House of Commons
Trade and Industry Committee

UK Biotechnology Industry

Government Response to the Committee’s Twelfth Report of Session 2002–03

Sixth Special Report of Session 2002–03

Report, together with an Appendix

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The Trade and Industry Committee

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Sixth Special Report

UK Biotechnology Industry

The Committee published its Twelfth Report¹ of Session 2002–03 on 3 September 2003. The Government’s response to this Report was received on 5 November 2003 and is published as an Appendix to this Special Report.

Appendix

Introduction

The Government welcomes this report from the Trade and Industry Committee, which is a valuable contribution to the current debate about the future of the UK biotechnology industry.

The last few years have not been an easy time for the global biotech sector. Following the announcement of the initial results of the Human Genome project in 2000, there was a period when biotech companies seemed to have few problems in obtaining the finance they needed to fund their development programmes. However times have changed since then, as investors have placed much more stringent conditions on their funding. Venture Capital funding has become more difficult to obtain and this has led to a debate in many countries about whether consolidation should take place to create fewer but stronger companies.

In the UK, several recent mergers and takeovers have suggested that the much-predicted consolidation is starting to take place. Some UK companies have recently been successful in obtaining substantial amounts of funding, and this has led some commentators to suggest that investment sentiment may be starting to favour biotech again. The next year will be a significant period for many biotech companies.

The UK plays a leading role in European biotechnology. 43% of new biotechnology drugs in late stage clinical trials (Phase III) in Europe are from the UK.² The UK is rightly still enviied for the strength of its science base. UK scientists have shared in the Nobel Prize for Physiology or Medicine for the last 3 years.

The Government has always been a strong supporter of the biotechnology sector. The importance of the biosciences has been endorsed on several occasions by the Prime Minister, most recently in a number of articles for the 50th anniversary of the discovery of the structure of DNA. In a speech that he gave to the Royal Society last year on ‘Why Science Matters’, he said, “The biosciences are, rightly, drawing much admiring attention at the present time.” And he went on to say: “I want Britain and Europe to be at the forefront of scientific advance.”

¹ Twelfth Report of Session 2002–03, UK Biotechnology Industry, (HC87)
² Ernst & Young, 2003
But it is right that Government support for the sector should be kept constantly under review. For this reason, we welcome the Committee’s contribution to the debate.

In January 2003, the Department of Trade and Industry and the Department of Health launched the Bioscience Innovation and Growth Team (BIGT), in partnership with the BioIndustry Association, and with Sir David Cooksey appointed as chair. Its mandate was to bring together experts from industry, the research base, the financial community and government to formulate a strategic approach to the future of the UK’s bioscience industry. Its terms of reference were:

- To identify and clarify the issues that are critical to the future competitiveness of the UK biosciences sector (focussing on healthcare)

- To identify any barriers that could significantly affect the future competitiveness of the UK biosciences sector, and to make recommendations on what action should be taken to overcome these barriers.

The BIGT recommendations will be independent of government but will set an agenda to which government must respond. The report is due to be published in November 2003. In the Government’s response to the Committee’s conclusions and recommendations, an initial indication has been given about some of the recommendations that are likely to be included in the BIGT report.

Following the publication of the BIGT report, Government will carefully consider the recommendations, and draw up an implementation plan. The Committee’s conclusions and recommendations will be fully taken into account during the BIGT implementation process.

November 2003

**Conclusions and recommendations**

**Resources for basic research**

1. The UK’s research expertise in biotechnology has made its relative prominence in commercial biotechnology possible. Excellence in research cannot in itself ensure commercial success in biotechnology but it does seem to us that its absence will preclude it. The strength of the commercial biotechnology sector cannot be guaranteed merely by putting ever greater sums of public money into higher education and academic research. However, given the integral links between education and research and commercial biotechnology, it is hard to see how strength can be achieved and sustained in the latter without the former being adequately resourced. Levels of investment remain a problem, with the UK spending less than its competitors on research and on the HE sector as a whole. Whilst the UK is still performing creditably, there must be some concern about the degree to which this can be sustained over the long term. (Paragraphs 24 and 31)
The Government regards higher education as a great national asset. We value its contribution to the skills, knowledge, economic and social well-being of the nation and are proud of our well-deserved international reputation for excellence. The Government is reversing years of under-investment by increasing funding for higher education in England by 6 per cent above inflation per year, up to 2005–06. Government funding per student will increase by 7 per cent in real terms between 2002–03 and 2005–06—a big improvement on the position before 1997, when per student funding was slashed year on year (36 per cent down in real terms between 1989 and 1997).

The Government also recognises the importance of long term investment in basic research in the Higher Education sector and accepts that it will take time to make up for the under-investment of past decades. The last two spending rounds have seen considerable strides taken to address this problem. Building on the 2000 spending review settlement which saw overall science spending increase by 7% year on year in real terms, the science budget is now set to grow at a rate of 10% year on year reaching just under £3 billion by 2005–06. The MRC and BBSRC will see their budgets rise to £502.8 million and £329.2 million by 2005–06, cash increases of 57% and 62% respectively on their budgets in 2000–01. This includes investment in cross council research programmes into stem cells and genomics.

The Government has also placed on a continuous footing a capital funding stream which will be worth £500 million a year from 2004-05 to address the effects of under-investment in the research infrastructure, which builds on investment totalling £1.75 billion (jointly with the Wellcome Trust) over the 1998 and 2000 spending review periods. In order to further ensure the long term sustainability of university research the science budget will also provide £120 million per year from 2005–06 to enable the Research Councils to pay a larger contribution than at present to the full economic costs of the research they fund.

All this must be set in the context, however, of an estimated backlog in teaching and research facilities of £8 billion. Higher spending on research will need to be sustained over many years to make up for the previous under-investment. In relation to higher education our proposals, whilst not immediately answering all the problems, will make university funding more sustainable. They will improve and reward excellent teaching; enable more people to enter higher education, especially those from disadvantaged backgrounds, by restoring grants, helping with fee costs and abolishing up-front fees; allow universities to secure a contribution from students of up to £3,000 per year to the cost of courses; give universities better financial security by helping them build up endowment funds; and improve the funding of research, knowledge transfer and universities’ roles in their local economies.

**Regulation of research**

2. While we agree that regulation should set clear, ethical limits beyond which researchers should not be allowed to go, public opinion in the UK seems broadly content with the difficult ethical balance struck in the regime here. We would therefore oppose any attempt to tighten regulation here. We are aware that the Government takes the same view, but we wish to underline the importance of continuing vigilance; the regulatory environment for biotechnology research in the UK is a real source of
advantage and must not be undermined by developments at the European level. (Paragraph 30)

The UK has a leading position in stem cell research, due to Government investment and a strong regulatory and ethical framework. This is a good example of forward-looking regulation, which meets ethical concerns, whilst also offering a reasonable and stable framework for research and business innovation.

There is international recognition for the openness of the UK’s ethical debates. The pragmatic and open legislative path taken by the UK in relation to stem cell research and other ethical issues has given it a cutting edge in attracting scientists and demonstrating to the biotechnology and pharmaceutical industries that the UK remains a favourable location for science and investment. The Government shares the view of the Committee that this advantage must not be undermined by developments at the European level. To tighten and add further hurdles to the regulatory system could be seen as a failing of a system which has undergone rigorous scrutiny in the UK.

The Government believes that it is essential that negotiations in Europe result in the flexibility for individual countries to arrive at different conclusions on what types of research may be appropriate in their national setting. The Government has maintained throughout negotiations in Europe that the detail and application of ethical principles which reflect the religious and cultural diversity in Europe, are a matter for Member State legislation and not within EU competence.

Technology transfer

3. The USA has a clear lead in the size, and also the sophistication, of its technology transfer effort. Some Universities, such as MIT and Stanford, have gained very large incomes from their commercialisation activities. But even at institutions where the revenues from such activities were much smaller, we were impressed by the commitment to transferring their research into the commercial world and making the most of any potential applications that it might have. The UK’s technology transfer process is less developed than the USA. In many ways it appears to be developing in the right direction. We applaud the efforts that have been made on the part of UK universities to increase the benefits to the public through commercial exploitation of scientific discoveries. (Paragraphs 52 and 53)

The Government also recognises the progress of many UK universities in this area. In the response to recommendations 5 and 7, some of the initiatives the Government is taking to assist universities with technology transfer are described.

Within the biotechnology sector specifically, DTI’s Bioscience Unit has taken the initiative to supplement the cross-sectoral work being done to stimulate the commercial exploitation of university-based bioscience research. The Biotechnology Exploitation Platform (BEP) Challenge, worth over £12 million in total with DTI support of £6.5 million, was launched in 1999 following a successful pilot to encourage universities and other publicly funded research institutions with complementary bioscience research to work together to better manage and exploit their IP.
The Government believes that, collectively, the BEPs have contributed significantly to the increased (and increasing) awareness among academics and in the NHS of the importance and value of publicly funded bioscience research. The programme has funded the formation of 22 BEP consortia, covering most of the UK and involving well over 100 organisations, including at least 56 universities and 25 NHS Trusts. When universities work together to exploit their technology they gain critical mass and can collectively gather the commercial expertise needed to optimise management of their technology assets.

Another relevant Government initiative, the Genetics Knowledge Parks, was established in January 2002. This is a £15 million initiative run jointly by the Department of Trade and Industry and the Department of Health. The parks are all linked to multidisciplinary centres of excellence and offer a blending of internationally recognised academic research with clinical expertise in relation to healthcare. The scientific and medical experts are working together to build the knowledge base on all aspects of human genetics, ensuring that the NHS is better placed to exploit the findings of genetics research and that clinical reality drives academic (and eventually commercial) research in these areas. The parks encourage entrepreneurship and provide platforms for consultancy services, technology transfer, and commercial exploitation. They are also developing economic, ethical, legal, and social frameworks for the effective delivery of genetics services and for a better public understanding of human genetics.

**Increasing commercial exploitation of IP**

4. We are not convinced that attempting to replicate the measures contained in America’s Bayh-Dole Act would have the same impact in the UK. In the USA the Bayh-Dole Act was introduced to increase the exploitation of publicly funded research in the context where regulations were acting as a deterrent to this. We received no evidence suggesting that a similar pool of unexploited technology exists here as a result of government regulations on the use of its intellectual property. However, we do suspect that the change in the IPR regulations that the Bayh-Dole Act brought about was only part of the reason for its success—its main contribution may have been the increased awareness among academics and companies about the potential of university based science and the enthusiasm for commercialisation it created amongst leading research universities. There has clearly been an increase in the UK’s technology transfer effort in recent years. Our impression is that the UK is still some way behind the USA in this area. However, this is as a result of a relative lack of experience and expertise, and a relative lack of resources, rather than as a result of constraints imposed by government regulations. (Paragraph 51)

The Lambert Review of Business-University Collaboration has considered issues related to commercial exploitation of IP, including a Bayh-Dole equivalent for the UK, and its report will be published this autumn. These are issues that the Government will be considering further when it responds to the Lambert review.

Elsewhere, higher education institutions are increasing their knowledge transfer activity, tempered with a realisation that there is no single policy that meets every need for commercial exploitation. The UK Patent Office has worked closely with knowledge transfer professionals to provide guidance to HEIs on this issue: there are plans for a wider
working group of ‘knowledge organisations’, meeting with the facilitation of DTI and the Patent Office, which will provide a wider forum for discussion and encouragement of commercial exploitation of university research. By sharing resources in this manner, the group aims to increase the effectiveness of knowledge transfer in the UK.

The NHS recently issued its own Framework and Guidance on the Management of IP in the NHS. This builds on a provision in the Health and Social Care Act 2001 that enables inventors to participate fully in the commercialisation of NHS research. Section 5 of the Act empowers NHS bodies for the first time to take a shareholding in spin-out companies set up to exploit IP. Importantly, NHS employees who contribute to an invention exploited through a spin-out company may also hold shares provided the employer does as well. An increasing number of NHS Trusts are already involved with the (BEPs), and the DTI is encouraging BEPs and the new NHS IP Hubs to work together as much as possible.

Technology Transfer Offices

5. The reports of variable quality led us to question the need for in-house technology transfer offices at all: could not the technology transfer activities be contracted out, perhaps with the good units taking over the less good? Whilst not ruling out this route, we were persuaded that good in-house technology transfer units were preferable. Although too many technology transfer staff may lack expertise, this will improve over time. However, in the meantime, efforts to promote best practice must be made. Whilst recognising the independence of universities and the sensitivity of individual government departments to incursions into their territory, we think that there may be a role for the relevant sectoral units in the DTI—in this case the Bioscience Unit—in bringing representatives from the various technology transfer offices together with industry representatives in order to exchange best practice and to obtain a clearer idea of what industry wants from the offices. Furthermore, efforts to inform and incentivise scientists in the possibility of commercialising their research must continue. (Paragraph 48 and 53)

The Government agrees that tribute should be paid to the excellent progress that many UK universities have made over the past 5 or so years in improving their technology translation operations. Evidence from the annual Business-Higher Education Interaction survey suggests that in terms of overall patent generation and creation of spin-out companies the UK may well be on par with North America. We also welcome the recognition that this has been delivered within a supportive fiscal and regulatory environment. However, the picture across the UK remains patchy and, as the Committee has suggested, we need to grow the expertise within TTOs and improve their access to external experts.

Government has increased the overall level of funding available to universities under the Higher Education Innovation Fund (HEIF) (£187m over 2004–05 & 2005–06). HEIF funding can be used to support a broad range of knowledge transfer activity including Technology Transfer Offices (TTOs)—including staff training and access to expertise. Recognising that current commercial training provision is somewhat limited both in scope and scale, OST launched a £1m fund in May 2003 to fund projects to address the shortfall in context based training provision for knowledge transfer professionals across the UK. Bids are currently being assessed but activities are likely to include provision of training,
course materials and associated support (information exchange, mentoring, sharing of best practice and signposting of provision).

Through this fund the Government is seeking to enhance training and course materials provision for the knowledge transfer profession, including TTOs, in a way that becomes embedded in the market and financially self sustaining. The intention is that this provision should be available to knowledge transfer practitioners working in HEIs, public sector research institutions, and industry at the business–HEI interface, across the UK. The selection of successful bids was made by a steering group that will include representatives from DTI (Office of Science and Technology and Innovation Group), CBI, universities, NHS and the Patent Office, who agreed that a consolidated bid by Auril, Praxis and Unico would be funded.

**Funding of biotechnology companies**

6. There are a number of highly successful UK biotechnology companies and more will come through in the coming years. However, it seems that less money is available from all sources for biotechnology companies in the UK than in the USA. Government support in its various forms, venture capital and angel funding, are all on a fraction of the scale that they are in the USA. There was little support for extensive government subsidy for commercial biotechnology in the UK. It is not clear that it will make better biotechnology companies. (Paragraphs 98 and 99)

The Government recognises that private funding for the UK biotechnology sector does not match that available in the US. The Government shares the view, however, that greatly increased Government funding is unlikely to lead to the creation of sustainable new firms, and it might indeed prejudice long-term success by distorting market mechanisms.

The Government can however play a role in terms of creating a favourable regulatory and taxation environment. The various government mechanisms to remedy market failure and support innovation and small business also apply to the bioscience sector as to any other.

The Research and Development Tax Credit system (mentioned by the Committee) has benefited many bioscience companies. A consultation on the definition of R&D for tax purposes has just been completed. The Government can also help UK companies improve their access to EU funding sources. The Bioscience Innovation and Growth Team is likely to include recommendations on this and other methods of helping UK companies access funding.

UK-based biotechnology companies can also take advantage of the Department of Trade and Industry's business support products. In response to recommendations from business and other stakeholders, DTI has started to restructure radically the way that it supports businesses. The aim is to develop and deliver support to businesses that is easy to understand, simple to access and strongly focused on driving up productivity. A new web-based Business Support Directory has also been put in place and this allows customers for the first time to access information on all of DTI's business support as well as selected information about support available from other Government departments.
Four products have been launched to date, all of which may be of use to biotechnology companies. Further new products are being developed and, at the same time, existing DTI schemes are being closed down.

The new products which were launched in Spring 2003 are:

- Small Firms Loan Guarantee
- Grant for Investigating an Innovative Idea
- Grant for Research and Development
- Knowledge Transfer Partnerships

The Grant for Investigating an Innovative Idea is new, the others build on the successful elements of former schemes that were shown to contribute to increased productivity. The Grant for Research and Development product builds on the SMART scheme, which has been particularly popular with the biotechnology sector.

The Regional Development Agencies and Devolved Administrations can also provide assistance for small technology based companies when they believe that regional conditions justify this support. For example, the London Development Agency is establishing a London Seed Corn Technology Fund, which is intended to provide assistance to technology companies in the critical period before venture capital funding is likely to be available. Yorkshire Forward financially supports the White Rose Technology Seedcorn fund which enables start-up businesses from the Universities of Sheffield, Leeds and York to spin-out. Funds for investment in smaller companies in the bioscience and other sectors are also available in the North West, North East and West Midlands regions of England and are planned in other areas.

Scottish Enterprise, meanwhile, has recently launched a scheme to amplify the scale of market-driven investments by business angels and venture capitalists by offering match public funding on equal terms.

7. Perceiving market failure in the earliest stages of company formation, government policy has been targeted at facilitating the commercialisation process by concentrating on seed and early stage funding through schemes such as the UCF. Support in this area has been considerably less than in both the USA and Germany. But, as the German case highlights, it is possible to make it too easy to start a biotechnology company. The companies have to be based around commercially viable technology, and there needs to be an adequate private equity market to develop and sustain the companies once they are established. (Paragraphs 83 and 100)

The Government continues to provide strong support for the commercialisation of research. The Higher Education Innovation Fund (HEIF) (which will in future incorporate funding allocated to University Challenge) and the Public Sector Research Exploitation Fund (PSRE Fund) are examples of government help in this arena.

The HEIF supports a broad range of knowledge transfer activity and can be used to provide funding to enable HEIs to establish and maintain Technology Transfer Offices (TTOs) to
respond to the needs of business through both the continuing development of capacity in universities to interact with business, and large, strategic, collaborative projects to strengthen university-business partnerships. Second Round HEIF will incorporate funding previously allocated to the University Challenge and Science Enterprise Challenge in order that support is provided for knowledge transfer through a single stream of funding.

The purpose of University Challenge was to enable universities to access seed funds in order to assist the successful transformation of good research into good business. £45m was allocated in the first round of the competition in 1999, (with 15 seed funds being set up) and £15m more recently in October 2001 (which provided for an additional 4 seed funds, and 1 extension). 57 Institutions now have access to UC seed funding.

The Science Enterprise Challenge established a network of centres in UK universities, specialising in the teaching and practice of commercialisation and entrepreneurship in the field of science and technology. Twelve Science Enterprise Centres were established in UK universities in the first round of the competition in 1999/2000, with £28.9m of government funding. Awards worth £15m for a further round of the competition were announced on 1st October 2001, involving some 39 institutions. This funding is helping to establish a new centre and expand the twelve existing science enterprise centres set up to promote a culture of enterprise and facilitate the commercial exploitation of scientific research.

The PSRE Fund (£15m over 2004-05 & 2005-06) will enable public sector organisations that carry out research—including Research Council Institutes and NHS Trusts—to develop their capacity to exploit their science and technology potential and to access seed funding to support the commercialisation of research.

Partnerships UK, itself a public/private partnership is also using its expertise and capital to support the commercialisation of public sector technological (and other) assets.

So far, the failure rate of the UK bioscience start-ups has been very low, indicating that most are built upon viable business plans, but Government is aware of the need to avoid distorting the market by making it artificially easy to set up new companies. As TTOs become more experienced, start-up options are being carefully balanced against other exploitation opportunities, such as commercial licensing of biotechnology to established companies. It is also important that government places no obstacles in the path of consolidation of existing, small companies, as critical mass is likely to be required for most to survive beyond a certain stage.

**Availability of Venture Capital funding**

8. Venture capital provides the backbone of biotechnology funding and the UK has the most developed venture capital sector after the United States. Nevertheless, in comparison with the USA at least, the venture capital funds are smaller and the amount of money they are prepared to commit to each investment is smaller. A further difficulty seems to be that the venture capitalists are looking to exit long before the companies are developed enough to be an appealing prospect for the public markets. Moreover, we have found evidence that UK investors are keener to invest in US biotechnology companies than they are to invest in domestic ones. The perception, at least, is that the US companies are superior to, and have better quality management
than, those from Britain or the rest of Europe. The result is that the UK venture capital market does not serve small biotechnology companies well. (Paragraphs 101, 103 and 83)

The Government agrees that it has become more difficult for UK and other European biotechnology companies to obtain the funding they need and that more is being invested in the USA than here. The bioscience sector in the USA is more mature and there are several profitable biotechnology companies there which have delivered the returns on capital that justify the risk of long-term investment in bioscience. These role models have yet to emerge in Europe (except, perhaps, Serono of Switzerland).

The Government is not convinced, however, that the UK venture capital market generally fails to serve small biotechnology companies well. Venture Capitalists are motivated solely by prospects of commercial success. Good UK companies are still receiving substantial injections of venture capital. Two companies, Arrow Therapeutics and Biovex received risk capital investment of a total of £38m in the first two weeks of October 2003 alone. It is right that capital must be restricted to those companies with sound business plans and prospects, in order that capital is not wasted, to the detriment of the sector as a whole.

It must also be understood that venture capital markets are not national in nature. Good UK companies receive investment from US, Canada, Scandanavia, Continental Europe and even as far away as Japan and Singapore. The UK-based venture capitalists are only a part of the finance environment for UK-based bioscience companies.

The Government is anxious not to distort market mechanisms for allocation of capital, so will only intervene if clear evidence of market failure can be supplied. No convincing evidence of generalised market failure has yet been offered. The Government has, however, in the past identified market failure, in some narrow areas of the Venture Capital market. Where this has happened, initiatives have been designed to remedy these failures.

For example, the Government developed an initiative to assist high-technology firms to access venture capital. This is the UK High Technology Fund (UKHTF), an element of the £180m Enterprise Fund, which was announced in the December 1998 Competitiveness White Paper.

The Fund was established on a “fund of funds” basis, investing in existing high technology based venture capital firms instead of directly in high technology companies. Its aim was to raise £105m from private sector investors alongside £20m of Government investment. The fund has actually raised £126.1m in total (£106.1m from private sector investors & the Government’s £20m investment) making investments in venture capital funds that specialise in investing in predominately UK based early-stage, technology-focussed companies.

Of the £126.1m raised, over £124m of this has, to date, been committed to 9 specialist venture capital funds (which includes Funds investing in BioTech e.g. Merlin’s Bio Science Funds and Advent). These venture capital funds have in turn made investments in over 115 technology-based companies of which around 73% are based in the UK. All investments are made on a strictly commercial basis and decisions on those funds invested in are made solely by Westport Private Equity Ltd, the appointed fund manager.
Other initiatives include the Regional Venture Capital Funds launched on a national basis for England through the Small Business Service in 2002 (see response to Recommendation 10), and the various funds set up by the RDAs and Devolved Administrations to combat localised, perceived market failures, in the regions and nations of the UK. The Government will continue to respond to market failure which prejudices UK economic development, but is not otherwise willing to interfere with market-based capital resource allocation.

The Venture Capital community has been represented in the Bioscience Innovation and Growth Team, and the issues raised by the Committee have been discussed. The BIGT focus is, however, on the flow of seed capital and improvement of public sector technology transfer activity on the one hand and the provision of a favourable regulatory and fiscal environment on the other. BIGT does not favour Government intervention in the venture capital market.

9. Increasing expertise in university Technology Transfer Offices may in time provide more attractive prospects for venture capitalists. However, even if better companies are spun out the ‘structural’ factors that deter the venture capitalists from becoming involved in the earliest stages would remain. Investors are under no obligation to support a sector that they feel is too risky for them. The role of government is to ensure a favourable regime so that investors are not deterred. Beyond this, it is the companies that must prove themselves viable commercial propositions in order to secure investment. (Paragraphs 83 and 103).

The Government only has a limited role in encouraging venture capitalists to invest in biotechnology companies. It cannot directly intervene in commercial decisions but, as the Committee notes, can contribute towards developing a positive climate for investment.

The Government is aware of the particular problems facing companies in their early days and this is what justifies the technology transfer, commercial validation and seed capital elements of HEIF and PSRE described in our response to recommendation 7 above. Once companies have established themselves, however, it is right that they should have to persuade commercial backers of their intrinsic commercial potential. If they cannot, they should merge with or be acquired by those companies that can offer commercial growth prospects.

Universities can also usefully consider how they might consolidate their technology at an early stage, in order to develop a strong proposition for funding. The DTI has provided some support for projects of this sort. Universities also have an important role in identifying academics who are particularly entrepreneurial by nature and are likely to succeed in the commercial world.

10. Whilst government measures to increase the flow of funds into venture capital would seem appealing, the problems of Germany should serve as a warning. The regional venture capital funds that are currently being established may provide valuable support in the absence of private funding. We received no evidence as to whether—and if so how—small biotechnology firms are using such funds: and, in any case, the funds are too new for any firm conclusions about their usefulness to be drawn yet. However it is important that the rigorous scrutiny of new investments and strict
commercial criteria that one would expect from private venture firms is maintained by these public funds. (Paragraph 83)

The Government agrees with the Committee that it is too early to draw firm conclusions on the impact of the Regional Venture Capital Funds on small biotechnology firms. In the short time since they became operational, these 'generalist' funds have made over 70 investments, including a few biotechnology investments. Rigorous scrutiny of new investments and strict commercial criteria are maintained, because the Government is a minority investor in all these private sector dominated funds. The funds were commercially structured and focused in order to attract private sector institutional investors.

**Flotation or M&A?**

11. The public market seems to have been the route that most of those involved in the biotechnology industry aspire to. However, it is evidently not always the most suitable option. Companies have approached IPO as merely another stage in the development process but the conditions under which public companies operate are very different. Public companies face a much more volatile climate than private companies and are subject to far greater pressure to deliver some tangible success. It is clear that not all those companies who aspire to the public markets, or indeed all of those that have already floated, have been ready for the harsher climate there. With the public markets closed to new biotechnology offerings, it may be that venture capitalists will have to wait longer before exiting and perhaps take a more proactive role in encouraging some consolidation in the sector, both of which could potentially strengthen it. (Paragraphs 101 and 102)

The Government agrees with the observations made by the Committee.

Some recent M&As (such as the mergers between British Biotech and both Ribotargets and Vernalis) suggest that consolidation is starting to take place in the UK sector.

The next 12 months will be a significant time for the sector, as it will become clearer whether further consolidation will take place, and whether the IPO 'window' will open. It is encouraging that there have recently been several biotechnology IPOs in the USA. Some observers expect IPOs in the UK in 2004 and there is speculation that some UK-based companies will seek to float in the USA, if London offerings remain too difficult.

**Clusters**

12. We are concerned that too many areas have targeted biotechnology as an industry to cultivate. Not only may considerable sums of public money be wasted in trying to force into existence local biotechnology companies, but also rivalry between regions may adversely affect those with existing strengths in the sector thus undermining the success of biotechnology in the UK as a whole. (Paragraph 121)

The Government appreciates the Committee’s concerns and agree that it would not be of benefit to the national sector if regions wasted money, overstated what they could offer and failed to co-ordinate. It is also agreed that particular attention needs to be paid to
reinforcing UK centres of excellence. However the Government believes that the existence of regional support initiatives can bring extra value to the UK, given the geographical spread of expertise in this sector and the breadth of opportunity across the wide range of bioscience sub-sectors.

There are pockets of scientific brilliance, industrial expertise and entrepreneurial flair in the biosciences all over the UK. Centres of excellence can sometimes be quite small, focussing on particular sub-sectors of Bioscience. The London/Cambridge/Oxford triangle is obviously dominant in many areas, but there is world-class expertise in tissue engineering, for example, in Yorkshire, in bio-processing in the North West and in Kent, in stem cell research in Scotland and the North East and in diagnostics in Scotland and Northern Ireland. Emerging companies, with the potential for strong growth, should not be neglected simply because they are located in “unfashionable” areas.

The Government believes that RDAs and Devolved Administrations (DAs) are ideally placed to identify these centres of expertise and commercial potential and, where appropriate, provide regional support and encouragement. The support offered through the RDAs and DAs varies by region in response to perceived localised market needs. For example, SEEDA is investing in action to improve the supply of skilled labour; a major focus in London is to ensure the availability of laboratory space; the North West is investing in the National Biomanufacturing Centre, Scottish Enterprise are offering match funding for business angel investments and, with Yorkshire Forward, are offering proof of concept funding to strengthen the quality of candidates for spin outs. DTI is supporting this focus on remedying localised market failure and is ensuring that experience on what works is being diffused across all regions.

Many of the centres of excellence are highly specialised and are not replicated in other regions. In other areas there are complementary skills between regions and cooperation can yield benefits for all players. As the biotechnology sector is still fairly young and developing rapidly, it would not be wise to ignore clusters outside the most well known areas of biotechnology expertise. By doing so, there would be a risk of losing significant opportunities for the UK.

DTI works closely with RDAs and DAs and has established a new team, based in Manchester, with the specific aim of promoting and facilitating collaboration between the regions in relation to bioscience. The team organises regular networking meetings with RDA and DAs. At these meetings, regional bodies exchange their experiences, identify best practice and receive an update on national developments. These meetings are valuable networking opportunities and reduce the possibility of wasteful duplication of activities.

It should also be noted that inter-regional collaboration already exists. For example, there have been several joint networking meetings organised by the London, Oxford and Cambridge clusters. This networking builds on existing links which have developed naturally.

The Government accepts that there is a risk that competing efforts to attract inward investment might, in some circumstances, be to the detriment of the UK as a whole, but steps have been taken to avoid this eventuality. Many RDAs formally collaborate on their efforts to attract inward investment into the UK. DTI is also working with RDAs and DAs
to ensure that UK overseas marketing efforts are better co-ordinated; and that potential investors are pointed towards the most appropriate region or regions.

**Skills**

13. We recommend that the Government and the BIA, perhaps along with the biotechnology specialists in the RDAs, look into ways to provide some systematic training in management. Given that so many companies are spun out of universities, they could also clearly play a role in this. Biotechnology is a high risk industry and some failures are inevitable. However with better quality management these failures can be kept to a minimum. (Paragraph 128)

The Government White Paper “21st Century Skills” published in July 2003 identified weaknesses in management and leadership in business generally, and announced a range of measures to address this (Chapter 1.16 c and 2.14–2.18). In particular the Department for Education and Skills (DfES) will work with the Sector Skills Councils (also known as the Skills for Business Network), Investors in People and other partners to develop a new programme linked to the new Investors in People Management and Leadership model. DfES will roll out a programme of tailored support aimed specifically at managing directors or other key directors of small and medium sized enterprises in pathfinders from December 2003 and nationally by March 2004.

DfES has asked each Sector Skills Council to look at cross-industry skills issues, particularly leadership and management, when drawing up sector skills agreements which set out their overall approach to skills in their sector (Chapter 3.20 & 3.23 d). RDAs will then take account of sector priorities when drawing up their Frameworks for Regional Employment and Skills Action (FRESAs), and local Learning and Skills Councils (LSC) will build these combined requirements when planning local provision (via LSC Strategic Area Reviews—StARS).

DfES also expects Sector Skills Councils to look at the management and leadership element within their occupational standards and qualifications frameworks as these are reformed. DfES expect new generic management standards to be approved by March 2004 and built into qualifications by April 2005.

These initiatives complement developments which the DfES is taking forward with the DTI and other partners to improve business support and its related signposting for employers. Also to improve the integration of training and development offerings at the high end, aimed at embedding modern management techniques and understanding of new technology, and achieved by improved collaboration between HE, FE, business schools, specialist providers, centres of excellence, and others.

The Bioscience Innovation and Growth team report is likely to include recommendations on how the UK should develop, attract and retain a high quality scientific and managerial talent base, in the bioscience sector.

14. We note concerns about a shortage of suitably qualified technicians. Again this would appear to be an area where the Department for Education and Skills should be working with bodies such as the BIA, the RDAs and the LSCs to ensure the adequacy of
training provision. We heard that Scottish Enterprise was working with local colleges with a view to increasing the provision of technician training. We applaud this and would encourage other regions to consider similar initiatives. (Paragraph 130)

The Skills Strategy identified shortages of people with technician, higher craft and associate professional level skills at level 3 as a significant gap and concern. To address this, the Department for Education and Skills (DfES) is working with its partners (DTI, LSC, SSDA and RDAs) to establish a more coherent system whereby each sector and region will identify its skills priorities at level 3. The LSC will then ensure access to public funding to support the delivery of L3 qualifications in the agreed skills priority areas. The aim is to pilot the new approaches in 2004–05 and implement them nationally in 2005–06.

Sector Skills Agreements are currently being developed to provide a mechanism for employers and government to collaborate in meeting the priority skill requirements of sectors, which will drive improved business performance. The agreements will offer employers, working through their Sector Skills Councils (SSCs), a means to identify and prioritise skills and productivity needs. They will provide opportunities to work with the funding, planning and delivery agencies to find solutions to meet those priority needs, ensuring demand for skills is matched to supply in order to meet the recognised needs of industry.

SEMTA, is the SSC which covers the biotechnology industry. SEMTA has established a Bioscience Sector Strategy Group (BSSG) specifically to address the skills weaknesses in the sector and, within this, will be considering qualifications, standards and apprenticeship frameworks. The BSSG includes the Bioindustry Association (BIA), the Association of the British Pharmaceutical Industry (ABPI), major employers (including GlaxoSmithKline, Astra Zeneca, and Celltech), HE Institutions (Imperial College and the University of Central Lancashire) and Government Departments (Department of Health and Department of Trade and Industry). The recommendations of the Select Committee are at the head their agenda and they share the Select Committee’s concern to improve the performance of management and the supply of suitably qualified technicians in the sector. In addition, Michael Stephenson (the Managing Director of Helena Biosciences), is a member of the Modern Apprenticeship Task Force, which is working to ensure that Modern Apprenticeship programmes respond to the changing needs of employers and young people.

As noted above, the Bioscience Innovation and Growth Team (BIGT) is likely to contain recommendations relevant to these issues.

**Biomanufacturing**

15. It may be too early to tell whether the lack of biomanufacturing will significantly limit the growth of the biotechnology industry in the UK, and also whether there is a market failure that the Government may need to address. Whilst much pharmaceutical manufacturing has moved abroad, this is not yet the case with biomanufacturing. The UK has the potential to retain it. Government and the RDAs should ensure that there are no obstacles to the establishment and retention of adequate biomanufacturing capacity accessible to the major R&D centres. (Paragraph 134)
A strong biomanufacturing/bioprocessing sector will bring direct benefit to the UK. It has been estimated that the total supply chain (including raw materials, production, and distribution) represents up to 25% of a biopharmaceutical drug, which, in the case of a blockbuster drug, would amount to around $250m.

As well as pharmaceuticals, biomanufacturing can bring real benefits to other sectors such as agriculture, food and drink, chemicals, cosmetics and skin care and environmental technologies.

Although the UK biomanufacturing sector is relatively small, there have been some very positive developments over the last couple of years, including the announcement of the £30m National Biomanufacturing Centre, which is being built at Speke, Merseyside. There have also been recent announcements of significant investments by Avecia (Billingham), Powderject (Speke), Smith and Nephew (York), Lilly (Speke) and Abbott (Dartford).

The Government agrees that the UK needs to build on its existing strengths in biomanufacturing and bioprocessing. The sector has to both attract more talent from a range of disciplines and increase the level of invention and innovation. It is also important the UK makes every effort to attract more inward investment in this area.

The Bioscience Innovation and Growth Team report is likely to contain recommendations on these priorities.

**Clinical trials**

16. Ultimately, whilst it clearly imperative that drugs are subjected to thorough trials, a long and drawn out process merely diverts resources away from more innovative aspects of R&D. Anything that can be done to smooth the process, without reducing necessary protection, should be welcomed. (Paragraph 138)

The Government recognises the importance of making the UK the best possible location for clinical trials. This issue has been addressed by two government/industry task forces, the Pharmaceutical Industry Competitiveness Task Force (PICTF) and the Bioscience Innovation and Growth Team (BIGT).

In its final report published in 2001, PICTF identified a number of ways in which the existing strengths of the UK as a base for clinical trials could be improved, in particular through reducing delays in the system for approving and overseeing clinical trials. The actions agreed in this area have been taken forward jointly with industry and overseen by the PICTF clinical research working group, which has continued to meet. The working group published an update last year and is monitoring performance through indicators that have been developed for inclusion in the annual PICTF competitiveness and performance indicators. The biotechnology sector now has representation on the working group through the BioIndustry Association.

In January 2003 the Department of Health and the Association of the British Pharmaceutical Industry agreed a model Clinical Trials Agreement as a standard contractual framework for commercial trials involving NHS patients. Accompanying guidance on the process for negotiation of arrangements for NHS participation in trials has also been published.
Member states are required to implement the provisions of the EC Clinical Trials Directive by May 2004. A Medical Research Council (MRC)/Department of Health joint project is exploring the key issues identified in an impact assessment prepared by the MRC. The project will clarify how the current arrangements for non-commercial trials will be affected taking into account any flexibilities in the relevant EC Directives, draft legislation and guidance. The project will draw up practical advice to enable those involved in publicly funded trials to comply with the new regulations, and to take advantage of provisions that simplify the commencement and conduct of trials. For example, electronic submission of standard applications and safety reports could make them easier to handle than under current practice.

One of the objectives of the Bioscience Innovation and Growth Team (BIGT) has been to consider how to develop mutually advantageous collaborations between the NHS and industry for patient benefit. It is likely to make positive and substantial recommendations on how to develop and support excellence in clinical trials and clinical research within the NHS.

Animal rights activism

17. Last year there was tightening of company legislation designed to give some greater protection to directors under threat of attack. Before advocating further measures we would like to judge the effectiveness of the recent measures. We recommend a wider review of company law to see whether investors in vulnerable companies could be similarly protected. We support moves to make a more concerted attempt to explain the necessity of animal experimentation in drug development and to raise awareness of its benefits. (Paragraph 140)

The Criminal Justice and Police Act 2001 introduced provisions which allow company directors, who would be at serious risk of violence if their residential address were made public, to apply for a Confidentiality Order so that their home address is not publicly available. The Government agrees that it would be sensible to judge the effectiveness of these measures before considering the issue of directors’ home addresses further.

In relation to the addresses of members of a company, the existing law requires a company to keep a register of its members and states that the register must contain the names and addresses of the members; however there is no requirement for that address to be the usual residential address of the member. The law also requires companies to permit inspection and provide copies of the register to any person. The White Paper “Modernising Company Law” stated that the Government is considering an approach which would permit companies not to provide copies of the register if they are to be used for inappropriate purposes, and to allow a company a right to apply to the Court for the relief from the obligation to provide a copy of the register.

Companies have to deliver similar information on company members in their annual returns to Companies House, who then make it available for public inspection. As above, members are not obliged to give their residential address.

The Coalition for Medical Progress (CMP) is an alliance of organisations from across the biomedical research community whose task is to address public reservations that arise over
the use of animals in achieving advances in medicine. CMP aims to establish better communication between the biomedical research community and the general public in the UK. Government fully supports the aims of the CMP.