

on average); it costs much more than in other sectors to bring a new product to market (£1.15bn per new medicine, including the costs of failure and capital); and there are very close links between the private and academic sectors.

The uncertainty and length of time involved means the outcome of a research project will not be known until many years after the decision to invest has been made, and significant sums have been spent. Companies aim to have a portfolio of high-risk and low-risk projects and the extent of innovation is unpredictable at the point when the investment in R&D is made. Understanding this is important in order to provide the right economic incentives to generate socially valuable R&D.

Pricing systems provide signals to the pharmaceutical industry about whether and where to invest in R&D, depending on what is rewarded and how. The relationship

between pricing mechanisms and rewards for innovation was discussed in the WHO Priority Medicines Report of 2004. This report argues, among other things, that prices in Europe are set at levels that do not fully reward innovation. This, along with delays to reimbursement decisions, leads to uncertainty among stakeholders and encourages companies to launch their products first in non-European markets.

Given the importance of pharmaceutical R&D investment to the UK economy, these considerations should command the attention of policymakers. To encourage continued pharmaceutical investment in innovation, the steady process of incremental advance and the different dimensions of innovation will need to be recognised and rewarded. Looking at the history of medicine development shows that it is just such incremental advances that have led to the considerable improvements in,

for example, antibiotics, anti-epileptics and statins, that have had such major patient benefits.

Therefore, a value-based pricing system will need to allow for a broad definition of innovation. Any policy that does not recognise all aspects of value in a new medicine, including value that accrues outside the health system, and that might increase the uncertainty of reward that companies face, might end up discouraging potential worthwhile R&D investment.

It is still early days for value-based pricing and the new system can – and must – be designed to recognise the reality of incremental innovation. Innovation is a complex, multi-faceted and uncertain matter and valuing it will undoubtedly be a daunting challenge. It is vital we succeed. Whether it is antibiotics or cancer, HIV or heart disease, our success in pushing medicine to its limits is inextricably tied to how well we

recognise and incentivise innovation. Only rewarding eureka moments would choke off that potential.

The stakes are high, not just for our health, but for our pharmaceutical and biopharmaceutical industries as well. Late last year, the Prime Minister launched the Government's life sciences strategy, acknowledging the importance of these industries to growth and jobs. Finding the way through to incentivise incremental innovation in pricing will be an important test of that strategy's durability and strength.

# IMPLICATIONS OF THE NEW EU DIRECTIVE REGULATING ANIMAL EXPERIMENTS FOR THE UK

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**On 9 November 2010 a new European Directive on the Protection of Animals used for Scientific Purposes (2010/63/EU)<sup>1</sup> came into force. If this is implemented in line with the intentions encompassed in its recitals, there will be a significant improvement in the regulation of animal experiments in many Member States. However, in the UK, which already has a well-developed law regulating animal use, there could be serious negative consequences.**

The Directive is largely based on the UK Animals (Scientific Procedures) Act 1986 (ASPA), but as Home Office Minister Lynne Featherstone MP has acknowledged, a number of its provisions are 'potentially less stringent'.<sup>2</sup> For example, a higher

level of suffering could be caused than is currently permitted – an exemption clause allows researchers to make a case for using procedures involving long-lasting severe pain, suffering or distress that cannot be ameliorated –

and it could allow animals to be used again after a procedure, causing severe suffering. Minimum cage and pen sizes for some animals may also be reduced, affecting both the space available for animals to move around and the capacity to provide appropriate environmental complexity.

If implemented in the UK, these changes alone would represent a significant retrograde step for animal welfare and humane science. The situation is exacerbated by the fact that current UK law is implemented through Codes of Practice, Guidance and protocols that interpret the Act and set out the expectations of how it should operate in practice. Over the years, these have provided the opportunity to improve on the statute, so that the regulation of animal experimentation in the UK has developed into a system that is commonly stated by successive Governments and spokespersons for industry and academia to provide strict regulation and high welfare standards. However, in transposing the Directive, the Codes of Practice and Guidance will also have to change – and it may not be for the better.

Member States are given some freedom to maintain their current standards where these are higher than in the Directive, so one might expect existing UK standards to be retained. But there is intensive lobbying by some factions within industry and academia to adopt just the minimum standards and reduce the regulation associated with animal experiments.

In transposing the Directive, the Home Office also seems to be considering transferring more control from the Home Office to individual establishments. Whereas there are advantages in the latter bearing greater

responsibility for what they do, it is worrying that controls at a local level could also be significantly reduced if the current local Ethical Review Process (ERP) is replaced by the Directive's 'Animal Welfare Body', which has a reduced membership and remit.

Compounding all of these problems is a recent reduction in the Home Office Inspectorate. Inspectors are central to the functioning of the current UK system; they not only authorise research projects and inspect establishments for compliance, but also provide scientific and welfare advice which is greatly valued by the research community and has provided a driving force in raising UK standards of both welfare and science. Any further reduction in Inspectorate numbers would be especially hard to understand given the universal acclaim within the research community for the work that they do, and the fact that the entire running costs of the Animals in Science Regulation Unit are covered by licensing fees. Given the level of public concern over animal experimentation, it is surely completely unacceptable to reduce the Inspectorate and therefore reduce the safeguards and protection for animals.

Animal welfare organisations such as the RSPCA are not alone in these concerns about the future regulation of animal experiments within the UK. Many of our colleagues at the 'coal face' in industry and academia are also deeply worried. Pressure to reduce regulation of animal use often cites the need to maintain a competitive science base for the UK. But competitive science has to be good science, and this is now widely recognised as depending on good animal welfare. There are many factors that affect competitive science

that have nothing to do with 'bureaucracy'. These include the poor standard of experimental design and reporting and questionable validity of some animal models increasingly acknowledged in the scientific literature,<sup>3,4</sup> together with a lack of basic understanding and respect for animal behaviour and biology. In the RSPCA's view, the scientific community ought to address these issues if it is truly concerned about the quality and competitiveness of UK science.

To conclude, choosing to adopt the new minimum baseline regulations set by Europe, whilst at the same time reducing the Home Office Inspectorate, would be a false economy that could have serious implications for the welfare of animals, the quality of science, and for public confidence that animal experiments are appropriately regulated and controlled. It is difficult to see how this would equate with the declaration of the House of Lords European Union Committee that there should be 'no weakening of standards in the UK'<sup>5</sup> and with statements by Home Office Minister Lord Henley giving 'an absolute and categorical assurance that we will not be dropping our standards in any way whatever'.<sup>6</sup> However, the devil is in the detail, and there are conflicting opinions amongst different stakeholders as to what might actually constitute a 'weakening' or 'reduction' of standards. As we have heard delegates in expert working group meetings significantly downplaying animal suffering, and even arguing about whether animals can experience suffering at all, the RSPCA would argue that the need to protect laboratory animals and give them the benefit of the doubt is as strong as ever – and it is

important that the new system of regulation reflects this.

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