

Chapter 2

Create a public and regulatory environment supportive of innovation

EXECUTIVE SUMMARY

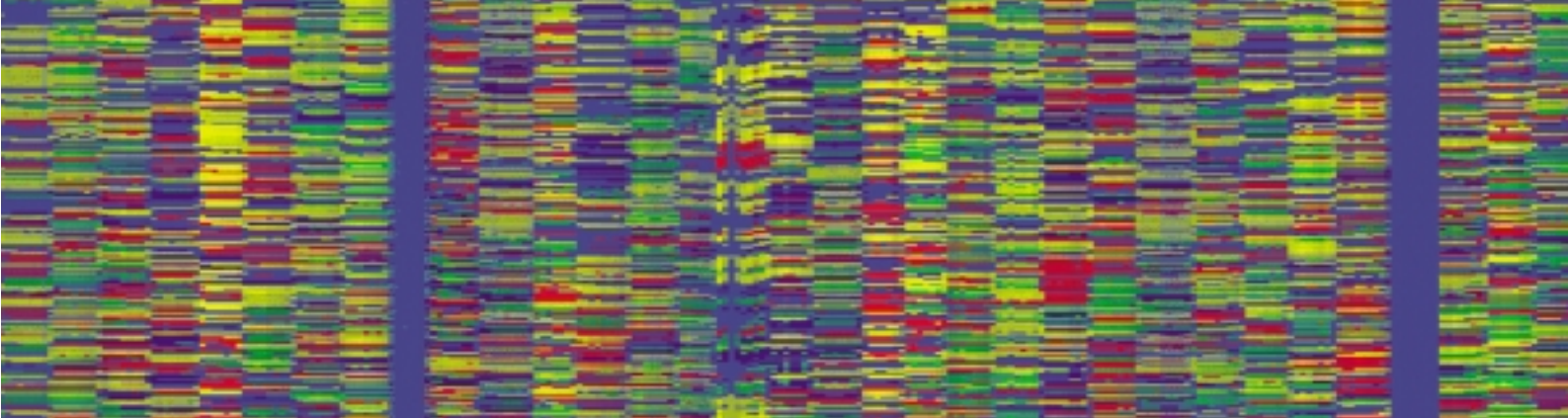
A supportive regulatory environment in the UK and Europe will be critical to the success of the UK bioscience sector. The UK has been a leader in establishing appropriate, science-based regulation in a number of areas, such as stem cell research. Considering the broad regulatory environment affecting bioscience today, two issues are particular concerns. First, the increasing requirement of regulation, due to heightened concern for the precautionary principle, threatens to stifle innovation. This is a particular concern in the UK, a market already known to lag in its uptake of innovative medicines. Second, as rapidly emerging technologies raise both moral and practical questions in both the UK and in Europe, a more proactive approach is needed to ensure a supportive regulatory environment in the future.

Addressing these two issues will require industry to work in collaboration with Government and the public to communicate clearly the risks and the benefits of bioscience. While there are many areas of regulation that affect the biosciences, the BIGT focuses on three areas that are considered most important.

The BIGT recommends that industry and Government work in collaboration to:

2.1 Improve regulatory support for the development, approval and use of innovative medicines in the UK. This involves industry, regulatory agencies, and Government, collaborating to:

2.1.1 Implement the EU Clinical Trials Directive in an effective manner consistent with the aim of achieving global leadership in clinical research.



2.1.2 Introduce a system for provisional licensing of drugs in the UK and EU, such as an adapted version of the French Autorisations Temporaires d'Utilisation (ATU) de cohort system. This will make promising new treatments available to patients where a genuine public health need exists, often before the completion of Phase III clinical trials. In addition, the UK should support the draft EU legislation that recommends creation of a European conditional marketing approval, a fast track procedure and harmonisation of compassionate use regulations.

2.1.3 Create a collaborative relationship between the EU and UK drug approval regulators and the bioscience industry, to ensure that approval times for approved medicines/therapies are competitive with the US.

2.2 Defend the responsible, regulated use of animals in medical research through two measures:

2.2.1 Introduce new, specific legislation to deal with animal extremism against those conducting legitimate medical research, associated organisations and service providers.

2.2.2 Support the work of the Coalition for Medical Progress in encouraging informed public debate on animal research, and seek to optimise the involvement of patient groups in this work.

2.3 Adopt a proactive approach to bioscience regulation and reputation management, actively shaping the UK and EU regulatory environments of the future. To enable this, Government, industry, academia, and patient groups should together:

2.3.1 Create a Bioscience Risk Assessment Forum (BRAf) under the auspices of the Bioscience Leadership Council (BLC) (*see Chapter 6*) to monitor and assess emerging issues, develop issue management strategies, and anticipate areas where regulation may be needed.

2.3.2 Create an ongoing programme of activity to shape opinion in Europe.

2.3.3 Create alliances across EU member states to support the bioscience industry on an issue-by-issue basis.

BIOSCIENCE REGULATION

The bioscience industry is influenced daily by a wide-ranging set of regulations formulated locally, in Whitehall, and increasingly at EU level. Bioscience companies deal regularly with regulation regarding land use, animal experimentation, drug licensing, intellectual property, clinical trials, and data protection, to name only a few. Clearly, a favourable regulatory environment – one that does not put the UK at a significant disadvantage to its competitors in Europe or the US – will be critical to the success of the bioscience sector. Greater harmonisation between the MHRA, EMEA and FDA will be crucial to achieving this. A comprehensive list of regulations impacting on the sector is provided in *Annex 7*.

Redress the balance between the ‘precautionary principle’ and innovation

Regulation monitors and sets boundaries and parameters to manage risk with the safety and welfare of the public as the primary concern. The BIGT believes that a better balance is required between this ‘precautionary principle’ on the one hand, and the need to stimulate and reward innovation that leads to patient benefit.

THE REGULATORY REQUIREMENTS

The bioscience industry is experiencing increasing regulatory requirements, as exemplified by:

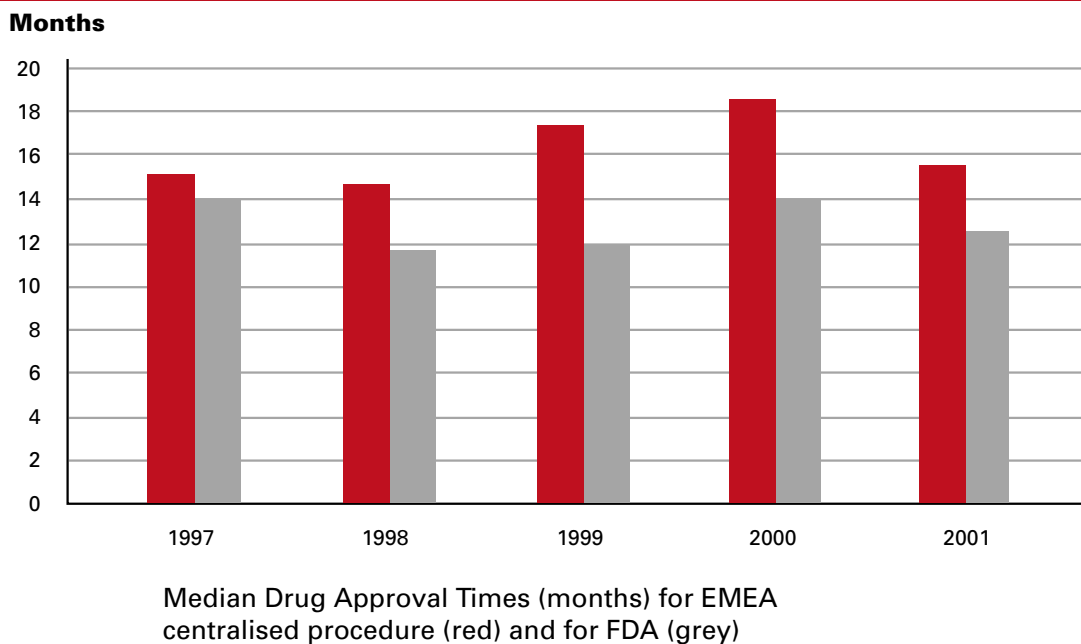
- **Stricter safety requirements**, as embodied in more lengthy clinical trials and in new measures such as the EU Clinical Trials Directive, which tightens regulation, monitoring, and standards for early stage clinical trials. The BIGT has serious concerns that the directive could have a negative impact on the attractiveness of the UK as a location for clinical research, and calls for proportionate transposition to ensure that implementation does not inadvertently produce negative disparities between the UK and other EU member states, and between the UK and US/Canada, etc. Implementation should also take into account the effect on investment in the UK, and the impact on R&D activities in the bioscience and pharmaceutical sectors.
- **Lengthy drug approval times**, which consume vital years of patent protection and delay arrival of drugs on the market. As *Table 2.1* indicates, drug approval times remain long for the EMEA centralised procedure, the process through which biotech drugs are approved – and longer than approval through the FDA.¹ In the US, moreover, FDA Commissioner Mark McClellan announced at the BIO2003 Convention in June 2003 that the FDA was due to update its regulations with the aim of reducing drug approval times by 10% or more.² No such commitment has been made by European regulators, despite the fact that they are starting from a higher base in terms of drug

¹ Priority approval through the FDA can be as rapid as 6 months

² BioWorld International, 2 July 2002. www.bioworld.com

approval times. Longer approval times shorten the period of effective exploitation of patent protection for new drugs. The length of patents has also historically been lower in Europe than in the USA. The BIGT notes and supports the existence of the Supplementary Protection Certificate in the EU, designed to redress the balance and offset the erosion of effective patent lives caused by the time taken to approve medicines, but if approval times in the EU remain longer than in the USA the effective period of patent exploitation will still be shorter than in the USA even after this change.

Figure 2.1 Median approval times through the EMEA and FDA³ (1997 - 2001)



Sources: FDA, CMR International

Overly restrictive regulation has several effects. Firstly, it reduces the incentive to investigate and develop innovative drug therapies. It lengthens the time, increases the cost, and constrains the market for innovative drugs. These cumulative constraints weigh particularly heavily on bioscience companies, as they have limited financial resources and are producing innovative and expensive medicines. As a result, bioscience companies suffer particularly from any further regulatory 'creep'.

Secondly, from a public policy perspective, there is a real risk that the health benefits of this regulatory tightening will be more than offset by significant health costs, including:

- Loss of some drug development (due to lack of R&D);
- Delays in drugs reaching the market;
- Higher cost of new therapies leading to de facto rationing of supply;
- Weakening of competition among suppliers through inhibition of new market entry.

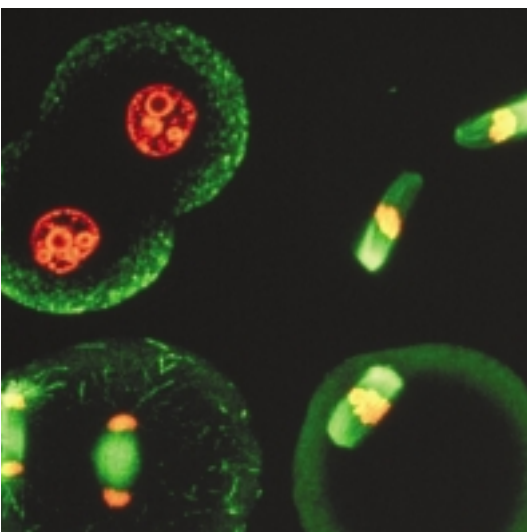
³ FDA www.fda.gov; CMR International, "The impact of the changing regulatory environment on review times", R&D Briefing No. 35, October 2002. www.cmr.org

This is worrying, particularly as the UK pharmaceutical market is already less receptive to innovative products than competitor countries. Newly launched drugs penetrate the UK market slowly relative to other countries. In 2000, only 16% of expenditure on medicines in the UK was on new medicines (of those launched between 1996 and 2000), compared with 25% in Germany, and over 33% in the US. As noted elsewhere in this report, the introduction of novel therapeutic approaches can lead to improved outcomes as well as reduced cost of patient care for healthcare providers such as the NHS. The UK ranks above only Japan on this innovation index. It also lags Italy, France, Australia, Switzerland, Spain, and Canada.⁴ Many different elements affect these outcomes, including the regulatory environment and clinical practice.

MAKE THE CASE FOR INNOVATION

The BIGT thinks it is essential to signal the UK's receptiveness to innovation, and more assertively promote the advantages of technological research and scientific progress. The precautionary principle has the weakness, which often stems from poor public understanding – both by Government and individuals – that it does not allow account to be taken of what constitutes an acceptable risk. Society is generally poor at calibrating risk, e.g. patients suffering from acute disease usually have a different view of safety thresholds than healthy people. Government should put the case for innovation, making clear that while it inevitably involves risk and cost, innovation also offers huge potential benefit.

Improve science education and public awareness



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Confocal micrograph of mouse embryos

The UK needs more vocal and persuasive advocates for science, and needs to improve the quality of public debate. Education – about science, medicine, and what constitutes acceptable risk – is crucial, both formally in schools and informally through the media. Ministers need to defend science more enthusiastically, more publicly and more often. Scientists and their supporters need to communicate more effectively with the public. According to a MORI poll, 44% of the public view UK scientists as uncommunicative.⁵

The UK needs to celebrate the successes of biomedical science while honestly addressing issues associated with biomedical research (including occasional accidents, animal testing, and ethical issues).

⁴ ABPI www.org.uk, cited in Parexel's Pharmaceutical R&D Statistical Sourcebook 2002

⁵ As opposed to the 11% of UK scientists who view themselves as uncommunicative: Wellcome Trust, "The Role of Scientists in Public Debate", MORI poll, 1999-2000. www.mori.com/polls/2000/wellcometrust.shtml

Build a positive reputation for UK bioscience

The bioscience industry in the UK is subject to some of the same perceptions that affect the pharmaceutical sector. The fact that the sector is seen to be innovative, creative and exciting is an enormous benefit. However, it is also the subject of constant and rapid change. It operates across global markets where the impacts of industry consolidation, new techniques for drug discovery, and the need to respond to growing 'patient power', and social and ethical considerations, are shaping success or failure.

The bioscience industry has a less well-established performance track record, limited resources and, because of its relative immaturity, a perceived paucity of tangible results. Consequently, as the medical benefits and success stories are too far away from actual patient benefit to be reported, the industry is an easy target for '*losses increase at*' type stories in the press.

Science is the systematic search for the unknown. This raises a significant issue for the scientific community when communicating about projects. It is often unable to state categorically, as a final conclusion from its evidence, that something 'will' or 'will not' happen. In this environment, uncertainty provides a fertile ground for pressure groups to multiply.

It is vital that science communication strategies address risk. Research shows that the public is not looking for 'zero risk' but for clear answers to the following two questions:

- What are the benefits and risks?
- Can the people responsible for managing and describing the risk be trusted?

SHAPE THE REGULATORY ENVIRONMENT OF THE FUTURE

One priority is to address the current situation. But shaping the emerging regulatory environment is also important. In the bioscience arena, both industry and Government have traditionally adopted a reactive posture toward regulation. They have taken action only when restrictive legislation (e.g. in the EU) threatens or when public outcry peaks. The focus tends to be on today's issues, rather than on those that will affect the industry in 5-10 years' time. The UK needs to be more proactive in shaping the regulatory agenda. The UK's foresight in selected areas – such as IVF treatment and stem cell research – has put this country in a strong position globally. The UK needs to create and maintain that leadership position in other areas that are important to the biosciences, including those that can only be imagined today.

ACTION REQUIRED

2.1 Improve regulatory support for the development, approval and use of innovative medicines in the UK. This involves industry and Government collaborating to:

2.1.1 Implement the EU Clinical Trials Directive in an effective manner consistent with the aim of achieving global leadership in clinical research.

The BIGT has serious concerns that the directive could have a negative impact on the attractiveness of the UK as a location for clinical research, in terms of extra costs, and bureaucracy, as a result of the implementation of

the directive. There are real concerns, in particular, about the requirement for all Investigative Medicinal Products (IMPs) to be Good Manufacturing Practice (GMP) compliant, and the increase in statutory time periods for regulatory and Ethics Committee approval of trials.

The BIGT fully supports the protection of public health under this directive. But calls for proportionate transposition, taking into account the effect on investment in the UK and the impact on R&D activities in the bioscience and pharmaceutical sectors. The MHRA's commitment to appropriate implementation of the directive is central to the realisation of the BIGT vision.

2.1.2 Introduce a system for provisional licensing of drugs in the UK and EU, such as an adapted version of the French Autorisations Temporaires d'Utilisation (ATU) de cohort system. This will make promising new treatments available to patients where a genuine public health need exists, often before the completion of Phase III clinical trials. In addition, the UK should support the draft EU legislation that recommends creation of a European conditional marketing approval, a fast-track procedure, and harmonisation of compassionate use regulations.



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Pharmaceutical drugs

Current situation: Drugs take 10-15 years to progress from initial research through to on-market sale, and spend at least three years in Phase III clinical trials and pre-registration (see *Figure 1.1, Chapter 1*). In some markets, pricing and reimbursement decisions further lengthen those timelines. Getting safe, innovative drugs to the patients who need them, quickly, is a shared objective of both industry and Government. However, improved mechanisms are required to allow the compassionate use of drugs for minority uses. For bioscience companies investing heavily in treating diseases with high unmet medical need (and facing a difficult financial environment), getting their products to market in one or two years, or even months earlier, can make a substantial difference to the company's financial viability.

The recommendation: BIGT recommends adopting an adapted version of the Autorisations Temporaires d'Utilisation (ATU) de cohort for provisional licensing, which has been in place in France since 1994. Despite lacking flexibility, this is an exceptional measure, allowing the sale of drugs that have not yet been granted a marketing authorisation. The aim of ATUs is to provide early access to new promising treatments where a genuine public health need exists, i.e. "in the treatment of patients suffering from serious disease and having reached a situation of therapeutic impasse." The diseases most frequently concerned are cancers, infectious diseases such as AIDS, and neurological diseases. It is important that authorised drugs are then funded for patients in need, e.g. see the status of antiretroviral drugs in France:

Antiretroviral drugs status in France

All the new antiretroviral drugs have been available in France by ATU an average 12 months before the Marketing Authorisation (MA) decision, for around 6,000 patients per drug. Since 1994, more than 400 medicinal products have applied for ATU status (including drugs already on the market in other countries). The French drug approval authority AFSSAPS granted ATU de cohort status to 43 drugs between January 2000 and March 2003, including Glivec, Herceptin, and Xeloda for cancer, and Viracept and Agenerase for HIV.

ATUs are typically granted for drugs where there is a strong presumption of efficacy and an acceptable safety profile. This typically occurs at an advanced stage of development, for example, when a marketing authorisation application is in the course of production or registration.

AFSSAPS grants ATUs on assurance that the manufacturer is committed to completing the Phase III programme, and will file for approval under the normal mechanisms by a fixed date. ATUs come in two forms: the named ATU, issued for a single named patient at the request and under the liability of the treating physician (standard in many countries), and the cohort ATU, which is the one that interests the BIGT most. The cohort ATU covers a group or sub-group of patients who are treated and monitored in accordance with fully defined criteria in a treatment use protocol.⁶

Instituting such a procedure in the UK would send a strong signal in support of innovation. This is important given the UK's record in take-up of innovative medicines, and of Government's willingness to meet patient needs rapidly. One of the factors that persuaded a leading US biotech company, with a strong HIV franchise, to locate European headquarters in France, was the ease of access to that market for its drugs. This procedure would also provide an incentive for bioscience companies to undertake research in areas of high unmet medical need, and would equip them to support permanent licensing and health economic decisions.

The real prize, from a patient and an industry perspective, is to implement this system, and other accelerators of the drug development and approval process, across the larger market of the EU. This starts to level the playing field, and potentially creates competitive advantage for the EU vs the US. The regulatory approval mechanism for biological entities is already run centrally through the EMEA, so a harmonised and centralised procedure for temporary licensing and related measures is appropriate.

Indeed, new draft laws revising the legal framework governing approval of medicines in Europe (revisions to

Directive 2001/83/EC (codification) and Regulation 2309/93/EEC (the EMEA centralised procedure)) are currently awaiting a common position from the Council before a second reading in the European Parliament. These proposals include three areas of particular interest to the BIGT:

- An accelerated assessment procedure for approval of drugs “which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation”;
- Conditional marketing authorisation for breakthrough medicines, subject to agreed clinical or pre-clinical testing; and
- Harmonisation of compassionate use procedures.⁷

The outcome of these proposals and the timing of their implementation remain unclear. The BIGT asks the Government to support these European proposals and in the meantime, to implement the proposed version of the ATU de cohort system in the UK.

2.1.3 Create a collaborative relationship between the EU and UK drug approval regulators and the bioscience and biopharmaceutical industry to ensure that approval times for approved medicines/therapies are competitive with the US.

Current situation: The issues surrounding the time taken for drug approvals have already been explored in this chapter. There are also concerns, however, about how quickly drugs can be effectively marketed in the UK after approval. Today NICE is often seen as a hurdle rather than a help to launch of new drugs and market penetration. Particular difficulties are foreseen with new

biotechnology products. NICE has an emphasis on mainstream drugs, whereas the bioscience industry often has niche products where the patient numbers involved falls below NICE’s economic threshold. As a review by NICE of a new drug comes after registration of that drug through the MHRA and before its availability to the NHS, it can be a barrier to diffusion.

The recommendation: Industry should work with NICE, MHRA and EMEA to improve transparency in order that:

- NICE is aware of clinical trials data at the earliest appropriate moment for each individual company. NICE and industry should engage in mutual education – about, for example, which drugs NICE will look at, NICE criteria for niche medicines/therapies, and the best framework for evaluating total cost of care.
- MHRA, EMEA and industry engage early in the development process to discuss which patient outcomes will be important for subsequent acceptance (along the lines of FDA-industry interaction).

In addition:

- NICE should take full account of the wider economics of health and social care when making decisions about the cost-effectiveness of therapies.
- MHRA and EMEA should seek to at least match the FDA’s target of reducing drug approval times by 10%.
- The FDA, EMEA and MHRA should also be encouraged to work closely together to ensure shared process and protocols.

⁷ Dr Ulrich Granter, “Surviving the regulatory obstacle course”, in Ernst & Young, www.ey.com
“The European Biotechnology Report 2003”, p.43; Sylvia Davidson, “Quicker drug approvals on the way for Europe”, Nature Biotechnology, September 2001, pp.798-799. www.nature.com

2.2 Defend the responsible, regulated use of animals in medical research through two measures.

2.2.1 Introduce new, specific legislation to deal with animal extremism against those conducting legitimate medical research, associated organizations and service providers.

Current situation: Since the nineteenth century, the UK has been a pioneer in the regulation of research involving animals. Today, these regulations provide a clear standard within which academic and commercial researchers operate. However, vocal, minority opposition to animal experimentation of any kind makes the UK a costly, and in some cases, a hostile place to conduct bioscience research.

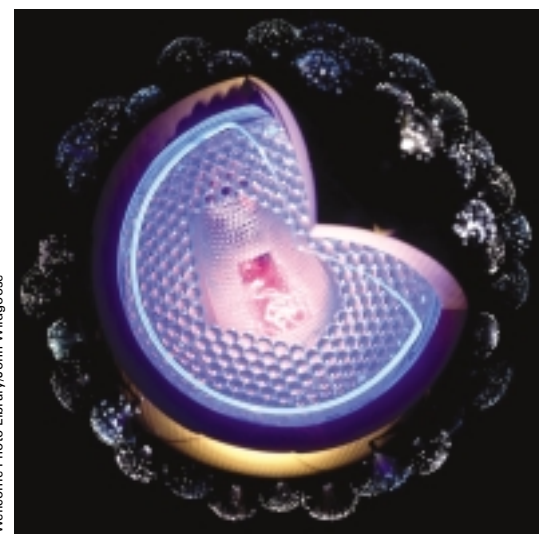
While 90% of the UK population supports animal experimentation, provided that the research is for medical purposes, and that the use of animals is properly regulated to minimise pain and suffering⁸, extremist organisations take a zero tolerance approach, subjecting scientists and managers in universities and bioscience companies, engaged in perfectly legal activities, to verbal and physical threats. This extremist activity, often publicised by the media, takes a significant, unjustified toll on the industry: *personal* – as individuals fear for their safety and that of their families; *financial* – as companies spend money on tighter security or lose investors who fear for their own safety; and *strategic* – as companies choose to locate in the US or on the continent. Animal extremism must not be allowed to obstruct the development of new medicines for patients whose lives and well-being are at stake.

Threats, intimidation and attacks against employees (and their families) involved in medical research using animals, and organisations that provide services to them, must stop. The BIGT acknowledges and applauds the considerable efforts made by Government to tackle these problems, e.g. the recent improvements to the Criminal Justice and Police Act. However, the BIGT still feels that current legislation is not working.

The recommendation: A coherent set of laws in a single piece of legislation should be introduced as soon as possible to combat intimidating animal extremist activity against those conducting legitimate medical research, associated organisations and service providers. Such legislation must ensure that legitimate protests and trade disputes are not restricted. This recommendation should be taken up with the Ministerial Committee on Animal Rights Extremists.

The BIGT has six specific recommendations, and it is important that they be implemented as a single, coherent package. Specifically:

- *Harassment:* Make it illegal to conspire to, organise, incite, support or conduct a campaign of harassment against a legitimate business.



Wellcome Photo Library/John Wildgoose

Cut-away model of the human immunodeficiency virus (HIV), the cause of AIDS.

- *Home visits:* Make any demonstration against a work or employment activity 'in the vicinity' of employees' and directors' private residences illegal (Section 42 of the Criminal Justice & Public Order Act 2001), including those demonstrations that are in sight or sound of the property and access routes (ensuring that the definition of 'vicinity' is clarified, and to make this illegal activity easier to police from an operational perspective).
- *Protests:* Reduce the number of protesters (from 20 to 3) required for the police to put restrictions on a demonstration.
- *Protect employees:* Allow companies to lodge harassment charges or act on an employee's behalf. Currently, it is only when a majority or all employees in a company are harassed and intimidated at the same time that a company can take action. This change is consistent with HSE legislation that requires companies to protect and look after the welfare of employees.
- *Restraining orders:* Allow restraining orders to be applied for by companies on behalf of individual employees, and restrict overseas travel of those with related convictions, akin to the Football (Offences and Disorder) Act 1999.
- *Trespass:* 'Office invasions' by extremists should be addressed, possibly by extending the offence of Aggravated Trespass (Criminal Justice and Public Order Act 1994) to include offences inside buildings.

The seriousness of this issue calls for immediate steps to be taken while this single piece of legislation is developed. Therefore, the BIGT supports efforts to amend and make more effective use of existing legislation to combat animal rights extremism in the short-term.

Legislation alone will not create a secure environment – this must be developed in parallel with ensuring police operations and enforcement practices are effective. The research community also has a role to play, through partnerships with Government and law enforcement agencies, and utilising appropriate civil routes. However, it is the role of Government to provide a safe and secure environment to sustain the UK as a world leader in medical research.

2.2.2 Support the work of the Coalition for Medical Progress in encouraging informed public debate on animal research, and seek to optimise the involvement of patient groups in this work.

Current situation: Despite the broad public support on this issue, as cited above, the perception remains of the UK as a country, which is hostile to research involving animals. The media tends to report on the activities of a vocal minority, with the views of scientists and patient groups less well represented. The public will want to draw its own conclusions on issues as emotive as this. It is our responsibility to promote a fact-based, rational discussion about the extent of animal experimentation in the UK today; the benefits that arise from such research; and the strength of current regulation surrounding it. Comparatively few people understand, for example, that the UK today runs the most stringent regulatory regime on animal experimentation in the world. The BIGT wants to raise the level of public debate, among people of all ages, on this critical issue.

The recommendation:

- Continue Government support to build on the work of the Coalition for Medical Progress (CMP). The CMP comprises a cross-section of organisations connected with such research – commercial, charitable, academic and funding – that have decided to step up their efforts to provide public information on this issue.
- Create a Government-funded, independent web forum for public debate on animal research, moderated and managed by a reputable third party. Whenever debates on biomedical research take place (e.g. at schools), the result is positive. It would be useful to enable this to happen on the Internet. www.sparkingreaction.info is a similar idea covering nuclear waste issues.
- Conduct a Government-funded survey, run by CMP, on the two issues shown to be of most concern to the public regarding animal research: the seriousness of seeking alternatives to animals and the avoidance of suffering. This survey would help focus communication and identify areas of change within the biomedical community that would be most appreciated by the public.
- Provide Government funding for schools materials on the use of animals in medical research, created and delivered by Biomedical Research Education Trust and the DfES. The BIGT is not aware of any such material currently being produced for schools for use under the new citizenship topic.
- In addition, the BIGT welcomes the recommendation by the House of Lords Select Committee on Animals in Scientific Procedures, that a centre for the 'Three Rs' – reduction, refinement, and replacement – should be established. The BIGT recommends that as part of this process, the Government funds a review of the contribution of the industry to the development of alternatives to animals in medical research.

2.3 Adopt a proactive approach to bioscience regulation and reputation management, actively shaping the UK and EU regulatory environments of the future.

A growing number of regulatory decisions are now made at EU level, with the result that influencing European legislation is crucial to ensuring a secure regulatory environment for the future. Recent examples of potential threats to UK competitiveness from EU legislation include the unnecessary cost and regulatory burden placed on early stage clinical research by the Clinical Trials Directive, which threatens to make the EU a less attractive location for clinical trials than the US. As well as the proposed amendments by the European Parliament to the Tissues and Cells Directive, which could prove obstructive to stem cell research.

Often the real threat from other EU member states, which either do not understand the potential benefits of bioscience or do not consider its continued development to be a priority.



High blood pressure

This threat was underlined by the Prime Minister, the Rt Hon Tony Blair, in Prime Minister's Questions on 18th June 2003.

“The biotech industry in this country is immensely important, and it is important for its future that it recognises that decisions made by Government will be based on proper scientific evidence. It worries me that there are voices, here and in the rest of Europe, that are not prepared to give enough consideration to the potential benefits as well as the potential downsides. All I say is that it is important to the future of our country and other countries that the decision is made on proper scientific grounds.”

Rt Hon Tony Blair, Prime Minister

It is also important that the UK does not settle for diluted compromises on EU legislation that would have an adverse impact on our competitive position. Equally, proportionate transposition of EU directives into UK law is essential, to avoid 'gold plating' EU legislation while other member states choose not to do this.

A more proactive stance is needed within Europe to shape future regulations and ensure they are acceptable to the UK. The BIGT believes the following steps should be taken:

2.3.1 Create a Bioscience Risk Assessment Forum (BRAFF)

under the auspices of the Bioscience Leadership Council (BLC) to monitor and assess emerging issues, develop issue management strategies, and anticipate areas where regulation may be needed.

The BRAFF should be created under the auspices of the Bioscience Leadership Council (BLC) (described in detail in *Chapter 6*). The BRAFF should be industry-led and include representatives from Government, academics, health professionals, ethicists, industry representatives, patient groups and other groups. The forum would have two major roles – horizon-scanning and regulatory issue management – which should be dealt with in separate working groups.

The group should explicitly take both a short-term (1-2 year) and a long-term (3-5 year) view, and meet as a whole once a year to:



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- Review new technologies and innovations of commercial or medical importance that require specific regulations within the UK and/or the EU, and to discuss any future regulatory issues that the UK may seek to influence.
- Monitor and assess emerging and current issues.
- Identify those issues that require active management (either because they present tangible threats or opportunities).
- Review any current activities and initiatives already underway by companies, industry, research or other groups.
- Make recommendations for the development of tightly focused, single issue management strategies.

Early assessment and prioritisation of risk issues – potential threats and also opportunities – are therefore critical success factors for helping to anticipate and plan for change. Planning and development of a single issue communication strategy, supported by trusted third parties, is an effective means of neutralising critical claims and misinformation, while also facilitating adequate time and resources to articulate complex information in jargon-free ‘benefit’ statements.

Considering how the bioscience industry should improve its approach to effective issue management and associated communication, it is also worth noting that:

- Experts no longer command automatic trust, no matter how genuine their expertise.
- Messages are judged first by whether their source is trusted.
- Trust is created by openness – listening and responding to stakeholder opinions and concerns.

Attempting to undertake broad public information or promotional campaigns is neither feasible in terms of resource, nor likely to be particularly effective because of the range of different interests and opinions to be influenced. Instead, the recommendation is to focus on a tailored and incremental approach to improving issue and reputation management for the industry, under the auspices of the BIGT.

Regulatory working parties could be formed within the group to develop precise recommendations for responses to regulatory issues of likely public concern. Raporteurs could be appointed to take forward further work with sub-committees as necessary, and relevant research could be commissioned by the BRAF.

Recommendations from the review process might focus on specific initiatives that could be co-sponsored. For example:

- To encourage competitiveness or innovation;
- A media campaign designed to improve information delivery and build relationships with key reporters/editors – providing them with a well produced industry briefing kit;
- A patient support group/medical charities workshop to harness a programme for presenting health benefit messages through individual patient experiences – which could be shared and promoted through a co-sponsored annual conference; and
- Educational initiatives, designed to improve the reputation of science at an early education stage, in order to contribute to the talent pool downstream.

A key objective is that senior industry and Government officials should

meet on a regular basis to discuss and agree a small number of high quality, high value strategies that can genuinely deliver on objectives.

2.3.2 Create an ongoing programme of activity to shape opinion in Europe. This would include:

- Government support for industry to run events in Brussels (and Strasbourg) on an ongoing and issue-by-issue basis, e.g. regenerative medicine, animal research. These events would be designed to inform and educate UK MEPs (and MEPs from other member states in conjunction with EuropaBio⁹) and key Commission officials about issues of importance to the bioscience industry. As the meetings would have to be both timely and relevant to attract interest from MEPs, the BIA could put forward speakers from UK industry, academia and especially patients groups and charities. These events could be organised into a high-profile 'Research Issues Week' in order to generate greater interest.
- A monthly email bulletin for MEPs, coordinated by the BIA, on timely and relevant research issues, to which a range of organisations could contribute: industry, research groups, and patient groups. This would ensure that a broad range of messages reach MEPs in an easy and convenient way, and also encourage cooperation within the

UK on issues of importance. The bulletin would tackle a single issue per month, covered from different angles, rather than a sweep over the bioscience developments of the month. As well as issues of high priority to industry, it should also address issues of high priority to MEPs.

2.3.3 Create alliances across EU member states to support the bioscience industry on an issue-by-issue basis.

There is no single set of countries with a consistently aligned view on bioscience issues in Europe. The position of different countries varies depending on the issue. The BIGT therefore recommends creating alliances on an issue-by-issue basis, both proactively (e.g. on issues identified by the BRAF) and reactively (e.g. in response to specific EU directives). This needs to be done through national associations, and should encompass research bodies and patient groups as appropriate in each member state. The involvement of science attachés in British embassies in the other member states could also be useful. In order to avoid diluted compromise positions on important issues, alliances should consist of smaller groups of four to five member states that are equally motivated, and where research bodies, patient groups, academia, and other parties, can also be mobilised.