THE INNOVATION REVIEW AN INDUSTRY RESPONSE

Nick Burgin
ABPI Board Member

In March 2011, the Government published its Plan for Growth, including a set of measures targeted at strengthening the UK's position as a leading location for life sciences investment. One of these measures called for NHS Chief Executive, Sir David Nicholson, to work together with a range of interested partners including industry representatives, to report on how the adoption and use of medical innovations can be accelerated across the NHS. This resulted in the development of Sir David's *Innovation Review*, which was launched on 5 December, alongside the *Strategy for UK Life Sciences.* These two very important policy documents inform a strategic approach to fostering innovation in a modernised NHS.

Innovation is the lifeblood of our sector, the source of both the breakthrough and the incremental advance; it is that part of our healthcare economy that reinforces the UK as a global destination for investment. But the process for generating pharmaceutical innovations is neither well-defined nor homogenous. Rather, innovations advance in stages, over long periods of time and often with some degree of uncertainty. The innovative process is one that involves search and experimentation, where outcomes cannot be predicted for their clinical impact or economic value. And yet medical innovations hold the potential to transform life-threatening diseases such as HIV/AIDS and certain cancers into chronic manageable conditions. They can extend life or affect the tolerability of a treatment, thereby boosting patient compliance and saving costs.

Creating an environment where innovation can thrive requires close working between a range of partners, including representatives from academia, clinicians, patients and the NHS. To this end, we applaud the spirit of collaboration and the refreshing leadership of Sir Ian Carruthers and Miles Ayling of the *Innovation Review*, in the approach that was taken to generate insights into these two very important policy instruments.

As the co-leader of the ABPI group invited to work on the initial submission response to Sir David Nicholson's call for evidence, my colleagues and I found the process to be inclusive and flexible. We were offered a range of different settings for meetings where we could engage and share ideas. Some of these included an external advisory board, informal dinners with stakeholder groups, and the secondment of a senior employee from the industry to assist Sir Ian Caruthers and his team whilst also providing excellent communication through the development process.

This joint-working experience presents a successful blueprint and pathway for how the industry and the NHS can work together. We hope that this example will be replicated to assure the effective implementation of the initiatives generated from this close working.

THE UK AS A LEADING LOCATION FOR LIFE SCIENCES INVESTMENT

The UK and, in particular, the NHS, is already well-regarded globally. The NHS ethos of providing care free at the point of entry is admired across the world, as is the training of our clinical staff.

From a commercial perspective, UK prices are directly referenced in 25 per cent of world markets and then indirectly in a further 15 per cent.[1] This price referencing can take place both at launch and throughout a product's lifecycle. In addition, decisions made by the National Institute for Health and Clinical Excellence (NICE) have influence around the world, with particular importance for British-headquartered companies where NICE is often the first technology assessment body to review a new medicine that the company will then plan to launch globally.

In the midst of a challenging global environment, the UK is increasingly under threat of becoming a mid- or late-tier launch market. An important factor is the issue of delayed local access to market following a positive recommendation by NICE. This is due in part to the structure and governance of the NHS, where there is a culture and tradition of caution regarding new medicines – exacerbated by what might be described as a disconnect between medicines that NICE

considers cost-effective and the reality of local health economies. This disconnect may then compel local NHS budget holders to regard certain medicines as unaffordable despite the national guidance.

These barriers to local market access are tackled directly through initiatives that aim to reduce variation and strengthen compliance with NICE appraisals through automatic yet planned inclusion into the NHS formulary within 90 days of a decision being made. This will be backed up by a NICE Implementation Collaborative to support prompt implementation of NICE guidance. Further support for these initiatives will be in the form of a proposed innovation scorecard designed to track compliance with NICE technology appraisals.

On the supply side, a number of Academic Health Science Networks (AHSNs) are being established to link up the system and drive up innovation. To manage local and regional NHS budget differences that may also act as a barrier to access, a shared savings formula is being introduced to break down NHS silo budgeting and encourage cross-boundary working. Plans to continue work on tariff development, especially in relation to payment for outcomes, are progressing. These initiatives will go a long way to building on the UK's strong global reputation, with more incentives for investors to regard it as a first to market location for their innovation products.

NHS CULTURE CHANGE

Actions to embed innovation in training and education through a range of competency frameworks, coupled with a leadership programme to strengthen board-level accountability throughout the NHS, are most welcome. These are measures that the industry has used to adapt to changing environments and customers' needs and we believe they will help the NHS to achieve its objectives. Organisational change is never easy, however, and we would like to offer our support, working jointly with NHS partners, to share programmes that we have developed for our own organisations.

Overall, we believe that effective implementation of these initiatives will be the key to improving international confidence in the UK as the fastest adopter of new ideas in the world. For example, my own company Eisai is now more likely to hold the intellectual property for *perampanel* in the UK which will result in sustained investment especially in manufacturing. This is just one small example of where the implementation of targeted initiatives can help to mark out the UK as an attractive site for investment in the midst of increasingly noisy competition from emerging markets.

REGULATION

Innovation has many dimensions, all of which need to be considered by third-party payers designing pricing and reimbursement policies. As such, we welcome the proposals for a fair regulatory process that is proportionate to investment risk. This will enable the UK to take a lead position in attracting research, clinical trials and manufacturing investment. Other plans to simplify regulation, reducing gold plating and unnecessary bureaucracy will help industry move further and faster, again reinforcing the UK as an attractive place to locate business.

The proposal for a group of experts including industry representatives to meet regularly to discuss regulation is in the spirit of fostering an NHS that is open to business and very welcome.

We further welcome the launch of the regulatory audit and Red Tape Challenge in March 2012, and commend the Government's commitment to review the stock of UK regulation that impacts upon the life sciences industry.

ACCELERATING THE USE OF INNOVATIONS ACROSS THE NHS

The commitment to providing earlier access to medicines where appropriate, allowing patients to benefit earlier from promising medicines whilst improving what we know about how these medicines work, is promising. This initiative would allow for patients with severe disease and no other recourse to treatment to have access to innovative medicines. Under these proposals, earlier access will be made available where benefit outweighs the risk. NHS funding must be cost-effective and the UK economy should benefit from the scheme.

The industry welcomes the action for the MHRA to bring forward for consultation proposals for an 'Earlier Access Scheme' as devised by the Ministerial Industry Strategy Group (MISG) New Technologies Advisory Panel. We welcome further detail on this very important proposal.

CLINICAL TRIALS

Clinical trials play a critical role in the cycle of discovery, development and delivery of innovative medicines and we welcome initiatives designed to further ensure that the UK is identified as an attractive site for clinical trials in the midst of an increasingly competitive global environment.

These initiatives include extending the Academic Health Science Centre (AHSC) model, where a healthcare provider works closely with a university. The industry has noted that organisations with AHSC status have made efforts to align their organisations, thereby integrating the strategy and operation of a medical school with its local NHS Trust. This is good practice and in the spirit of the sort of collaborative working that fosters medical innovations.

Under this initiative, the Cambridge, Oxford and London Biomedical Research Centres (BRCs) will work with the Biomedical Research Unit (BRU) in Leicester to develop a national resource. This will help to seal the UK's position as the 'go-to' location for experimental medicine by providing a national cohort of healthy volunteers, patients and their relatives who wish to participate in experimental medicine research. This will be supported with published information detailing which NHS trusts are involved in clinical research, including information on how they are performing.

Importantly, the National Institute for Health Research (NIHR) Clinical Research Network (CRN) is partnering with *The Guardian* newspaper to create the Clinical Research Zone. This will showcase the research that individual NHS Trusts are taking part in and will be located beneath the existing *Guardian* Healthcare Network site.

Other supporting initiatives include the development of a smartphone app to increase access to information about clinical trials and the re-launch of

an enhanced web-based UK Clinical Trials Gateway in March 2012. These will aim to provide patients and the public with authoritative and accessible information about clinical trials in the UK.

DEVELOPING CAPABILITIES IN eHEALTH AND INFORMATICS

The move towards the integration of health records and data linkages will open up the information created by the NHS as a unique data source of strong interest to industry globally. Furthermore, the introduction of data collected as part of NHS care (with appropriate protection for patient confidentiality) is to be welcomed.

Proposals for the Health and Social Care Information Centre set to open by September 2012 offer a range of options to secure, share and preserve data. Some of these options include a secure data linkage service that will deliver data extracts using linked data from primary and secondary care and other sources on a routine basis. These data will be provided on an unidentifiable, individual level and will be able to be used by the specialist Clinical Practice Research Datalink (CPRD) service. It will also be available to all users of health and care information in order to drive improvements in care, enterprise and innovation. The centre will operate on a self-financing basis where users pay the cost of the linking process.

The Clinical Practice Research Datalink (CPRD), which is a £60 million investment by NIHR and MHRA, will service the specialised needs of the research and life sciences communities by offering data services: providing access to data for researchers (NHS, social care and others); data matching and linkage services; and data validation to support the clinical trial and observational study work of the life sciences research community. It will also work to support patients to have access to novel treatments and be part of the development of wider patient benefits by consulting on amending the NHS Constitution so that there is a default assumption (with a facility for opt-out) for information collected as part of NHS care to be used for approved research with appropriate protection for patient confidentiality; and 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 in a research study.

This is very welcome as is the drive to ensure leadership in all these instances so that research is a core strand of the NHS's role to drive innovation and develop new medicines.

ECOSYSTEM

We welcome the Government's support for the entire life science ecosystem, including the gap or 'valley of death' funding for early stage research and SMEs. As the pharmaceutical industry comes under new global pressures, the survival of the sector is reliant on this health ecosystem. Recognition of this is very welcome.

FISCAL INCENTIVES

We welcome the fiscal incentives as announced in the Chancellor's statement – reinforcing the Government's commitment to establishing the Patent Box, a measure that will reduce corporation tax on profits from patents to 10 per cent from April 2013. This will create a competitive tax environment for companies and encourage them to locate high-value jobs and activity associated with the development, manufacture and exploitation of patents in the UK.

Other measures include an R&D tax credit system that will move from super deduction relief to a credit offset against corporation tax in boosting the level of R&D investment in the UK, give this relief to Contract Research Organisations and others when routine R&D testing is subcontracted, and provide a simpler pre-clearance system for smaller companies (such as spin-outs) making their first claim.

The Technology Strategy Board launched a competition to form a Cell Therapy Technology and Innovation Centre which will help to support the development and commercialisation of therapeutics, as well as the underpinning technologies for manufacturing, quality control and addressing safety and efficacy challenges for new treatments.

WHAT THESE ACTIONS COULD MEAN FOR INDUSTRY, THE NHS AND THE UK ECONOMY

The process of innovation is one of search and exploration, where uncertainty and serendipity coincide. Medical innovations confer societal benefits that extend beyond the patient to the economy as a whole. The launch of policy directed at placing innovation at the heart of the NHS marks a positive step forward for the NHS itself and also for industry and patients, and they are most welcome.

Launching the Life Sciences Strategy, the Prime Minister called for a new paradigm for the life sciences sector where the NHS is open for business and the UK is a 'hotbed of innovation'. He also called for the industry to work hand in hand with the NHS and academia, with better collaboration, more out-sourcing and a greater number of early clinical trials.

We strongly believe that the effective implementation of the actions outlined in the *Life Sciences Strategy* and the *Innovation Review* will go a long way to achieving these aims. The process of designing these reports has been very inclusive. As other negotiations that are crucial to the industry continue – such as those around pricing – the industry hopes to continue to work in the same spirit of collaboration together with Government, academia and the NHS.

References:

1. OFT report 2007, Global Insights February 2011, PhRMA (March 2011) Issue in Brief: International Reference Pricing & IMS World Review 2011