

The image features a central graphic design on a white background. A horizontal brown band spans the width of the page. Within this band, a white rectangular area contains the text. This white area is framed by thin white lines that connect to several brown circles of varying sizes. Two circles are positioned above the white area, and four are below it. The circles are connected to the white area by thin white lines, creating a network-like structure. The text is centered within the white area.

Genome Valley

The Economic Potential and Strategic
Importance of Biotechnology in the UK

R e p o r t

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Executive Summary

I Biotechnology has the potential to improve quality of life, in both the developed and the developing worlds, as well as offering economic potential. Many people see it as the next revolution following the IT revolution. Some of the techniques used in biotechnology (particularly genetic modification) have raised concerns, especially in their application to crops and food, and have prompted important questions about whether there may be potential risks to biodiversity, the environment or even to human health. These concerns need to be addressed by the scientific community, industry and Government so that there can be informed debate with consumers and the wider public, nationally, in Europe and internationally. This report looks at the UK's position in biotechnology and describes some of the ways in which biotechnology is already benefiting many sectors of the economy – pharmaceuticals, agriculture, food and drinks manufacturing, environmental clean up and cleaner manufacturing processes in diverse sectors. The report is addressed to everyone who is interested in biotechnology, including consumers, investors, companies, academia and Government.

II The industrial sectors which stand to benefit from biotechnology are amongst the UK's most successful, vigorous and innovative – pharmaceuticals, agriculture, food and drink, chemicals, and environmental technologies. These employ over 1.75 million people in the UK and account for about 10% of UK GDP. The essential building block for biotechnology is the bioscience research base. This is one of the UK's great strengths – in our universities, Research Council Institutes, medical charities' laboratories, Government Research Establishments and in clinical medicine. The UK now has some 270 specialist biotechnology companies employing 14,000 people and many of these have come directly from the science base. Figure 1 lists UK strengths.

III The UK currently leads Europe in biotechnology, but some European countries, particularly Germany, have taken action designed to overtake the UK. The US is the dominant world leader with 153,000 people employed in 1,300 specialist biotechnology companies and rapidly growing sales of biotechnology products (\$13.4 billion in 1998). The US has 10 years more experience than the UK. The scale of expenditure on bioscience research in the US is enormous – Government funding of \$18 billion in 1999 alongside enormous R&D investment by pharmaceutical companies. Total UK Government funding on bioscience R&D is approximately £600 million per year. Similarly, although the venture capital market in the UK is more mature than elsewhere in Europe, it is

far easier to raise finance for biotechnology in the US than it is in the UK. Experienced business managers are present in the US but are in short supply in the UK: share option packages to attract them can be more attractive in the US than in the UK. While the UK has a well-trained, skilled workforce in most aspects of biosciences, there is a shortage of expertise in bioinformatics – a crucial field which will enable us to make use of gene sequencing and other data. Thus the UK faces some major challenges in maintaining its leading European position.

Figure 1 UK Strengths in Biotechnology

- World-class biological science and clinical research groups.
- Investment in academia by industrial companies.
- Well established links between industry and researchers.
- An entrepreneurial climate which has encouraged start-up companies and SMEs (now over 270 employing an estimated 14,000 people).
- Mature venture capital market (some funding gaps remain, however).
- Regional biotechnology clusters in which synergy between the research and industrial communities is developing, and in which the support infrastructure (such as specialised financial, legal and patent advice) is becoming established.
- A legislative and regulatory environment which has assured safety and has allowed biological science and medical research to develop, and has provided a framework which has encouraged industrial innovation.
- Strong EU patent system for small molecules/technology.
- Strong range of small to large industrial bioscience companies, some of which are already starting to exploit biotechnology in the UK, EU, US and worldwide.
- Imaginative DTI and Research Council initiatives to help researchers to manage and exploit their intellectual property (IP) for the economic benefit of the UK.
- DTI initiatives to provide advice on finance and growth to start-ups and SMEs (mentoring and incubator schemes); BIO-WISE programme to encourage the uptake of biotechnology across industry; on manufacturing for biotechnology.
- A trade association for biotechnology SMEs – the BioIndustry Association.
- Public support for bioscience in medicine.
- Prestigious, respected European organisations associated with biosciences and medicine located in the UK – European Medicines Evaluation Agency, European Bioinformatics Institute.

IV While the UK is undoubtedly well placed to develop its competitive position in biotechnology, this will not be achieved without concerted action on a range of issues – some are specific to biotechnology and others relate to all high-technology sectors. The Government already has schemes in place to encourage entrepreneurs in biotechnology, to help with the initial identification of exploitable IP; mentoring and incubation of start-up companies; signposting to private sector sources of finance. Many of the fiscal changes announced in Autumn 1999¹ stand to benefit SMEs in sectors such as biotechnology and have been welcomed by the sector – particularly the proposed R&D tax credit for SMEs. Schemes such as University Challenge, Science Enterprise Challenge, Reach Out Funds, Joint Infrastructure Fund and the DTI's Enterprise Fund are well suited to support biotechnology.

V In order to pull through biotechnology research into products and processes, the UK will need to continue to attract and hold onto internationally mobile R&D investment made by pharmaceutical and agri-food multi nationals. Investment decisions are influenced by the regulatory framework, the financial and fiscal environment, and social factors can also be influential. The recent media coverage of genetically modified (GM) food and crops; the apparent lack of confidence in science; consumer concerns about GM food; actions against GM crop trials and against those involved in animal experimentation, are all taken into account as companies consider locations for future investment. If the UK is to benefit from the potential which biotechnology offers and continue to encourage innovation, it must have a regulatory framework which ensures that safety and environmental concerns are met without stifling research, alongside fiscal regimes which encourage entrepreneurs.

VI Figure 2 lists key areas which will be crucial in determining whether the promise of biotechnology can be fulfilled in the UK. DTI, with other Government Departments, Research Councils and Trade Associations, the City, consumers, industry and NGOs, will need to work together to draw up an action plan to put in place a framework which encourages this knowledge-based sector to continue both to create jobs and improve quality of life.

¹ Pre-Budget Report, HM Treasury November 1999 "Stability and steady growth for Britain"

Figure 2 Key Areas for Action in the UK

Social and Culture

- Industry and Government to find ways to increase informed public debate about potential risks and benefits of biotechnology, and about ethical and social issues.

Research

- maintain long term investment by Government, Trusts and charities in the bioscience base in the UK;
- increase public confidence in science;
- continue to consider the ethical, confidentiality and practical issues surrounding bioscience research, including use of NHS clinical records and tissue banks in genomics research.

Education and Training

- build on world-class centres in the UK – use them as a magnet to attract further research groups and to “feed” industry;
- introduce entrepreneurship in science degree courses (particularly through the Science Enterprise Challenge);
- ensure training at all levels – technician to postgraduate – is meeting industry requirements;
- stimulate excellent biologists and mathematicians to go into bioinformatics;
- encourage HEIs to devise more specialist courses and modules in science communication, regulatory affairs, commercial and financial aspects of business;
- develop biotechnology and biochemical engineering elements in undergraduate courses, together with teaching about manufacturing methods, quality control and regulation;
- consider the need for a biotechnology GCSE, learning from experience with the Scottish Higher.

Figure 2 Key Areas for Action in the UK *(continued)*

Enterprise

- create a UK business and fiscal environment to attract, and retain, internationally mobile investment in biotechnology, and to retain pharmaceutical R&D and growing biotechnology companies here;
- get conditions right for all stages of development of biotechnology companies, i.e.:
 - ensure that the regulatory framework (international, EU, UK) has safety and environmental concerns as paramount but allows innovation to continue;
 - an appropriate system of patent protection;
 - clarify ownership of IP derived from publicly funded research so that exploitation is facilitated;
 - improve the quality of knowledge transfer to identify and exploit public sector IP;
 - continuously adjust and improve the finance and entrepreneurial climate;
 - develop tax incentives for founders and investors and for key top managers;
 - keep Stock Exchange regulations under review;
 - improve the availability of property – need for incubators, laboratory premises, shorter flexible rental agreements;
 - provide mentoring for start-ups;
 - ensure that adequate biotechnology manufacturing facilities exist in the UK.
- stimulate companies to use biotechnology (for example in energy efficient, cleaner processes).

Chapter 1

Introduction

Biotechnology

1.1 Biotechnology is an enabling technology; it is not an industrial sector. Biotechnology is the application of knowledge about living organisms, and their components, to make new products and to develop new industrial processes.

1.2 People have used biotechnology for centuries. For example, through using selective breeding to change the gene set, we have produced crops better fitted to their environment with a higher yield, and have increased the yield and quality of milk in dairy cattle. Fermentation processes have been used for centuries to produce beer and wine and yoghurt, and naturally occurring enzymes have been used to produce cheese, and other foods. Modern biotechnology has developed a new range of techniques derived from knowledge of the chemical basis for the genetic code which is common to all living organisms – DNA. The fundamental research was done in the UK by Watson and Crick at Cambridge (1953), who showed that the genetic information was “encoded” in the ordering of the four different chemical groups (bases) which make up the long DNA molecule. Some of the techniques used in biotechnology (particularly genetic modification) have raised a lot of concerns, especially in their application to crops and food, and have prompted important questions about whether there may be potential risks to biodiversity, the environment or even to human health. These concerns need to be addressed by the scientific community, industry and Government so that there can be informed debate with consumers and the wider public, nationally, in Europe and internationally.

1.3 Biotechnology has already had a major impact; it has led to the creation of new industries such as diagnostics, bioremediation (clean-up using micro-organisms) and novel processing technology. It is revolutionising the way pharmaceutical companies go about finding new drugs, and making the process more efficient and less wasteful. It is providing cleaner technology for traditional manufacturing industry. Biotechnology offers enormous opportunities for improving our quality of life, in terms of health, agriculture, food and environmental protection.

Overview

1.4 The UK currently leads Europe in biotechnology. The UK's science base is second to none; the entrepreneurial climate and well-developed venture capital market has stimulated more start-ups and specialised biotechnology SMEs than elsewhere in Europe (over £1 billion invested in the last 10 years; 270 specialist biotechnology companies employing 14,000 people, with a further 200 companies with 25,000 employees providing related services). Most of the major multi national pharmaceutical companies have substantial R&D and some manufacturing in the UK and that adds to the richness of the research base as well as offering a route to market for biopharmaceuticals. The UK has competitive strength in the principal sectors which stand to benefit from biotechnology: pharmaceuticals; agriculture; food and drink; chemicals; environmental technology and services. Figure 1 summarises UK strengths in biotechnology.

1.5 The UK position is under threat because other countries have introduced incentives to attract internationally mobile bioscience research and manufacturing, and Governments have put measures in place to stimulate the sector. Germany, for example, has stated that it aims to be number 1 in Europe by 2000. The UK will need to decide whether it is prepared to see British experts and potential products leave the UK. If the UK is to maintain its lead, we will need to set an environment which means that investors see the UK as the natural place for biotechnology (second only to the US).

1.6 If UK SMEs are to grow as their ideas mature and come to market, they will need substantial investment (the financial community estimates £1.5-£2.0 billion in the next five years). Some early research ideas have not yielded their hoped-for promise. For example, several potential drugs have failed in clinical trials and, even though for the pharmaceutical industry it is accepted that only one product in every 10 entering clinical trials is likely to come through as an effective drug with acceptable side effects, these failures have shaken investor confidence. This raises a question as to whether the necessary finance will be forthcoming.

Figure 1 UK Strengths in Biotechnology

- World-class biological science and clinical research groups.
- Investment in academia by industrial companies.
- Well established links between industry and researchers.
- An entrepreneurial climate which has encouraged start-up companies and SMEs (now over 270 employing an estimated 14,000 people).
- Mature venture capital market (some funding gaps remain, however).
- Regional biotechnology clusters in which synergy between the research and industrial communities is developing, and in which the support infrastructure (such as specialised financial, legal and patent advice) is becoming established.
- A legislative and regulatory environment which has assured safety and has allowed biological science and medical research to develop, and has provided a framework which has encouraged industrial innovation.
- Strong EU patent system for small molecules/technology.
- Strong range of small to large industrial bioscience companies, some of which are already starting to exploit biotechnology in the UK, EU, US and worldwide.
- Imaginative DTI and Research Council initiatives to help researchers to manage and exploit their intellectual property (IP) for the economic benefit of the UK.
- DTI initiatives to provide advice on finance and growth to start-ups and SMEs (mentoring and incubator schemes); BIO-WISE programme to encourage the uptake of biotechnology across industry; on manufacturing for biotechnology.
- A trade association for biotechnology SMEs – the BioIndustry Association.
- Public support for bioscience in medicine.
- Prestigious, respected European organisations associated with biosciences and medicine located in the UK – European Medicines Evaluation Agency, European Bioinformatics Institute.

1.7 If markets for biotechnology applications are to grow, there needs to be public confidence in the science, in the regulatory system and in testing. While public acceptance of biotechnology in health care remains high, there is a need for industry to do more to explain the developments which are in the pipeline. Public acceptance of biotechnology across the wide spectrum of potential application areas will hinge ultimately on the success of its products and services. At present there are relatively few products on the market but the number of UK biotechnology products approved for use is growing.

1.8 The US is the dominant world leader in biotechnology. In 1998 there were nearly 1,300 specialist biotechnology companies employing some 153,000 people directly. The sales of biotechnology products reached \$13.4 billion in 1998 – this was an increase of 17% over the 1997 figures. The US has a very strong research base – the companies themselves spent \$10 billion on R&D in 1998, including that of the strong multi national pharmaceutical companies. The National Institutes of Health had their largest ever increase (14%) in funding for basic bioscience research for 1999 in their budget of \$15.6 billion. Further basic research is supported by the National Science Foundation whose budget for 1999 is \$413 million. The US Departments of Agriculture and Energy (which cover human genome mapping) spend a further \$2 billion per annum on biotechnology research. Given the scale of this effort it is unrealistic for the UK to aspire to catch up or overtake the US. The venture capital market is more mature than that in the UK and financing for biotechnology companies rose to \$773 million in 1997 – though the number of deals was lower than in 1996. Over the last 2 years, investors have started to prefer Internet and telecommunications rather than biotechnology, but it is still easier to raise risk capital (either from venture capitalists or from the large number of multi-millionaire business angels) in the US than in the UK. A further substantial advantage of the US over the UK is the sheer experience that there has been with the cycle of development of biotechnology. There is a greater understanding and sympathy for the fact that some promising potential products will not in fact come through from research. The volume of industrial biotechnology activity in the US also means that if a company fails there is a market for its manufacturing facilities and there are plenty of jobs for the biotechnology staff who are laid off. This means that the inevitable failures of some products have less impact on the sector as a whole in the US, than they have had so far in the UK.

Chapter 2

The current UK position

Science base

2.1 The fundamental building block which underpins all biotechnology is the science base. This is strong in the UK – Appendix 1 shows the leading University, Research Council and Medical Charity funded research groups. The Government (helped by the Wellcome Trust) is reinforcing the science base through provision of additional funding of £1.4 billion over three years following the Comprehensive Spending Review. Funds are being directed towards providing the modern equipment needed to ensure that graduates are familiar with the latest methods and approaches to biological research.

2.2 The principal foundation of modern biotechnology is knowledge of DNA and its role in the genes to control processes in cells in health and in disease. The Medical Research Council (MRC) funded research in the UK that led Watson and Crick to elucidate the structure of DNA (1953) and more recently the UK has contributed major breakthroughs, such as monoclonal antibody production² and DNA fingerprinting probes.³ It was two researchers in the UK, Bodmer and Solomon, who, in 1979 proposed that the whole of the **human genome** should be sequenced. That meant finding out the sequence in which the 4 bases (the building blocks of DNA) occurred along the DNA in the human chromosome set – a total of 3 billion base-pairs. This ambitious project is being carried out on an international collaborative basis. Originally scheduled for completion by 2005, the pace of the work is accelerating and the project is now expected to be completed by 2003, with a rough first map due to appear by Spring 2000. UK researchers at the Sanger Centre in Cambridge will be sequencing one third of the genome.

2.3 An important emerging science is **genomics** – the understanding of what each gene sequence actually does. The Wellcome Trust and 10 major international pharmaceutical companies announced, in April 1999, a consortium (the SNP Consortium), involving European and US researchers, designed to go beyond the basic gene sequence data and obtain information about changes in the genetic code associated with particular characteristics and diseases: they

² Kohler and Milstein at the MRC Laboratory of Molecular Biology

³ Professor Alec Jeffreys, University of Sheffield

will look for differences in single bases and will produce a map. Companies have already been set up – in the US and France particularly – to bring IT and genomics together to analyse the huge volumes of data coming from the gene sequencing work. The leader, the US company Incyte (whose CEO came from England) has a number of commercial database products. One of the purposes of the SNP Consortium is to ensure that some genomics databases are available in the public domain for access by all researchers. Availability of this data, and an ability to use it to yield real information, will be crucial in the next stage of functional genomics (i.e. working out what the different parts of the gene actually do in terms of stimulating proteins and other substances to be made in the body).

2.4 The UK has also been a leading partner in international gene sequencing projects for non-human species. The MRC funded the Sanger Centre to work with a research group in Washington University to sequence the genes of a nematode worm (*C.elegans*) – completed in 1998. The John Innes Centre in Norwich is co-ordinating the European input (including teams at Nottingham and other UK Universities) into work on the “model” crop plant, *Arabidopsis*. It is becoming clear that the genetic code for certain characteristics, and for making particular proteins, is very similar in distantly related species. This means that it will be possible to research some aspects of human physiology through experiments using very simple organisms. Some important gene sequencing is being done at the national level – for example the BBSRC and the Wellcome Trust are supporting research to sequence *Streptomyces Coelicolor* which is the source of most commercial antibiotics. The MRC is funding underpinning research to maintain the UK lead in the study of mouse models of human disease and recently awarded £7.5 million to a UK consortium to sequence large regions of the mouse genome.

2.5 The UK’s scientific strength in biology is not confined to genetics and genomics as can be seen in Appendix 1. Companies have long established and close links with University and other groups in biological sciences, pharmacy, chemistry, biochemistry and biochemical engineering which have proven to be economically useful in pointing towards new products. The well developed academic-industry links are a further UK strength.⁴ The UK also has collections of organisms and cells for a wide range of research – for example the European Central Animal Cell Culture facility which is at the Centre for Applied Microbiology & Research.

⁴ There are 35 Teaching Company Scheme projects involving 43 associates in the biosciences, and 200 CASE awards across three Research Councils. A number of LINK schemes have been funded by the Research Councils and DTI in biotechnology

2.6 IT and computing developments will be needed in parallel with other research developments to enable us to mine the information about genetic components of diseases from the vast quantities of gene sequencing data. One way of discovering which parts of the genetic code are involved in diseases is to look at the gene sequences of groups of affected individuals and to identify features of their genetic code which differ from that of unaffected controls. Such an approach requires the development of new techniques to 'visualise' the complex data and also the development of standards for databases in order that data can be shared amongst researchers. It is in this type of application that the new discipline of **bioinformatics** will be crucial. The UK has the opportunity to be amongst the leaders in this field, but we need to build up our expertise fast.

2.7 The Sanger Centre and the European Bioinformatics Institute, (both of which are based on the Wellcome Trust site at Hinxton near Cambridge) provide a world class centre of excellence which is as well equipped as any centre in the world and is right at the pinnacle of gene sequencing work. The UK could be amongst the leaders in bioinformatics if we could shape the evolution of database standards and develop a lead in methods to use the sequence data and to integrate it with related biological data. Concerted action is needed in the UK to ensure that we do not miss an opportunity to be amongst the leaders in bioinformatics. Competitors, especially the US and France, have recognised the strategic importance of this activity and have public and private sector organisations setting the standards for databases and information handling. Germany recently announced (July 1999) a major bioinformatics initiative, as has Japan.

2.8 The UK has some University postgraduate courses in bioinformatics but we will need to find imaginative ways to attract high quality students, not only from biology but also from maths, physics, IT and computing, into bioinformatics. Many qualified bioinformatics graduates are being enticed to leave the UK and go to work in the US because there is a worldwide shortage of expertise in this field. The Research Councils are working jointly on initiatives to strengthen the UK research base and training in bioinformatics.

2.9 The collection of DNA samples, with associated health records, would facilitate studies to detect susceptibility to genetic disease, and to understand the impact of genes on diseases. Iceland passed a Bill in December 1998 to make its national patient database of tissue samples available to researchers without compromising patient confidentiality. The National Health Service (NHS) in the UK is the largest source of clinical data and would be invaluable

for comparative studies. The Medical Research Council (MRC) is supporting work to generate new data which will have a significant impact on health care. The Wellcome Trust and the MRC are actively considering the ethical issues associated with individuals' donations of DNA for experimental use, and are starting to explore (with the Department of Health (DH)) the possible ways in which NHS data, particularly in regional groups of patients with a particular disease, might be used. Informed consent from individual donors and confidentiality for those donating DNA must be assured, but data protection legislation needs also to take account of research needs. Any proposal to use NHS data for studies will have regard to the legal framework protecting the confidentiality of the data and DH guidance related to it; full and careful consideration will also be given to the issue of consent.

Clinical trials

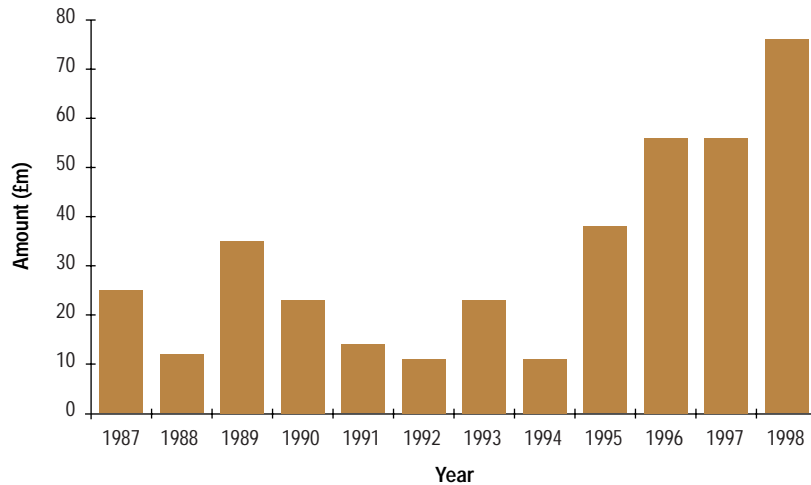
2.10 Clinical trials, in which potential new drugs are assessed in patients, are the final phase of research in the pharmaceutical industry. The number of clinical trials being done in the UK under the NHS has fallen from 9% to 4.5% of the world total. This is at a time when this field has become more of a business and has become increasingly competitive. In the UK, prior approval for a medical trial must be obtained from the Medicines Control Agency (MCA) and the relevant Local Research Ethics Committee (LREC). The UK MCA has a reputation worldwide for professional excellence and has a very well established regulatory system for clinical trials. Its exemption system for approval of commercially sponsored clinical trials has been in place for 18 years. It provides a rapid procedure for deciding that it is safe for a clinical trial of a new product to commence, supported by monitoring, inspection and enforcement systems which create a safe environment for patients, investigators and industry. With regard to ethical approval, where the trial involves 5 or more sites, the (new) Multi-Centre Research Ethics Committee (MREC) must also approve the protocol. The MREC approves the science and ethics of a protocol and the LRECs approve the local aspects, with the aim of producing a streamlined system. For the UK to be competitive in this area, it must ensure that clinical trials are done on time, to high quality and with a high standard of ethical review, in an efficient manner.

The economic and industry position in the UK

2.11 The UK has created a business environment which has stimulated biotechnology start-ups. Although there are now reported to be some gaps in provision of funding for biotechnology companies, the recent record has been one of supportive investment. Over the last 10 years (1989-1998) venture

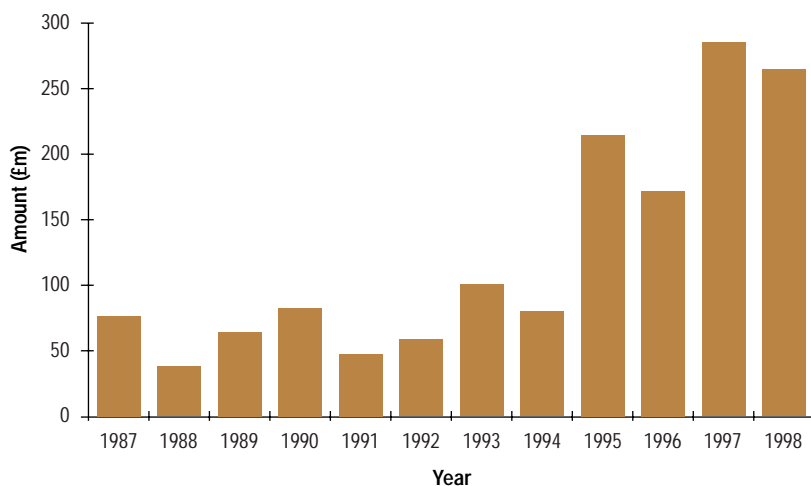
capital investment in a broad range of health care, medical and biotechnology companies has reached £1.37 billion. That for biotechnology specifically, reached £344 million. In 1998, venture capital of £265 million was invested in health care/biotechnology (see Tables 1 and 2).

Table 1 UK Venture Capital Investment in Biotechnology



Source: European Venture Capital Association

Table 2 UK Venture Capital Investment in Biotechnology, Medical & Health care



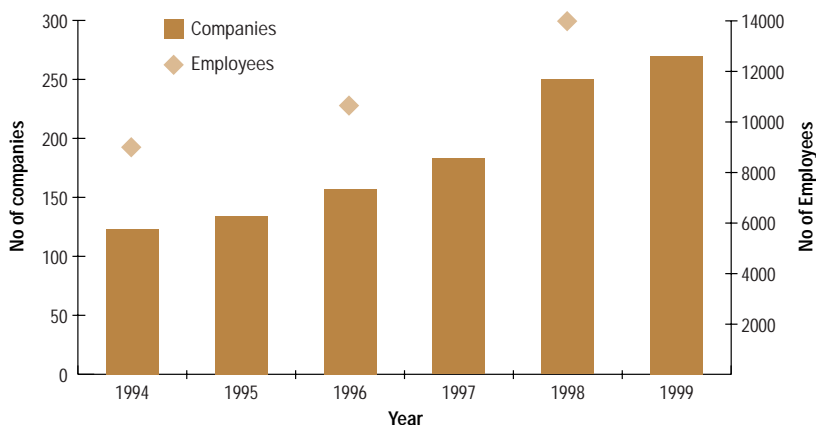
Source: European Venture Capital Association

Specialist biotechnology companies

2.12 During the 1990s there has been rapid and sustained growth in the number of small specialist biotechnology R&D based companies in the UK. There are now over 270, employing an estimated 14,000 people. If a wider definition is taken, (i.e. including consultancy and services), there are some

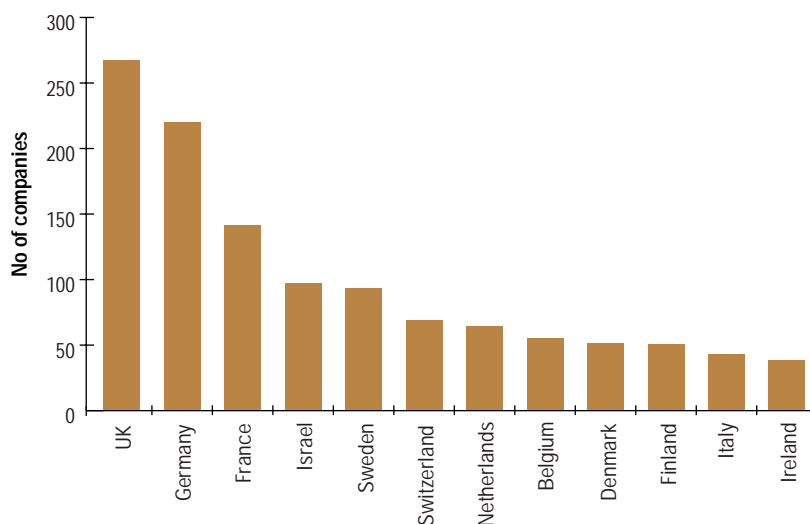
460 bioscience companies employing some 40,000 people.⁵ There has been a 30% increase in the number of companies in the last two years. Table 3 shows the growth in the UK biotechnology companies and employment. Table 4 shows that the UK has more specialist biotechnology companies than other EU countries. Table 5 shows that 35% of the specialist companies are working in biopharmaceuticals, 22% in diagnostics and 15% in agri/environmental.⁶ Over 25% are suppliers of specialist products.

Table 3 Growth in UK Specialist Biotechnology Companies



Source: Ernst & Young/Arthur Andersen

Table 4 EU Specialist Biotechnology Companies 1999

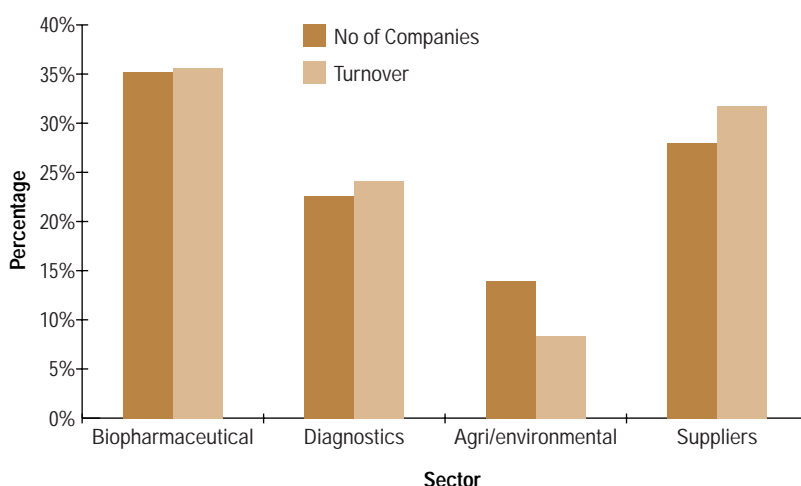


Source: Ernst & Young

⁵ UK BioIndustry Association

⁶ Arthur Andersen

Table 5 UK Specialist Biotechnology SMEs by Sector



Source: Arthur Andersen

2.13 While over 40% of UK biotechnology companies employ less than 10 people, the top 3 specialist companies now have operating costs in excess of £40 million, and the most mature are beginning to bring their first products to the market (see Table 6). The UK also accounts for three quarters of all European publicly quoted specialist biotechnology companies.

Table 6 Leading UK Specialist Biotechnology Companies

	Market Cap £ millions	Share Price pence	Employees [†]	R&D Expenditure £ millions [†]	Operating costs £ millions [†]	Losses (profit) after Tax £ millions [†]
	8-Oct-99	8-Oct-99	1998/9	1998/9	1998/9	1998/9
Celltech	701.3 ^{††}	463.5 ^{††}	208	21.5	24.5	3.1
Chiroscience			330	29.2	58.7	17.2
PowderJect Pharmaceuticals	564.3	761.5	87	7.3	9.0	4.7
SkyePharma	252.3	52.5	279	5.7	27.3	22.0
British Biotech	216.3	32.5	376	35.4	47.9	39.8
Biocompatibles	217.0	177.5	486	14.9	49.1	43.7
Oxford Asymmetry	146.6	355.0	187	0.9	29.7	£1.4m profit
Oxford Glycosciences	131.0	352.5	117	13.2	16.1	8.68
Vanguard Medica	73.6	222.5	60	21.0	24.3	16.0
Cantab Pharmaceuticals	62.3	141.5	127	12.1	13.8	7.2
Cambridge Antibody	50.3	199.0	123	9.1	11.3	7.0
PPL Therapeutics	40.9	82.5	209	13.5	15.8	14.2
Oxford Molecular	32.6	37.5	254	6.6	18.9	£1.7m profit
Peptide Therapeutics	30.5	39.0	88	8.1	9.4	7.5

[†] Based on latest annual accounts for 1998-1999

^{††} Share price and market cap of Celltech Chiroscience following merger in August 1999

2.14 The annual research and development spend of UK biotechnology specialist companies is running at some £300 million. A large amount of this comes from venture capital and the money raised from flotations, but significant sums also come from partnerships between specialist SMEs and multi national pharmaceutical companies. These partnerships are also of growing importance to multi nationals, attracted by the cutting-edge capability and lower cost base in specialist SMEs. Some recent examples include: Powderject Pharmaceuticals expanded its alliance with Glaxo Wellcome for DNA vaccines for HIV therapy; a research and product development agreement between Wyeth-Ayerst Laboratories (a division of American Home Products) and UK specialist biotechnology company, Cambridge Antibody Technology (CAT), to develop a portfolio of human antibody-based drugs; CAT purchased Aptein Inc. and is now exploiting US research in the UK; a collaborative agreement between Novartis and the pioneering UK specialist drug delivery firm, SkyePharma, to jointly develop a new beta-antagonist formulation for the treatment of asthma; a deal between Cambridge Genetics and Mayo Clinical (US) to exploit gene therapy technology; an agreement between Roche and the UK specialist SME, Vanguard Medica, to develop an endothelin antagonist for the prevention of acute renal failure; agreements under which Prolifix is exploiting technology from the Netherlands and Germany. The increasing pace of consolidation amongst biotechnology specialist companies in the UK follows a similar pattern to that in the US and is seen by many industry observers as part of the natural evolution of the sector, which may help to provide fresh opportunities to raise finance.

2.15 Appendix 1 shows the locations of the UK centres of bioscience research and of pharmaceutical companies and SMEs in the UK. The maps reveal that there are a number of clusters developing in the UK. Most of these (but, interestingly, not all) include 5* research groups in the vicinity. A separate complementary study led by Lord Sainsbury (Minister for Science) looked at the dynamics of biotechnology clusters and identified barriers to their continued growth in the UK.⁷

2.16 Some specialist biotechnology companies have faltered because potential products have failed in trials. Press coverage has judged some management aspects harshly and the whole sector has been affected with investors becoming more cautious. The BIA has drawn up a Code of Practice for the sector to help companies in addressing their various regulatory requirements

and obligations, in particular in handling information and communications. The code has been discussed with companies in the sector and with the City and it will start to be implemented shortly.

Pharmaceutical industry

2.17 The relationship between the multi national pharmaceutical companies and the biotechnology sector is pivotal. Biotechnology is critically important to the discovery, development and delivery of new medicines and vaccines (one company estimates that 70%-90% of all new pharmaceutical R&D is biotechnology related). Biotechnology is the basis for advances in our ability to diagnose accurately and quickly, and is the key to developing completely new treatments for a range of diseases. Biopharmaceuticals are estimated to now comprise 5% of all global sales. Some analysts believe that in the long term this could rise to 25% – some £40 billion at today's prices. Within the UK, all of the leading R&D based pharmaceutical companies are engaged in biotechnology – both within their own research groups and also in collaboration with specialist SMEs. Collaboration is seen as a cost-effective route to market for SMEs' biopharmaceutical products – it often underwrites the costs of clinical trials and saves SMEs the high costs of investment in their own manufacturing plants. The continued presence of pharmaceutical company R&D in the UK is likely to be a critical factor in the continuing success of UK biotechnology. 44% of European entrepreneurial biopharmaceutical companies are UK based. The UK also has ten of the world's fifty highest capitalised companies.

2.18 The pharmaceutical industry is the biggest investor in R&D in the UK – 25% of the total; over £3 billion each year (amounting to some 15% of sales). Individual pharmaceutical companies are also the top three R&D spenders in the FTSE 100 companies (see Table 7).

Table 7 Top Pharmaceutical R&D Spenders Worldwide in 1997 (\$million)

Company	Pharma R&D spend % change ⁸	% pharma sales	
Glaxo Wellcome	1,882	- 1.1	14.4
Novartis	1,813	+14.7	18.6
Roche ⁹	1,760	+21.1	21.1
Pfizer ¹⁰	1,710	+12.4	16.0
Merck & Co ¹¹	1,684	+13.2	11.9
Eli Lilly ¹²	1,382	+16.2	16.2
Hoechst Marion Roussel	1,374	+10.3	17.0
Abbott ¹³	1,302	+ 8.1	11.0
Johnson & Johnson	1,285	NA	16.7
SmithKline Beecham	1,272	+17.0	17.5 ¹⁴
American Home Products	1,246 ¹⁵	+11.7	16.0 ¹⁶
Pharmacia & Upjohn ¹⁷	1,217	- 3.9	18.5
Bristol-Myers Squibb	1,200	+20.0	12.1
Astra ¹⁸	1,146	+23.9	19.5
Bayer ¹⁹	1,134	+13.0	14.4
Rhône-Poulenc	1,012	+ 3.5	17.7
Schering AG	913	+25.0	20.6
Schering-Plough ²⁰	847	+17.0	12.5
Boehringer Ingelheim	833	+23.0	20.7
Zeneca	721	+12.8	17.2

Source: SCRIP, 3.7.98

⁸ in domestic currencies⁹ includes over the counter (OTCs) products and Genentech¹⁰ includes hospital products¹¹ includes animal health/crop protection, excludes Medco sales of non-Merck products and Medco services¹² includes animal health and health care management¹³ includes nutritionals, hospital and laboratory products¹⁴ sales exclude DPS¹⁵ includes veterinary pharmaceuticals¹⁶ excludes infant nutritionals¹⁷ includes animal health, nutrition, diagnostics, chemical & contract manufacturing, and Biotech/Biacore¹⁸ includes medical devices¹⁹ includes consumer products and diagnostics²⁰ includes animal health and other health care products

2.19 In economic terms, the pharmaceutical industry is one of the most important in the UK. It contributes approximately 0.6% to total GDP and 3% of manufacturing GDP (almost £4.5 billion). It is among the UK's largest exporting sectors with exports in 1998 of £5.9 billion and a positive balance of trade of £2.4 billion. In 1998 pharmaceuticals was the third largest earner by trade surplus after North Sea oil and power generation equipment. The pharmaceutical industry provides direct employment of some 60,000 – a third of them in R&D – and 300,000 jobs overall associated with the industry.

2.20 The UK pharmaceutical industry is truly international in character, benefiting from long-term large scale foreign investment in addition to the UK-owned world class multi nationals Glaxo Wellcome, SmithKline Beecham and AstraZeneca (which remains UK registered and headquartered after the merger of Zeneca with Swedish-owned Astra). Overall, one third of the UK-based industry is UK-owned and a further one third US-owned (see Table 8). This international make-up has contributed to the UK pharmaceutical industry's record of consistently 'punching above its weight' internationally. It accounts for 7% (£11.5 billion) of world sales (fifth largest) although the UK itself represents only 3% of the world market; it is the third largest direct exporter of pharmaceuticals and has the third largest world trade surplus; and accounts for 10% of world pharmaceutical R&D expenditure.

Table 8 Pharmaceutical Companies in the UK

Pharmaceutical company	UK employment	World sales, 1998	Nationality	Type of work in UK
Glaxo Wellcome	14,000	\$13.2 bn	UK	M,R
AstraZeneca ²¹	15,000	\$12.7 bn	UK/Swe	M,R
SmithKline Beecham	8,300	\$7.7 bn	UK/US	M,R
Pfizer	3,400	\$11.8 bn	US	M,R
Bayer	3,000	\$4.8 bn	German	R
Rhone-Poulenc Rorer ²²	2,500	\$5.4 bn 1997	French/US	M,R
Roche	2,500	\$8.1 bn	Swiss	M,R
Eli Lilly	1,750	\$8.6 bn	US	M,R
Abbott Laboratories ²³	1,750	\$7.1 bn	US	M,R
American Home Products	1,500	\$8.1 bn	US	M,R
Novartis	1,400	\$10 bn	Swiss	M,R
Merck, Sharp & Dohme	1,300	\$15.3 bn	US	M,R

M = notable UK manufacturing presence

R = notable UK R&D presence

Source: Department of Health

²¹ Zeneca and Astra officially merged on 6 April 1999, forming AstraZeneca

²² Rhone-Poulenc and Germany's Hoechst are in the process of merging, to create "Aventis"

²³ World sales include nutritional products

2.21 Looking at products derived from biotechnology, the first medicine specifically developed using DNA technology (so-called recombinant medicine) was insulin. It was developed by the US biotechnology company Genentech and eventually brought to market in 1982 by Eli-Lilly (US). More than 50 biotechnology-derived products have received marketing approval and as many as 500 are in clinical trials. So far, biotechnology-derived products account for only 5% of the world medicines (by sales) but already represent 25% of new therapeutic entities in development (including those involving monoclonal antibodies). The majority are aimed at diseases for which there are no, or only unsatisfactory, treatments. Table 9 shows the biotechnology-derived products which were approved by the European Medicines Evaluation Agency during 1998.

Table 9 EMEA-Approved Biotechnology Products for Human use in 1998

Brand Name	Company	Therapeutic Area	Therapeutic Compound	Date of decision/validation
Primavax	Pasteur Merieux-MSD	Bacterial and viral combined vaccines	Combined vaccine	10/2/98
Rebif	Serono	Multiple sclerosis	Interferon beta-1a	5/5/98
MabThera	Hoffmann-La Roche	Stage III-IV follicular lymphoma	Rituximab	3/6/98
HumaSPECT	Organon Teknika	Imaging of carcinoma of colon or rectum	Votumumab	29/9/98
Simulect	Novartis	Prophylaxis of acute rejection in renal transplantation	Basiliximab	14/10/98
Triacellucax	Chiron S.pa	Pediatric vaccine for diphtheria, tetanus and pertussi	Bacterial vaccine	8/10/98
Infergen	Yamanouchi Europe	Chronic hepatitis C	Interferon alphacon-1	3/12/98
Forcaltonin	Unigene	Hypercalcaemia of malignancy and Paget's disease	Recombinant salmon calcitonin	20/10/98
Rescupase	Gruenthal GmbH	Thrombolytic therapy for acute myocardial infarction	Saruplase	22/10/98
Beromun	Boehringer Ingelheim Int.	Adjunct to surgery for sarcoma of the limbs	Tasonermin	19/11/98
Zenexpax	Roche Registration Ltd	Prophylaxis of acute rejection in renal transplantation	Dacliximab	16/11/98
Refacto	Genetics Institute	Control and prevention of haemorrhagic episodes	Recombinant factor VIII	17/12/98
Regranex	Janssen-Cilag Int	Healing of full thickness of diabetic ulcers	Becaplermin	17/12/98

Source: EMEA, London

Diagnosics

2.22 Diagnostics is a rapidly growing area of biotechnology application which offers prospects of radical improvements in speed and accuracy of diagnosis. As Table 10 shows, many of the fundamental discoveries that have led to the development of diagnostics as a business sector, were made by UK scientists. However, the UK has failed to exploit the R&D, with the consequence that the

large companies which dominate this sector are now foreign owned. Some, like Abbott Diagnostics (ex-Murex, Dartford), retain R&D teams in the UK, but the failure to capitalise on truly novel research in the UK serves to illustrate the need to find ways to ensure that we reap the economic benefit of biotechnology R&D which is currently being carried out here.

Table 10 Key Innovations in Diagnostics

Innovation	Date	Country of Origin
Radio immunoassay	1953	UK/US
Enzyme labels (ELISA)	1972	Netherlands
Monoclonal antibodies	1975	UK
Flow-through membranes	1976	UK
Time-resolved fluorescence	1979	UK
Enzyme amplification	1980	UK
Chemoluminescence	1980	UK
Enhanced luminescence	1982	UK
Biosensors	1970s	UK/US/Japan/Sweden
DNA fingerprinting	1984	UK
PCR Amplification	1985	US
Immunochromatography	1986	UK/US
DNA chip	1991	UK/US
Lab on a chip	1993	UK/US

Source: BIVDA

2.23 The worldwide market for health care diagnostics is static at about \$20 billion. The UK market of £300 million is just 1.5% of the world market but is still the fifth largest in Europe in value terms. The UK has 250 diagnostic companies but most are very small. The world market for diagnostics is dominated by large multi national companies with comparatively little UK-based activity and there is a trend towards further acquisition and merger which is set to exacerbate the dominance of large companies as they compete for market share. There is, however, an increasing trend for pharmaceutical majors to become involved in diagnostics R&D, based on developments in genomics knowledge.

2.24 There are a number of historical factors contributing to the relatively small UK domestic market for diagnostics. The NHS is the dominant purchaser of diagnostics allowing it to determine which products are offered and the prices paid (which are historically lower than elsewhere in Europe). Many European countries operate schemes in which the GP is reimbursed for the tests that are undertaken. In the UK, GPs have to pay for many of the tests and this may have the effect of keeping down the number of tests carried out. Many NHS

laboratories find it cheaper to develop and use their own assays for some tests. This may result in lower commercial sales. The increasing importance of product liability is likely to change this.

2.25 The Technology Foresight Programme concluded that the DNA diagnostics sector was likely to grow at a faster rate than pharmaceuticals and recommended increased investment because barriers to entry for small firms are comparatively few, and time to the market is considerably shorter than for pharmaceuticals.

2.26 Molecular diagnostics is expected to have a dramatic impact on health care delivery over the next decade in terms of enabling doctors to identify the most effective/safest/cost-effective therapy for a patient, taking into account that patient's unique characteristics; addressing the problem of antibiotic resistance; understanding the underlying causes of major disease symptoms; and predicting the likely course of a disease. Modern diagnostics already enables diagnosis to be made at an earlier stage of a disease before symptoms become pronounced. If treatment can begin earlier, then less tissue damage has occurred, the disease is likely to progress less far, side effects can be avoided, and the quality of life for the patient can be improved.

Health care

2.27 The section above describes the impact biotechnology is having on pharmaceutical developments. Biotechnology, and in particular applied genomics, is expected to revolutionise health care. It will make it possible to tailor treatments for each individual on the basis of knowledge from each person's genetic code (i.e. his/her predispositions for diseases, allergies and an understanding of which drugs will work most effectively for that individual); provide faster, more accurate diagnosis; and provide new methods of drug delivery. Other new developments nearing clinical trials include cell therapies involving xenotransplantation and the use of products from the milk of transgenic sheep – e.g. alpha-1-antitrypsin (AAT) as a potential treatment for cystic fibrosis. It is essential that the media and public are kept well informed by researchers and industry so that advances and new techniques can be fully discussed and their risks, implications and ethics fully explored. It will also be important for the NHS to prepare to adapt to novel approaches, where these are cost-effective, and to an increased emphasis on early diagnosis and preventative medicine. The NHS as a purchaser will set the pace for uptake of the new biotechnology in the UK. The National Institute for Clinical Excellence (NICE), which came into being in April 1999, will have an important part to play.

Agriculture and food

2.28 Biotechnology is already making an impact in almost every phase of the crop production cycle, in animal health, in research on diseases of livestock, and it offers promise for improving the sustainability and welfare of livestock as well as in product quality.

2.29 Of the applications of biotechnology to plants, the most promising applications are in crop breeding for growth in difficult climatic conditions, the analysis of host-pest relations, disease and pest diagnostics and crop protection. Genome mapping and the application of a better understanding of gene expression now underpins the development of more rapid conventional plant breeding. Plant breeders are better able to target the genes they wish to transfer and are able, quickly, to find out whether they have been successfully transferred. The new techniques will lead to more disease-resistant plants and pest-resistant plants with a consequent reduction in the use of pesticides. Nutritional properties of food crops can be improved (e.g. higher vitamin content) and their suitability for food processing and animal feed can be enhanced.

2.30 Diagnostic techniques are being developed to improve the targeting of pesticide application and to identify crops at a very early stage of risk of fungal attack, so that treatment is given only when needed rather than 'just in case', thereby reducing the amount of pesticides and fungicides required. Biotechnology has led to the development of new fungicides based on biodegradable natural products. Industrial biotechnology-based production of host, pest or predator products, or the production of pest pathogens, will make the possibility of biological control possible and will impact on pesticide use in broadacre crops.

2.31 Biotechnology-based R&D is contributing to improved knowledge of animal disease, including the mechanisms used by organisms to invade, colonise and cause disease in animals, and the ways in which animals respond to the pathogen, and how they control and kill and eliminate the disease-causing organisms.

2.32 The use of biotechnology in food processing and manufacturing was expected to grow but at present it has been stopped by retailers in response to consumer demand. Although few foods recently offered for sale in the UK offered an immediate benefit to the consumer, the technology has considerable long-term potential for improving the nutritional value, shelf life and flavour of foods in the future, and these benefits are expected to begin

appearing in the next generation of products. In addition, the development and use of high performing yeast, bacteria and enzymes will improve the efficiency of production processes and the quality of the final product. It remains to be seen whether the companies which are developing GM crops can convince European consumers of the advantages of the new crops and foods.

2.33 Biosensors offer the potential to help the consumer to know when food is fresh, uncontaminated and to assure its authenticity and traceability. Biosensors are being developed which will enable the measurement of very low levels of contaminants, including allergens, in foods. Very fast, very specific tests for microbial contamination of foods are also being developed which will enable the source of the contamination to be traced easily.

2.34 Table 11 shows sectors of the food and drink processing industry which depend significantly on biotechnology.

Table 11 Sectors of the Food and Drink Processing Industry that depend significantly on Biotechnology

Sector	Characteristics
Alcoholic drinks (wine; beer; cider; whisky)	Fermentation processes that depend on high performance yeast and adjuncts such as enzymes ; also process design and control (biochemical engineering)
Malted wheat and barley	Germination processes that depend on process adjuncts and process design/control of the malting process
Bread and other baked goods	Depends on high performance yeast and/or enzymes
Dairy products (yoghurt and cheese)	Depends on high performance lactic acid bacterial starter cultures and adjuncts such as enzymes for texture and flavour development
Fermented meats (e.g. salami)	Depends on high performance lactic acid producing bacterial cultures
Vinegar	Depends on high performance bacteria
Fruit juices	Assisted by enzymes that enhance extraction efficiency and improve clarity and flavour
Food flavours, preservatives and other special ingredients	Assisted by enzyme or cell culture mediated production
Starch based sweeteners (glucose syrups)	Depend on enzymatic processes
Cross cutting uses	Cleaning agents. Waste treatment processes. Sensors and diagnostics for cleanliness of plant and materials. Quality control from raw materials through to finished product; allergen tests; microbiological tests; authenticity tests; freshness indicators; other process indicators such as time-temperature indicators; basis for traceability.

2.35 Table 12 shows the economic importance of the UK agri-food industries. Taken together the whole sector, including retailing and catering, accounts for gross added value (GAV) of £63 billion (8.9% GDP) and provides 3.2 million jobs. Food and drink manufacturing accounts for GAV of almost £19 billion (2.6% GDP). Although the share of GDP is in long term decline, nevertheless, during the 1990s the industry has managed to slow the decline by introducing new high value added products and by increasing exports. Exports of processed food are worth £9 billion and make up over 5% of UK exports – this includes £3 billion for alcoholic drinks, amongst which is Scotch whisky. Estimates of the value of agricultural biotechnology worldwide over the next 20-25 years vary from \$50 billion to \$500 billion and with most estimates at around \$100 billion.

Table 12 Economic Importance of the UK Agri-food Industries: 1997

	Employment thousands	Gross Domestic Product		
		% of total £ billion	% of total	% of total
Agriculture	527	2.0	7.6	1.1
Fishing	19	0.07	0.6	0.1
Food and drink manufacturing	450	1.7	18.8	2.6
Food and drink wholesaling	215	0.8	5.7	0.8
Food and drink retailing	894	3.4	19.2	2.7
Catering	1,103	4.2	11.4	1.6

Source: MAFF

2.36 Crops for non-food use are also being developed (not all of them are genetically modified). These offer interesting alternatives to other, often non-renewable, resources and for novel production methods, for fuels, fibres, chemicals and pharmaceuticals. This is an area of considerable potential for UK biotechnology and, also, for sustainable development. Researchers, industry and Government need to assess the potential risks and benefits and to conduct an informed debate with the public and users.

Chemicals

2.37 The UK chemical industry has annual world sales of around £33 billion. More than half the chemicals produced are exported producing a net surplus of over £4 billion per year to the UK economy. The sector of the industry which stands to gain most from applying biotechnology in its processes is specialised organic chemicals – the sector has an annual turnover of £4-£6 billion in the UK. Another sector which similarly concentrates on high value, low tonnage chemicals is the speciality chemicals sector, which includes a higher proportion of SMEs. This diverse sector manufactures dyes, pigments, varnishes and paints, soaps, detergents and pharmaceutical intermediates. This sector is

starting to use biotechnology. Speciality chemicals account for over 45% of total UK sales – £15 billion per year. The sector operates on some 1,200 sites throughout the UK. The chemicals manufacturing sector has significant potential for greater use of biotechnology at all stages of manufacture – from raw materials; use of biotransformations in manufacturing processes; use of biotechnology in clean-up and effluent treatment, abatement of pollutants, and in solid waste disposal. Biotechnology often provides processes which require less energy and which yield fewer waste products. OECD figures already show a 20% reduction in waste by using biocatalysts in the fine chemical industry despite a four-fold increase in chemical output.

Environmental biotechnology

2.38 Biotechnology provides methods to make industrial processes cleaner for 'end-of-pipe' clean up, and for environmental clean up – for example after oil spills at sea and similar incidents. Naturally occurring plants and micro-organisms play an important part in clean up processes for treatment of discharges to air and water and for remediation of contaminated land. Some genetically modified organisms are used in biosensors for monitoring specific pollutants in effluent. A LINK project has produced an assay based on ecologically relevant bacteria which is more sensitive and reliable than current toxicity tests for measuring the quality of industrial effluent. The biosensors have proved suitable for testing diverse waste streams including industrial and domestic sewage sludge, a whisky distillery and paper mill effluent. The market has been stimulated by regulation and tighter environmental controls. The regulatory regime in Germany led to the development of a strong environmental sector there which is still well ahead of that in the UK. Biotechnology finds environmental applications in many industrial sectors including food processing, chemicals, textiles, paper, leather and in manufacturing engineering. The Natural Environment Research Council (NERC) is developing an environmental genomics programme in collaboration with other Research Councils, especially the BBSRC.

2.39 In the UK, the sector is small but is growing: the UK has some 100 specialist companies in the environmental biotechnology field employing 6,000 people. Environmental biotechnology is estimated to account for about 20% of the whole of the environmental products and services market – i.e. some \$75 billion in 2000. The UK has a trade surplus in the sector as a whole – \$502 million in 1995. The UK market is currently estimated at up to \$2.75 billion per year.

Chapter 3

Future scenarios

3.1 In 1997, the European Trade Association, EuropaBio, published a report on the European industry.²⁴ The report set out four scenarios for the future – looking forward to possible scenarios in 2005 and taking 1995 data as their starting point. Table 13 shows their forecasts. The three key external business factors which they factored in were: the market conditions (favourable or not); whether effective protection of IP exists; and the framework of regulatory controls, since that is important in determining where biotechnology takes place and the extent to which companies use it in their products and production processes.

Table 13 Europabio – Scenario Outcomes: Value of Products using Biotechnology

<i>(Ecu billion)</i>	1995	2005			
		Scenario A	Scenario B	Scenario C	Scenario D
Human Health care	8	32	40	27	13
Agriculture	5	60	105	17	0
Food & Drink	17	35	70	18	6
Chemicals	9	12	12	12	5
Materials Processing	0	7	12	5	0
Environment	1	4	11	1	1
Total	40	150	250	80	25

3.2 The four scenarios were as follows: –

A) **The base case**, based on steady development. This assumed a marginally more supportive business environment than was the case in 1995, notably assuming that consumers and producers had ‘become more comfortable with biotechnology’; adequate patent protection and regulatory framework which imposed no additional constraints on R&D, production or marketing. This scenario assumed that the main areas of growth would be pharmaceuticals (increased use of biotechnology in production and sales); agriculture (steady growth in the use of enzymes as processing aids); and pulp and paper (use of

²⁴ Benchmarking the Competitiveness of Biotechnology in Europe, June 1997. An independent report for EuropaBio by Business Decisions Limited and the Science Policy Research Unit, University of Sussex

enzymes in manufacturing). This scenario also anticipated continuing activity by European Governments to ensure that Europe's business environment maintained its position relative to the US.

B) **Fast development**, based on rapid improvements in consumer and manufacturer attitudes; a generally favourable regulatory environment; favourable health economics regimes stimulating rapid penetration of novel biotechnology products in the European pharmaceuticals sector; WTO favouring biotechnology in agriculture, and CAP reform. It also assumed considerable pressure for a "cleaner environment". Under this scenario the principal additions over the base case would be greater use of new plants and improved animal feed, and greater use of biotechnology in the manufacturing of food and drink. Under this scenario it is assumed that other parts of the knowledge-based industries would develop faster as a result of faster growth in the use of biotechnology in Europe.

C) **Limited development** This scenario assumes little change with only relatively slow uptake of biotechnology in production. It also assumes that the competitiveness of European companies declines relative to those in the US. It assumes rates of growth in agriculture, food and drink which are slower than in the base case.

D) **Failed development** This scenario assumes that the external business environment is very hostile to biotechnology and that consumer attitudes deteriorate (compared with 1995). It also assumes that manufacturers perceive little benefit in trying to overcome consumer resistance to biotechnology. The model also assumes tighter controls on pharmaceutical pricing and little use of advanced methods of health care management, thus significantly reducing the penetration of novel biopharmaceuticals. Under this scenario European companies could lose competitive position relative to US companies. Europe would face the risk of rising imports from the US and elsewhere. The competitive position of European agriculture and industry would decline and consequently exports to third countries would fall substantially. In this scenario the value of goods and services using biotechnology falls by nearly half between 1995 and 2005, because biotechnology is virtually eliminated from agriculture, food and drink sectors. Only in human health care is there any increase in sales. The lack of investment in biotechnology would also damage prospects for other new knowledge-based industries.

3.3 The scenarios included estimates of employment related to biotechnology. The figure for 1995 was 300,000 – 400,000. The scenarios pointed towards a range from a decline in scenario D to an increase to over 3 million employed under scenario B.

3.4 Now that we are in the second half of 1999 it seems as though we are falling somewhere between scenarios A and C. The main dampening factor has been European public and consumer opinion which has led to food manufacturers and retailers turning against GM products. It is realistic to anticipate that the value of biotechnology products will reach ECU100 billion and that 1 million jobs throughout Europe will be based on biotechnology.

Chapter 4

Barriers to development in the UK

Public perception

4.1 Public acceptance of biotechnology, across the wide spectrum of potential application areas, will hinge ultimately on the success of its products and services in the market place. At present there are relatively few products on the market. Unfortunately, the future prospects for biotechnology have yet to be demonstrated and the public will rightly need to be convinced of the genuine benefits. The decisions by all the major retailers and food manufacturers to phase out the use of GM materials in processed foods shows their commitment to respond to consumer demand. It seems likely that the debate will continue throughout Europe for at least 2-3 years before the situation clarifies in terms of GM food and crops. It is to be hoped that the wider application of biotechnology, to the benefit of consumers and companies, will ultimately be realised.

Financial and investment issues

4.2 Within the UK, we are starting to face a problem over future funding for our growing SMEs. Each start-up needs £2–£5 million within a year, while it continues to research and has no revenue. If we have 50 new companies in the UK there will be a requirement for £100–£250 million of investment capital to cover that. These companies need re-financing in their 3rd or 4th years and each will need between £5 million and £10 million: the requirement at the UK level is for £250–£500 million. Beyond that, if the successful companies with products about to enter the market want to grow and perhaps even manufacture themselves, they will need a further £10–£20 million from a private placing or IPO. All this points to a need in the UK for between £800 million and £1.8 billion of investment over the next 5 years. Unless we can persuade institutional investors to invest more in the biotechnology sector, it is difficult to see how such sums could be raised. There might be some attraction in encouraging US venture capitalists to consider investing in the UK – they would bring with them different ideas about rates of growth of companies and different strategies of consolidation. Such re-invigoration of the UK venture capital base is seen as highly desirable by some established UK companies who are currently facing an increasingly difficult financing environment in the UK.

4.3 Companies and financial investors have identified the following specific problems facing the biotechnology sector: -

- Lack of seedcorn funding for initial work in start-ups – i.e. funding of up to £250,000 to enable them to work up business plans and be well prepared as they go on to seek venture capital.
- Lack of seedcorn and venture capital for environmental biotechnology ideas.
- Maximum award under the SMART scheme for feasibility studies is too small at £45,000.
- Need for improved access to business angels.
- Need for increased provision of advice and mentoring for start-ups and spin-outs.
- Need for improved quality and expertise in advisers helping Universities and other researchers to manage and exploit IP and to effect transfer of technology.
- Scarcity of experienced managers for biotechnology companies. The UK needs to attract top quality managers from overseas (particularly from the US) to help to take emerging UK companies through the next stages of growth. Incentives need to be examined.
- Stock Exchange listing rules²⁵ need to be reviewed to ensure they are better adapted to the needs of emerging companies and to those working in novel fields such as genomics.

The Government has, however, already introduced a number of measures to encourage investment in SMEs with a particular emphasis on high-technology based businesses, including Venture Capital Trusts, and tapered relief on Capital Gains Tax. The Government has also announced plans for the UK High Technology Fund and Regional Venture Capital Funds. The details of a number of further measures were announced in the Autumn 1999 Pre-Budget Report (see footnote 1) – these include further proposed changes to Capital Gains Tax, the proposed R&D Tax Credit, support for Corporate Venturing and targeted tax incentives to help recruit and retain key staff through equity remuneration.

²⁵ Chapter 20 and proposals for a new Chapter 25

Planning and accommodation

4.4 Lord Sainsbury's team, who looked at biotechnology cluster development, highlighted the problems which are being faced by small companies as they grow. In the UK the normal terms for leasing industrial premises are to enter into a 10 year lease. This causes problems for small companies (in any sector) because they may outgrow their premises and find it difficult and costly to move. This is in stark contrast to the position in the US where leasing agreements are more flexible. Some University accommodation and some science parks in the UK offer the flexibility which start-up companies need.

4.5 In some areas of the country it is difficult for academic spin-out companies to find laboratory space. This shortage is being addressed as 'incubator' facilities are developed – some of these have been purpose built (e.g.: Manchester and Newcastle), while in other areas laboratory space is being refurbished with the needs of biotechnology start-ups in mind (such as the Porton Down Science Park and Babraham Institute).

4.6 Companies often start off near the academic institution from which their IP or expertise is derived. In some areas of the UK, flourishing technology clusters are developing, particularly around Cambridge, Oxford and in central Scotland. It is natural and appropriate for the companies to want to grow in the place where they are established and where they have synergistic links with other companies in the cluster. However, planning permission for expansion has not been easy to obtain in some cluster locations. The needs of growing high technology businesses are being addressed as part of the reviews being undertaken by the Department of the Environment, Transport and the Regions, and the Biotechnology Clusters report made specific recommendations about the way in which areas might be designated for cluster development.²⁶

Manufacturing for biotechnology

4.7 The next few years will see a major change as specialist biotechnology companies in the UK start to move beyond research and development into the manufacturing phase. There is a perceived lack of suitable contract manufacturing facilities in the UK for some biotechnology products, which is already seeing some companies being forced to meet their requirements overseas. The DTI has commissioned a consultancy report²⁷ to assess the

²⁶ In conjunction with the Autumn 1999 Pre-Budget Report (see footnote 1) the Deputy Prime Minister announced further changes to the planning system to strengthen support for the development of clusters

²⁷ The supply and availability of facilities to manufacture biopharmaceuticals for pre-clinical and early stage clinical trials: MfB website <http://www.dti.gov.uk/mfb>

future manufacturing requirements for different types of molecule and to look at the existing and planned manufacturing capability in the UK to see whether there is, in fact, any gap in provision. If products are going to come to market they have to go through stringent approvals procedures, or clinical trials in the case of pharmaceuticals. Academic start-up companies have little knowledge of the quality standards and approvals procedures needed to permit products to be used in clinical trials. Teaching about Good Manufacturing Practice and the role of regulatory authorities (like the US FDA, the British MCA and the European EMEA) might usefully be included in undergraduate courses.

International threats

4.8 Most developed, and many developing, countries have identified biotechnology as the next industrial revolution and many Governments are putting in place policies and schemes of assistance to attract pharmaceutical and biotechnology companies to move into their countries. In addition, many Governments have introduced systems of loans or guarantees for start-up and SME biotechnology companies. Other countries, or regional authorities, have decided to build accommodation which combines office and laboratory space to attract small biotechnology companies.

4.9 Table 14 (see pages 32-33) gives some illustrative examples of the incentives offered by other countries. Ireland has been very successful in attracting pharmaceutical companies. With its population of only 3 million people, Ireland has attracted £1.3 billion of capital investment by the pharmaceutical industry since 1990. In 1996-7, £428 million was invested by existing inward investors in expansion. 9,000 jobs have been created. Ireland is also starting to focus on biotechnology R&D with a view to attracting more scientists and start-ups.

4.10 Starting from a very low base 5 years ago, Germany has announced that she wants to be the leader in Europe in biotechnology by 2000. Through a regionally based competition (Bio-Regio), recent German Governments have successfully stimulated an exceedingly rapid burst of activity and hundreds of new, small start-up companies have been set up. Germany now has nearly 220 small biotechnology companies. However, some commentators have stated that Germany still remains a long way behind the UK because the total investment in each start-up averages only £250,000, whereas many UK SMEs have progressed well beyond that stage. Germany has not yet developed the venture capital base of the UK but has the advantage that institutional investors and high street banks are more prepared to back risky biotechnology ventures.

We are also starting to hear of UK venture capitalists setting up offices in Germany; that implies that German start-ups may compete for UK funds. In July 1999, Germany announced a range of measures to build up strength in the crucial discipline of bioinformatics.

4.11 France has signed a formal Government to Government agreement with Germany to work together on biotechnology but there is little tangible evidence of collaborative projects as yet. France has some medium-sized companies in niche markets in biopharmaceuticals/vaccines and in genetic databases as well as some Government-funded groups. The Government is taking action to encourage greater entrepreneurial activity amongst researchers and recently announced a specific biotechnology scheme.

4.12 Sweden and Switzerland are advertising widely their rapidly growing biotechnology industries (Sweden claims to be 3rd fastest growing). Their regions offer grants and incentives for start-up and developing bioscience companies. Both have major pharmaceutical companies and excellent skilled workforces and offer attractive working conditions. In Canada the Government has committed CDN\$250 million to Genome Canada in the period 1999-2004 with the aim of achieving "genomics pre-eminence".

4.13 There is an enormous range of Government and private sector activity in biotechnology in the US.²⁸ The US is far ahead of the UK – it has 10 years more experience; its biotechnology companies and venture capital are far more mature. Lord Sainsbury's study of biotechnology clusters looked at lessons which can be learned from the US. There are some well established regional clusters within which Federal and State funding can be obtained for assistance with buildings (e.g. rent-free accommodation including purpose-built biotechnology manufacturing facilities), as well as more traditional types of grants and a range of tax exemptions. States are keen to attract biotechnology companies and many of the most promising UK SMEs are being courted with attractive incentive packages.

4.14 Japan announced in July 1999 a five year (£3–£10 billion) programme to expand the biotechnology market by a factor of 25 by 2010 and support for 1,000 new biotechnology companies. The programme is in response to a number of areas of weakness both in technology and in entrepreneurial business venturing in Japan. Japan is also leading international efforts to

²⁸ See paragraph 1.8 for statistical details on the US biotechnology sector

sequence the rice genome and is planning to provide additional funding to complete its own sequence by 2004. China is stressing the importance of commercialising S&T and agriculture (including genetic modification) is the top priority for the next 5 year plan. Health is also a priority and recent changes in the pricing regime for drugs were designed to make China more attractive as a manufacturing (and R&D) base for multi national pharmaceutical companies. China has 20 biotechnology health care products on the market and has large commercial plantings of 6 GM crops (cotton, tomatoes, virus-resistant sweet peppers) amounting to 100,000 hectares. 10 more licences are expected by the end of 1999. Two types of transgenic fish are undergoing 'field' trials and, like the UK, the Chinese are working on transgenic sheep and pigs. There is very little public concern about any of this work in China. The Chinese Government has recently created two human genome centres.

Table 14

	UK	Ireland	France	Germany	Netherlands	Puerto Rico	Singapore
Applicable corporate tax rate	<i>Current position</i> 30%. – 20% for SMEs. – new 10% rate from April 2000 for profits up to £10,000, companies with profits up to £50,000 benefit as 10% rate tapers up to 20% for profits between £10,000 and £50,000.	<i>Current position</i> 10% rate applies to existing projects (or expansions of existing projects) until 2010. The 10% rate can be obtained on new projects until 2003, but there is an annual quota of 77 companies. New applications need to be approved by the Industrial Development Association (IDA). 28% – standard rate of corporate tax. From 1 January 2003 the standard rate will be 12.5% and it is expected that there will be annual reductions between now and 2003.	<i>Current position</i> 40% including surcharges.	<i>Current position</i> 40% on undistributed profits. 30% on distributed profits.	<i>Current position</i> 35%.	<i>Current position</i> Progressive rate from 20% to 39%. Those qualifying for industrial exemption can obtain a 90% exemption on net income.	<i>Current position</i> 26%.
Depreciation and Capital allowance (for tax purposes)	Depreciation is ignored for tax purposes: instead capital allowances used: Plant & equip – 25% ^{**} . New indust'l bldgs – 4%. Scientific research cap-ex – 100%. capital allowances for SMEs: 40% 1st yr until July 2000. ^{**} plant & equip with a life > 25yrs+ based on original est'd life, not life left on acquisition – 6%. This does not apply if annual expenditure is less than £100,000: then 25% rate applies.	Book depreciation is not deductible. Instead straight line allowances at following rates: Industrial bldgs – 4%. Plant and eqpt – 15%. Accelerated allowances on bldg expenditures in certain designated areas (e.g. Shannon).	Business can use one of three methods: 1. Straight line. 2. Declining balance. 3. Exceptional (100% for certain items). There are also tax credits for: Increase in R&D expense (50%), increase in training expense.	Straight line or declining balance methods permitted. From 1999, the depreciation method of tax allowance is not expected to be available (subject to final approval).	Straight line or declining balance. Flexible, accelerated allowances for certain investments (environmental or energy related).	Normally straight line.	Depreciation is not allowed. Instead the following tax allowances are permitted: <i>Industrial buildings</i> – initial allowance – 25%; annual allowance – 3%. <i>Plant and machinery</i> – initial allowance – 20%; annual allowance – 33.33% (straight line basis). Approved know-how and patent rights. Computer, prescribed automation equipment, highly efficient pollution control and energy efficient equipment – 100%.

Table 14 (continued)

	UK	Ireland	France	Germany	Netherlands	Puerto Rico	Singapore
Incentives and grants	<p><i>Current position</i></p> <p>Proposed R&D tax credit for SMEs from April 2000.</p> <p>Discretionary cash grants available to support capital expenditure projects creating jobs in designated zones.</p> <p>Award ceilings range from 15% to 30% depending on location.</p> <p>Additional training incentives can be available.</p> <p>DTI schemes including SMART awards.</p>	<p><i>Current position</i></p> <p>Discretionary cash grants are available to support capital expenditure jobs anywhere in the country.</p> <p>Theoretical award ceilings for new projects range from 45%-60% depending on location.</p> <p>Additional training incentives available.</p>	<p><i>Current position</i></p> <p>Discretionary cash grants available to support capital expenditure projects creating jobs in designated zones.</p> <p>Award ceiling between 17% and 34% depending on location.</p> <p>In addition, local and national training and tax incentives can be available, particularly if there is an R&D element to the project.</p>	<p><i>Current position</i></p> <p>Discretionary cash grants available to support capital expenditure projects creating jobs in designated zones. Jointly funded by Federal and Länder Governments.</p> <p>For large companies (not SMEs) award ceilings range from 18% in certain western areas to 35% in eastern Germany.</p> <p>Additional training incentives can be available.</p>	<p><i>Current position</i></p> <p>Incentives largely tax based, but cash grants can be available particularly in the north of the country. Award ceilings in these areas is 20% of eligible costs.</p>	<p><i>Current position</i></p> <p>Basically 90% tax exemption for a period of up to 10 years (more in some industrial zones).</p> <p>This incentive programme started in 1987 and so early adopters may be close to losing tax exemption.</p>	<p><i>Current position</i></p> <p>Various types of tax incentives are awarded to new and expansion projects.</p> <p>Main incentives are:</p> <p><i>Pioneer Status:</i> exemption of corporate tax on profits arising from pioneer status. Tax relief period ranges from 5 to 10 years.</p> <p><i>Development & Expansion Incentive:</i> corporate tax rate of 15% for up to 10 years with provision for extension.</p> <p><i>Investment Allowance:</i> exemption of taxable income of an amount equal to a specified proportion (up to 50%) of new investment in productive equipment.</p> <p><i>Expansion Incentive:</i> exemption of corporate tax on profits in excess of pre-expansion level. Tax relief period of up to 10 years with provision for extension.</p> <p>The requirements to qualify for the above incentives must be carefully checked with the project. Not all incentives listed above can be combined. Some other tax-related incentives, such as exemption from real estate taxes, can extend the total incentive package.</p>

Chapter 5

What does industry want from Government?

5.1 In consultations with pharmaceutical companies, agri-chemicals and food manufacturers, SMEs, venture capitalists, potential users of biotechnology and academics starting to set up companies, the following issues emerged as those which industry would like to see Government address to support the biotechnology sector. Industry would like to see coherence across the wide range of policies which affect biotechnology:

- Long term support for the science base in bioscience.
- A balanced regulatory regime in the UK, EU and internationally which encourages industry while at the same time ensuring public and environmental safety.
- A fiscal regime which encourages investment in the sector and provides attractive incentives to those who risk their own capital.
- A discriminating and informed NHS which considers fully the potential benefits of novel treatments and helps to pull through commercial opportunities while taking into account evidence of clinical and cost effectiveness. A willingness for Government Departments and industry to work together to consider how clinical, purchasing and prescribing practices might evolve as a result of scientific progress.
- Availability of NHS information for research purposes within an appropriate ethical framework.
- Changes in school curricula to encourage young people to study biological sciences and to make them informed consumers; provision of modern biological research equipment into schools and especially into Universities to prepare the generation who will reap the benefits of the biotechnology revolution. Better targeted courses to meet the future skills needs of industry. More competitions to encourage entrepreneurship among degree and postgraduate students.
- Strengthened technology transfer machinery and better quality teams to manage publicly-funded research for the economic benefit of the UK.

Chapter 6

Government activities which support biotechnology

6.1 The Government keeps under review the fiscal climate of the UK. Some measures announced in the 1999 Budget were designed to stimulate high technology companies and these measures have been welcomed by the biotechnology trade associations. One of the most helpful measures was the R&D tax credit since most biotechnology SMEs continue to spend on R&D for many years before they become profitable. Schemes such as University Challenge, Science Enterprise Challenge, Faraday Networks, Reach Out Funds, the DTI Enterprise Fund (regional venture capital and a high-tech challenge fund), and the Enterprise Management Incentives all provide mechanisms which help the exploitation of bioscience and start-up companies in biotechnology.

6.2 DTI acts to encourage industrial exploitation of biotechnology, to sustain and enhance UK industrial competitiveness, and deliver the economic and quality of life benefits which the technology offers. DTI has already taken a number of actions including a study, under Lord Sainsbury's leadership, of the dynamics of biotechnology clusters which identify barriers to development and proposed actions. DTI has set up a number of schemes to assist knowledge transfer and help young biotechnology companies start up and grow, including:

- encouraging the biotechnology community to use Government schemes such as LINK, SMART, EUREKA and EC Framework programmes (currently 70 biotechnology R&D projects are being supported);
- the Biotechnology Exploitation Platforms (BEPs) Challenge which enables groups of Higher Education Institutions and public research institutes to obtain specialist advice about all aspects of IP and helps them to manage their knowledge and exploit it effectively;
- the Biotechnology Mentoring & Incubator (BMI) Challenge which stimulates the creation and growth of quality biotechnology companies by supporting intermediaries who provide specialist advice and hands-on assistance and specialist laboratory and office space;
- the UK Biotechnology Finance Advisory Service (FAS) which provides free confidential advice on obtaining funding for new and existing biotechnology companies;

- the Manufacturing for Biotechnology initiative which helps SMEs devise their own manufacturing strategy and improve their knowledge of manufacturing and its regulation. The programme also includes a study of the future UK needs for the manufacture of different types of biotechnology products;
- the BIO-WISE programme which encourages companies in a wide range of sectors to use biotechnology to reduce costs and improve competitiveness and to introduce environmentally cleaner processes. The programme includes demonstrator projects.

6.3 DTI also maintains a close contact with industry on regulatory issues, including chairing a quarterly industry/Government group (Biotechnology Industry/Government/Regulatory Advisory Group) to discuss regulatory developments at a national, European and international level. DTI also ensures that industry concerns are included in inter-departmental discussions to work out an overall UK position. DTI has been encouraging industry and trade associations to be more pro-active in explaining their work in biotechnology to the media and to wide public audiences, including patient groups and young people, with the aim of encouraging a well-informed debate involving all stakeholders. DTI has organised a UK seminar and an EU-level Round Table involving producers, retailers, the science base, environmental and consumer organisations. DTI is working to promote better communication between entrepreneurs and investors; acting as a catalyst for the development of regional networks to underpin the growth of the biotechnology SME sector; and contributing to the development of Government policies which affect sources of finance for biotechnology SMEs. DTI also works with national and regional inward investment bodies, other sponsor Departments, (especially the Department of Health) and individual companies to attract, and retain, internationally mobile investment.

6.4 There are also a number of working groups which have been looking at issues of importance to the sector – for example on exploiting IP from public sector research organisations. The DTI's group on intangible assets is developing best practice and means to measure intangibles to improve the flow of finance to firms, like those in the biotechnology sector, which have few tangible assets.

Chapter 7

Conclusion and key areas for action in the UK

7.1 The UK has the essential strengths in the bioscience base, together with an increasingly entrepreneurial culture, to make it well placed to maintain its lead in Europe in the exploitation of biotechnology. There are, however, a large number of key actions which will be critical to continuing success (Figure 2). It will be important for Government to continue to monitor all these factors and to take action to ensure that the entrepreneurial, fiscal and regulatory frameworks are set in a way which makes the UK the chosen location for major internationally mobile investments in biotechnology.

Figure 2 Key Areas for Action in the UK

Social and Culture

- Industry and Government to find ways to increase informed public debate about potential risks and benefits of biotechnology, and about ethical and social issues.

Research

- maintain long term investment by Government, Trusts and charities in the bioscience base in the UK;
- increase public confidence in science;
- continue to consider the ethical, confidentiality and practical issues surrounding bioscience research, including use of NHS clinical records and tissue banks in genomics research.

Education and Training

- build on world-class centres in the UK – use them as a magnet to attract further research groups and to “feed” industry;
- introduce entrepreneurship in science degree courses (particularly through the Science Enterprise Challenge);
- ensure training at all levels – technician to postgraduate – is meeting industry requirements;
- stimulate excellent biologists and mathematicians to go into bioinformatics;
- encourage HEIs to devise more specialist courses and modules in science communication, regulatory affairs, commercial and financial aspects of business;
- develop biotechnology and biochemical engineering elements in undergraduate courses, together with teaching about manufacturing methods, quality control and regulation;
- consider the need for a biotechnology GCSE, learning from experience with the Scottish Higher.

Figure 2 Key Areas for Action in the UK *(continued)*

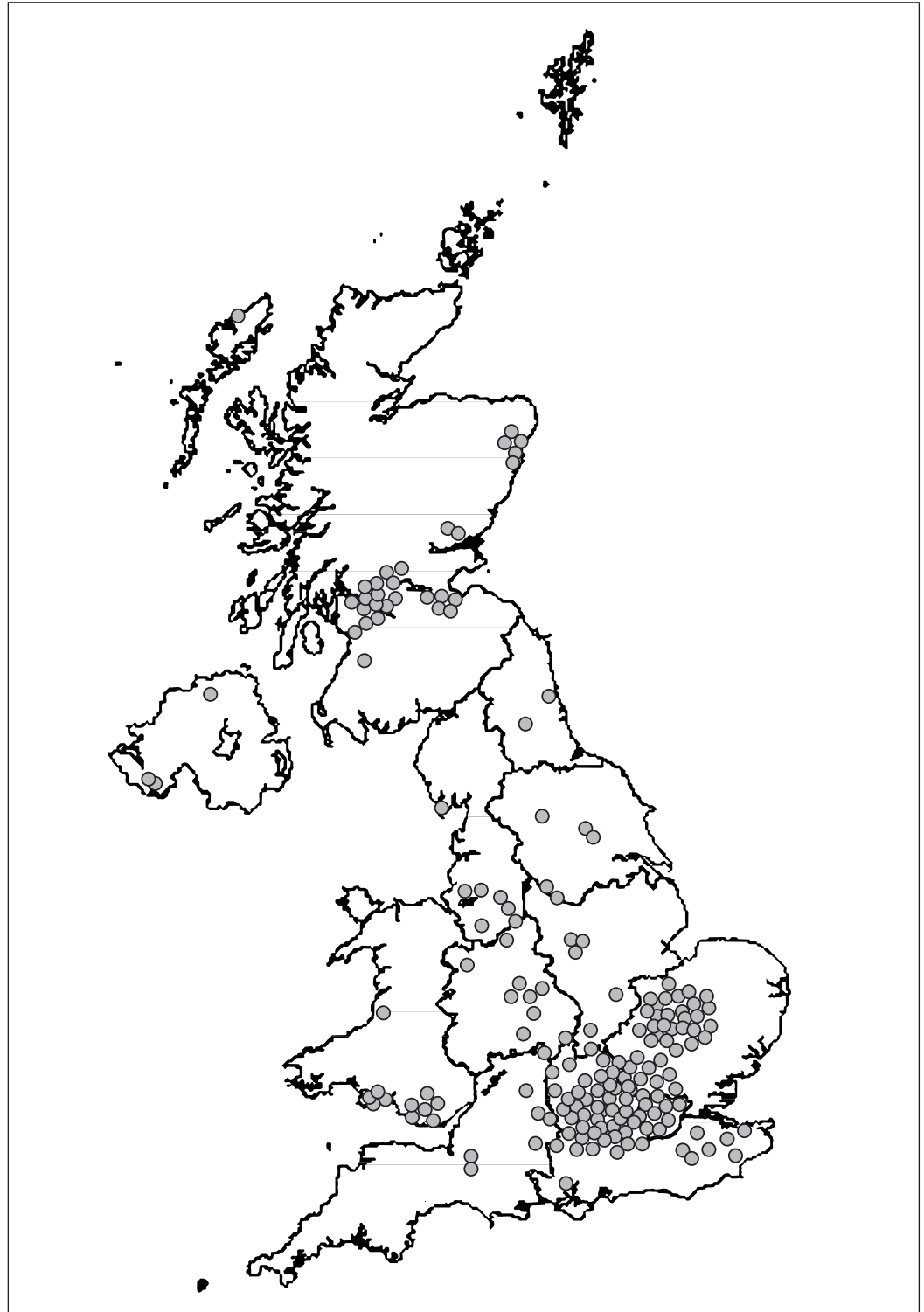
Enterprise

- create a UK business and fiscal environment to attract, and retain, internationally mobile investment in biotechnology, and to retain pharmaceutical R&D and growing biotechnology companies here;
- get conditions right for all stages of development of biotechnology companies, i.e.:
 - ensure that the regulatory framework (international, EU, UK) has safety and environmental concerns as paramount but allows innovation to continue;
 - an appropriate system of patent protection;
 - clarify ownership of IP derived from publicly funded research so that exploitation is facilitated;
 - improve the quality of knowledge transfer to identify and exploit public sector IP;
 - continuously adjust and improve the finance and entrepreneurial climate;
 - develop tax incentives for founders and investors and for key top managers;
 - keep Stock Exchange regulations under review;
 - improve the availability of property – need for incubators, laboratory premises, shorter flexible rental agreements;
 - provide mentoring for start-ups;
 - ensure that adequate biotechnology manufacturing facilities exist in the UK.
- stimulate companies to use biotechnology (for example in energy efficient, cleaner processes).

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Location of UK specialist biotechnology companies



Source: Based on Ernst & Young 1999

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Public centres of research excellence relating to biotechnology

i) RAE rating of disciplines impacting on biotechnology⁽¹⁾

Institution	1996 Rating	Flagged Research Groups
Clinical Laboratory Sciences⁽²⁾		
Institute of Cancer Research	5*	
Royal Postgraduate Medical School	5*	
University of Oxford – Dunn School of Pathology	5*	
Institute of Cancer Research	5	
London School of Hygiene & Tropical Medicine	5	Parasite Chemotherapy and Molecular Diversity (Biochemistry and mode of drug action); Clinical Epidemiology and Control (Entomology – control of malaria vectors)
University of Birmingham	5	
University of Cambridge	5	
University of Oxford – Clinical Laboratory Sciences	5	
Imperial College of Science, Technology and Medicine	4	Immunology; Bacterial Pathogenicity
Royal Free Hospital School of Medicine	4	
University College London	4	Magnetic Resonance; Near Infrared Spectroscopy
University of Bristol	4	Immunology
University of Dundee	4	Molecular and Environmental Toxicology
University of Edinburgh	4	Human Genetics Group; Human Cancer Biology Group; Cell and Tissue Injury Group
University of Glasgow	4	Parasite Immunology; FC Receptors Group
University of Southampton	4	Human Genetics
University of Wales School of Medicine	4	Biochemical Immunology; Medical Genetics
University Aberdeen	3a	Medical Genetics; Biomedical Physics and Bio-Engineering
University of Leeds	3a	Molecular Medicine (inc Histopathology)
University of Leicester	3a	Microbial Pathogenicity

⁽¹⁾ Centres of excellence as those departments rated 5*, 5, or 4

⁽²⁾ 3a rated departments included as centres of excellence

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	1996 Rating	Flagged Research Groups
University of Liverpool	3a	Microbiology (snake venom); Parasitology and Entomology (insect immunity and molecular genetics); Reproductive Immunology Group
University of Newcastle	3a	Human Genetics; Clinical Genetics 5* rated
University of Nottingham	3a	Haematology

Pre-clinical studies

Imperial College of Science, Technology and Medicine	5	
King's College London	4	Developmental Biology; Allergy and Asthma
St George's Hospital Medical School	4	
United Medical and Dental Schools	4	Developmental Neurobiology; Cardiovascular Research Group
University of Manchester	4	Cell-Cell Interactions

Physiology

University of Liverpool	5*	
University of Bristol	5	
University of Cambridge	5	
University of Newcastle upon Tyne	5	
University of Oxford	5	
University College London / Royal Free Hospital School of Medicine	4	Exocytosis and Cell Signalling; Transmitter Transport Processes
University of Birmingham	4	

Pharmacology

University College London / Royal Free Hospital School of Medicine	5*	
University of Leicester	5*	
University of Bristol	5	
University of Cambridge	5	
University of Liverpool	5	
University of Oxford	5	
Queen Mary and Westfield College	4	
University of Dundee	4	

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	1996 Rating	Flagged Research Groups
University of Edinburgh	4	Systems Neuroscience
University of Nottingham	4	

Pharmacy

University of Nottingham	5*	
Institute of Cancer Research	5	
School of Pharmacy	5	
University of Bath	5	
University of Manchester	5	
University of Wales, Cardiff	5	
King's College London	4	
University of Strathclyde	4	

Other studies and professions allied to medicine

University of Southampton – Nutrition	5*	
University of Strathclyde	5*	
University of Ulster – Biomedical Sciences	5*	
Loughborough University	5	
University of Surrey – Toxicology	5	
University of Wales, Cardiff	5	
Aston University	4	
King's College London – Gerontology	4	
King's College London – Nutrition	4	
Napier University	4	
Sheffield Hallam University – Biomedical Sciences	4	
UMIST	4	
University of Bradford – Biomedical Sciences	4	
University of Bradford – Optometry	4	
University of Glasgow	4	
University of Greenwich	4	
University of Portsmouth	4	
University of Surrey – Nutrition	4	

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	1996 Rating	Flagged Research Groups
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Biochemistry⁽²⁾

University of Cambridge	5*	
University of Dundee	5*	
University of Oxford	5*	
Imperial College of Science, Technology and Medicine	5	
University College London/Royal Free Hospital School of Medicine	5	
University of Birmingham	5	
University of Bristol	5	
University of Glasgow	5	
University of Leeds	5	
University of Leicester	5	
University of Manchester	5	
University of Newcastle upon Tyne	4	
University of Nottingham	3a	

Biological sciences⁽²⁾

Institute of Cancer Research	5*	
University of Cambridge – Genetics	5*	
University of Cambridge – Zoology	5*	
University of Nottingham – Genetics	5*	
Birkbeck College – Crystallography	5	
Imperial College of Science, Technology and Medicine	5	
UMIST	5	
University College London	5	
University of Bath	5	
University of Cambridge – Biotechnology	5	
University of East Anglia	5	
University of Edinburgh	5	
University of Glasgow – Molecular Genetics	5	

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	1996 Rating	Flagged Research Groups
University of Leicester – Genetics	5	
University of Oxford – Zoology	5	
University of Sussex	5	
University of Warwick	5	
University of York	5	
Cranfield University	4	
Institute of Zoology	4	
Lancaster University	4	
Queen Mary and Westfield College	4	
University of Birmingham	4	
University of Bristol	4	
University of Cambridge – Plant Sciences	4	
University of Essex	4	
University of Glasgow – Functional Ecology	4	
University of Glasgow – Infection and Immunity	4	
University of Kent at Canterbury	4	
University of Leeds	4	
University of Leicester – Botany and Zoology	4	
University of Liverpool	4	
University of Manchester	4	
University of Nottingham – Life Science	4	
University of Oxford – Plant Sciences	4	
University of Sheffield	4	
University of Southampton	4	
University of St Andrews	4	
Brunel University	3a	
Keele University	3a	
King's College London	3a	
Open University	3a	
Oxford Brookes University	3a	
The Queen's University of Belfast	3a	
University College of North Wales	3a	

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	1996 Rating	Flagged Research Groups
University College of Swansea	3a	
University of Aberdeen	3a	
University of Dundee	3a	
University of Durham	3a	
University of Exeter	3a	
University of Portsmouth	3a	
University of Reading	3a	
University of Stirling	3a	
University of Surrey	3a	
University of Wales, Cardiff	3a	
University of Wales, Aberystwyth ⁽³⁾	2	Microbial Physiology; Analytical Biotechnology

Agriculture

University of Reading – Plant Science	5*	
The Queen's University of Belfast	5	
University of Edinburgh	5	
University of Newcastle upon Tyne	5	
University of Nottingham	5	Animal Science
Natural Resources Institute	4	
University College of North Wales	4	
University of Aberdeen	4	
University of Leeds	4	
University of Reading – Agriculture, Soil Science, Agricultural Economics and Management	4	Centre for Dairy Research
University of Stirling	4	
Cranfield University ⁽³⁾	3a	
University of Exeter ⁽³⁾	3a	
Wye College, University of London ⁽³⁾	3a	Plant Molecular Biology

⁽³⁾ Included because department contains groups of excellence impacting on biotechnology

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	1996 Rating	Flagged Research Groups
Food science and technology		
University of Leeds	5*	
University of Nottingham	5*	
Heriot-Watt University	4	
The Queen's University of Belfast	4	
University of Reading	4	
University of Surrey	4	
Veterinary Science		
Royal Veterinary College	4	Reproduction; Musculoskeletal Pathobiology
University of Bristol	4	Muscle and Connective Tissue Biology
University of Cambridge	4	Neurology: Infection and Immunity
University of Edinburgh	4	Physiology; Clinical and Molecular Immunology
University of Glasgow	4	Parasitology; Pathology
University of Liverpool	4	Cell Physiology
Environmental sciences		
University of East Anglia	5*	
University of Reading	5*	
Lancaster University	5	
University of Southampton	5	
Imperial College of Science, Technology and Medicine	4	
University College of North Wales	4	
University of Edinburgh	4	

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

ii) RAE ratings of disciplines interfacing with biotechnology⁽¹⁾

Institution	1996 Rating	Flagged Research Groups
Chemistry		
University of Cambridge	5*	
University of Oxford	5*	Small molecules
University of Edinburgh	5	
University of Exeter	4	
University of St Andrews	4	
University of Strathclyde	4	
University of York	4	
Computer science departments with bioinformatics capability		
University of York	5*	
University of Manchester	5	
University of Edinburgh	5	
University of Nottingham	5	
University of Aberdeen	4	
University of East Anglia	4	
University of Reading	4	
University of Sheffield	4	
University of Wales, Aberystwyth	4	
University of Wales, Cardiff	4	
University of York	4	
Chemical engineering		
Imperial College of Science, Technology and Medicine	5*	Biochemical engineering
University College London	5	Biochemical engineering
University of Bath	5	Biochemical engineering
University of Birmingham	5	Biochemical engineering

⁽¹⁾ Departments with groups interfacing with biotechnology

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

iii) UK centres of research excellence in biotechnology not included in RAE

Institution	Region	Area
BBSRC institutes		
Babraham Institute	Cambridge	Animal models
Roslin Institute	Roslin, Edinburgh	Animal models, transgenics, applied genomics
Institute of Animal Health	Newbury	Animal Biology; infectious disease, pathogenesis
John Innes Centre	Norwich	Plant genomics and disease
Institute of Grassland & Environmental Research	Aberystwyth, Brecon and Okehampton	Grassland-related agriculture
Institute of Food Research	Norwich	Food safety, quality, nutrition and health
Institute of Arable Crop Research	Rothamsted, Long Ashton and Broom's Barn	Plant genomics
MAFF institutes		
Central Science Laboratory (CSL)	York and Norwich	Advice, technical & enforcement support, underpinned by appropriate R&D to underpin food safety
Horticulture Research Institute	Warwick and East Malling	R&D and transfer to horticultural industry
Royal Botanic Gardens	Kew and Edinburgh	
Scottish Executive institutes		
Hannah Research Institute	Ayr	
Moredun Research Institute	Moredun, Edinburgh	Animal health/welfare
Rowett Research Institute	Rowett, Aberdeen	Nutrition
Scottish Crop Research Institute	Dundee	
NERC institutes		
Institute of Freshwater Ecology	Ambleside	
Institute of Terrestrial Ecology	Huntingdon	
Institute of Virology and Environmental Microbiology	Oxford	

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	Region	Area
MRC institutes/units		
MRC/BBSRC Neuropathogenesis Unit	Edinburgh	TSE
MRC Biostatistics Unit	Cambridge	
MRC Cell Mutation Unit	Brighton	
MRC Centre for Molecular Medicine	Oxford	
MRC Clinical Sciences Centre, Hammersmith Hospital	London	Genetics
MRC Environmental Epidemiology Unit	Southampton	
MRC Functional Genetics Unit	Oxford	
MRC Human Biochemical Genetics Unit	London	
MRC Human Genetics Unit	Edinburgh	Genetics
MRC Human Genome Mapping Resource Centre and Gene Function Unit	Cambridge	Sequencing /functional studies
MRC Laboratory of Molecular Biology	Cambridge	
MRC Mammalian Genetics Unit	Harwell	
MRC Molecular Haematology Unit	Oxford	
MRC Mouse Genome Centre	Harwell	
MRC National Institute for Medical Research	London	
MRC Protein Phosphorylation Unit	Dundee	
MRC Toxicology Unit	Leicester	
Other Government research centres		
Centre for Applied Microbiology & Research	Porton Down, Salisbury	Infectious diseases/vaccines
Chemical & Biological Defence Establishment (DERA)	Porton Down, Salisbury	
Multi-funded research centres		
International Centre for Life (Millennium Commission/Tyne & Wear Development Corporation/EC/the Wellcome Trust)	Newcastle	Genetics
The Edward Jenner Institute for Vaccine Research (MRC/BBSRC/DH/Glaxo Wellcome)	Newbury	Vaccines

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Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Institution	Region	Area
Charities		
Arthritis Rheumatism Council		
Beatson Institute	Glasgow	Cancer research
British Diabetic Association		
British Heart Foundation		
Gray Laboratory	London	Cancer research
Imperial Cancer Research Fund	London	Cancer research
Institute of Cancer Research/ Royal Marsden	London	Cancer research
Leukaemia Research Trust	London	
Lister Research Institute	London	Infectious disease
Ludwig Institute	London	Cancer research
Marie Curie	Surrey	
Paterson Institute	Manchester	Cancer research
Wellcome Research Trust	London	Infectious disease
Genomic centres		
European Bioinformatics Institute	Cambridge	
Nottingham Arabdopsis Stock Centre	Nottingham	Plants
Sanger Centre	Cambridge	Prokaryotic genomes (include M tuberculosis) Eukaryotic genomics Human Chromosome X, 1,6,20,22
UMDS Guy's & St Thomas'	London	Human genetics
Wellcome Trust Human Genetics Centre	Oxford	

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Public centres of research excellence relating to biotechnology



- = All centres
- ◆ = University with 3 or more 5 or 5* departments in disciplines relating to biotechnology

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Principal pharmaceutical industry R&D and manufacturing (M) sites in the UK

SmithKline Beecham:

Harlow, Essex – R&D
Worthing, W.Sussex – M
Irvine, Ayrshire – M
Crawley, W.Sussex – M

Glaxo Wellcome:

Stevenage, Herts – R&D
Greenford, Middlesex – R&D + M
Beckenham, Kent – R&D
Ware, Herts – M
Dartford, Kent – M
Barnard Castle, Co. Durham – M
Ulverston, Cumbria – M
Montrose, Angus – M
Speke, Merseyside – M

AstraZeneca:

Alderley Park, Macclesfield – R&D + M
Brixham, Devon – R&D
Avlon Works – Severnside, Bristol – M
Grangemouth, Scotland – M
Charnwood, Loughborough – R&D
Corby, Cambridgeshire – M

Eli Lilly & Co.:

Basingstoke, Hants – M
Windlesham, Surrey – R&D
Speke, Merseyside – M

Roche:

Welwyn Garden City, Herts – R&D + M

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Merck Sharp & Dohme:

Hoddesdon, Herts – R&D (*Development*)

Terlings Park, Essex – R&D (*Research*)

Cramlington, Northumberland – M

Ponders End, Middlesex – M

Hoechst (Hoechst Marion Roussel) (*discounting imminent merger with Rhone-Poulenc to create Aventis*)

Swindon, Wilts – M

Milton Keynes – M

Novartis:

Institute for Medical Sciences, University College London – R&D

Horsham, W.Sussex – R&D + M

Bristol-Myers Squibb:

Moreton, Merseyside – R&D

Bayer plc:

Stoke Court, Stoke Poges, Slough – R&D

Abbott Laboratories:

Queenborough, Kent – M (*plus small R&D facility*)

Rhone-Poulenc: (*discounting imminent merger with Hoechst to create Aventis*)

West Malling, Kent – R&D + M

Dagenham, Kent – R&D

Holmes Chapel, Cheshire – R&D (*Development*)

Pfizer:

Sandwich, Kent – R&D + M

American Home Products (Wyeth-Ayerst/Whitehall Laboratories):

Havant, Hants (Wyeth-Ayerst) – M

Havant, Hants (Whitehall Laboratories) – R&D

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Monsanto (Searle):

Morpeth, Northumberland – M

BASF (Knoll):

Beeston, Notts – R&D + M

Cramlington, Northumberland – M

Medeva:

Ashton-under-Lyne, Manchester – M

Speke, Merseyside – M

Organon:

Newhouse, Scotland – R&D

Boehringer Ingelheim:

Bracknell, Berks – M

Sanofi-Synthelabo:

Fawdon, Newcastle – M

Alnwick, Northumberland – R&D + M

Yoshitomi:

Glasgow – R&D

Eisai:

University College London – R&D

Appendix 1

Locations of UK biotechnology companies, public centres of research excellence and pharmaceutical industry R&D and manufacturing sites

Principal pharmaceutical industry R&D and manufacturing sites



- Manufacturing site
- R&D site

Appendix 2

Contributors to the report

DTI would like to thank all those who took part in specific discussion groups to develop our thinking (listed below) and also very many others whose presentations at conferences and seminars inspired and informed this work. We also want to thank those who submitted papers to us.

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Appendix 3

Acronyms

BBSRC	Biotechnology and Biological Sciences Research Council
BIA	BioIndustry Association
BIVDA	British In Vitro Diagnostics Association
CAP	Common Agricultural Policy
CGT	Capital Gains Tax
DNA	Deoxyribonucleic Acid
DTI	Department of Trade and Industry
EMEA	European Medicines Evaluation Agency
EU	European Union
FDA	Food and Drug Administration (US)
GAV	Gross Added Value
GCSE	General Certificate of Secondary Education
GDP	Gross Domestic Product
GM	Genetically Modified
GMP	Good Manufacturing Practice
GPs	General Practitioners
HEIs	Higher Education Institutes
IP	Intellectual Property
IPO	Initial Public Offering
IT	Information Technology
LREC	Local Research Ethics Committee
MCA	Medicines Control Agency
MRC	Medical Research Council
MREC	Multi-Centre Research Ethics Committee
NERC	National Environment Research Council

Appendix 3

Acronyms

NGOs	Non-Governmental Organisations
NHS	National Health Service
NICE	National Institute for Clinical Excellence
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development
S&T	Science and Technology
SMART	Small Firms Merit Award for Research and Technology
SMEs	Small & Medium sized Enterprises
SNP	Single Nucleotide Polymorphisms
VCTs	Venture Capital Trusts
WTO	World Trade Organisation

Appendix 4

Glossary

Antibodies – These are part of the immune system, and are produced to help fight against infection. Antibodies are made by a type of blood cell called a lymphocyte, and are tailor-made in response to foreign material entering the body; this means that a new and specific antibody is made for each new antigen, the part of the foreign protein which provokes the immune response. Blood contains many different antibodies.

Antigen – A protein or part of a protein which provokes an immune response.

Assay – A chemical test to 'look for', and measure the amount of, a specific chemical in a mixture of ingredients.

Bioassay – A test to measure something using a living system – for example the metabolism of bacteria can be used to measure the levels of oxygen in water.

Bioinformatics – The organisation and use of information on biological and molecular subjects. This includes: organising biomolecular databases; managing the quality of data input; getting useful information out of such databases; and integrating information from disparate sources. One application of bioinformatics is to bring together gene-sequence data with that about the physiological functions of the proteins whose production they stimulate. Investigations of three dimensional protein structures and high throughput screening in drug discovery are creating demands for huge databases.

Biopharmaceuticals – Medicines made by biological processes rather than by chemical synthesis. Many medicines developed using recombinant DNA techniques are termed biopharmaceuticals.

Bioremediation – The use of biological systems, usually micro-organisms, to clean up a contaminated site.

Biosensors – Devices which use a biological component as an essential part of a sensor.

Chromosome – Structures into which DNA is packaged.

Cloning – A clone is a group of genetically identical organisms. Many plants are easily cloned; they can be grown from cuttings. Higher animals are more difficult to clone; the only cells in mammals which are capable of growing naturally into a new mammal are fertilised egg cells or cells from very early embryos – up to the stage where the embryo consists of just eight cells. ('Dolly' represented such a major breakthrough because a sheep was 'cloned' by making an ordinary body cell reproduce itself, by injecting the nucleus of the cell into a fertilised egg from which the nucleus had been removed).

Culture collections – Storage facilities for samples of micro-organisms and cell lines. They provide access to research groups to obtain and use the same organism. They also provide a depository for patented organisms, e.g. American Type Culture Collection (ATCC) which collects all types (i.e. definitive specimens) of micro-organisms and cell lines. The European Central Animal Cell Culture facility (ECACC) is at Porton Down.

DNA – Deoxyribonucleic acid, the chemical which in most organisms contains the genetic code. DNA is made up of four sub-units (referred to as bases) called adenine, guanine, cytosine and thymine – A, G, C, T. The DNA molecule is made up of two strands winding round each other – the double helix. A always pairs with T, and C with G.

DNA sequencing – see *Gene sequencing*.

Enzyme – A catalytic protein which is necessary for a particular chemical process to take place in a living cell. Many different types of enzyme can be extracted and used in manufacturing and production, including those used in detergents (proteases and lipases – enzymes which break down proteins and fats), in the dairy industry (e.g. chymosin, in cheese making) and in food processing.

Fermentation – Strictly speaking, this refers to the growth of micro-organisms in the absence of air, traditionally used for the production of beer, wine and leavened products such as bread. The term is now used to cover the growth of micro-organisms in liquid under a wide range of conditions.

Functional genomics – The use of biological experiments and database searches to establish what the different sequences in a gene actually do, e.g. what protein/enzyme is produced and what it does in the body when a particular gene sequence is activated. Some gene sequences have a controlling function – switching on and off other parts of the DNA.

Gene – A section of DNA which codes for a defined biochemical function (such as the production of a particular protein). The number of genes varies from species to species; humans contain about 100,000 genes.

Genetic modification – The production of new combinations of genetic material, usually by transferring a specific sequence of DNA into an organism in which it does not naturally occur.

Gene sequencing – Finding out the order of the four sub-units of DNA (adenine, guanine, cytosine and thymine), to determine its primary structure.

Gene therapy – Changing either the ‘germ cells’ (i.e. the sperm or eggs) which will have a permanent effect on the individual and any resultant offspring, or changing processes in the cells of an adult by introducing new DNA into the cells (somatic cell gene therapy), which only affects the individual. Bone marrow therapy, through which cells reproduce in the bone marrow to create changed blood cells (without disease) is an example of somatic gene therapy. Treatments designed to destroy tumours using gene therapy are under development.

Genome – The total set of genes in an organism or species. The human genome consists of about 3 billion DNA bases coding for about 100,000 genes, packaged in 23 pairs of chromosomes.

GMO – see *Recombinant DNA technology*.

High throughput screening – An approach for finding new drugs which looks for chemicals which act on a particular enzyme or other molecule. For example, if a chemical inactivates an enzyme, it might prove to be effective in preventing a process in a cell which causes a disease. High throughput methods enable researchers to try out thousands of different chemicals against each 'target' very quickly, using robotic handling systems and automated analysis of results.

In vitro – Literally 'in glass' this means living processes outside a living system (e.g. in vitro fertilisation).

In vivo – In the living system, for example in a living animal.

Lipases – Enzymes which break down fats (lipids) into their components.

Metabolism – The chemistry inside all living organisms, which turns inputs (food, water, oxygen, sunlight, etc.) into new cells or parts of the body, and enables it to grow and stay healthy.

Micro-organisms – Usually single-celled organisms which are so small that they can only be seen under a microscope. They include bacteria, yeasts, moulds and simple animals and plants.

Monoclonal antibodies – Made by growing large numbers of a single lymphocyte producing a specific antibody. The antibodies produced are therefore all the same, and they will bind to just one specific antigen. This makes them very useful as a means of identifying proteins. Monoclonal antibodies are used in diagnostics and in purifying useful proteins from mixtures. They are being developed to deliver medicines to specific cells in the body (e.g. for cancer treatment).

Mutation – A mutation is a change in the basic primary structure of the DNA of an organism (e.g. where one or more sub-units is changed, deleted or added). The effect of a mutation depends on where it takes place.

Orphan drug – A drug to treat a relatively rare disease, where the small numbers of patients involved mean that it will not be possible to recover the development and registration costs normally associated with bringing a new medicine to market.

Polymerase chain reaction – A method to produce sufficient DNA for analysis from a very small amount of DNA. The method was invented by Kary Mullis in 1985 and he was awarded the Nobel Prize for Chemistry for this work in 1993.

Proteins – Proteins are one of the products that genes code for. They are made of chains of amino acids folded into complex three dimensional structures. It is this structure that helps determine their function.

Proteomics – The study of gene activity by looking for the entire range of proteins which are produced by a particular gene, genome or cell.

Recombinant DNA technology – The set of techniques which enables DNA from different sources to be identified, isolated, and recombined, so that new characteristics can be introduced into an organism. An organism which has been changed by the introduction of recombinant DNA is known as a genetically modified organism (GMO).

Single nucleotide polymorphism (SNP) – A difference of a single base in the sequence of a gene, which alters the structure and function of the gene product. These differences occur naturally in any population, and help to account for differences between individuals (e.g. a SNP can mean a minor change in the primary structure of a protein, but this in turn can have a more significant effect on the protein's three dimensional structure, leading to possible changes in the protein's function). SNPs are being investigated to gain greater insights into the basis for disease, and to help develop more effective, tailor made treatments.

Streptomycetes – A type of bacteria which is used to produce a range of chemicals, especially antibiotics.

Transgenic – A transgenic organism is one where one or more genes, usually from another species, have been introduced using recombinant DNA technology. A transgenic organism is said to have been genetically modified.



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