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Exciting Future

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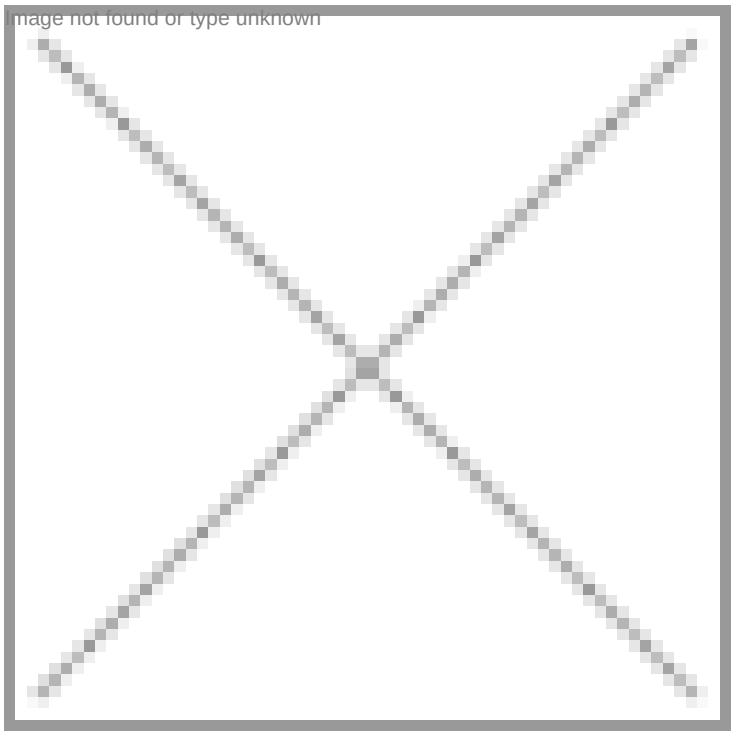


The UK Bioscience

Exciting Future

From the greatest scientific discovery of the 20th century, the double helix structure of DNA 50 years ago in Cambridge, Britain has been at the forefront of some exciting bioscience.

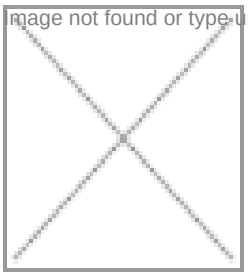
A visit to Cambridge and anyone would point you to the Eagle pub. The reason: it was in this pub that on 28 February 1953 one of the greatest discoveries was announced. Francis H Crick declared here that he and his colleague James D Watson had discovered â€œthe secret of lifeâ€?. Crick and Watson had discovered the structure of deoxyribonucleic acid (DNA). This revolutionized biology. The story of the UK Biosciences does not stop there. In 1997, Dolly, the sheep, was born. This was the first mammal cloned from an adult cell. In 2003, the human genome project was completed. Speak to any scientist, industry, or government official, they would narrate the success of science in the UK tirelessly. Prime Minister Tony Blair, in his foreword to Bioscience 2015 Report, wrote: The bioscience industry is a British success story. From the discovery of the double helix structure of DNA 50 years ago in Cambridge, Britain has been at the forefront of bioscience. Our academic and research scientists remain amongst the best in the world. The UK bioscience industry faces an exciting future...

This track of excellent scientific discovery has led to the success of the UK's pharma and biotech industries. â€œThere are approximately 480 dedicated biotech businesses in the UK with over £2.8 billion revenues in 2001,â€? said Ian Young of Department of Trade and Industry (DTI), Bioscience Unit. According to Simon Sargent, pharmaceutical industry advisor, Bioscience Unit, DTI, the pharma industry employs about 65,000 people. Out of that 27,000 are employed in R&D and two of the world's top five pharma companies GlaxoSmithKline and AstraZeneca have their global headquarters in the UK. Sargent informed: â€œThe UK is the world's leading exporter of pharmaceuticals with exports in 2002 standing at £10,031 million. During the same time, pharma companies spent £3.2 billion on R&D, accounting for approximately 10 percent of the global R&D spending. And about 47 companies had 561 potential medicines undergoing clinical trials in the UK at the last count in August 2001.â€?

The pharma story is very important for two reasons. One, most of the biotech companies in the UK today work on biopharmaceuticals. Informed Prof. Sir David King, Chief Scientific Advisor, HM Government, â€œWe are very strong in the pharmaceutical industry. So it is not surprising that many of the biotech companies are linked into the pharmaceutical type.â€? Two, the success formula of the pharma sector would be replicated in biotech too. â€œDTI, BioIndustry Association (BIA), and Department of Health (DH) have jointly come out with a report, Bioscience 2015. This is the Bioscience Innovation and Growth Team (BIGT) report, which has formulated a strategic approach for the future of the UK's bioscience industry. The success of the UK's pharma industry was on account of a similar report submitted to the government.â€?

Wide portfolio

According to Tom Salusbury, leader, biotechnology & pharmaceuticals team, UK Trade & Investment, â€œThe UK biotech companies range from listed companies (up to â‚¬7bn market cap.), pre IPO companies (up to â‚¬70m market cap.), to start-ups and research bodies. The industry predominantly constitutes SMEs. The main sub-sectors include healthcare, environmental, diagnostics, agriculture, and industrial. And the companies are mainly located in clusters.â€?



The industry is very much based on small companies, though there may be some exceptions like Celltech, which has operations in the US as well. â€œThere are two-three reasons for that. Biotech is still quite a young industry. To some extent it is a matter of choice. Quite a number of biotech companies do not want to go too big. They want to stay very small and do first few phases of developing drugs and do not want to get into the next phase like the Phase-3 trial for getting the regulatory or marketing approvals. Some UK companies look forward to pharmaceutical companies to do that. For instance, Antisoma PLC, a biopharmaceutical company specializing in the development of novel anti-cancer drugs, has an arrangement with Roche worldwide to take some of its drugs into the market,â€? explained Young. The collaborative agreement gives Roche worldwide exclusive rights to R1549 (formerly Pemtumomab), R1550 (formerly Therex), AS1404 (DMXAA). Antisoma received an upfront payment of $43 million and will be eligible for milestone payments upon reaching key stages in development and royalties on any product sales.

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Amongst the 480 odd companies in the biotech, most of them would be in the health care. Some of those are working on vital technology platforms like medical diagnostics and drugs informed David Masino, senior policy advisor, EU & International Bioissues, Bioscience Unit, DTI. Within the health care area, the UK companies are working on all sorts of disease areas. â€œBut genomics and proteomics, oncology, neurosciences, vaccines, and infectious diseases are major areas of expertise. Companies are also looking at tissue engineering. The sector is growing,â€? added Jeanette Walker, business development director, ERBI Ltd. The country has specialist biotech companies in the areas of agbio (animal health, agriculture, biopesticides and food technology), biodiagnostics (environmental and health care), bioremediation, biomaterials, bioprocessing, bioinformatics, functional genomics and high-throughput screening. Some of them involved in the agribiotech are mainly waiting for the GM crops policy. It is not that the agribiotech companies are working only in transgenics, they are also working on plant biotech for chemical extraction etc. â€œThe UK is also a major center of biomanufacturing, competing with Switzerland for leadership in the production of complex protein and DNA-based treatments,â€? said Dr Linda Magee, director of Bio Now.

Largest in Europe

The sector wise figures were not available. But the industry experts pointed out that the UK biotech industry is the largest in Europe, though Germany has more number of specialist biotech companies. According to The New Economy Strategies (a Washington DC-based consultancy organization) report, England had 310 companies in 2001, while during the same time Germany had 365 specialist biotech companies. Dr Jiansheng Du, DTI International Technology Promoter referring to Ernst & Young Report pointed out that the UK has about 154 products in the pipeline. Out of these, 49 are in the pre-clinical phase, 39 in Phase-I, 45 in Phase-II, 21 in Phase-III. But Germany has a total of just 11. Added Salusbury, â€œThe UK companies account for 43 percent of the products in the pipeline by European public companies. Also 43 percent of new biotechnology drugs in Phase III clinical trials in Europe are from the UK.â€?

A range of factors contributes to the UK's strength as location for all types of biotechnology applications. Industry and DTI officials site them as:

â€”The combination of excellence in research with the presence of major multinational companies that can place products into world markets.

â€”Government annual expenditure on bioscience research is approximately $960 million. Charities such as the Wellcome Trust and the Cancer Research UK provide significant funding. The Wellcome Trust is to invest at least $5.4 billion in the next five years to support biomedical research

â€”A knowledgeable investment community, high-caliber patent agents and management consultants, and world class toxicology testing, clinical trials, and other specialist services.

â€”A strong and established partnership between the government, industry and the finance community to develop and maintain a supportive climate in which the biotechnology sector can flourish.

Growth converters

Du pointed out that R&D is underpinning the biotech growth. The UK alone can lay claim to over 20 Nobel prizes in the life sciences. There were about 46 Nobel Prizes in the last 50 years and since 1901, there were 72. Besides, it also has a very strong entrepreneurial ethos. There were about 70 spinouts between 1994 and 1999. During 1999-2000 alone, there

were 199 spinouts. He further added that there has been a spinout per â‚¬13 million spent on R&D. According to experts, the UK researchers are among the most prolific in the world, producing 16 papers per $1 million of research funding. Total spending on research and development by the UK biotechnology companies in 2002 amounted to £1.25 billion, more than the rest of Europe combined together, according to independent research by Critical I.

Since 1994, there has been an increase in the importance given to policies to encourage collaborations between university and industry and to commercialize research in biotechnology. The UK has witnessed an increase in all commercialization activities between 1995-96 and 1999-2000. Informed Salusbury, â€œThe universities of Cambridge, Oxford and London form the hub of one of the few world-class high-technology clusters that competes with the US. Edinburgh has become the center of an emerging agricultural biotechnology cluster that is home to 85 companies such as Ardana. In Dundee, Cyclacel is developing new types of cancer treatments based on Professor Sir David Lane's discovery of p53, a key gene involved in tumor suppression. Clusters are also growing in Kent, York and Manchester.â€?

Spinout of companies from the universities in the UK has been a very important activity. University of Cambridge and University of Oxford have led the trend. In fact, University of Oxford has a very unique model. The University has a wholly-owned subsidiary, Isis Innovation Ltd. It is the technology transfer company of the University, commercializing the research generated by the University researchers and owned by the University. It has helped in the formation of more than 30 University spinout companies. Pre 1997, there were 9-10 spinouts. "It was about a spinout every four years then, now it's eight companies a year," explained Dr Tim Cook, managing director, Isis Innovation. "The research income in medical sciences and life and environmental sciences is £83.2 million and £21.8 million, respectively, accounting for 56 percent and 15 percent of the total income. So we have focused to help those researchers who wish to commercialize the results of their research."

The UK has an active investment community and has Europe's largest venture capital sector. In the first half of 2001, the UK Biotech companies raised about $256 million of venture capital funds (39 percent of the UK total). In 2001, 95 percent of Europe's biotechnology companies were privately owned. A number of VC companies in the UK specialize in biotechnology and related investments.

Regulations

The role of the government has been primarily to keep the regulations simple. Said Young, â€œThe UK government is committed to minimizing the regulatory burdens on the industry, as well as ensuring that human health and safety are protected.â€? Is there a biotech policy? Said Young, â€œThe government works with the biotech industry. We do not have a written down policy. But there are regulations and measures to facilitate the growth of biosciences. The BIGT was set up to identify any barriers that could significantly holdback the growth of the biosciences sector and make recommendations to overcome the obstacles. Its report to the government was published in November 2003. The government is considering its response to the report.â€?

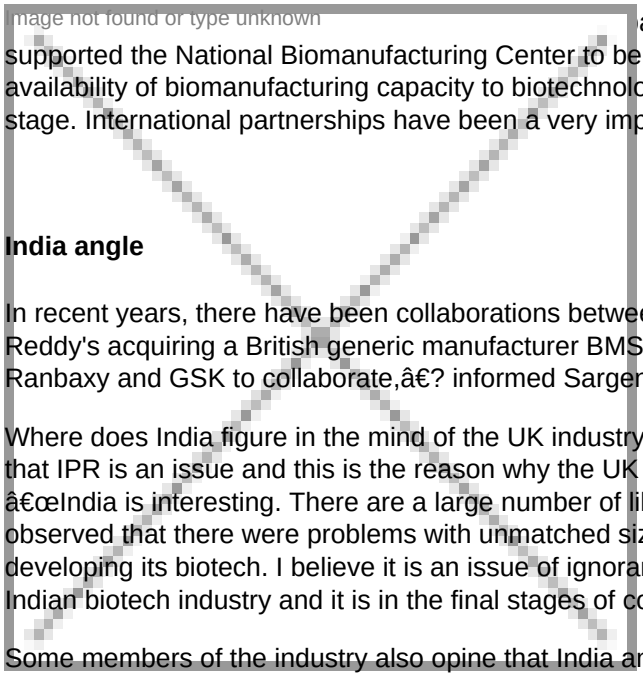
Informed Laura Gilbert, head of public affairs, BIA, â€œThe UK is working in Europe to ensure that regulations and other measures affecting the development of biotechnology take full account of the concerns of business.â€? Britain has practical and effective arrangements in place for clearance of products, such as novel foods, through the Advisory Committee on Novel Foods and Processes (ACNFP) and diagnostics, through the Medicines and Healthcare products Regulatory Agency (MHRA). The Gene Therapy Advisory Committee (GTAC) has taken a pragmatic and sensible approach to controls on gene therapy. The Advisory Committee on Releases to the Environment (ACRE) provides advice on GMO consents. Following a review of the regulatory system, the Government has established the Agriculture and Environment Biotechnology Commission (AEBC) to consult widely on biotechnology issues and the environment. The Human Genetics Commission (HGC) has been set up to look at genetic technologies and their impact on humans, providing strategic advice to the Government. The Food Standards Agency (FSA) has taken responsibility for the assessment of GM foods and the development of new policies.

Further, The European Medicines Evaluation Agency (EMEA) is responsible for fast-track approval of biotechnology-derived pharmaceutical and veterinary products throughout Europe. It provides a single EU-wide licence valid in all member states. The UK (MHRA) provides approval of other medicinal products and has a strong international reputation. The UK is governed by the Embryology Act together with the Human Fertilization (Research Purposes) Regulations 2001.

Government role

The DTI plays a very important role in the growth of biotech. â€œWithin the DTI, there is a Bioscience Unit. This aims to increase the competitiveness of the UK biotech sector by exploiting the science base and influencing all the conditions necessary for the development of the sector,â€? informed Young. It also offers a range of support to the UK biotech sector through programmes like Harnessing Genomics, The Biotechnology Exploitation Platform (BEP) Challenge, BIO-WISE, grant for R&D, the Link scheme, Eureka, The EU Sixth Framework Programe (FP6), Enterprise Fund, and The New and Renewable Energy Programme.

The government has introduced R&D tax credit mechanism under which all small companies investing in R&D in the UK are entitled to a deduction from their taxable income of 50 percent on current spending on qualifying R&D, on top of the normal 100 percent deduction. Large companies are entitled to 50 percent deduction.



arks with the Department of Health (DH). â€œWe have also supported the National Biomanufacturing Center to be built in the North West,â€? said Young. This is to improve the availability of biomanufacturing capacity to biotechnology businesses particularly at the development and clinical trials stage. International partnerships have been a very important consideration for the UK Pharma and the biotech.

India angle

In recent years, there have been collaborations between the UK and the Indian pharmaceutical industries. â€œWe saw Dr Reddy's acquiring a British generic manufacturer BMS Laboratories in 2002. There has been an agreement between Ranbaxy and GSK to collaborate,â€? informed Sargent.

Where does India figure in the mind of the UK industry? There are diverse views. While several people at the DTI perceive that IPR is an issue and this is the reason why the UK companies have shied away from India. But said Salusbury, â€œIndia is interesting. There are a large number of like sized companies. This is important as in the past it has been observed that there were problems with unmatched size partnerships. And India can offer the right match. India is also developing its biotech. I believe it is an issue of ignorance and unfamiliarity.â€? Salusbury's team has done a report on the Indian biotech industry and it is in the final stages of compilation.

Some members of the industry also opine that India and the UK biotech companies can collaborate. According to Dr Mark Payton, business development manager, Oxxon Pharmaccines, a couple of Indian companies have shown interest to manufacture our products. Oxxon Pharmaccines Ltd is a biotechnology company developing novel immunotherapeutics, specifically therapeutic vaccines (pharmaccines), based on its unique PrimeBoost technologies for the treatment of chronic infectious diseases and cancer. According to Payton, by going to India, they will be able to outsource their manufacturing. This would not only reduce their costs but can also bring their products quickly to the market place.

Dr Peter Wrighton-Smith, CEO, Oxford Immunotec, a clinical diagnostics company, which develops and sells clinical diagnostic products, based on its patented CLINISPOT technology, said, â€œIndia is a good market for clinical diagnostics.â€? Going there will be good for us.

Kevin Bazley, manager, business growth team, Scottish Enterprise, shared some very interesting facts. A lot of Indian students are coming to the UK. Abertay Dundee University offers a course in MSc in Biotechnology and BioInformatics. There are 65 students in the course and 58 of them are from India. He believes these students may have been sponsored by the leading corporates from India. Further, he suggests the UK companies and universities can partner for addressing the tropical diseases. Certainly, there has been an increased interest between the two countries.

Future road

So where is the UK biotech headed? Experts believe that the market is expected to reach $8.5 billion in 2005. Clearly, biotech is a priority for many of the UK's Regional Development Agencies. As a result of focused efforts several niches are emerging. For example biomanufacturing is growing in North West England; stem cells, bioinformatics, and

biomanufacturing are growing in North East England; tissue engineering, medical devices and plant sciences are growing in Yorkshire and Humber. And when BGIT report recommendations will be adopted, the UK will emerge out the depressed phase of slow growth currently.

â€"Ch. Srinivas Rao

DTI Programmes

- **Harnessing Genomics**
  It is a $41 million programme to help businesses take up rapidly developing biotechnology/genomics science and apply it in new ranges of commercial products, processes and services.

- **The Biotechnology Exploitation Platform (BEP) Challenge**
  This is a $25 million programme (including pilot) with DTI support of nearly $14 million. It is a competition (now closed to new proposals) for grants for publicly funded science base institutions aimed at encouraging them to collaborate through the formation of consortia (the BEPs) with complementary bioscience research to better manage and exploit the results of that research.

- **BIO-WISE**
  It is a $21 million programme, set up in 1999, which aims to improve the competitiveness of UK industry through the use of biotechnology and support the development of the UK biotechnology supplier industry.

- **Grant for R&D**
  This DTI initiative provides grants to help individuals and small and medium-sized businesses to review their use of technology, access technology and research and development, and develop technologically innovative products and processes (which includes technology reviews, technology studies, micro projects, feasibility studies, development projects, and exceptional development projects).

- **The LINK Scheme**
  It is a well-established framework for collaboration between the public and private sectors in support of science and technology in areas of strategic importance to the national economy. Currently, DTI supports around 30 biotechnology projects through LINK programmes. Government Departments and Research Councils provide up to 50 percent of the eligible costs of a project, with the balance coming from industry.

- **EUREKA**
  This aims to improve industrial competitiveness and exploitation of advanced technologies through partnerships between companies and organizations in EUREKA member states. Projects are industry-led and pre-competitive, and offer companies, particularly SMEs, an established platform on which to seek new partners from the European bioscience community.

- **The EU Sixth Framework Programme (FP6)**
  It is the European Community Framework Programme for research, technological development and demonstration designed to fund and promote research. With a budget of â‚¬17.5 billion for the years 2002-2006, it represents about 4 to 5 per cent of the overall expenditure on Research Technology Development (RTD) in the EU member states. The bulk of research is separated into seven key priority areas. Biotechnology falls into â€œLife sciences, Genomics and Biotechnology for Healthâ€? which integrates post-genomic research into the more established biomedical and bio technical approaches. This research has been allocated â‚¬2255 million.

- **Enterprise Fund**
  DTI provides the Small Firms Loan Guarantee Fund to help small firms with viable business proposals to obtain

finance if conventional finance cannot be found. The Enterprise Fund also includes the establishment of Regional Venture Capital Funds (via RDAs) and the UK High Technology Fund.

- **The New and Renewable Energy Programme**
  Currently managed by Future Energy Solutions, the DTI scheme supports work on the production and utilization of fuels from biomass and biological wastes.

Research Councils

- **In the UK there are seven Research**
  Councils charged with the responsibility for supporting research and training in a range of scientific disciplines. Ofthat, three are involved in biotechnology, each one possesses its own research institutes carrying out research related to biotechnology. The Councils promote a programme of fundamental research and collaboration between academia and industry.

- **Biotechnology and Biological Sciences Research Council (BBSRC)**
  With an annual budget of $243 million (BBSRC Annual Report, 2003), BBSRC is Britain's leading funding agency for academic research and training in the biosciences, at universities and institutes throughout the UK. BBSRC has the responsibility of optimizing the exploitation of the research and training programme supported by the Council.

- **Medical Research Council (MRC)**
  With a total budget of $480 million, the MRC is funded primarily by the Government (Office of Science and Technology). In 2000-01 the MRC received $512 million in government funding and with these funds the MRC supports a substantial amount of fundamental researchâ€”both in its own establishments and universitiesâ€”which underpins those aspects of biotechnology which are of relevance to human healthcare, such as work in genetic and protein engineering, monoclonal antibodies, gene therapy and infectious microorganisms. Whilst the MRC does not itself normally finance the work on the development of specific products, the Council's policy is to foster collaboration between its establishment and industry in order to promote the transfer of industrially relevant skills and technologies, the commercial exploitation of Council inventions, and development of new products in healthcare.

- **Natural Environment Research Council (NERC)**
  NERC has a distinctive role to play in biotechnology through its responsibility for, and expertise in, research on the ecology and variation in microbes, plants and animals in the natural environment.