors – who are equipped with the full range of skills needed to advance understanding and develop novel interventions and diagnostics for major diseases. Opportunities for flexible collaboration across sectors need to be seized by developing a biomedical workforce with the skills to move between and bridge sectors. For the commercial sector to thrive, it requires a workforce and leadership trained to demand, understand and utilise research and innovation for patient benefit. As such, doctors and healthcare professionals must be encouraged and supported in their research training, and efforts to build UK biomedical research capacity must be enhanced, focusing on developing interdisciplinary researchers and workers in key areas of current and future need, including quantitative science and bioinformatics, systems biology, ageing, physiology and pharmacology.

² http://www.research.northwest.nhs.uk/programmes_of_work/exemplar_program

³ <http://www.acmedsci.ac.uk/p47prid88.html>

The Academy looks forward to working with others and continuing its role in bringing scientists from across the sectors together with research funders and policy makers, to stimulate an environment that ensures that collaboration and innovation can prosper.

If you have any further queries on this consultation response, please contact Laurie Smith (+44 (0)20 3176 2167; laurie.smith@acmedsci.ac.uk).

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Laurie Smith', written in a cursive style.