



Government Autumn Package and Innovation Review

Report analysis

5 December 2011

The Innovation Launch

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The Government has today launched a range of initiatives to support the Life Sciences sector, including the 'NHS Chief Executive Review of Innovation' and the 'Life Sciences Autumn Package' and a keynote speech by the Prime Minister, providing leadership to the industry.

NHS Chief Executive Review of Innovation

The final report contains the following actions which closely reflect the solutions in the ABPI submission and the priorities agreed with the Board of Management:

Reducing variation and strengthening compliance

- A NICE Compliance Regime to reduce variation and drive up compliance with NICE technology appraisals
- All NICE technology appraisal recommendations are incorporated automatically into relevant local NHS formularies in a planned way that supports safe and clinically appropriate practice
 - Inclusion on formulary should take place within 90 days to support compliance with the three month funding direction and the NHS constitution
- A NICE Implementation Collaborative to support prompt implementation of NICE guidance
- Value Based Pricing is mentioned within the section on 'reducing variation and strengthening compliance', but there is no new information

Metrics and information

- Development and publication of a straightforward innovation scorecard designed to track compliance with NICE technology appraisals
- A single comprehensive and publicly available web portal for innovation in the NHS

Creating a system for delivery of innovation

Establish a number of Academic Health Science Networks (AHSNs) across the country to link up the system and drive up diffusion of innovation

Incentives and investments

Alignment of financial, operational and performance incentives to support adoption and diffusion of innovation by:



- Development and introduction of a shared savings formula to breakdown silo budgeting and encourage cross boundary working
- Continuing work on tariff development, especially in relations to payment for outcomes
- Establishment of a Specialised Services Commissioning Innovation fund

Developing our people

- 'Hard wire' innovation into educational curricula, training programmes and competency frameworks at every level
- Establish joint Industry and NHS training and education programmes for senior managers
- Establish a new Industry and NHS CEO network

Leadership for Innovation

The NHS Operating Framework asks the NHS to prioritise the adoption and spread of effective innovation and good practice

- Strengthen leadership and accountability for innovation at a board level throughout the NHS
- Clinical Commissioning Groups will be under a duty to seek out and adopt best practice, as part of the legal duty to promote innovation
- This section also refers to the strategic partnership between the ABPI , ABHI and NHS Confederation and outlines the NCB support for delivery of this collaboration

Implementation

The implementation plan is outlined including an Implementation Board made up of senior stakeholders, to oversee delivery chaired by Sir Ian Carruthers reporting to the NHS Chief Executive, and a series of Task and Finish groups comprised of multidisciplinary experts to deliver individual actions. A 3, 6 and 9 month timeline is included.

Other comments

Additional actions included in the report relate to a new procurement strategy to help the NHS achieve the QIPP efficiencies and high impact innovations which will systematically be spread at pace and scale.



Life Sciences Autumn Package

Many of the initiatives the ABPI has called for have been included in the Life Sciences Autumn Package and the industry welcome the following details:

Support for the whole life sciences ecosystem

- This report announces a significant focus on translating fundamental biomedical research into commercial application. Focus on translating fundamental biomedical research – ABPI will work with funders and academia to ensure fit-for-purpose in addressing industrial discovery and development challenges in producing new innovation medicines.

Education and Skills aspects

- Through Cogent, the Government will develop a strategy to increase the uptake of industry placements in the UK.
- Together with Cogent and others, we will develop a process to kite-mark FE and HE programmes. This will be piloted in 2012.
- Through Cogent, we will establish the Technical Apprenticeship Service 'one-stop shop' for employers in science-based sectors. This will be operational from January.
- We will introduce, via Cogent, Higher Level Apprentices (HLAs) covering post A-level education. Our ambition is to deliver 420 Apprenticeships over the next five years.
- Through Cogent we will provide information on careers in life sciences, for students, employers and educators.
- Through the Society of Biology, we will improve practical teaching standards, by expanding the accreditation programme for undergraduate biology degrees.

Early stage investment in SMEs

New funding to support early stage companies through the early gap funding stage is welcomed.

- Introduction of a new Seed Enterprise Investment Scheme offering a 50% income tax relief and initial capital gains tax exemption.
- Injection of £180M over the next 3 years in a joint MRC-TSB Biomedical Catalyst Fund to attract private equity investment.

Regulatory Innovation

- The ABPI welcome 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: <http://www.mhra.gov.uk/Howweregulate/Medicines/MISGNewTechnologiesAdvisoryPanel/Earlieraccesstonewmedicinesintheuk/index.htm>
- We 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 the life sciences industry

Improving cross-sector collaboration

ABPI welcomes the initiatives announced.

- High level aspiration to nurture highly skilled researchers, clinicians and technicians and assist them to work collaboratively across traditional boundaries to create value



throughout the ecosystem. ABPI looks forward to working with government to make this a reality.

- People mobility across sectors – see Skills comments focused on Cogent under Support for the R&D ecosystem.
- New £130M initiative to support consortium programmes in translational science in Stratified Medicine.
- Elixir – investment of £75m to support curation and access to biological data for translational science

Clinical research

- Extending the AHSC model – this is welcomed by industry as those organisations with AHSC status have sought a range of different models to closely align or integrate strategy and operation of their local medical schools and NHS trusts.
- The Cambridge, Oxford and London BRCs will work with the BRU in Leicester, to develop a national NUHR Bioresource, to make the UK the “go-to” place for experimental medicine – by providing a national cohort of healthy volunteers, patients and their relatives who wish to participate in experimental medicine research.
- Publication of information about which NHS Trusts are involved in clinical research and how are they performing. The NIHR Clinical Research Network (CRN) is partnering with The Guardian to create The Clinical Research Zone. This will publish data on individual NHS Trust participation in clinical research, and sit beneath the existing Guardian Healthcare Network site.
- Development of a smartphone app to increase access to information about clinical trials.
- Re-launch of an enhanced web-based UK Clinical Trials Gateway in March 2012.
- To provide patients and the public with authoritative and accessible information about clinical trials in the UK.
- 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 ability to opt out): for data 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.
- Clinical leadership to ensure that research is a core part of the NHS’ role to drive innovation and develop new medicines

Developing capabilities in eHealth and informatics

The Health and Social Care Information Centre by September 2012

- A secure data linkage service.
- It will deliver data extracts using linked data from primary and secondary care and other sources, on a routine basis
- Data provided at an unidentifiable, individual level.
- It can also be used by the specialist research service (CPRD – see below).
- It will be available to all users of health and care information in order to drive improvements in care, enterprise and innovation



- It will operate on a self financing basis where users would pay the cost of the linking process.

The Clinical Practice Research Datalink (CPRD) which is a £60 million investment by NIHR and MHRA.

- It will service the specialised needs of the research and life sciences communities.
- It will offer 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.

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 ability to opt out): for data 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.

Support for advanced manufacturing

Taken together, the Life Sciences Strategy and the Chancellor's Autumn/PBR statement have delivered most of what industry asked for, which includes:

- The Patent box: The Government has reconfirmed their commitment to introducing the Patent Box, a measure which will reduce corporation tax on profits from patents to 10% from 1 April 2013. It 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.
- R&D tax credits: The R&D tax credit system will: move from the current super-deduction relief to a credit offset against corporation tax in boosting the level of R&D investment in the UK; give the 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.
- Cell therapy TIC: "Supporting the investment already made in regenerative medicine, the Technology Strategy Board launched a competition to form a Cell Therapy Technology and Innovation Centre. The centre, with a focus on cell therapies and advanced therapeutics, will help support the development and commercialisation of therapeutics as well as the underpinning technologies for manufacturing, quality control and addressing safety and efficacy challenges for these new treatments."
- "The advanced manufacturing sector, for example, will require a work force that is skilled in engineering as well as in areas such as biological and cell-based medicines, high-tech medical devices and information-driven health systems. We will work with our partners to develop greater experience in technical skills and commercial expertise to create the right talent base for the UK Life Sciences industry. *The availability of a pool of sufficiently skilled and trained staff at all educational levels will be essential for the development of the advanced pharmaceutical manufacturing sector in the UK. ABPI look forward to working closely with HMG in developing the strategies for delivering this.*



- Regulatory Environment for manufacturing The Government has pledged that the MHRA will work with industry on the call for action on advanced manufacturing to ensure medicines regulation does not act as a barrier to the adoption of innovative manufacturing technology, and consider opportunities for creating a more enabling regulatory environment.

A single, coherent government policy that is ambitious about the success of the life sciences industry in the UK

- Two Life Science Champions – one to chair the Life Sciences Advisory Board, the second champion to promote clusters.
- Series of events to promote the UK's leading position in healthcare and life sciences in advance of the 2012 Olympics
- Increase trade and investment with China on translational and personalised medicine

Life Sciences Prospectus

To complement these reports, and provide links between the two initiatives the Government has also launch a 'Life Sciences Prospectus' which provides coverage of UK successes and headlines of the changes the Government has introduced today.