

The *Academy of Medical Sciences* | FORUM

Response to Sir David Cooksey's Review of UK Health Research Funding

July 2007

Introduction

This paper is the product of initial discussions organised by the Academy of Medical Sciences' FORUM with industry. In response to the publication of Sir David Cooksey's Review of UK Health Research Funding¹, the FORUM convened a dedicated session to consider the implications of the report for its members. Attendees at the meeting are listed in the annex to this paper. The key points raised at that meeting were brought together in a draft paper, which was considered first by a small working group, and then at the FORUM Annual General Meeting, where all members were given the opportunity to comment.

The points below relate to selected themes from the Cooksey Report that are of particular relevance to the FORUM.

Key themes

A single fund for health research and the Office for Strategic Coordination of Health Research (OSCHR)

Research should be viewed as a continuum from basic research to product development. The FORUM takes the view that the research budget of the Medical Research Council (MRC) must be maintained to at least at the current level; there is a strong case for increased funding for basic biomedical research. Areas identified in the Cooksey Report as requiring additional money (such as training) must be supported by new funding from the forthcoming Comprehensive Spending Review (CSR), rather than from existing committed MRC resources.

Bringing the MRC and NHS R&D together under the oversight of OSCHR provides an unprecedented opportunity to increase UK competitiveness in health research. However, care should be taken to enable the MRC to maintain its links with the other research councils. Furthermore, the MRC and NHS R&D need to work more effectively with industry; the FORUM welcomes this opportunity to define how this essential engagement can best be achieved.

¹ Cooksey D (2006). *A review of UK health research funding*. HM Stationary Office, London. http://www.hm-treasury.gov.uk/media/4/A/pbr06_cooksey_final_report_636.pdf

There are concerns about the impact of OSCHR on the future of UKCRC (the UK Clinical Research Collaboration) and the potential limitations for biomedical research integration in the devolved administrations, since the MRC deals with the whole of the UK, while NHS R&D relates only to England.

Research priority setting

The FORUM supports the Academy's original response to Sir David Cooksey's consultation, which cautions against over reliance on a 'top-down' approach to setting research priorities. Priority setting should be non-exclusive; some critical discoveries have come from unpredicted sources and it is important that such curiosity-driven research should not be excluded by too much focus on targeted programmes. Dialogue with a broad constituency is important, and the input of other sectors will allow better-informed decision-making.

A focus on the UK's disease priorities should also not mitigate against supporting research in areas such as basic immunology and inflammation. These may not have an immediate clinical outcome but a greater understanding of such mechanisms will help to develop treatments for a range of diseases in the longer term.

We emphasise that it is not possible for the UK to lead in all research fields and instead advocate a greater focus on existing areas of UK research excellence and on strategically important areas where the UK should seek to build leading positions. The UK is very strong in basic research and early stage experimental medicine and these strengths must be maintained. It is becoming increasingly difficult for the UK to compete for later stage commercial clinical trials, which suggests that the benefits of additional funding in this area may be limited. Across the field, the quality of research is paramount; there is no value in funding poor research, even in a priority area.

The importance of transparent and robust peer review in all funding applications remains essential if the best research is to be undertaken. We strongly recommend that greater efforts are made to secure increased involvement of industry scientists in this process.

Role of the Translational Medicine Board (TMB)

Translational research is not only a very important element in healthcare development but one in which it should be possible for the UK to evolve a leading position. The TMB will be a critical body for uniting the MRC and NHS National Institute for Health Research (NIHR) in this vital area. If the TMB is envisaged as a priority-setting board, we question whether it should have its own budget for funding translational research.

Implementation of research

The Cooksey Report's vision to for a more research-oriented culture in the NHS is welcome, particularly its support for the clinical research networks. There is scope for significant improvements in the implementation of new research technologies and drugs in the NHS; building an improved relationship with industry would be especially helpful here.

Early /conditional licensing and approval of new drugs

This issue is covered in chapter 6 of the 2005 FORUM report '*Safer medicines*'.² The FORUM is supportive of the overall goal of streamlining and shortening regulatory review of new medicines, but remains sceptical that conditional approval could really be achieved, even at a European level. It is important to define exactly what is meant by the term 'conditional approval'. We believe it should be defined broadly to encompass increasing early patient access to new medicines.

The implications of conditional approval, for example on company liability and intellectual property, also need careful consideration. The FORUM looks forward to contributing to the proposed Ministerial Industry Strategy Group (MISG) Regulatory/Technology Forum³ discussion on this aspect of the Cooksey Report.

The implementation of the NHS National Programme for IT (NPfIT) through 'Connecting for Health' could be a key enabler in stimulating greater collection of drug safety data in a real-life setting. It could also support observational studies on drug and multi-drug effects. A key and ongoing area of work for the FORUM involves the many other opportunities for improving the drug discovery pathway.

National Institute for Clinical Excellence (NICE)

We support the suggestion that there should be earlier dialogue with NICE regarding new medicines. However, it is essential that MHRA regulatory approval and NICE approval remain independent of each other.

There is a suggestion within the report that NICE could become involved in the design of clinical trials. Care should be taken to ensure that guidance from NICE on clinical trials does not become too prescriptive. Although NICE guidance on the criteria likely to be required for a drug to enter the UK market would be welcomed at an appropriate stage, it is important to recognise that these issues are quite separate from the design of clinical trials to prove both efficacy and safety, which necessarily form part of a global programme. In addition, improved interaction between NICE and the Health Technology Assessment (HTA) programme would be welcome.

Other issues

The UK as a research base for industry

Although industry's research endeavours in the UK do map relatively well onto current NHS healthcare needs and priorities, caution should be exercised in the extent to which industry's research programmes can be influenced by UK health needs, as opposed to UK

² Academy of Medical Sciences (2005). *Safer Medicines*. Academy of Medical Sciences, London. See <http://www.acmedsci.ac.uk/p99puid61.html>

³ http://www.dh.gov.uk/en/PolicyAndGuidance/MedicinesPharmacyAndIndustry/IndustryBranch/DH_4113974

expertise and capabilities. The pharmaceutical industry is global and whilst the UK currently represents 10% of global pharma R&D, it holds only 2-3% of the global pharmaceutical market.

Biotechnology and small businesses

A healthy biotechnology industry is important for the UK. SMEs provide an essential contribution to the translation of basic research into the clinic and ultimately into patient benefit. A strong SME sector can play a key role in helping the UK pharmaceutical industry to remain strong. As discussed above, priorities need to be defined broadly to ensure small biotechnology companies working in only one or two areas are not disadvantaged.

Cost of drugs

The FORUM welcomes opportunities to improve the R&D process and the potential reduction in the cost of drug development that could arise from the implementation of the Cooksey Report's recommendations. We challenge the parts of the Review that imply that the escalating cost of drugs is placing an unsustainable burden on the NHS; in fact costs have remained relatively stable through the years.

Training

We hope that the forthcoming 2007 CSR will include consideration for the funding of clinical fellowships and emphasise the need to ring-fence training budgets. If the UK wishes to remain competitive, we need to stimulate a greater interest in research amongst clinicians, for example by funding more MB/PhD studentships, and secondment of clinicians into industry for training (and vice versa).⁴ Creating a culture within the NHS where research is facilitated is crucial (as covered in '*Best research for best health*').⁵

⁴ Academy of Medical Sciences (2007). *Careers in Industry*. <http://www.acmedsci.ac.uk/publications>

⁵

http://www.dh.gov.uk/en/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentStrategy/DH_4127109

Conclusions

- The unification of biomedical and healthcare research, as recommended by the Cooksey report, provides an unprecedented opportunity to create a leading international medical science environment in the UK to drive success both for patients and the economy.
- MRC funding for basic research must be maintained and preferably enhanced.
- The MRC must maintain strong links with other Research Councils; both MRC and NIHR must improve their relationships with industry. Industry's role as a 'third partner' in biomedical and healthcare research should be more explicitly recognised.
- OSCHR provides a critical opportunity to prioritise research areas but must accept that the UK cannot be internationally competitive in all fields. An emphasis on funding research in areas where the UK is already strong and seeking to support strategically important new topics (e.g. stem cells) is justifiable.
- OSCHR must consider the needs of SMEs.
- It is essential that curiosity-driven research is not compromised by an overly top-down prioritisation process.
- Transparent and robust peer review must be fully integrated into all funding considerations.
- There are concerns about the impact of OSCHR on UKCRC and how integration will be achieved in the devolved administrations.
- The TMB is a vital component of the new process. If it is not to have its own budget, it must be able to influence the priority setting of MRC and NIHR.
- There is scepticism about the likelihood of conditional approval for new medicines being accepted internationally.
- NICE processes must be kept separate from that of the MHRA; while NICE advice pertains only to the UK, clinical trials are necessarily aimed at international regulatory approval.
- We strongly support for the Report's emphasis on training, but emphasise that this must be supported by additional funding, to avoid depleting existing research grant resources.

Annex: Meeting attendees and FORUM Advisory Board

Meeting attendees

Dr Barry Furr OBE FMedSci (Chair)
Dr Sue Middleton, GlaxoSmithKline
Dr Jeff Kipling, GlaxoSmithKline
Dr Aileen Alsopp, AstraZeneca
Dr Richard Torbett, Pfizer
Dr James Carmichael, AstraZeneca
Dr Helen Munn, Academy of Medical Sciences
Ms Jenny Steere, Academy of Medical Sciences (Secretariat)

Advisory Board

Dr Barry Furr OBE FMedSci, AstraZeneca
Dr John Young, Merck Sharp & Dohme
Dr Mike Collis, Independent consultant
Dr Jeff Kipling, GlaxoSmithKline
Dr Richard Sullivan, Cancer Research UK

The Academy of Medical Sciences

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Academy of Medical Sciences
10 Carlton House Terrace
London, SW1Y 5AH
Tel: +44(0)20 7969 5288
Fax: +44(0)20 7969 5298

E-mail: info@acmedsci.ac.uk
Web: www.acmedsci.ac.uk

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