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Summary

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Summary

An implicit public–private partnership for the pharmaceutical industry in the UK

The UK Government has been at the forefront of developing public–private partnerships (PPPs). These partnerships are based on the view that neither public ownership nor privatisation is the only answer to the provision of public services, but that a partnership between both sectors can exploit the strengths of each.

Since its establishment the NHS has had close links with the pharmaceutical industry. Although there has been no formal PPP there has, in effect, been an implicit public–private partnership for the provision of pharmaceuticals (that is, medicinal drugs). The pharmaceuticals industry and government interact and work together in a number of important ways, from early blue-skies research that might throw up new ways of developing drugs, through to the final stage when decisions are made about the use of drugs within the NHS.

This implicit PPP involves the following main elements:

- **Research and development (R&D)** The private sector is the main spender on R&D for pharmaceuticals, although the public sector offers support through subsidies or tax breaks to the industry and also carries out and funds medical research on its own account.

- **Patents** The pharmaceutical industry is bound by the patent laws applicable to all branches of enterprise. Patents offer protection from competition, which creates the conditions within which profits can be made. These profits finance the large-scale R&D that drug development requires.

- **Access to NHS patients and facilities** The development of drugs from laboratory to actual application is dependent on the availability of NHS patients for trials of the drugs. Pharmaceutical companies also need to use physicians and researchers, many of whom will be NHS employees, to carry out the trials.

- **Medicines control** State regulatory bodies determine what drugs can be sold and under what conditions – in the United Kingdom these are the Committee on the Safety of Medicines, the Medicines and Healthcare Products Regulatory Agency and the National Institute for Clinical Excellence (NICE).

- **Price control** In the United Kingdom, as in most other developed countries, prices are controlled through a voluntary agreement known as the Pharmaceutical Price Regulation Scheme (PPRS). This is deliberately designed to leave companies an adequate profit margin to finance a high level of research, at the cost of increased prices to the NHS.

- **Scientific and clinical professions** These groups work within the public and private sectors but they are also to some degree autonomous, operating under rules of their own.

The implicit partnership has been strengthened and made more explicit through the work of the Pharmaceutical Industry Competitiveness Task Force (PICTF). This task force, set up in 2000 and jointly chaired by a minister and a senior industry figure, has identified a number of ways in which the Government can improve the process of drug development and in so doing help maintain a strong pharmaceutical industry in the United Kingdom.

Has the implicit PPP delivered?

Within the existing implicit PPP the pharmaceutical industry has been the active driver, largely free to provide products that it considers likely to be profitable. The Government has tended to be a passive purchaser, rarely proactive and only in limited instances making clear requirements for specific outputs.

Given this, it is no surprise that the implicit PPP has been an economic success. For example, in 2001, the value of UK pharmaceutical exports was over £9 billion, with a record trade surplus of some £2.9 billion.

However, there are two significant problems with the way in which the implicit PPP currently operates.

First, because it is focused on new medicinal drugs, the implicit PPP neglects some other research areas that may be potentially beneficial for promoting people's health, such as alternative therapies. Research designed to protect and promote health currently attracts far fewer resources than research focused on the search for new pharmaceuticals.

Second, the implicit PPP does not fully take the needs of some major groups, including children and older people, into account. The Government has introduced a number of initiatives designed to empower patients and the public in the governance and delivery of health care. However, these reforms have not yet been extended to pharmaceuticals research.

There are weaknesses with each element of the implicit PPP. More importantly, the partnership as a whole is not sufficiently focused on achieving better health for the UK population. A reshaping of the framework within which the implicit PPP operates is needed if users of the health care system are to get a better deal.

Widening the implicit PPP

The current implicit PPP needs to be widened to include citizens and service users more effectively in decision-making, and to undertake research into areas of potential health benefit other than new forms of drugs treatment.

To promote these outcomes the roles of the private sector, public sector, the scientific and clinical professions and health service users need to be reworked. Changes by sector include:

- **Private sector** Incentives for the private sector have to be re-examined and modified in favour of ones that can be better used to promote publicly chosen objectives. This is likely to involve experimentation with elements of the implicit PPP (*see* p 1 for description), such as alternatives to patents.

- **Public sector** The Department of Health is unclear about where the current health research economy is failing. To address this it requires a greater strategic capacity. The benefits of expanding the public role also needs examining in the areas of basic research, pre-competitive research, neglected therapeutic areas, care delivery, and clinical research and trials in areas that attract no commercial funding. The independence of the whole process must be guaranteed, with more public oversight. The regulatory role should be modified to ensure openness, absence of bias, high scientific standards, and the promotion of trials that promise the greatest health gains.

- **Scientific professions** Further measures should be taken to ensure the science underlying the development of drugs and other therapies is independent.

- **Citizens and service users** Health service users are being encouraged to take a more active role in their own care and there are moves to involve members of the public as citizens and service users in the running of the NHS. These developments suggest that users should also be formal partners in any revised PPP for pharmaceuticals. The broader involvement of citizens could lead potentially to a radical reordering of research priorities and possibly encourage research into areas such as low-risk drugs, self-administered treatments, non-invasive interventions and measures which avoid the need for treatment.

Recommendations

While economic success is clearly a legitimate objective for a UK government to pursue, so too is the health of the nation. An implicit PPP focused on health-oriented research and development would be based on the following key principles:

- ☑ There should be systematic evaluation of neglected areas of research and development where there is potential high benefit, whether in the development of new drugs or therapies, or in areas such as post-licensing clinical trials.

- ☑ There should be equality of opportunity (in research terms) for different therapeutic options.

- ☑ All parts of the drug (therapy) development process should be considered at one and the same time.

- ☑ Citizens and service users should have a voice at all stages of the research process.

- ☑ It has already been identified that some groups are neglected or poorly served by existing research and development programmes in the public and private sectors. There is therefore a case for a Health Research and Development (R&D) Task Force. This task force could set about systematically identifying all the areas poorly served by the current implicit PPP and identify the appropriate response on behalf of the Government, the rest of the public sector and the private sector.

  This Health R&D Task Force should be established according to the following guiding principles:

  - The task force itself should not directly involve any research providers. It should only include users of research such as clinicians and other decision-makers, and current and potential users of health services.

  - Taking into account the principle above, its membership should be diverse in terms of disciplines and fields of expertise as well as personal experience.

  - It should be able to commission research in its own right into the priorities of citizens and service users, and into the current balance of research effort between new forms of treatment and other types of health care.

  - It should operate on a continuing basis.

  - It must be seen to be independent and therefore its operations need to be completely transparent.

  Specific issues the R&D Health Task Force might consider include:

  - how the public sector could be a better purchaser by developing the role of NICE 'upstream' and ensuring that the earlier stages in the therapy development process produce the data it needs
  - the gaps in the health research economy
  - the economic advantages of alternatives to patents, which preserve incentives to drug development within the private sector
  - how to redesign the process of defining the need for clinical trials so as to create a level playing field between trials that are driven by commercial interests and those undertaken for socially beneficial reasons
  - how the process as a whole – not simply the individual parts – can be improved.

  The recommendations set out above are intended to lead to the development of a public–private partnership (PPP) for the promotion of health. What the proposed Health R&D Task Force would in fact recommend remains an open question but it is likely that, at least in some respects, its proposals would conflict with the private

sector's view of its own interests as creators of employment and other benefits to the UK economy. The Department of Health would therefore be faced with the tricky problem of how to put together the results of the work done by the proposed Health R&D Task Force and that of the Pharmaceutical Industry Competitiveness Task Force (PICTF).

It has to be recognised that if the department were to attempt this task it would face a fundamental difficulty: regulation of the pharmaceutical industry is an international enterprise and so there are limits to what one country can achieve on its own, particularly if, like the United Kingdom, that country has a substantial industry. But while this presents an obstacle to some possible policies, such as a substantial change in the licensing regime, it does not get in the way of others, such as a redirection or expansion of the funds currently devoted to health-related research.

Moreover, in this field, a greater degree of internationalisation would be a positive factor since all developed countries share similar problems around such issues as adherence to drug regimes and control of their drugs spending. The recent report from the G10 (European Commission 2003) is an example of the scope for joint work. This report identifies a number of areas for international action but some, such as the creation of incentives to encourage research in line with public health priorities, can also be tackled at national level.

The Department of Health has recently restructured itself so as to focus on the strategic issues that only it can tackle. The task of getting the best – from the health viewpoint – out of the UK pharmaceutical industry and the wider health research economy is surely one such issue.

Ways forward

The King's Fund is ready to support the establishment of a Health R&D Task Force, if others express an interest in its development. For this task force to be effective it must include the views of all those who may be poorly served by the existing arrangements. This means, primarily, the general public, who are current and/or future users of health care. It also means clinicians and public health experts who may challenge the focus of research programmes on new treatment as opposed to the effective application of existing interventions, or highlight bias towards commercially viable interventions over other approaches such as behavioural change or public health measures.

On a wider front, the King's Fund remains committed to improving health for all and to challenging the inequalities faced by particular groups in society. Our activities include:

- **Promoting greater public and patient involvement in health and health care issues** – as a route to greater ownership of health and health issues at individual and community level, and to more responsive and inclusive services.

- **Drawing attention to areas where public interests, or the needs of particular communities, are under-represented** – such as the health-related research discussed in this paper, or the case for investing in local health 'advocates' in some of London's most deprived areas, to act as a bridge between health care professionals and their communities' needs.

- **Helping develop an effective health system** – with a greater focus on health outcomes, not simply on service delivery. In 2004, we launch a broad programme of work looking at how a complete 'health system' might work – for example, by building stronger leadership at national, regional and local levels, or by developing local health organisations that help people safeguard and improve their health throughout their lives.