



The American Pharmaceutical Group

Cooksey Review submission

1. Introduction

1.1 The American Pharmaceutical Group welcomes this government's commitment to innovative health research in this country and the pledges it has made to support and develop the British science base. We are very pleased to have the opportunity to submit evidence to this review.

2. American Pharmaceutical Group

2.1 The American Pharmaceutical Group (APG) represents the ten leading research based US owned pharmaceutical companies who invest in the UK. The group was established in 1985 to improve understanding of the industry, and the healthcare contribution of the American companies in particular, among government, parliament and interested stakeholders.

2.2 Collectively, we account for over 35% of UK sales of prescription medicines and employ over 17,000 highly qualified staff with over 4,500 working in research and development (R&D) and almost 4,000 in manufacturing. As a group we invest over £1.5 billion a year in R&D and export more than £1.7 billion of prescribed medicines. Much of our time and investment is spent on the investigation of highly pioneering medicines and we represent some of the UK's most innovative research companies.

3. Supporting innovation

3.1 While a single fund for public-funded research will ensure guaranteed funding for health research and aid the move towards a more innovative British business society, it is important not to lose site of the prime sponsors of health research in this country: the pharmaceutical industry.

3.2 The UK based pharmaceutical industry is knowledge driven, research and manufacturing based and has a very real impact on the health and wealth of the nation. Pharmaceuticals account for £2 billion in terms of trade balance in the UK. In addition, the pharmaceutical industry, and the innovation driven companies in particular, are incremental in supporting the science research base in this country. Not only does the industry employ almost X% of the nation's scientists, but also sponsors, partners with and generally supports other research facilities such as university science departments and small start up companies.

3.3 Innovation brings health improvements for patients and savings for healthcare systems, makes a strong contribution to economic prosperity and

development and without it there could be no generic pharmaceutical industry. Due rewards for both radical and incremental innovation are necessary for the continued delivery of these benefits in the UK.

3.4 If the UK is to continue to attract high-value and high-quality inward investment from US headquartered global pharmaceutical companies which in turn will foster innovation, it needs to remain committed to investing in the science base and making the UK marketing, pricing, tax and regulatory environment really attractive to those companies. Most importantly, such an environment guarantees continued access to new, safer and more effective medicines for NHS patients and the UK population, while also improving efficiency in public services. There must be appropriate rewards for innovative companies to both sustain their efforts and raise the bar of their achievement.

4. Health research: Speed, Quality and Cost

4.1 There are three factors which influence where a company locates its research base globally: speed, quality and cost. Compared to the emerging economies the UK is proving more expensive and slower as a location for clinical research, although it retains some of the world's most talented researchers. The quality of clinical research available in the UK means it is still an attractive location for health research investment. However, other countries, such as India, are steadily improving the quality of their clinical research and so the UK must protect and support its science base, while attempting to reduce the cost and time delays of the clinical research process.

Speed:

Return on investment

4.2 The UK is perceived to be slow at starting clinical trial projects and at achieving its trial participant recruitment deadlines. The UK also has the lowest take up of new medicines across Europe. These factors impact upon the speed at which patients receive new medicines and affect the size and speed of a company's return on investment. The reasons for low uptake are complex but include conservative prescribing, the lengthy review process by the National Institute for Health and Clinical Excellence (NICE) and slow implementation of NICE guidance.

NICE

4.3 NICE is the world's leader of evidence-based medicine and has done much to promote this concept. However, NICE presents some problems for the research-based pharmaceutical industry, especially the delays it causes before a company can receive a return on investment (ROI) for their new medicine.

4.4 The APG would suggest the following changes which could be made to ease the negative impact of NICE on health research and development in this country:

- Earlier dialogue between NICE and clinical researchers would help to better direct research to ensure a satisfactory and speedy NICE appraisal.
- The government must restate its position on prescribing in the absence of NICE guidance. The industry has found that many prescribers and NHS trusts are reluctant to prescribe or fund a new medicine before NICE has reviewed it. As well as preventing patient access to new, innovative medicines, this produces a delay on ROI.
- NICE topic selection and the appraisal process must become speedier and more transparent. The APG welcomes the move by NICE to introduce a speedier assessment process.
- NICE must widen its focus to include current inefficient NHS practices. The APG welcomes the government's announcement on 21 July 2006 challenging the NHS to end inefficient practices.
- NICE must re-examine its criteria for assessing the impact a medicine has on quality of life and should consider adjusting the arbitrary QuALY limits set.
- There must be moves to ensure that NICE guidance is implemented consistently throughout the country and that funding is made available to do this.

MHRA

4.5 Similarly the Medicine and Healthcare Products Regulatory Agency has admitted its own slowness in reviewing and licensing of medicines. This must improve to allow companies and others to realise return on investment and allow patients access to new medicines.

Quality:

Science base

4.6 The UK is a world leader in healthcare research and the APG acknowledges the government's commitment and actions to ensure that the UK remains at the forefront. However, the pharmaceutical industry remains concerned about the depleting quantity and quality of British science graduates. This is especially evident in the fields of chemistry, clinical pharmacology and in vivo biology. High quality scientists are fundamental to research in this country and are the drivers of scientific change and discoveries. There has also been a steady brain drain of high-class academics to countries abroad as British institutions fail to compete on the world stage in terms of salaries and research funding. The opportunity to collaborate with these individuals and institutions is one of the UK's main attractions to health research investment and so the effect of their loss should not be underestimated.

4.7 The government must commit to the continuation of clinical trials in this country by ensuring that the approval and regulation process is not overly bureaucratic or arduous. The opportunity to partake in clinical trials allows researchers to play a leading role in cutting edge science. If clinical trials are lost to countries abroad, this will result in a further brain drain.

Cost:

Clinical trials

4.8 The UK is the second most expensive location in the world to host a clinical trial. The cost of researching and developing a new medicine typically costs in the region of £500 million and clinical trials contribute to 60% of this cost. In the wake of the tragic Northwick Park incident it is important to remember that additional approval and regulatory processes will only add to this cost, reducing the UK's competitiveness.

Pricing

4.10 In addition, as a result of successive Pharmaceutical Pricing Regulation Scheme price cuts and the ending of many medicine patents, medicines are 21% cheaper in real terms now than they were 10 years ago. The fall in return on investment means the UK has been steadily losing ground to the USA in terms of research and development, development of innovative medicines and worldwide sales over the last decade.

5. Funding health research

Commitment

5.1 The APG welcomes this government's high profile commitment to maintaining the UK as a leader of health research. However, a careful balance is required between political commitment to health research and the influence of political concerns on research priorities. Long-term funding commitments are required if research is to generate successful outcomes and research priorities should be set by all stakeholders, not just the government.

Blue sky versus applied research

5.1 While the Chancellor has stated that he wishes to 'align health research more closely with health objectives', funding should always be made available to 'blue-sky' research as well as more applied research. 'Blue-sky' research increases our scientific understanding and leads to many novel discoveries, which benefit the research community and society as a large. For companies who must make a ROI in order to survive in the long-term, 'blue-sky' research is extremely difficult to fund. The pharmaceutical industry already shares the Chancellor's ambitions by focusing heavily on research which is aligned with health objectives by looking

for medicines which will mostly benefit the maximum numbers of patients (for example chronic diseases), or those suffering from orphan diseases. However, new medicines have often been discovered as a result of accident or unrelated research and there is a need to ensure that research with less direct or clear objectives is funded, otherwise opportunities will be lost. State funding of 'blue-sky' research is therefore crucial, especially if the UK is to retain its leading edge in scientific knowledge.

5.2 The Chancellor has also stated that he would like a more coherent approach for translating results into economic benefit. This translation would be aided by better collaboration between basic and applied health science. There is need for those working in clinical research to have a sound grounding in basic research to allow better communication with those working in basic science through a common scientific language.

Other methods of funding

5.3 Other methods of funding are equally as important as state funding if the UK is to remain competitive. The pharmaceutical industry is the prime sponsor of medicines research in this country and reinvests 30% of its sales income into research and development.

5.4 The pharmaceutical industry's continued presence in this country brings investment into UK academic research centres and provides the opportunity for collaboration. If entrepreneurial spirit is to be embedded in this country, it must be fostered and access to the capital markets must be easy and common. This is already institutional in the US, where smaller companies and university spin offs have better opportunities to find investments and are proactive in their quest to secure this.

Examples of other methods of funding:

5.5 Translational medicine research collaboration

The translational medicine research collaboration, TMRC, is a partnership between Wyeth pharmaceuticals and NHS Grampian, Greater Glasgow, Lothian and Tayside, and will embrace 70% of the Scottish population.

The TMRC structure will encompass four partners: Wyeth, Scottish Enterprise, the NHS and four leading Scottish Universities. The TMRC will establish four centres of excellence within the universities of Aberdeen, Edinburgh and Glasgow, which will support a focal research institute at the University of Dundee.

Specialised clinical research programs will be undertaken at each of the university's medical schools. The four centres of excellence will also perform specialist patient-based studies, linking with the research laboratory.

Wyeth has spent more than £1.4 billion on research and development in 2005 and has assumed a leadership role in translational medicine, bridging the gap between basic pre-clinical drug discovery and the clinic. Wyeth is investing £33 million and Scottish Enterprise £17 million toward this pioneering initiative.

“This translational medicine research collaboration, TMRC, represents a truly novel concept in industry-academic-government partnership.” Frank Walsh, Ph.D. Executive Vice President, head of Wyeth Discovery Research.

Jack Perry, Chief Executive of Scottish Enterprise, says, “Translational medicine provides a major opportunity to reduce the bottlenecks in the development of new drug treatments, resulting in significant benefits in economic development and health.”

5.6 The UK Clinical Research Collaboration (UKCRC)

Janssen Cilag Ltd, part of the Johnson & Johnson family of companies, is committed to the continued support of clinical research in the UK, due to the excellent quality of data and clinical investigators. The UK is an expensive location to perform research and is perceived to be slow at starting projects and achieving its recruitment deadlines. Therefore, Janssen-Cilag Ltd has taken the decision to go into partnership with the Mental Health Research Network, part of the UK Clinical Research Collaboration (UKCRC). The UKCRC is a partnership of organisations working to establish the UK as a world leader in clinical research by harnessing the power of the NHS. Janssen-Cilag Ltd is the first company to have a project adopted by one of the research networks.

6. Summary

The UK is a world leader of health research due to strong commitment from the government and sustained research and development investment by the innovative pharmaceutical companies. If this country is to retain its position it must take actions to speed up the process of clinical trials, protect its strong science base, fund both blue-sky and applied research and ensure companies are able to make a fair return on investment.

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