Government Response to Review and Refresh of Bioscience 2015 Report

May 2009
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Foreword

As the UK economy is rebalanced we need to build on our strengths and look to high-tech sectors as the new drivers of growth and prosperity: the medical biotechnology industry is one such sector with the key attributes to play a leading role in driving our economy in the future.

This Government Response to the Review and Refresh of Bioscience 2015 is the first and key part of a broader cross government strategy on life sciences. This summer we will publish a Life Sciences Industrial Strategy prepared by the new Office for Life Sciences.

The Government is clear that we need to maximise UK strengths in the science base and the NHS in the face of increasing competition in order to maintain our global ranking. That is why I welcome the recommendations presented by the report.

The life sciences industry brings benefit to the UK economy and the health of our population via the research it conducts and products it delivers. The rejuvenation of the NHS research system being delivered by the National Institute for Health Research and the NHS Operating Framework national ambition to double the number of patients participating in clinical trials signals the importance the Government places on realising these benefits.

Thanks to scientific advances it is becoming easier to judge how specific groups of patients are likely to respond to drugs. By stratifying the patient population, drugs can be identified that will be effective in a niche population. To do this requires research into the underlying basis of diseases, offering opportunities for earlier disease diagnosis as well as better treatment. That is why I have welcomed the recommendation to create and execute a stratified disease strategy and this will be coordinated by the MRC on behalf of OSCHR and TSB working closely with industry.

We want companies to make positive investment decisions to continue to base their manufacturing and R&D in the UK. The Government committed in Budget 2009 to consider the evidence for changes to the way the tax system encourages innovative activity, including intellectual property. Working with representatives across the business community, the Government will assess the evidence on the potential impacts of any reforms on economic activity, consult further with industry and set out its assessment and proposed approach before the Pre-Budget Report.
The report highlighted the changing business models of the medical bioscience industry and the difficulty in accessing the finance and development funding needed. Enterprise Capital Funds were set up in 2003 in order to address the finance gap. We are encouraging strong applications from the bioscience sector. BERR will be taking forward a review to consider whether, and in what form, further Government intervention could increase the supply of long-term growth capital for small and medium-sized businesses. We have also launched a £750 million Strategic Investment Fund to support industries of strategic importance to UK competitiveness. As I set out in *Building Britain’s Future: New Industries, New Jobs*, this includes the life sciences.

I would like to thank Sir David Cooksey and all who contributed to the Review and Refresh of Bioscience 2015.

Peter Mandelson
Introduction

Life sciences is one of the key strategic sectors of the future, and has a vital contribution to make as the UK comes through recession: the Government needs to ensure that the industry is in a position to flourish. We will focus on rebalancing the economy towards those sectors where we have a competitive advantage and opportunity to be a global leader. Therefore we need to take urgent and focused action to support this sector.

The UK already offers an excellent location for life sciences companies, but the Government is not complacent and we must listen to the needs of our industry and be constantly vigilant and improve our offer to the industry.

For these reasons Sir David Cooksey, in partnership with the Bioindustry Association (BIA) was asked by BERR, in January 2008, to review and refresh his previous report to Government “Bioscience 2015.”\(^1\) He reported back to Government in January 2009 with 23 recommendations to strengthen work to date and ensure future industry success.

This is the Government response to the Review and Refresh of Bioscience 2015\(^2\) (BIGTR2).

Building on progress to date in taking forward Bioscience 2015, the Government has further confirmed its commitment to the life sciences industry by establishing the Office for Life Sciences\(^3\). This goes above and beyond the recommendations in both Bioscience 2015 and its subsequent review and refresh. The Office was set up by the Prime Minister in January 2009 and its work is being taken forward with industry under the leadership of Lord Drayson.

The Office has an important role to play in the coordination of the life sciences agenda across Whitehall in partnership with industry and other key stakeholders. In the summer a Life Sciences Industrial Strategy will be published setting out the delivery of cross Government action to address the key issues affecting the pharmaceutical, medical biotechnology and medical devices sectors. This Government Response is an important start to this work. The Government, with industry partners is seeking to ensure that the breadth and detail are addressed properly. We are determined to ensure that the UK offers the most competitive package available to a company wishing to do business in this sector.

\(^1\) http://www.bioindustry.org/bigtreport/downloads.html
\(^3\) http://www.dius.gov.uk/ols
We recognise that we already have key strengths in the science base and the NHS and we aim to build on those.

This Government Response is structured around three key themes: finance, increasing the uptake of new therapeutics, and human capital. These areas reflect the most important issues affecting medical bioscience today and are key to its future success.
Chapter 1: Stocktake of Bioscience 2015

Recommendation 1: Sustain Research Capability

The good progress in establishing the Research Capability Programme in England should be sustained and every effort taken to ensure that the services delivered via its Health Research Support Services and equivalents in the Devolved Administrations meet the needs of the sector. Funding bodies should work together to maximise the preparedness of the research community and industry to use it.

The National Institute for Health Research/NHS Connecting for Health’s Research Capability Programme has completed its enabling phase and is now preparing the full business case for investment in a Health Research Support Service (HRSS). There is active coordination among research funders, including industry, with a view to maximising preparedness for the research opportunities that will open up when the HRSS begins operation.

Under the auspices of the Office for Strategic Coordination of Health Research (OSCHR), the OSCHR office has facilitated discussions between public and charity funders able to gauge and develop the preparedness of the research community. The organisations involved in discussions to date are:

- Medical Research Council (MRC)
- National Institute for Health Research (NIHR)
- Economic and Social Research Council
- Chief Scientist’s Office, Scottish Government Health Directorates (CSO)
- Engineering and Physical Sciences Research Council (EPSRC)
- Wales Office for Research and Development
- The Wellcome Trust
- Cancer Research UK.

These funders are developing a Strategic Framework for Health Informatics in Support of Health Research. This Framework will provide a vehicle for long-term, UK-wide, strategy coordination that will help maximise the impact of the HRSS developed by the Connecting for Health Research Capability Programme and analogous programmes in Wales, the Secure Anonymised Information Linkage System, and the Scottish Health Information System.
Recommendation 2: Incentivise Clinicians

Funding partners should work together under the umbrella of OSCHR to incentivise clinicians to become clinician scientists following a research degree e.g. PhD route to ensure sufficient supply for industry and academia. The numbers of successful clinician PhDs awarded should be published annually.

In 2008, OSCHR partners including the Department of Health initiated work on human capital. The aim is to identify what further work partners need to do to establish a skilled and highly motivated research workforce with sufficient capacity and capability across the full range of medical research to meet the needs of the NHS, academia and industry. This workstream will report to OSCHR in May this year, and will build on what has already been achieved, such as the new integrated career structure for clinical academics.

There has already been a significant increase in investment by the UK Health Departments in integrated academic training for health professionals. For instance, NIHR is making funds available for 250 new Academic Clinical Fellowships and 100 new Clinical Lectureships each year (equivalent to 750 and 400 respectively, at steady state). The schemes provide research experience for academically gifted medical and dental trainees with the potential to be independent researchers of the future, whilst allowing them to continue their clinical training to achieve full specialist registration.

Evidence suggests that the quality of applicants for PhD fellowships is already rising as a result of the new integrated academic pathway. We expect this to feed through in turn to increasing demand from high quality academic clinicians for the post-doctoral Clinician Scientist awards funded mainly by NIHR, the MRC and the Wellcome Trust.

Funders of medical research training are working together to get better information about trainee numbers and clinical research career pathways. This will include publishing annual data on the numbers of successful clinician PhDs.

Recommendation 3: Maximising Awareness of Opportunities

A targeted communication and marketing exercise is needed to maximise awareness of the opportunities offered to industry by the new infrastructure, funding and collaboration put in place since Bioscience 2015 was published. This could be done as part of the UK Life Science Marketing Strategy.

The Government warmly welcomes this recommendation. We believe that globally, the UK already offers a strong base for lifesciences and the improvements that will be made as a result of BIGTR2 as well as the on-going actions to be coordinated by the Office for Life Sciences will add further to our global position and allow more companies to prosper here. The UK Life Science Marketing Strategy4 was launched on 12 November 2007 to enhance the international trade and inward investment of the biotechnology, pharmaceuticals and healthcare sectors over the next five years.

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4 See www.marketinglifescience.co.uk for further information on the UK Life Science Marketing Strategy.
years. The strategy is led by a joint industry and Government Board, chaired by Chris Brinsmead, President of the Association of the British Pharmaceutical Industry (ABPI) and chairman of AstraZeneca UK. UK Trade and Investment (UKTI) are the lead Government Department for the marketing strategy and provide the secretariat.

By harnessing the collective strengths of key stakeholders, the strategy aims to ensure that the UK is known as the global centre for Life Science creativity, enabling partners and companies to drive innovation through to market success. The strategy will:

- Forge closer links between industry, Government and the wider sector, so that the sectors can work together to market UK excellence;
- Market UK’s strengths through consistent and compelling messages, facts and case studies;
- Drive the marketing of UK life science using a single integrated strategy ensuring messages get through to the right people, in the right way at the right time; and
- Focus resources and effort on the countries and sub-sectors that can really make a difference to the UK.

In addition, the strategy will systematically gather sector information on market dynamics, UK capability and overseas opportunities for the common good; develop effective and regular marketing communications based on this evidence; and address perceived barriers in key target markets.

The Board is taking forward six work streams to drive implementation of the strategy in consultation with the wider UK sector. Each will work on specific areas, which, together, will ensure the UK continues to be a world leader in our competitive market place. The workstreams are:

- Messaging and supporting collateral;
- Country workstreams for China, India, Japan and the US; and
- Finance.

Key deliverables include the recent launch of an on-line marketing toolkit. The Toolkit will explain current and planned developments in infrastructure, funding and collaboration. This will enable UK companies and stakeholders to use common messages when promoting their capabilities overseas.

A series of events will roll out the strategy, mobilising the Life Science community to collectively market the UK proposition overseas more effectively. As resources allow, country communication plans will be implemented in target markets.

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5 For further details on the UK Life Science Strategy Board and its activities to date see www.marketinglifescience.co.uk
Recommendation 4: Include Participating in Research in the NHS Operating Framework

Participation in research has been included in the NHS Operating Framework and should be accounted for via the annual Quality Accounts submitted by NHS Healthcare Providers with the aim of doubling the current number of people enrolled in clinical trials and large scale evaluations conducted in the UK by 2012 across the full spectrum of clinical trials including biologics.

● Every NHS Trust should have a Board member, preferably one of the Executive, designated to take responsibility for the efficient running of clinical research in the Trust;

● There should be a specific objective of doubling the number of patients recruited to clinical trials in NHS Trusts over the next three years;

● The performance of the Trust in conducting clinical research should be one of the quality measures against which Trusts are assessed;

● Trusts should indicate their commitment to research by publishing goals for the number of patients involved in clinical studies on a half yearly basis and report in their quality accounts;

● Every NHS Trust taking part in clinical research should record and publish the average time it takes for the local approval process to be completed; and

● With the introduction of the coordinated system for NHS Permissions within the NIHR Comprehensive Local Research Networks over the next six months, every NHS Trust should commit to actively embracing the new system and not introduce activities at local level.

Quality Accounts offer a transparent way to ensure that Trusts report to their local populations on research activities, which are a key element of the quality of care. We will work with the NHS to ensure that providers who conduct research include in Quality Accounts the number of patients recruited in the previous year to clinical research (i.e. research which has received Research Ethics Committee approval). We will also explore other appropriate research indicators that link to the quality of care for inclusion in Quality Accounts, and/or other national reporting mechanisms.

The Department of Health (DH) Research Governance Framework for Health and Social Care (RGF) issued in 2005 requires providers of care to be aware of all research being undertaken within their organisation and ensure that it meets the standards set out in the RGF. Accountability lies with the Chief Executive who may delegate responsibility to a qualified and senior member of staff. Rather than asking each Trust to designate a Board member to take responsibility for research, the DH believes that it would be more effective for Trusts to set goals for research within their organisation and report on their achievement at least annually to the Board and in their annual report. The Department will be writing to the service shortly about this.
The objective contained within the Operating Framework is to double the number of patients taking part in clinical trials and other well-designed research studies within five years. We believe that the five year time-frame to deliver this is more realistic than three years.

As stated above we propose to include in the Quality Accounts a requirement for providers to report on the number of patients recruited in the previous year to clinical research (i.e. research which has received Research Ethics Committee approval).

The letter which the Department will be writing to the service will ask Trusts to set goals for research in their organisation. The indicator in the Quality Accounts will require Trusts to report on the number of patients involved in clinical studies. The letter will ask Trusts to publish the average time it takes for the local research approval process to be completed.

This letter will also ask Trusts to ensure that they use the NIHR Coordinated System for gaining NHS permission and that they do not develop unnecessary additional activities or bureaucracies locally.

**Recommendation 5: Leadership on EU Clinical Trials Directive**

The UK Government should take a leadership role within Europe to ensure that the revisions to improve the EU Clinical Trials Directive reinforce the UK’s attractiveness as a prime location for clinical trials and to reflect the better regulation aspects of Government.

The Medicines and Healthcare Products Regulatory Agency (MHRA) on behalf of the UK Government continues to lead discussions in the EU committees dedicated to improving the implementation of the Clinical Trials Directive, working with colleagues in the other Member States to improve harmonisation of assessment. The MHRA continues to try to assess clinical trial applications well within the prescribed timelines to meet the Government’s overall objective of ensuring the UK remains an attractive location for research and clinical trials.

**Recommendation 6: Follow on in Bioprocessing**

Relevant Research Councils and Knowledge Transfer Networks along with the Technology Strategy Board and industry should build on the success of the Bioprocessing Research Industry Club to develop a set of follow-on activities. New funding must be in place for distribution in 2009 and onwards to build capacity for multidisciplinary bioprocessing research and training to 2015. The growth in capacity should make the emergence of new centres of excellence possible, and be sufficient to meet the needs of academic and industry recruitment. The Technology Strategy Board should continue to provide financial support to the provision of a Knowledge Transfer Network at least at the current level that will deliver the bioprocessing agenda set out in Bioscience 2015 beyond 2009.

The Government broadly supports this recommendation.
The Biotechnology and Biological Sciences Research Council (BBSRC) is currently evaluating the early impact of the Bioprocessing Research Industry Club\(^6\) (BRIC). An independent panel will be convened to report and make recommendations by summer 2009.

The Club Steering Group and others will then consider whether there should be follow-on activities and what form these should take. Future plans will take into account the outcomes of the evaluation, BIGTR2 recommendations, as well as needs of industry and the impact of the economic downturn. Initial recommendations will be developed by a BBSRC-led Working Group in consultation with the BRIC Steering Group and wider Club membership.

In addition, BBSRC continues to allocate funds to masters training and PhD studentships in this area. The BBSRC welcomes the support from the BIGTR2 for the Knowledge Transfer Network (KTN), which has fulfilled a valuable role since its establishment.

The Technology Strategy Board (TSB) will work to ensure that collaborative working between key partners in the public and private sectors is achieved. Its KTNs, which also cover the area of bioprocessing, will receive appropriate funding, and it will work with the BBSRC to develop suitable follow-on activities to BRIC.

The TSB has completed a review of the KTNs and will now look to re-focus the work of the KTNs to align them more closely with the innovation priorities it has identified. It will also be increasing the support the KTNs give to international activities. The budget changes and the review of remit mean that a new combined KTN will be asked to put together a business plan in which bioprocessing will be a key activity as well as regenerative medicine and manufacturing operational excellence. In this context, the TSB will also work to ensure that collaborative working between key partners in the public and private sectors is achieved and that its KTNs, which also cover the area of bioprocessing, will receive appropriate funding. It will also work with the BBSRC to develop suitable follow-on activities to BRIC.

**Recommendation 7: Annual Progress Report**

**BERR should ensure the provision of good quality evidence in order to accurately assess the state of the sector, working together with industry to ensure the capture and tracking of an agreed set of metrics that will assist in determining the extent to which the sector is growing and prospering moving forward.** The BIA, ABPI and BERR should produce a short annual report on progress and challenges against the recommendations in this report; this should be presented to the Ministers with responsibility for bioscience within BERR, DH and DIUS.

The Government accepts that the lack of reliable data specifically for the medical biotechnology sector has made it difficult to track and measure progress and we therefore welcome this recommendation. BERR, UKTI and DH have commissioned a

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\(^6\) Further information about BRIC is available on the BBSRC website: [http://www.bbsrc.ac.uk/business/collaborative_research/industry_clubs/bric/background.html](http://www.bbsrc.ac.uk/business/collaborative_research/industry_clubs/bric/background.html)
database covering the medical biotechnology, industrial biotechnology and healthcare technology sectors for improved industry metrics. UKTI will also use some information from the database to promote the UK’s medical biotechnology, medical technology and industrial biotechnology industries as part of their Life Sciences Marketing Strategy via a publicly accessible website. The database will be populated by summer 2009 with company data from a range of different commercial and publicly available sources. We will be able to provide specific commentary and analysis of each sector by autumn 2009. This activity will be supported by a range of national and regional support networks, such as the relevant trade bodies, KTNs and Regional Development Agency funded networks.

BERR will lead on producing an annual report on progress and challenges against the BIGTR2 recommendations. This will be done in consultation with the BIA, ABPI and the Office for Life Sciences. The first report will be presented to relevant Ministers in January 2010.
Chapter 2: A new Vision and Business Model

Recommendation 8: Attracting Overseas Interest

The UKTI should:

- Use its life sciences marketing strategy to focus on attracting high quality overseas companies to list on the London Stock Exchange, persuading overseas funds, including Sovereign Wealth Funds, to invest in the UK and also assisting UK companies to gain investment from foreign funds by holding road shows for non-UK investors both in the UK and abroad; and

- Boost its resources in the Global Entrepreneurs Programme and encourage closer relationships with Angel Networks (for example the BIA BioAngels). By doing this UKTI could also enhance the bioscience investment opportunities that it presents to US funds.

The Life Science Marketing Strategy is a UK wide strategy, owned by industry and Government. One of the current workstreams in the Strategy is focused on Finance. The Finance Workstream recommends that a two stage plan is implemented to encourage greater corporate venture activities in the UK:

- Stage 1 consists of research by UKTI and the Finance Workstream to identify corporate venture contacts, analyse their portfolios and through a series of interviews identify measures which would encourage further UK activity. It is proposed that focused events will be organised to coincide with major investment conferences.

- Stage 2 of the initiative would be to provide assistance and encouragement to these corporate venture arms in the form of information, networks, deal flow and, if necessary, access to support facilities.

UKTI will develop a plan to initiate Stage 1, coordinating their specialist resources accordingly.

UKTI is continuing to deliver the Global Entrepreneur Programme7 (GEP). Since its inception in 2003, the GEP has helped over 59 companies and 38 entrepreneurs and early-stage technology companies to establish in the UK. Regarding the Life Sciences sector, the GEP has helped to:

- establish 8 companies/organisations;

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7 Further information about the GEP is available on its website: www.entrepreneurs.gov.uk
● appoint 16 entrepreneurs to executive/board/advisory/mentoring positions in the UK;
● raise £19.5 million.

Going forward, the GEP life sciences strategy will build on the success to date with initiatives aimed at fund raising, further mentoring/advisor opportunities, introducing technologies/businesses to the UK, and helping to develop UK science.

Future resources will depend upon overall resource constraints and decisions on the UKTI corporate plan. UKTI will continue to develop close relationships with Angel Networks and as such enhance the bioscience opportunities that are presented to global investors.

Recommendation 9: Extend Tax Credits

To extend R&D tax credits through:

● Extension of relief to cover benefits in kind;
● Relief on payments to self-employed individuals and high quality management talent at CEO and CSO level;
● Remove the PAYE/NI limit on repayable credit;
● Extension of the relief to rent costs; and
● Extension of the relief to cover IP costs.

Research & Development (R&D) tax credits are designed to incentivise innovative activity across all sectors of the economy. They are the Government’s most important policy in support of R&D investment by companies in the UK, demonstrating our continued commitment to unlocking innovation and enhancing UK productivity. The latest national statistics confirm the continued success of the schemes, with over 36,000 claims made by 2006-07, and over £2.8 billion of relief claimed.

R&D tax credits are designed to target a specific market failure, focusing relief on maximising the positive spillovers of innovative activity. The tax credits are designed to channel relief to genuine R&D activity to ensure the targeting and effectiveness of the relief. In designing the R&D tax credits, the rules were kept as simple as possible by limiting the categories of expenditure to the most substantial costs involved when R&D is undertaken. A widening of the qualifying costs would increase the cost of the scheme with no clear benefit in additional R&D.

The rates of relief for R&D tax credits were increased in 2008, following extensive discussion with the European Commission, to substantially increase the generosity of the schemes. The current reliefs have been strongly endorsed by businesses and we do not see a case for further change at the present time. However, Government continues to discuss the effectiveness of the R&D tax credit with industry and, as with all aspects of tax, will keep this under review.
Recommendation 10: Extend EIS Scope

Extend the applicability of the Enterprise Investment Scheme and Venture Capital Trusts by for example extending their scope to cover SMEs, following the definitions used for R&D tax credits. Extend EIS and VCT scope to cover shares acquired through shareholder to shareholder transaction.

The tax-based venture capital schemes – the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs) scheme – continue to play an important role in ensuring small companies are able to access appropriate levels of finance, by incentivising equity investments in small, higher-risk companies. Over 14,500 companies have benefited from EIS investment since the start of the scheme. Between 2004 and 2007, the scheme raised around £2 billion, of which hi-tech companies (including those involved in R&D) received over 25 per cent. VCTs have raised £3.5bn since inception, and invested in over 1,500 companies.

The Government took the decision to focus the EIS and VCT scheme on the smallest companies in 2006, to address the ‘crowding out’ effect that was witnessed when medium-sized companies were eligible for investments made through the schemes. This ensures that smaller, higher-risk companies (with gross assets of less than £7m before investment) continue to access finance. The schemes also aim to raise additional finance for small companies, so only newly-issued, full-risk shares are considered to be qualifying investments. Allowing relief for investments in second-hand shares could lead to a dilution of the number of first-round investments, which could threaten the impact of the schemes.

The Government is keen to ensure the EIS remains an effective means of promoting growth and enterprise, and so carried out a consultation into the EIS last year, to identify opportunities to improve and simplify the rules and processes that govern the scheme. The results were summarised in The Enterprise Investment Scheme: summary of responses published at the Pre-Budget Report 2008. As a result of this consultation, the Government recently announced four legislative changes to the EIS that will simplify and improve the operation of the scheme. One of the changes, relaxing the timing rules for employing money raised from an EIS share issue, will also be applied to the VCT and Corporate Venturing Schemes.

However, the schemes are notified state aids, and state aid approval must be secured from the European Commission to allow the schemes to continue to operate. They are therefore legally required to comply with the European State Aid Risk Capital guidelines. Requirements concerning the maximum number of employees and the maximum amount of investment companies can receive through the scheme each year were therefore introduced in 2007 to ensure the schemes comply with state aid guidelines. The Government continues to work with the Commission to ensure that proper account is taken of the economic arguments for Government intervention when applying these guidelines, but the changes announced in 2007 were necessary to secure the future of the schemes, and to offer greater security to investors and the companies in which they invest. Under current guidelines, a relaxation of these requirements (to allow larger companies to use the schemes) is not possible at present.
Recommendation 11: Encourage Enterprise Capital Fund applications

Capital for Enterprise Ltd, which delivers Enterprise Capital Funds on behalf of BERR, should particularly encourage strong bids from bioscience in future funding rounds in view of its importance to the UK economy and the lack of such bids to date.

The Government welcomes strong applications to Enterprise Capital Funds (ECFs) from the bioscience industry and other sectors of the economy. BERR will task Capital for Enterprise Limited, which delivers the ECF programme on BERR’s behalf, with encouraging bids from the bioscience industry in future rounds.

Recommendation 12: Incentives for Big Pharma

To create incentives for big pharmaceutical companies to invest in UK biotechnology, and to spin-out assets in the UK to create new companies, through development of the tax incentives described above.

The Government is committed to maintaining the overall competitiveness of UK corporation tax regime. Surveys by respected international bodies such as the World Bank and the World Economic Forum consistently show that the UK provides a business friendly environment and competitive tax system.

As part of the Government’s commitment to examine the challenges facing the UK tax system and ensure its competitiveness, and focus on supporting the high value-added priority sectors in which the UK can excel in the future, the Government announced in Budget 2009 that it will consider the evidence for changes to the way the tax system encourages innovative activity and the relative attractiveness of the UK to global firms as they make decisions on where to locate their R&D and other innovation activities. Working with representatives across the business community, the Government will examine the balance of taxation of innovative activity, including intellectual property. The Government will assess the evidence on the potential impacts of any reforms on economic activity, such as the development and exploitation of patents and other intellectual property, location of manufacturing, R&D, investment and employment (as well as on where intellectual property assets are held), and on tax receipts. The Government will consult further with industry and set out its assessment and proposed approach before the Pre-Budget Report. This assessment will draw on the expertise of the Business-Government Forum on Tax and Globalisation and on existing analysis such as the Review and Refresh of Bioscience 2015 report, as well as a wider range of stakeholders.
Chapter 3: Exploiting the Knowledge Base and increasing uptake

Recommendation 13: Redesign Regulation

The Ministerial Industry Strategy Group should build on existing work to develop a vision for the future evolution of global biopharmaceutical regulation, taking into account initiatives which are already underway in the major regulatory jurisdictions. MHRA should work with its EU and international counterparts to develop and promote the vision.

A working group of industry and Government representatives which will report to the Ministerial Industry Strategy Group (MISG) is looking at ways in which new medicines might be made available to patients at an earlier stage of their development. They will consider possible changes to the wider legal and regulatory framework to support earlier access to medicines through a system of conditional licensing under the broader Cooksey agenda, so that the UK can influence future change to the European system. They will report to the MISG before the end of 2009. The MHRA is well placed as a leading European regulator to promote any changes to global biopharmaceutical regulation with its EU and international counterparts.

Recommendation 14: Stratified Disease Strategy

A stratified disease strategy should be created and executed by Government through a multi-organisation integrated programme. This should involve BIA, ABPI, OSCHR, TSB, NIHR, MRC, industry, academia and other relevant organisations. The strategy should set out common therapeutic goals, building on areas of UK competitive strength and lead to: enhanced patient outcome; accelerated uptake of medicines; and better value through more effective targeting.

The Government agrees with this recommendation. It sees development of a Stratified Disease Strategy as a key component in the coordination and delivery of new and innovative medicine for the future. Stratified medicine is considered a priority area for activity, particularly for the MRC and the TSB who will work closely together. The MRC will coordinate activities on behalf of OSCHR bringing together the key stakeholders from the public and private sectors, to ensure coordination and to address research, capacity and methodology issues.

Through its soon to be published Medicines and Healthcare Strategy, the TSB will provide a business-led vision for the sector to drive forward business innovation in the next generation of disease prevention and management, diagnosis and treatment.
Stratified medicine is considered a priority area for activity, and the TSB will work closely with the key stakeholders to position the UK to derive maximum benefit, and address complementary market shaping measures such as regulation, procurement and fiscal drivers in this area.

**Recommendation 15: Reward Academic Collaboration**

The Research Excellence Framework should recognise and reward excellence in both stand-alone research and collaborative research with industrial partners. There are real opportunities for the academic sector to play a greater role in a rapidly changing bioscience industry. In order to realise these opportunities the evaluation framework used by the funding councils needs to promote greater collaboration between academia and industry.

The Government is broadly supportive of this recommendation. In a departure from the previous Research Assessment Exercise (RAE) in 2001, the most recent RAE in December 2008 was specifically designed towards better recognition of excellence in user-focused research. All of the 67 RAE panels were asked to think about how best to recognise a variety of user-focused work. Looking ahead, the next assessment will be done under a new “Research Excellence Framework”. That system, currently being developed by the Higher Education Funding Council for England, will build on the positive developments of the 2008 RAE. It will also go further and will take account of the impact of research.

The Government encourages and supports the Research Councils in recognition of all forms of collaborative research, not only with industrial partners but also excellence in impact in other ways, such as influence on policy and clinical practice.

**Recommendation 16: Independent Inquiry into NICE**

There should be an independent inquiry to assess NICE’s long term impact on cost, access to, and uptake of, medicines in the UK. There should also be an independent review of the way in which NICE values medicines so that the current economic evaluation is complemented by clinician, patient and research inputs on the value of the innovation from their perspectives. A revised NICE should offer health economic data to companies as a way to support the functions of market forecasting, and determining likely revenues within in the NHS, as this would incentivise R&D.

Much progress has been made since the creation of the National Institute for Health and Clinical Excellence (NICE) in 1999, and its guidance has benefited many thousands of NHS patients. As recognised by Sir David Cooksey’s report, NICE’s work has been commended by the World Health Organisation and NICE is viewed as a world leader in its field. NICE has also evolved since its creation with the introduction of the “fast track” Single Technology Assessment (STA) appraisal process, more explicit flexibility in appraising innovative drugs for less common end of life conditions, and other important developments.
NICE has open and transparent processes. It consults periodically on both its technology appraisal methods and its appraisal processes, and is currently concluding the latest scheduled review of its appraisal process manual. It is important to remember that, although technology appraisals are an important element of NICE’s overall work programme, they constitute only one part of a much broader remit. This remit includes broadly-based clinical guidelines, work on public health programmes and interventions, interventional procedures and – for the future – the development of quality standards for the NHS. In this context, we do not believe that an independent inquiry as proposed by Sir David is the right way of addressing the specific issues his report raises.

Issues of access to and uptake of medicines in the NHS were discussed substantially as part of the recent Pharmaceutical Price Regulation Scheme (PPRS) negotiations and through Lord Darzi’s review: High Quality Care for All. The PPRS innovation package specifically includes a commitment to develop new metrics for the uptake of clinically and cost-effective medicines starting with a number of drugs positively appraised by NICE and publication of comparative international data. The NHS Constitution makes it explicit that everyone across the country will have access to drugs that have been recommended by a NICE technology appraisal, where clinically appropriate. Along with the introduction in the PPRS of new flexible pricing arrangements, and a more systematic approach to the use of patient access schemes to support improved availability of new drugs, these measures will help promote better patient access to cost-effective innovative medicines.

Both NICE and the Government recognise the importance of promoting innovation in the NHS and agree with Sir David that this specific issue should be considered further. NICE’s Chair, Sir Michael Rawlins has therefore announced that the Institute is commissioning an independent study of value in new innovative health technologies. The study will involve submissions and the use of a series of workshops involving the healthcare industries, patients and the wider public, together with representatives of the NHS to explore this issue. Professor Sir Ian Kennedy, Emeritus Professor of Health Law, Ethics and Policy at University College London has agreed to lead the independent study and has been asked to report in time for the July 2009 NICE Board meeting. NICE’s Citizen’s Council will also look at this issue simultaneously to ensure full input from stakeholders.

Recommendation 17: Translational Scale-Up Centres for Regenerative Medicine

Create two cell scale-up centres at research institutions to build capacity and capabilities (skills training and technology) in this specialist area of bio-processing. Centres should work at the interface between the researcher, the manufacturer and the physician. It is also essential that Government should support the delivery of an enhanced industry representation.

The Government welcomes the emphasis in BIGTR2 on developing centres of excellence, in which basic cell research, clinical science, safety, materials science and manufacture expertise come together. Given the rapid pace of change in stem cell science, these centres will need not only critical mass, but also flexibility, quick reactions, and excellent scientific connections.
We agree that the UK needs to develop strengths across a range of translational activities needed for effective stem cell therapies. The Research Councils including MRC and also TSB should help overcome this bottleneck. The right approach will vary widely according to the site and nature of therapy. Scale up issues will need to be addressed early in the scientific development of new treatments, at the same time as questions about the type and status of cells, numbers, dependence on tissue matrix, safety controls, and tolerance of variations are explored.

MRC has supported the development of the Centre for Regenerative Medicine in Edinburgh, which brings together basic research, Good Manufacturing Practice capacity, and good bioindustry and Scottish Enterprise links, and will explore further opportunities with partners in the public, charitable and private sectors, building on existing centres.

EPSRC has supported several relevant activities that bring together academia, industry (particularly manufacturing) and the clinician in Regenerative Medicine. These are:

- An Innovative Manufacturing Research Centre (IMRC) for Bioprocessing at University College London led by Professor Nigel Titchener-Hooker
- An associated IMRC Grand Challenge in Regenerative Medicine led by Professor David Williams at Loughborough – “Regenerative Medicine – a New Industry”
- An Integrated Knowledge Centre in Regenerative Therapies and Devices led by Professor John Fisher at Leeds (with BBSRC and TSB).

Close alignment of funding for early clinical research, basic science, materials science, processing and safety science will increase in importance, and the Research Councils (BBSRC, EPSRC and MRC) will continue to work together to ensure the science base funding is well coordinated.

The Government recognises the importance of regenerative medicine and the potential benefits of developing hubs of excellence in the scale-up of the various activities associated with this area. The Government also recognises we need wider skills and capabilities than are addressed within bioprocessing (essentially cell growth issues).
Chapter 4: Human Capital

Recommendation 18: Attracting Leaders and Managers

UKTI should use its in country expertise and life sciences marketing strategy to attract leaders and managers to become re-engaged and provide the benefits of their experience. Such people should be encouraged in both full time positions and as non-executive Directors, mentors, or advisors.

UKTI utilises its market expertise to maintain relationships with a large number of Life Science influencers. UKTI is currently considering options on how to maintain an international network of individuals who can contribute to selling the UK as a place to do business, or who may in the future do business in the UK. UKTI will seek views on the relative values of the use of the various sorts of networks that might be supported. These networks could comprise a relatively small number of influential business people, or there might be a separate emphasis on overseas students or non-UK individuals who have returned from the UK. The study will consider the value and (sector) focus of such networks, and how they could be best structured and supported by UKTI.

Any network would need to be underpinned by methodology for capture, retention and development of the individual relationships within the network(s) with the potential to contribute to the UK’s economic success.

Recommendation 19: Maximising Capital recycling

Government and industry should work with the entrepreneurial community to produce an implementation plan identifying the infrastructure and mechanisms needed to make the most of the human and knowledge capital that flows from the restructuring of the UK bioscience industry. As part of this plan an information pack should be produced that shows the path from leaving a pharmaceutical company to successfully running a biotechnology company.

BERR is liaising with Trade Associations to consider how they might take forward the provision of an information pack that shows the path from leaving a pharmaceutical company to successfully running a biotechnology company.

In response to the very rapid changes in the UK and global economies the Research Councils have introduced Skills Gap Awards. This new, and interim, scheme aims to ensure that high quality scientific or research support skills, which currently reside in industry, and in areas where it has previously been hard to recruit into UK universities, are retained in the UK, through recruitment to UK universities.

The scheme, sponsored by the MRC, EPSRC and BBSRC, aims to provide fast-track start-up funding for appointments relevant to biomedical or biotechnology research which addresses important skills’ needs in universities. Appointments will support...
high priority skills that underpin biomedical or biotechnology research, from any part of the private sector – in any area of biology, chemistry, imaging, engineering, clinical research, informatics or statistics. BBSRC will consider applicants working in the strategically important areas of 3R’s (Replacement, Refinement & Reduction of animals in research) and in vivo mammalian physiology.

The MRC, who are managing the scheme on behalf of the Research Councils, expects to make 8-10 awards under the interim scheme, however additional funding may be made available if a high volume of good quality applications are submitted. It is expected that many of the appointees will be specialists or early career researchers, rather than leaders of large programmes; however proposals for very senior appointments will be considered. The Research Councils are currently considering proposals to provide support for two-way academic-industry exchanges on a more permanent basis.

Funds will be provided to establish new posts over the first one, two or three years, while the appointee may be seeking grant funding. Funding will be focused on situations where a new appointment would help address a well established, strategically important, skills gap, and the relevant role would complement and support existing research council investment, and would reinforce the university’s research strategy. The host university will be expected to make a long-term commitment to the role. The appointment should also clearly address the strategic priorities of the supporting research councils.8

The MRC’s Strategic Appointment Scheme similarly aims to enhance the UK’s research capability by attracting senior, internationally-recognised scientists and clinicians to work at professorial level in UK academic institutions. The scheme aims to support responsive and rapid appointments in an area of research that is particularly competitive. Primarily aimed at supporting scientists and researchers from outside the UK, the scheme may exceptionally support scientists from the UK industrial sector.

BBSRC is running a pilot Industrial Impact Fellowship Scheme8 to enable highly-skilled research and technology leaders to transfer their skills and experience from the industrial sector to BBSRC-funded centres, institutes or academic departments with significant BBSRC-funded research programmes. The scheme is aimed at researchers currently or recently in industry, who have skills and capabilities complementary to university research (such as project management, commercialisation and translational research). Between 5 and 10 fellowships are available to start by the end of 2009.

8 Further information is available from the MRC’s website at www.mrc.ac.uk/Fundingopportunities/Initiatives/SGA/index.htm

9 Further information about the Industrial Impact Fellowship Scheme is available on the BBSRC website: http://www.bbsrc.ac.uk/business/people_information/industrial_impact_fellowships.html
Recommendation 20: Implement Bioscience SSA

Given that Semta has recently published the Bioscience Sector Skills Agreement and the Action Plan, we propose that the focus of activity should now be on early and tangible implementation of the SSA. As part of this Semta should ensure that a comprehensive list of current regional initiatives is compiled by the end of Q1 2009. This should be circulated widely perhaps via Trade Associations and intermediaries and a mechanism put in to place to annually review and update it. This list should be used to share best practice, assess where there is overlap of initiatives, and measure impact.

Semta published the Bioscience Sector Skills Agreement (SSA) with a launch at the House of Lords supported by the Secretary of State on 6 February 2008. Work is well underway on the priority skills and the themes for action. Semta agree that early and tangible implementation of the SSA should be the focus of activity for the Sector Strategy Group (SSG) and stakeholders. The composition of the SSG is being considered to ensure that the right stakeholders are represented to progress implementation.

Bioscience Regional Networking meetings have been used to map regional activity across the UK for the purpose of sharing and promoting best practice, reviewing and sharing different approaches and strategies and identifying any gaps that exist. The initial phase of the mapping has already been started. However, this will have to be an on-going process as the activities across the country will continually change and require updating on an annual basis.

Semta will circulate this list widely via Trade Associations and other stakeholders and will be made available on the Semta website.10

An example of a new project is the development of a new Life Sciences Modern Apprenticeship in Scotland where Semta are supporting this project with Scottish Enterprise. This project is a tangible implementation of the Bioscience Sector Strategy Agreement trying to solve the issue of gaining more staff with the practical skills we need.

Recommendation 21: Review SSA metrics

We propose that the Semta Bioscience SSA Action Plan should be updated to contain a series of outcome indicators. Implementation of the SSA Action Plan should be reviewed on a quarterly basis by Semta’s Sector Strategy Group (SSG)11 (of which BERR is a member) at the SSG Meetings as set out in the Terms of Reference for the Group. The membership of the SSG should be reviewed annually and consist of representatives from both large and small companies.

10 www.semta.org.uk
11 Sector Strategy Group made up of senior employers, they are principal advisory bodies to the Semta Board providing strategic leadership and driving delivery of the Sector Skills agreement.
Semta agree that it is important to be able to measure implementation. For this reason Semta have developed a set of key performance indicators (KPIs) linked to the Bioscience Action Plan jointly with the Sector Strategy Group (SSG) for review, development and monitoring. The KPIs will provide a useful monitoring tool and process to ensure activity is progressing in line with the SSA Action Plan. The Action Plan is updated on a quarterly basis and published on the Semta website. Bioscience Highlights, published bi-annually, outlines best practice already underway.

To support delivery of the Action Plan the SSG has formed thematic sub-groups to lead key areas of work and these sub-groups cover Leadership and Entrepreneurship, Top Quality Workforce, Higher Education, and Image and Attractiveness. These sub-groups are developing pragmatic solutions to address issues and report back to the SSG at every meeting.

Semta agree that membership of the SSG should be reviewed annually and that it should consist of both large and small companies. For this reason the SSG is currently considering a proposal on membership. Suggestions include new members from smaller companies, regional and academic and industrial biotechnology representation is also sought.

**Recommendation 22: Pilot Leadership Programme**

**Semta and BIA work with the SSG members and other stakeholders to implement the proposal for a Pilot Leadership Programme with pump priming funding from Semta that would enable the BIA to maximise the impact of the programme. Other funding would come from companies themselves. The Scheme should also look at how to draw in the expertise and knowledge of expatriates working in the industry. The pilot should start in 2009 with a pool of at least 12 identified potential leaders in the first year and then climbing to 72 over five years. The process should be reviewed at the end of the second year.**

Semta recognise that good leadership within this sector is vital to its success and it is one of the priority themes to come out of the Sector Skills Agreement. Semta welcome the work that has been done within the Sector Strategy Group to propose a Pilot Leadership Programme. Semta and BIA are currently discussing how to fund this programme and support others across the UK with regional clusters. Semta’s Sector Compact grants to small and medium sized companies through Train to Gain that allows development of a key leader through their provider of choice may be part of the answer. Semta are currently in discussion with the Learning and Skills Council and DIUS about the level of funding and the number of employees eligible for the Leadership & Management grant.

BERR recognise that expatriates could make a valuable contribution to this work. BERR will consider how to take this forward with other stakeholders including UKTI and Semta. This part of the recommendation is also linked to recommendation 18.
Recommendation 23: Review *in vivo* skills

Government should consider how an appropriate study of graduates with *in vivo* skills should be maintained including whether *in vivo* skills should be included under the strategically important and vulnerable subjects (SIVS) list.

BBSRC, MRC and others will continue to strengthen the UK’s training base and science in *in vivo* areas. Initiatives over the last five years have strengthened the UK’s position, but we recognise that more is needed, and MRC will expand its PhD studentship funding for the area in 2009. We are currently developing our Framework for the future of Higher Education for the next 10-15 years. As part of this process we are looking at how strategic subjects might be designated and supported to best meet the needs of the economy and society in the future. Our approach to a variety of subjects, including those incorporating *in vivo* skills, will need to be examined in this context.

EPSRC currently supports over 400 students from engineering and physical sciences disciplinary backgrounds studying for a PhD at the life sciences interface through 15 Doctoral Training Centres. A number of these centres include training in *in vivo* skills, including the centres based at the University of Strathclyde (medical devices), the Universities of Loughborough, Keele and Nottingham (regenerative medicine) and the Universities of Leeds, Sheffield and York (regenerative medicine).

BBSRC and the MRC have invested in Capacity Building Awards in Integrative Mammalian Biology Research, a partnership between Research and Higher Education Funding Councils, Learned Societies and a consortium of pharmaceutical companies. The £11 million fund is intended to springboard capacity building in integrative mammalian biology. A total of 46 studentships have been funded under the initiative.12

BBSRC has co-funded with the British Pharmacology Society and Physiological Society short courses in *in vivo* Integrative Pharmacology and Physiology Techniques. These courses are intended to address the shortage of researchers that obtain a good training in *in vivo* research techniques and to practise skills in whole-animal studies. The courses provide practical knowledge and understanding of the essential principles underlying mammalian *in vivo* systems-based research, including protocol and experimental design.

The MRC has awarded 22 new PhD studentships in *in vivo* sciences to seven universities at a value of £1.91m for 2009 and it is anticipated that similar numbers of awards will be available in 2010 and 2011. Additional support for capacity building in *in vivo* sciences may also be provided through initiatives focused on integrative mammalian biology, toxicology and drug safety science which collectively aim to support over 50 new PhD studentships and 2 new fellowships over a five year period.

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12 Further information can be found on the BBSRC website: http://www.bbsrc.ac.uk/media/releases/2005/050617_mammalian_biology.html
BBSRC and the MRC are also working together to support jointly funded places on *in vivo* Masters courses. Twelve awards have been made for 2009 (£170k) and it is anticipated that a similar number of awards will be available in 2010 and 2011.

Furthermore, BBSRC will be meeting with MRC to discuss the provision of additional costs awards on PhD studentships in the *in vivo* area to meet more of the full cost of research training in this area.
Annex A

Recommendation 1: Sustain Research Capability

The good progress in establishing the Research Capability Programme in England should be sustained and every effort taken to ensure that the services delivered via its Health Research Support Services and equivalents in the Devolved Administrations meet the needs of the sector. Funding bodies should work together to maximise the preparedness of the research community and industry to use it.

Recommendation 2: Incentivise Clinicians

Funding partners should work together under the umbrella of OSCHR to incentivise clinicians to become clinician scientists following a research degree e.g. PhD route to ensure sufficient supply for industry and academia. The numbers of successful clinician PhDs awarded should be published annually.

Recommendation 3: Maximising Awareness of Opportunities

A targeted communication and marketing exercise is needed to maximise awareness of the opportunities offered to industry by the new infrastructure, funding and collaboration put in place since Bioscience 2015 was published. This could be done as part of the UK Life Science Marketing Strategy.

Recommendation 4: Include Participating in Research in the NHS Operating Framework

Participation in research has been included in the NHS Operating Framework and should be accounted for via the annual Quality Accounts submitted by NHS Healthcare Providers with the aim of doubling the current number of people enrolled in clinical trials and large scale evaluations conducted in the UK by 2012 across the full spectrum of clinical trials including biologics

- Every NHS Trust should have a Board member, preferably one of the Executive, designated to take responsibility for the efficient running of clinical research in the Trust;
- There should be a specific objective of doubling the number of patients recruited to clinical trials in NHS Trusts over the next three years;
- The performance of the Trust in conducting clinical research should be one of the quality measures against which Trusts are assessed;
- Trusts should indicate their commitment to research by publishing goals for the number of patients involved in clinical studies on a half yearly basis and report in their quality accounts;
● Every NHS Trust taking part in clinical research should record and publish the average time it takes for the local approval process to be completed; and

● With the introduction of the coordinated system for NHS Permissions within the NIHR Comprehensive Local Research Networks over the next six months, every NHS Trust should commit to actively embracing the new system and not introduce activities at local level.

**Recommendation 5: Leadership on EU Clinical Trials Directive**

The UK Government should take a leadership role within Europe to ensure that the revisions to improve the EU Clinical Trials Directive reinforce the UK’s attractiveness as a prime location for clinical trials and to reflect the better regulation aspects of Government.

**Recommendation 6: Follow on in Bioprocessing**

Relevant Research Councils and Knowledge Transfer Networks along with the Technology Strategy Board and industry should build on the success of the Bioprocessing Research Industry Club to develop a set of follow-on activities. New funding must be in place for distribution in 2009 and onwards to build capacity for multidisciplinary bioprocessing research and training to 2015. The growth in capacity should make the emergence of new centres of excellence possible, and be sufficient to meet the needs of academic and industry recruitment. The Technology Strategy Board should continue to provide financial support to the provision of a Knowledge Transfer Network at least at the current level that will deliver the bioprocessing agenda set out in Bioscience 2015 beyond 2009.

**Recommendation 7: Annual Progress Report**

BERR should ensure the provision of good quality evidence in order to accurately assess the state of the sector, working together with industry to ensure the capture and tracking of an agreed set of metrics that will assist in determining the extent to which the sector is growing and prospering moving forward. The BIA, ABPI and BERR should produce a short annual report on progress and challenges against the recommendations in this report; this should be presented to the Ministers with responsibility for bioscience within BERR, DH and DIUS.

**Recommendation 8: Attracting Overseas Interest**

The UKTI should:

● Use its life sciences marketing strategy to focus on attracting high quality overseas companies to list on the London Stock Exchange, persuading overseas funds, including Sovereign Wealth Funds, to invest in the UK and also assisting UK companies to gain investment from foreign funds by holding road shows for non-UK investors both in the UK and abroad; and
● Boost its resources in the Global Entrepreneurs Programme and encourage closer relationships with Angel Networks (for example the BIA BioAngels). By doing this UKTI could also enhance the bioscience investment opportunities that it presents to US funds.

**Recommendation 9: Extend Tax Credits**

To extend R&D tax credits through:

● Extension of relief to cover benefits in kind;
● Relief on payments to self-employed individuals and high quality management talent at CEO and CSO level;
● Remove the PAYE/NI limit on repayable credit;
● Extension of the relief to rent costs; and
● Extension of the relief to cover IP costs.

**Recommendation 10: Extend EIS Scope**

Extend the applicability of the Enterprise Investment Scheme and Venture Capital Trusts by for example extending their scope to cover SMEs, following the definitions used for R&D tax credits. Extend EIS and VCT scope to cover shares acquired through shareholder to shareholder transaction.

**Recommendation 11: Encourage Enterprise Capital Fund applications**

Capital for Enterprise Ltd, which delivers Enterprise Capital Funds on behalf of BERR, should particularly encourage strong bids from bioscience in future funding rounds in view of its importance to the UK economy and the lack of such bids to date.

**Recommendation 12: Incentives for Big Pharma**

To create incentives for big pharmaceutical companies to invest in UK biotechnology, and to spin-out assets in the UK to create new companies, through development of the tax incentives described above.

**Recommendation 13: Redesign Regulation**

The Ministerial Industry Strategy Group should build on existing work to develop a vision for the future evolution of global biopharmaceutical regulation, taking into account initiatives which are already underway in the major regulatory jurisdictions. MHRA should work with its EU and international counterparts to develop and promote the vision.
Recommendation 14: Stratified Disease Strategy

A stratified disease strategy should be created and executed by Government through a multi-organisation integrated programme. This should involve BIA, ABPI, OSCHR, TSB, NIHR, MRC, industry, academia and other relevant organisations. The strategy should set out common therapeutic goals, building on areas of UK competitive strength and lead to: enhanced patient outcome; accelerated uptake of medicines; and better value through more effective targeting.

Recommendation 15: Reward Academic Collaboration

The Research Excellence Framework should recognise and reward excellence in both stand-alone research and collaborative research with industrial partners. There are real opportunities for the academic sector to play a greater role in a rapidly changing bioscience industry. In order to realise these opportunities the evaluation framework used by the funding councils needs to promote greater collaboration between academia and industry.

Recommendation 16: Independent Inquiry into NICE

There should be an independent inquiry to assess NICE’s long term impact on cost, access to, and uptake of, medicines in the UK. There should also be an independent review of the way in which NICE values medicines so that the current economic evaluation is complemented by clinician, patient and research inputs on the value of the innovation from their perspectives. A revised NICE should offer health economic data to companies as a way to support the functions of market forecasting, and determining likely revenues within the NHS, as this would incentivise R&D.

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Government should consider how an appropriate study of graduates with in vivo skills should be maintained including whether in vivo skills should be included under the strategically important and vulnerable subjects (SIVS) list.

\textsuperscript{13} Sector Strategy Group Made up of senior employers, they are principal advisory bodies to the Semta Board providing strategic leadership and driving delivery of the Sector Skills agreement.