



**The Association of the
British Pharmaceutical Industry**

Consultation Response

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Subject: **REVIEW OF UK HEALTH RESEARCH**

Date: 28 July 2006

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Executive summary of ABPI input

The Cooksey review represents a potential turning point for the UK's prospects in the life sciences and for the human health businesses they create and sustain. With its history of strong basic life science and the development of major global companies, the UK has been a global leader in the sector, but its position has begun to seriously erode. Over the last decade R&D investment has grown more rapidly in the US (both in terms of public and private sector R&D) and the consolidation of the worldwide pharmaceuticals industry has made the US the corporate base for the majority of larger companies. Hence the US has become the first choice location for most life scientists and corporate R&D groups. And R&D investment outside the US is increasingly going to high growth Asian and Eastern European economies, rather than to Western Europe, as a result of determined and well-funded support from the governments concerned and/or the lower costs available.

To address this serious situation and reinvigorate the UK's leadership position, within the resources available, we need imagination and realism in equal measure. So our recommendations build on existing strengths in peer-reviewed public-funded basic research, they strengthen areas, processes and skills that span the public-private interface and they create high-performance hubs and networks for world-leading clinical research in selected disease areas, for the benefit of both public and private sector trials, and especially for patients.

In summary, we recommend:

- **The creation of a Health Research Board** with an overview of the total budget for UK health-related life sciences R&D, a budget that should be set at the maximum affordable level, in the range £1.25-1.5billion*. This 'arms length' agency should have key senior representatives from both public, private and charitable sectors and be

measured on, and accountable for its performance in strengthening the UK's competitiveness across the whole spectrum of health research, and for the impact of innovation on the quality of care to NHS patients.

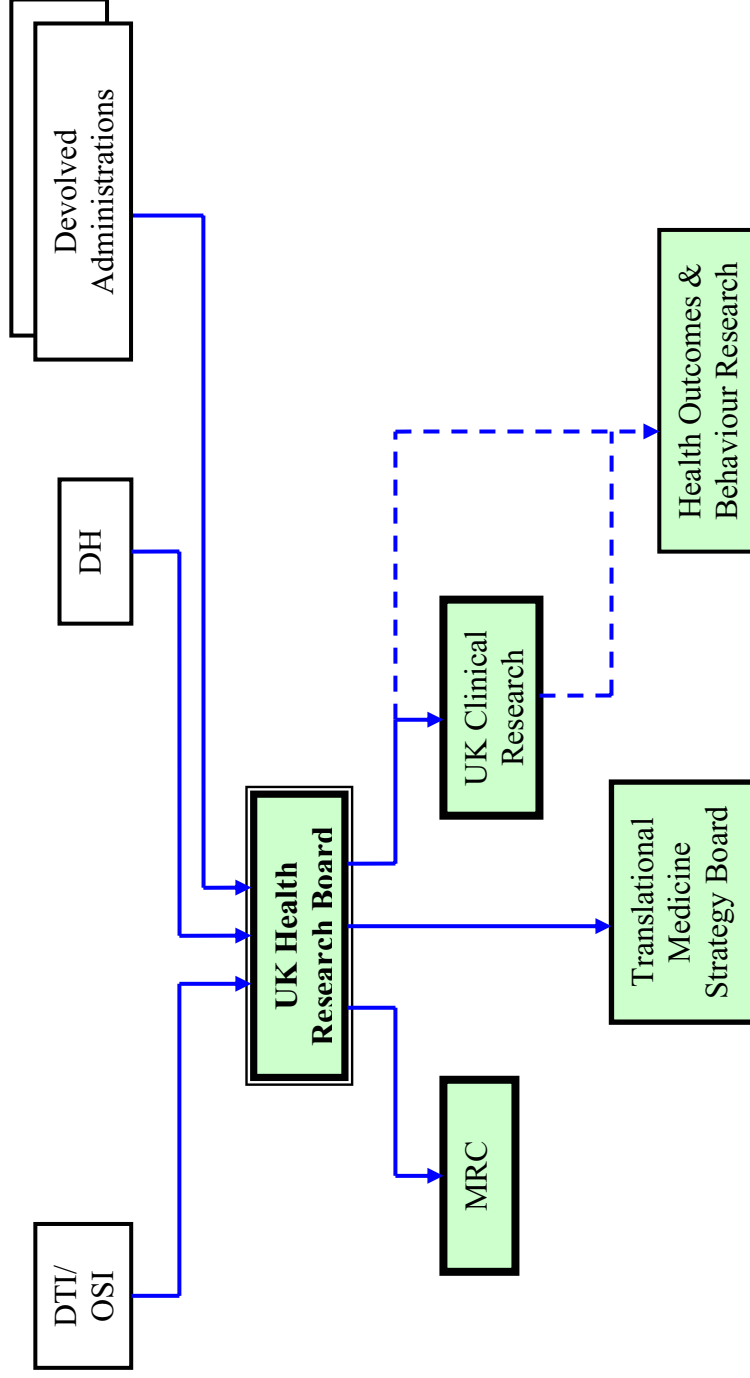
- **The preservation of the bulk of the basic biomedical research** financed through the MRC, at a level of approximately £500million*. This should sustain work sponsored in universities and its own institutes, with broadly the current balance between responsive and commissioned research. We would encourage even greater dialogue and cooperation between the MRC, the other research councils, industry, the Wellcome Trust and other research charities to promote key growth areas of interdisciplinary research in which the UK can lead.
- **Stronger incentives for collaboration** between MRC-sponsored research and companies to ensure that commercial relevance is one theme to guide biomedical research priorities and to help shift the 'ivory tower' culture remaining in some parts of UK science and medicine. Enhanced industrial membership, along with other stakeholders, on the various panels and boards would be of use to align high quality research and training with UK needs.
- **The creation of a Translational Medicine Strategy Board** to forge a more connected link between basic and clinical science, by supporting the creation of pre-competitive tools such as biomarkers and imaging facilities and the expertise and facilities for first-into-man studies. Such an initiative should include public/private partnerships where consortia or individual companies have an interest in developing new tools, such as the use of stem cells for predictive toxicology. A budget of approximately £100million* seems appropriate to ensure these opportunities are grasped; if successful in building these capabilities in the UK, we will also be able to compete effectively for European funds under the now-agreed IMI initiative. To be effective, the UK must also train more MD/PhDs and clinical pharmacologists able to bridge between biomedical science and clinical medicine – the MRC and NIHR must work together to build UK capability.
- **The completion of disease-specific clinical trials networks** with substantially more user-friendly and competitive features. These networks should have a clear 'hub', in the form of a globally recognised medical centre and single, accountable operational leader, and 'spokes' in the form of associated centres and investigators. Importantly, trial sponsors must be offered a single point of access, a clear and internationally competitive cost structure, an effective and timely evaluation process and the tools to ensure rapid identification and recruitment of patients.
In this connection, the capability offered by the NPfIT programme in England and its counterparts in Scotland and Wales is a vital component of future competitiveness, and adequate funding must be provided to the CfH organisation for the incorporation of research-related features early on in the programme. If necessary, we would support the use of Health Research Board funds to catalyse this. In addition, we propose specific incentives for Trusts and investigators to engage in clinical research.
An overall budget for clinical research of (say) £700million* seems appropriate if this is dedicated to trials infrastructure, training in clinical science, provision of incentives and the conduct of publicly funded trials. There should be single ministerial responsibility within DH for delivering the impact of this substantial investment.

- **The formation of a specific Health Outcomes and Behaviour Research initiative** to assess the real-world impact of new therapies and procedures; it would also investigate the drivers of public and patient behaviours that promote wellness and adherence to therapy, and to trial new approaches and technologies to changing behaviour. Again, the capability inherent in NPfIT will be critical to UK leadership in this area, and it will be an important element in both accelerating uptake of new clinical approaches and demonstrating their economic impact. A budget of approximately £100million* would make a big difference in this area.
- **Balanced implementation across the four nations.** While we favour channelling the whole UK budget through the Health Research Board, we would give it an explicit mandate to encourage centres of excellence in each of the four nations, working closely and where appropriate co-funding with the devolved administrations.

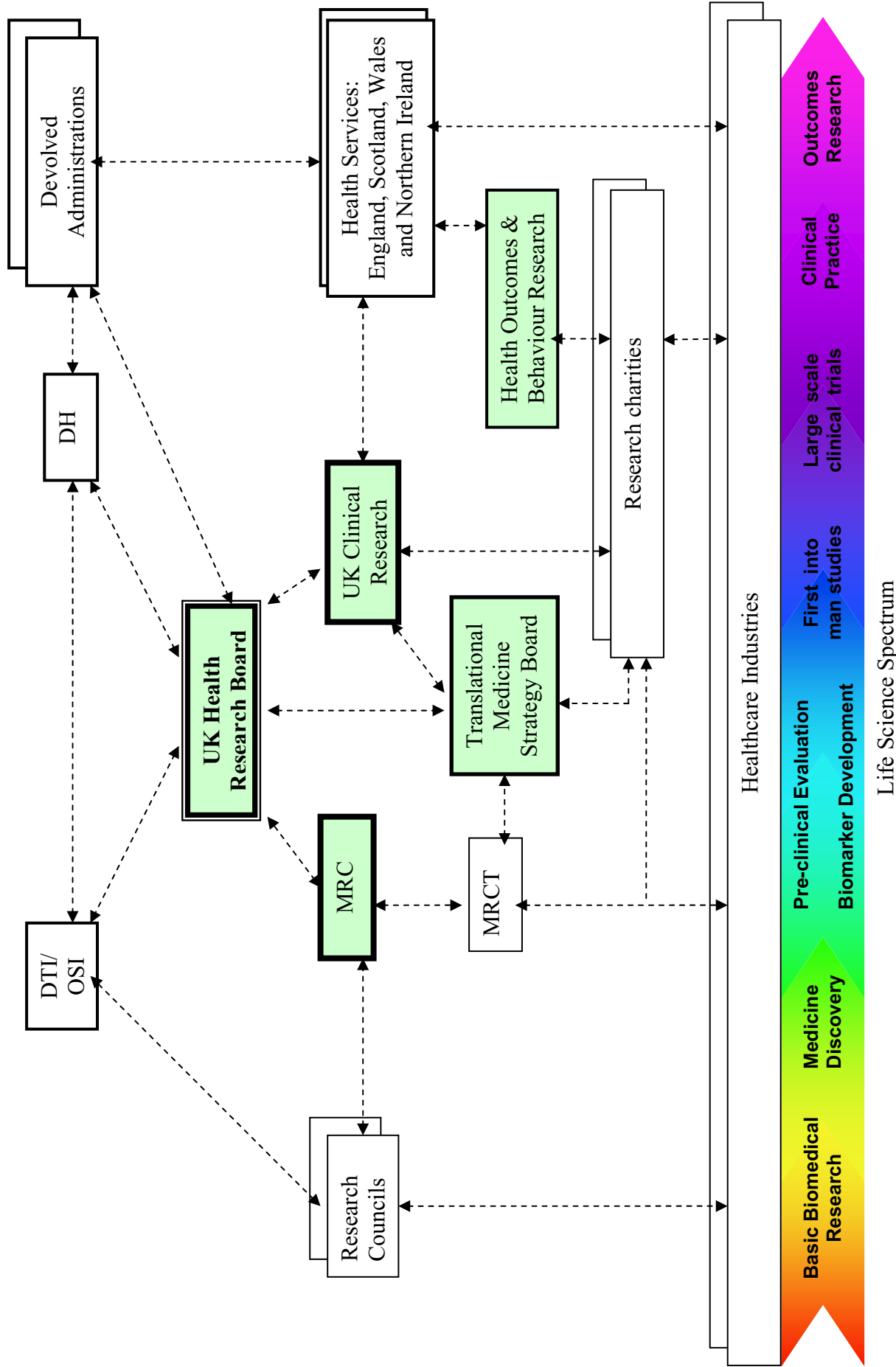
The aim of our proposals is not only to safeguard and build disciplines of distinctive UK leadership, but also to make the UK a place of maximum connectedness throughout the journey from molecule to medicine, from scientific advance to clinical care.

* The levels of funding stated above are only indicative and would be reviewed periodically allowing long-term commitment to individual projects whenever possible.

Proposed Organisation and Funding Model



Stakeholder Interactions



Introduction

The Association of the British Pharmaceutical Industry (ABPI) is the trade association for more than 75 companies in the UK producing prescription medicines. Its member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the National Health Service (NHS).

The strengths of biomedical and clinical research in the UK are vital to the pharmaceutical industry to carry out R&D and have been a key element in attracting investment to the UK. Links between all research stakeholders should be reinforced in order to facilitate joined up working relationships for more successful outcomes. This would require strengthening capability and skills, from preclinical to clinical research, accessing new and emerging knowledge through collaborations and utilising this knowledge base more effectively. This would also necessitate building on the current clinical infrastructure to achieve world class clinical research capability in selected disciplines. Health outcome research is also essential for demonstrating positive patient health outcomes which would support better uptake of successful new medicines.

Key principles

The industry welcomes the initiative to create a new single fund from the MRC and the NHS R&D Programme budgets and is in agreement with the terms of reference stated in the consultation document.

In particular, key UK strengths that should be built upon are as follows:

- Sustain the quality of the science base, especially strengths relevant to medicines discovery (biology, chemistry and investigation of disease mechanisms) and to preclinical research through to experimental medicine, including early clinical proof of concept.
- Continue to facilitate collaboration between the Research Councils for inter- and multi-disciplinary research, out of which much new advance comes.
- Build ‘next generation’ capabilities in translational medicine.
- Build on traditionally high quality UK clinical research to create globally competitive networks in UK-relevant disease areas, under the umbrella of UKCRC.
- Support the development of the National Institute of Health Research and the outcomes of the NHS review of R&D.

We support the intent that NHS R&D funding be properly ring-fenced and aligned with NHS operational and clinical needs. It is also essential to create the infrastructure that would support phase 2 and 3 clinical trials and provide the NHS with clinical research capabilities to support health outcomes. Also vital will be the leverage of unique opportunities from *Connecting for Health* to support clinical and operational research with a working electronic infrastructure and feed in to earlier discovery and preclinical development – including appropriate access by companies. *Connecting for Health* can also provide a facility for active surveillance of newly introduced medicines and other therapeutic interventions, making the UK more attractive as a place to launch and monitor new therapies.

However, a number of questions that remain unanswered need to be considered as part of the creation of a new single fund:

- How will NHS R&D funds allocated be taken into account in relation to the dual support system?
- How will the Scotland, Northern Ireland and Wales question be resolved? One approach could be akin to the arrangement with the Research Councils – for example amounts to support infrastructure are allocated from central fund by devolved NHS departments to follow research and training funding.

Response to Consultation Questions

1. What are the strengths and weaknesses of the MRC and NHS R&D programmes at present? How do each of these support the research and training needs of the NHS, social care, industry and academia? Does more need to be done?

The Medical Research Council is characterised by a high quality science base with long track record of international achievement. Its historical supply of skills, especially *in vivo* sciences encompassing pharmacology and toxicology, plus the traditionally strong supply of medicinal chemists (with EPSRC involvement) has led to sustained investment in the UK. Consequently 24 of the world's top 100 selling medicines originated in UK-located industry laboratories.

However, the MRC has relatively poor levels of collaboration with industry which it regards largely as a licensing opportunity rather than a true partnership (as other Research Councils tend to do). The MRC must also be open to broader collaboration (for example via linkage to the DTI's Technology Strategy Board initiatives).

The NHS R&D programme provides access to potentially 60 million people in the UK and progress has been good so far although it is early to assess its real impact. Its strong engagement with both the UKCRC and industry, as well as its existing work programme to establish the Clinical Research Networks, are very positive contributions towards UK healthcare research. Centres of Excellence in the NHS should be supported further within specific areas of expertise (e.g. paediatrics and oncology), building on Clinical Research Networks. It is essential to create a culture of change in terms of clinical and operational effectiveness and transform the NHS by supporting innovation at all levels. Cultural and infrastructure changes should aspire towards continuous innovation. An initiative on product and/or device development through to clinical application could be one mechanism to drive innovation through to patient benefit.

The NHS has not proved to be very successful with its past programmes of change or improvement and needs to tackle the innovation issue through the recognition of its impact on patient care and improved mechanisms to encourage clinicians to conduct research. The creation of new integrated infrastructure to support research is welcome. The devolution of management to individual NHS trusts gives rise to concerns due to variations in approval structures. NHS trusts should be encouraged to take part in the NHS R&D process through stronger incentives and open competition between trusts to receive them.

In relation to training needs, the UK suffers from a poor supply of clinical research skills and translational pharmacologists which should be tackled by both the MRC and NHS R&D. addressing these needs explicitly is crucial if UK health research is to thrive. ABPI recently conducted a comprehensive review of the STEM skills pipeline required for the pharmaceutical industry. ABPI have worked closely with SEMTA, the Sector Skills Council for Science,

Engineering and Manufacturing Technologies, over the last three years during which time little progress has been made towards creation of a Sector Skills Agreement to identify and deliver the skills required by the pharmaceutical industry, despite considerable time being spent on collaboration by ABPI staff and representatives of the pharmaceutical and bioscience industries.

The main concerns we have with the Skills for Business network are:

- There is currently no effective mechanism for Sector Skills Councils to work together to meet the needs of an industry such as ours which cross the boundaries between several SSCs;
- Credibility with employers in the science sector has been patchy and, with little progress made, they have become disaffected;
- Progress towards a Bioscience Sector Skills Agreement continues to be very slow, despite appointment of a bioscience consultant to address this issue, and we have concerns at how any momentum achieved will be continued after his 12 month appointment finishes as very few staff have any understanding of the needs of science based industry.

We anticipate that the UK Health Research Board could overview the biomedical science skills provision through ensuring joined up thinking between MRC, the UK Clinical Research Board and the Translational Medicine Strategy Board. However it must be recognised that the needs of physical science skills, those required for manufacturing and for economic and social science must also be addressed.

2. What do you believe are the key scientific and organisational challenges facing health research, and underpinning training, in the UK over the next decade? How might the UK Government best help address those challenges? What do you believe should be the Government's objectives for health research, and why?

New generations of medicines require new mechanisms of pre-clinical R&D and clinical research and practice. The historical UK strengths of discovery research, preclinical development (pharmacology) and safety assessment are all being eroded and the skills base¹ needs significant investment to re-establish the UK's distinct competitive advantage. Consequently a number of issues must be addressed:

- The number of doctors emerging from medical schools with experience and training in research must be enhanced, and clinical pharmacology should be more strongly represented in all medical school curricula.
- Translating new medicines, therapies and clinical practice across the NHS requires a more positive approach to innovation (being defined as “the successful exploitation of new ideas”) and greater engagement of all levels of NHS staff.
- Government must actively support Modernising Medical Careers and there must be dedicated research time available within consultants and GP contracts for those who are or want to be involved in research.
- Government must consider, with some urgency, the funding that will be available for research post 2008 after which NHS funding is projected to grow less rapidly.

¹ *Sustaining the skills pipeline in the pharmaceutical and biopharmaceutical industry*, ABPI, November 2005.

- More effective engagement of patients and the wider public are key – encouraging positive health behaviours in terms of prevention and disease management will be critical in realising the potential of medicine in the 21st century at an affordable cost.
- The UK is well positioned to be a leader in infectious disease and funding in this area will clearly add to UK investment in developing world health.

3. What should be the Government's priorities for health research? Is there anything it should stop doing or funding? What is it not doing or funding that it should do, and, in the absence of further sources of support, what can it lower in order to release the necessary funds?

As summarised in the UK Health Research Mapping by UKCRC, there is a good spread of research capability, but the emphasis should be on:

- **Quality research** – mechanisms akin to those seen in the Research Councils should be adopted, with strong peer review. There needs to be clarity around what is collaborative research (shared cost and shared intellectual input with shared benefits) and contract research.
- **Enhanced skills supply** – from discovery research (key biological disciplines and chemistry), preclinical sciences through to clinical pharmacology and clinical research skills all need to be boosted, with a more focused approach to support young scientists when their capabilities and expertise are emerging and their energy is at the highest.
- **Further infrastructure development** – MRC has a good balance of funding Centres of Excellence and the NIHR/UKCRC have laid the groundwork for creating a good research infrastructure for clinical studies: the latter must be followed through and further specific Centres of Excellence established on a competitive basis.
- **Public health outcome and behaviour research** – evaluation of health outcomes and understanding and modification of patient/public behaviour are key areas on which to focus. Staff at all levels across the NHS should also be encouraged (perhaps through small awards) to develop research and innovative practices that will spread good practice and progressively change the culture.
- **Enhanced uptake of new medicines in UK** – participation in clinical studies, through to rapid uptake of the innovative medicines that result from these, represents a continuum which leads to real patient benefit. The currently poor uptake in the UK is a significant barrier to research being placed here.
- **Health Technology Assessment** – this is a critical area for guiding NHS expenditures but the current HTA process (NICE, etc.) needs considerable improvement to enhance quality of assessment and create tighter links to local clinical practice.
- **GP contract** – The Quality Framework within the GP contract should include research as one element.

4. How should decisions be taken on the balance between the long-term economic and social benefits of a high quality biomedical research base; and the needs for research to improve healthcare and other public services? What is the appropriate balance between public funding for investigator-led and priorities led research? How do we balance funding for basic science, translational science and applied science? Is this something that should vary over time? What mechanisms should be used to make judgements about this balance?

ABPI believes that a high-level “UK Health Research Board” should be established to address the balance of funding. The Board would:

- Have broad, high level composition: this could include the CMO’s of the four Home Nations, the S&I Director, leading academics, research charities and senior international level industry R&D representation (from pharmaceutical, biopharmaceutical and diagnostic/device backgrounds), plus nursing and patient representatives.
- Provide guidance and direction on the balance of and allocation of health research funds between the basic research base (i.e. Medical Research Council) and NHS-oriented, clinical research, clinical practice advancement and health outcomes research.
- Be charged with sustaining high quality research, and monitoring the short-term and long-term impact of health research funding.
- Establish disease-specific networks covering key NHS priorities. Funding areas where the UK has little strength or capability will undermine competitiveness and waste money.

5. In your experience, how have the results of publicly-funded health research in the UK been used, both in the development of new treatments and to influence / change wider policy and healthcare practices? What lessons can usefully be learned to improve the uptake of advances in science and medicine?

The MRC has a long history of innovation in medicines and therapeutics development (for example, monoclonal antibodies arose from MRC-funded research and, more recently, the Dundee Kinase Consortium is opening up several new therapeutics research avenues). The impact of R&D funding in the NHS is less clear, but it is too early to assess the impact of the UKCRC and the NIHR. Arguably all new medicines have required access to patients for late stage clinical development – support for trials placed in the UK will have had a positive impact on patient outcomes. The National Cancer Research Network (NCRN) is an excellent example: 11% of cancer patients are now in clinical trials, higher than anywhere in the world (the average in the USA is 3-4%). This outcome needs to be emulated in all the other disease networks, for both publicly funded and commercially sponsored research.

6. How might better links be forged between ‘basic’, translational and applied researchers, working across the whole field of health research, from the laboratory bench to the front line of the NHS? How might better links be forged across disciplines, e.g. with engineers, physicists, and social scientists?

The best form of knowledge transfer is “on the hoof”. The best transfer of technology and research knowledge into application occurs through working relationships between people – successful schemes in this regard include LINK, Teaching Company and joint industry-university PhDs. In

this context we advocate a greater focus on ‘translational medicine’, bridging between preclinical science and clinical development in man.

Translational medicine is not just about moving a specific medicine from preclinical to clinical stages, but includes the development and application of technologies to speed the process. The creation of a Translational Medicine Strategy Board – building upon the model of the DTI Technology Strategy Board – would support the translation of key strategic technologies from the research base into application in both companies and the clinic. The Board would fund:

- Translational medicine research programmes from across MRC, NIHR and other stakeholders (other Research Councils, industry and Departments). These could take the form of:
 - LINK or Technology Programme-type initiatives.
 - One- or multiple-year programmes.

Each Programme would have a Steering Group to manage and monitor the programme, reporting to the Strategy Board. A flexible approach could be adopted reflecting differences between discovery and underpinning research and operational, clinical outcome oriented research. Examples could include stem cell research and biomarker initiatives (e.g. in predictive toxicology).

- Training and personnel exchange programmes to assist with transfer of new clinical tools and approaches between public and private sectors.

Consideration should also be given by the UK Health Research Board, to the MRC Technology fund also being placed within the remit of the Translational Medicine Strategy Board to assist with seed-corn and venture funding of new ideas. This could also expand the concept of the proposed MRC “road shows” of research across all health research areas.

Successful initiatives adopted abroad should also be investigated. As an example, in the USA, within the NCI, investigators leave their research laboratories to visit patients on the wards, to give them greater insight into the real clinical situation. This type of approach could be adopted in the UK Centres of Excellence. Consultant contracts and excellence awards should also reward research involvement.

7. How can the Government encourage translation, entrepreneurship and innovation in health research to improve public services in the UK?

Consideration should be given to an “innovation” fund to support local initiatives across the whole NHS organisation. Awards could be small and allocated on a Strategic Health Authority and Primary Care Trust basis. This would require further consultation and views, but innovation is not just about new products – in fact a new product itself is not innovation: it requires successful exploitation. The concept of the training and personnel placements described in question 6 could assist. Reward systems should be put in place that align research and innovation with outcomes and uptake.

8. How can UK health research funding be most effectively used to provide the appropriate infrastructure for basic, translational and applied research, whether funded by the UK public sector or other sectors? How can UK health research funding be most effectively used to support the work of NICE, facilitate innovation and collaboration with industry, and address market failures in the application of healthcare?

Funding through the UK Health Research Board, and consequently both the NIHR and MRC, should be long-term. Funding of infrastructure especially should be regarded as a long-term commitment and both funding bodies, along with the proposed Translational Medicine Strategy Board, should have long term research strategies (five to ten years) against which funding should be allocated. Underpinning research and NHS/patient oriented research will require differing types of infrastructure. The NIHR, with advice from the MRC and the UKCRC, is best placed to identify needs and initiatives. However the UK Health Research Board should monitor and provide direction to ensure there are no gaps in provision.

There are a number of critical areas that the NIHR, working closely with the Economic and Social Research Council, should focus on, in addition to clinical research. These are:

- Health outcomes research;
- Health Technology Assessment;
- Health economics; and
- Patient and public health behaviour research.

Capacity and quality needs to be built in all these areas and consideration should be given to funding targeted studentships and fellowships. In addition placements from the research base into clinical environments can also assist; there have been a number of initiatives in the past in other arenas (e.g. the Teaching Company Scheme and Senior Academics in Industry), that could be used as models.

It is critical that Connecting for Health provides broad and robust capability for outcomes tracking and hence enables good research. This would give NICE access to a much broader evidence base and hopefully also improved interpretation of that evidence, including both health and overall economic impact of new technologies.

9. What lessons should the UK learn from other countries in making the proposed changes to the institutional arrangements for the funding of health research?

Care must be taken in interpreting other countries' institutional arrangements – in terms of the research base at least, the UK is seen as among the leaders with its Research Councils. Key points are:

- The USA has strong clinical networks, especially for late clinical development – the UK could learn from this and build upon the CRNs to enhance capability in this area.
- Some US organisations (like Kaiser Permanente and the Cleveland Clinic health system) provide a more unified interface with clinical trial sponsors. Local barriers and variability between Trusts in carrying out clinical studies must be addressed, and variation in overhead costs needs to be eliminated.
- England could learn some lessons from the devolved nations, particularly Scotland, on how to develop efficient research networks.

- The delay in getting trials started is having an adverse effect, with trials going to other parts of the world, especially the much lower cost Eastern European and Asian countries.
- The UK is also one of the slowest countries in the EU to adopt new treatment regimens and must change this – it is a significant issue when considering placement of clinical research.

10. In implementing the single fund for health research, to what extent should the MRC and DH / NHS R&D be merged or brought together? And to whom should the single, ring-fenced fund be accountable? Please provide reasons and any supporting evidence for your response.

To maximise the UK's opportunities we need to build on existing strengths, so we believe the UK Health Research Board should receive and manage a single fund, as a joint initiative between DH and DTI (OSI).

However, there are a number of arguments against merging the MRC and NIHR organisations themselves:

- The MRC must maintain strong links with the other Research Councils.
- NIHR should retain an outcome/patient oriented agenda and therefore close links with the NHS.
- The NIHR (as currently constituted) covers England and MRC covers the whole of the UK.
- MRC funding leverages the block grant in universities from HEFCE, SFC and HEFCW, while NHS funds require infrastructure support through a different route.
- The potential downside of the organisational disruption likely to result from a full MRC/NIHR merger does not seem to be justified by any major gains from such a move.

The Health Research Board will clearly be jointly accountable to its Departmental funders (DTI, DH), but it may be worthwhile to create a singular reporting point in the form of a Cabinet sub-committee with PM/Chancellor chairmanship to resolve any differences of view that might arise. Pragmatically, it is likely that the funds will be distributed through existing Departmental routes and the only part of Government where ring-fenced funding for R&D currently exists is the Office of Science & Innovation – hence it is ring-fencing of research funds within DH that is the key new challenge.

The UK Health Research Board should direct and monitor health research funding across Government and publish an annual review that assesses progress against specific metrics. A recent McKinsey report showed that industry funds 70% of UK health R&D and therefore will be a major source of innovations in the UK. Hence industry should be regarded as a key stakeholder in this process.

11. To what extent does the success of recent innovations in health research (e.g. Clinical Research Networks) and the proposed structures rely on the new Connecting for Health NHS IT system, and to what extent should it do so?

The Clinical Research Networks are creating the human infrastructure to support UK capabilities in particular areas. These should continue to be supported and are an important part of realising the opportunity from the NIHR and delivering the objectives outlined in the consultation document of both improving health and wealth.

Connecting for Health is a unique potential asset which provides a significant opportunity to further enhance UK health research in several ways:

- Recruiting patients for clinical studies
- Assisting with the implementation of ‘personalised medicine’
- Assessing the real-world outcome of new therapies
- Providing support for earlier research by linking, for example, health outcomes or biomarker research from the clinic back into discovery and preclinical research

However *Connecting for Health* has yet to be delivered as a working system and therefore the Clinical Research Networks and other UKCRC initiatives should not wait for its arrival. However, it is vital that, as it is designed and delivered, *Connecting for Health* supports not only routine care but also research - if the UK is to remain a major centre for health research in the world of epidemiology, drug safety and clinical research.

Although it might be too early to judge whether the Clinical Research Networks have been successful, they have been a very welcome initiative. Other areas that would also benefit from a review are as follows:

- CT approval process – it would be beneficial to make this process faster.
- Behaviour as the key element of health improvement, rather than the traditional focus on late stage intervention.

12. Given that NHS R&D is currently devolved, but that the work of Research Councils is not, how can these functions work best together to maximise the health and economic benefits to the UK?

The structure we propose would solve the issue of devolution and NHS funds as follows:

- MRC funds should continue to apply across the UK, with dual funding (QR) support coming from HEFCE, SFC and HEFCW as appropriate.
- NHS R&D funding should also be identified on a UK-wide basis and be targeted at infrastructure support and incentives to encourage R&D across the 4 nations, but we favour a specific NIHR mandate to encourage centres of excellence in all four, with perhaps a ‘floor’ level of funding to be allocated to each nation.
- The Translational Medicine Strategy Board should include Welsh and Scottish funding representatives who can participate and contribute to the funding of specific initiatives and projects. (See response to question 6).

The ABPI appreciates the opportunity to respond to this vitally important consultation and is ready to amplify and/or discuss any of the points in this submission.