

Budget 2011 and The Plan for Growth:

Implications for the Healthcare and Life Sciences Sectors



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Budget 2011 and The Plan for Growth: Implications for the Healthcare and Life Sciences Sectors:

The Coalition's Budget of 2011 had been dubbed a "budget for growth" for several weeks running up to its publication on 23rd March although, with so many leaks to the media the weekend prior, many were wondering if there would be any surprises at all. Osborne managed a few surprises – particularly regarding fuel duty and corporation tax - but, overall, this was an austere budget for austere times.

The Plan for Growth which was published alongside the Budget is a more revealing document in how the Coalition intends to ensure the UK is "open for business". The Plan contains a chapter on healthcare and the life sciences which explains in detail how the Government intends to support innovation in the NHS, social care and life sciences sectors.

Key Budget proposals relevant to healthcare

- Publish a further consultation on the introduction of a patent box in May 2011, setting out details of how the regime will operate, followed by draft legislation in autumn 2011. The Patent Box will provide a reduced 10 per cent corporate tax rate for profits from patents, which will encourage UK businesses to retain high-value jobs associated with commercialisation of patents and to invest further in innovation.
- Introduce an opt-in exemption from corporation tax on the profits of foreign branches of UK companies. This will contribute to the Government's aim of a more territorial corporate tax system and help make the UK a more competitive location for international businesses.
- As well as introducing the Patent Box, the Government has reaffirmed its commitment to research and development (R&D) tax credits. Following consultation, the Government has announced:
 - ▶ *an increase in the SME rate of R&D tax credit to 200 per cent from April 2011, and 225 per cent from April 2012, subject to State aid approval; and*
 - ▶ *simplification of the R&D tax credit schemes.*
- The Government will invest an additional £100 million in 2011-12 in science capital development to provide facilities for the commercialisation of research, accommodation for innovative SMEs and new research capabilities.
- The Government will launch the first Technology and Innovation Centre in high value manufacturing; this will integrate the activities of a number of existing high-performing centres in Rotherham, Coventry, Strathclyde, Sedgefield, Redcar and Bristol.

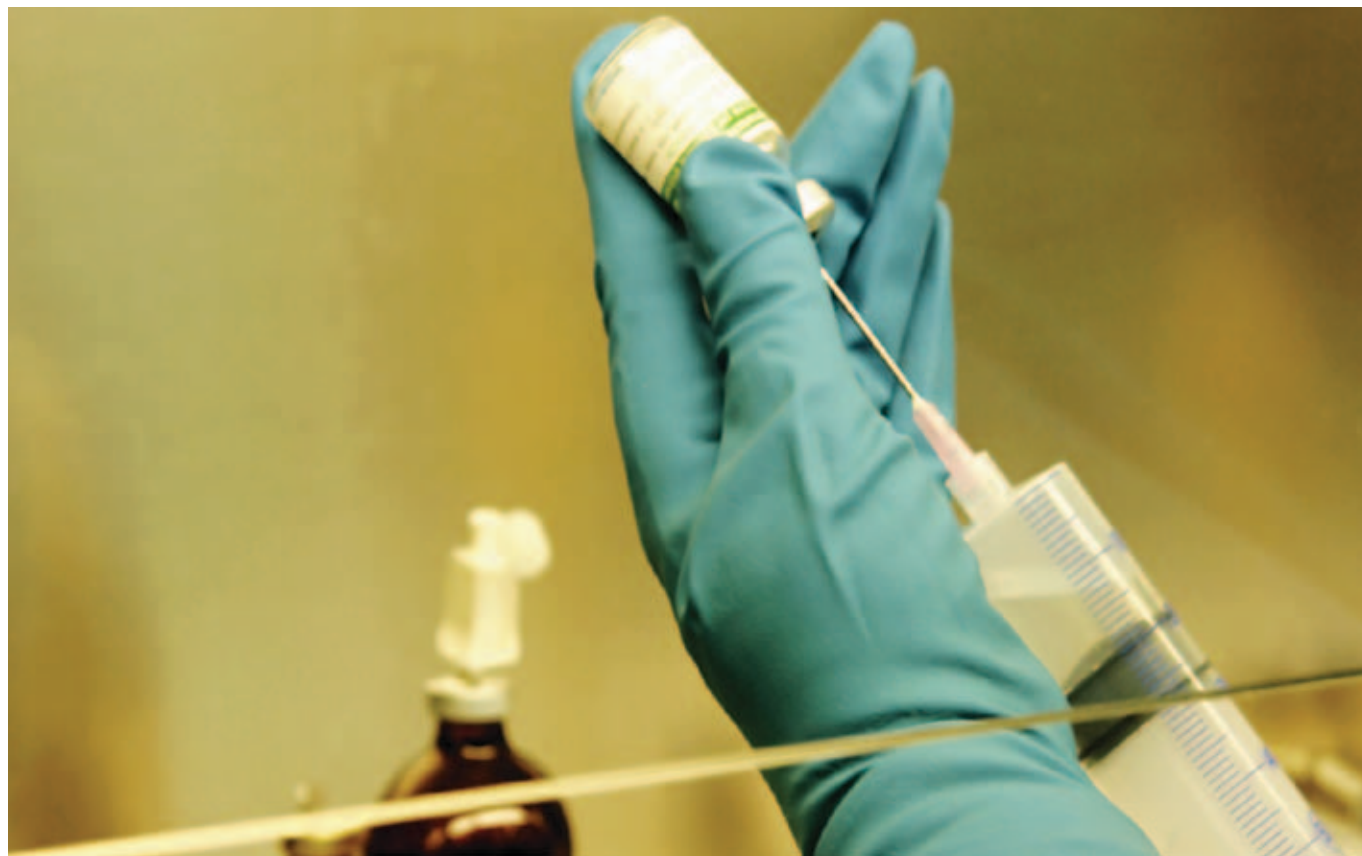
The Budget itself was relatively light on detail for the health and life sciences industries; there was no mention of pharmaceuticals in the whole document. However, HM Treasury has attempted to send a clear signal of support through the announcement of plans to simplify R&D tax credits – something the industry has been calling for for several years. The Budget as a whole focuses on SMEs but it is interesting to see this theme has been continued in the measures proposed to encourage innovation SMEs in “science capital development”. This measure suggests that the Government has heard calls to encourage smaller biopharma companies and is trying to offer support where it can.

Corporation Tax

The introduction of an “opt-in” exemption from corporation tax on foreign profits is unlikely to affect many of the big pharmaceutical companies as few of them are headquartered in the UK these days; however, for those which are, it will be an important box to tick for their accountants.

Patent Box

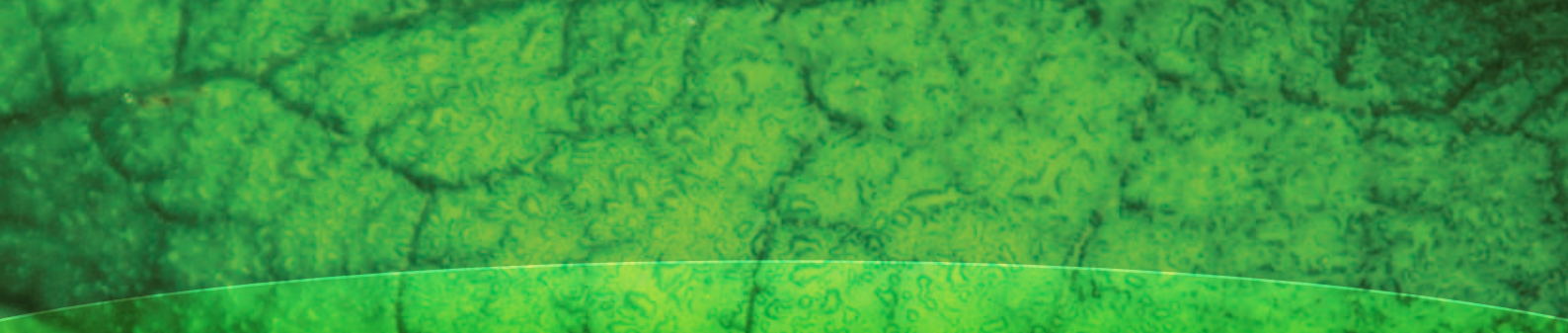
It is worth noting that the Government has proposed a further consultation into the Patent Box, even though the previous consultation on it only closed on 22 February 2011. The Patent Box was first announced by Alistair Darling, then Chancellor of the Exchequer, in 2009. This Government has committed to producing draft legislation in autumn 2011, but it remains to be seen if this will transpire.



Key Plan for Growth proposals relevant to healthcare

The Government has announced plans to:

- Set up a new health research regulatory agency to streamline regulation and improve the cost effectiveness of clinical trials. It will make future National Institute for Health Research (NIHR) funding to providers of NHS services conditional on meeting benchmarks, including a 70 day benchmark to recruit first patients for trials.
- Increase the proportionality of EU Clinical Trials Directive (CTD) and its application.
- Open up information about clinical trials to enable the public to get involved.
- Build a consensus on using e-health record data to create a unique position for the UK in health research.
- Open up information on clinical research to promote collaboration and innovation.
- Consider opening up prescribing data.
- Form new Translational Research Partnerships from its £775 million investment in NIHR Biomedical Research Centres and Units.
- Remove any barriers that limit the further development of geographical clusters, working with industry, local government, universities, NHS and funders.
- Launch a competition to form a Cell Therapy Technology and Innovation Centre.
- Improve market signalling by bringing companies and educators together, to ensure educators provide the skilled individuals the sector needs to grow.
- Ensure that the Intellectual Property (IP) system supports life sciences businesses.
- Take forward a range of measures to encourage innovation in NHS procurement. The NHS Chief Executive will provide a report by November 2011, in consultation with industry, academia and other interested parties, on how the adoption and diffusion of innovations can be accelerated across the NHS. This report will inform the strategic approach to innovation in the reformed NHS.
- Take forward a package of measures to improve the take up of assisted living technology.
- Strip out regulations that were never meant for the social care market and are preventing market entry and flexible services.
- Establish a proactive, entrepreneurial NHS Global to make the most of the NHS brand internationally and to offer support and advice to NHS trusts.



Seven pages of the Plan for Growth are dedicated to encouraging growth in the healthcare and life sciences sectors. Of particular interest is the frequency with which the Academy of Medical Sciences (AMS) is mentioned. It is clear that both HM Treasury and the Department of Business, Innovation and Skills (BIS) have been persuaded by AMS calls to reduce health research regulation and governance. AMS has clearly been consulted as a key stakeholder on how to improve growth in health and life sciences as the paper explicitly refers to “measures that would achieve some of the AMS’s aims”. The AMS is the only stakeholder that is name-checked in the paper, which should raise some concerns if HM Treasury and BIS are only consulting with one stakeholder group that cannot represent the views of the entire sector.

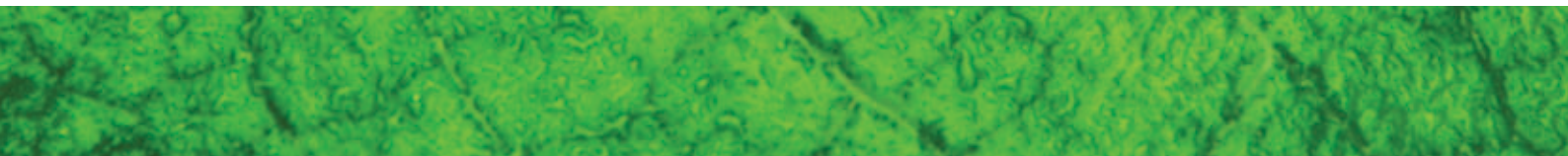
The health and life sciences section of the Plan for Growth can be subdivided into three separate areas: Innovation, Regulation and Information.

Innovation:

The Government explains that innovation has “already been recognised as one of the four pillars of the NHS improvement agenda”; the Plan for Growth attempts to encourage innovation across the healthcare service. The NHS Chief Executive will provide a report in November 2011 recommending how the adoption and diffusion of innovations can be accelerated across the NHS. As with the Patent Box, it would not be surprising if there was a sense of déjà vu here: policies to make the NHS more open to innovation have been appearing for a number of years, including when Lord Mandelson was Secretary of State for BIS and published “Going for Growth”. However, some practical steps have been included that will make an immediate difference, particularly the scrapping of Pre-Purchase Questionnaires (PQQs) for NHS contracts of less than £100,000 and encouraging the NHS to avoid using PQQs altogether. PQQs can be a timely and costly process for smaller organisations and should make it much easier for SMEs in the healthcare sector to offer their services to the NHS.

Plans to launch a competition to form a Cell Therapy Technology and Innovation Centre could be the beginnings of an innovative centre that aids the translation of research into technology that can be commercialised, utilised and practically applied in the UK. The details behind the “competition”, hosted by the Technology Strategy Board will be of interest. The Technology Strategy Board describes its competition process as “*Applications for funding and awards for contracts are invited through a range of competitions which address a specific area of priority identified by the Technology Strategy Board as being of critical importance to the growth of the UK economy.*” It seems to be a variation on a traditional tendering process. Depending on which organisation wins the competition and how long it takes to get up and running, this centre could send strong signals that the UK is serious about cell technology and innovation, thereby encouraging inward investment.

Perhaps the most unusual and, as yet, unclear policy from the Plan for Growth is the plan to establish NHS Global. This could be an excellent way of bringing money into the NHS by promoting the wealth of knowledge and expertise held by NHS staff and organisations, although the timing – in the middle of such a controversial and wide-ranging reform of the NHS – looks odd, at best, and may be problematic. The National Institute for Health and Clinical Excellence (NICE) is a good example of how a UK special health authority can successfully reach out to an international audience. However, it will be important to ensure that aspirations to take the NHS to a global audience are not marred by accusations of irresponsible spending on travel for bureaucrats, consultants and branding.



Information:

This is perhaps the most controversial aspect of the Plan for Growth. The Government plans to “open up” information about clinical trials, clinical research and will consider making prescribing data more widely available. The reasoning behind the first of these is to enable the public to see for themselves if there are trials taking place that might be relevant to them, through establishing the UK Clinical Trials Gateway.

Dr Clare Gerada of the Royal College of General Practitioners (RCGP) has already come out against the plans to open up prescribing data claiming that “it is meaningless unless you understand the context it’s made in” and could open doctors up to targeting from pharmaceutical companies.

Another controversial suggestion in the area of information is the proposal to use e-health record data to “create a unique position for the UK in health research.” The intention is to boost UK health research by capitalising on the UK’s unique position in having so much data through NHS records. However, as with prescribing data, there are likely to be some who feel this is not an appropriate use of patient information. The Government has attempted to make a clear statement through this plan that they are serious about attempting to improve the UK’s status in clinical research. As ever, it remains to be seen if this can be translated into reality.

Regulation:

In fitting with the Government’s “one-in one-out” policy on regulation, the Plan for Growth states that a new health research regulatory agency will be set up to “streamline regulation and improve the cost-effectiveness of clinical trials”. This, combined with plans to ensure IP law supports life sciences and the Government’s plans to negotiate and change the EU Clinical Trials Directive (CTD) to reduce burdens on industry, ought to lead to the UK being a fertile environment for clinical trials. Negotiation of the CTD will not begin before 2012 and the Plan clearly states the Government will seek to influence the European Commission and Parliament; the next 12 months will, therefore, be a vital time for the industry to engage with Government on what it requires from this policy.

Industry and Media Reactions:

The different pharmaceutical and life sciences industries provided a collective response to the Plan for Growth under the umbrella of Life Sciences UK. The ABHI, BIVDA, ABPI and BIA all broadly welcomed the Government’s plans and expressed that belief that they would make the UK a stronger competitor for business in life sciences.

Overall, in the same way that healthcare and life science were not key themes of the Budget, they were not a focus for the media either. It was The Daily Telegraph that pointed out Dr Clare Gerada’s (RCGP) reservations about opening up prescribing data, describing the policy as the “little-noticed section of HM Treasury’s Plan for Growth”. The Institute of Fiscal Studies warned that, given the inflation figures, it was likely that the NHS funding would fall in real terms. Anonymous Government sources were quick to say this would not be allowed to happen.

Conclusion

The Budget and the accompanying Plan for Growth are not groundbreaking. The Chancellor of the Exchequer seems to have had little room for manoeuvre financially, particularly as much of the spending was already decided in the Comprehensive Spending Review at the end of last year. However, the Chancellor has attempted to give a nod to the pharmaceutical industries via the Patent Box, even though this is not a new policy.

The Plan for Growth provides more detail on exactly how the Government intends to improve the number of clinical trials and therefore make life sciences a growth sector in the UK. Once again, this is hardly new; Labour were promising the same in the last few years of their government. What the Plan for Growth could indicate, however, is a resurgence in the fortunes of BIS. Under Lord Mandelson, BIS was a very powerful department and a must for any pharmaceutical or life sciences industry engagement. Under the current Chancellor of the Exchequer much of its power has been grabbed back for HM Treasury. This Plan could be a sign that BIS is determined to come to the fore once again and that now could be the time to ensure its civil servants and ministers are fully briefed to champion the life sciences industry.

Jenny White, March 2011

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