

# Pharmaceutical Industry Competitiveness Task Force

*Executive Summary – March 2001*

Websites – Department of Health: [www.doh.gov.uk/pictf](http://www.doh.gov.uk/pictf)  
– Association of the British Pharmaceutical Industry: [www.abpi.org.uk](http://www.abpi.org.uk)

# Executive Summary

- 1.1** The Pharmaceutical Industry Competitiveness Task Force (PICTF) was set up following a meeting in November 1999 between the Prime Minister and the CEOs of AstraZeneca, Glaxo Wellcome and SmithKline Beecham. At the meeting the industry had made the point that the traditional factors that underpinned the UK's past success in pharmaceuticals were no longer on their own sufficient to guarantee good performance, and an initiative was required to ensure the UK retained its competitive edge. They expressed particular concern about issues relating to market access, and intellectual property protection.

## Context

- 2.1** The importance of the PICTF initiative is clear. The pharmaceutical industry is one of the UK's most successful industrial sectors. Its products improve the welfare of millions of people in this country and worldwide. The UK enjoys benefits in terms of pharmaceutical production and R&D investment wholly disproportionate to the size of the UK market. With a positive trade balance of over £2 billion, around 23% of total expenditure on manufacturing industry R&D in the UK (£2.85 billion in 1999), and direct employment of 60,000 people, the industry is a major contributor to the economy. Work in PICTF has calculated the net contribution of the industry to the UK at £0.7–2 billion per annum.
- 2.2** The conditions required for the industry to retain its competitive position are changing in the face of significant shifts in the global business environment. These shifts are driving pharmaceutical firms to take a much closer look at what each location offers in terms of access to required skills, proximity to technical partners, attractiveness of local market conditions, operational costs, and taxation rates. Companies now have a real choice as to where they should invest for the future.
- 2.3** The UK can therefore no longer count on a continuing significant share of industry investments simply by virtue of being one of a few plausible candidate countries, or on the basis of its past performance. Decisions and actions taken by Government will have a major influence on future investment decisions made by the industry and thereby on the contribution

it makes to the UK economy. It is against this background that a new partnership between UK industry and Government has been formed. The importance therefore of the PICTF initiative cannot be overstated.

## Assessment

- 3.1 PICTF has delivered an impressive number of important and tangible outputs that will contribute to UK competitiveness in the pharmaceutical sector. The relationship generated in PICTF has also benefited wider discussions between industry and Government. The industry has had helpful discussions, for example, with the Treasury on a range of fiscal and taxation issues.
- 3.2 There remain important matters where further progress is needed. Government and industry continue to work together to address tensions within the EU Single Market for pharmaceuticals, resolve issues over the potential impact of NICE on market access for new medicines, and maintain a supportive environment for the full range of essential medical research in the UK.
- 3.3 The participants in the Task Force process are pleased with the outcome. Joint working between Government and the pharmaceutical industry has been a success. Both Government and industry are committed to carrying the new spirit of co-operation forward into agreed successor arrangements which will address outstanding issues.

## Terms of Reference

- 4.1 PICTF met for the first time on 13 April 2000 and drew its initial business to a close on 1 March 2001. The terms of reference focused on:

*“The Pharmaceutical Industry Competitiveness Task Force will bring together the expertise and experience of the industry leaders in the UK with Government policy makers to identify and report to the Prime Minister on the steps that may need to be taken to retain and strengthen the competitiveness of the UK business environment for the innovative pharmaceutical industry.”*

## PICTF Approach

- 5.1 PICTF quickly identified the key areas of UK competitiveness where progress might usefully be made and established six high-level working groups to deal with the following areas:
- Developments in the UK Market
  - Intellectual Property Rights
  - Regulation of Medicines Licensing
  - Science Base and Biopharmaceuticals
  - Clinical Research
  - Wider Economic Climate
- 5.2 Early steps were taken in most cases within the lifetime of PICTF to improve UK competitiveness in the area concerned and measures agreed to continue the work. Competitiveness and performance indicators were agreed and action plans formulated to address areas where further progress might be made. The key indicators will be reviewed annually with periodic publication, providing a benchmark against which future major policy initiatives can be tested.

## Developments in the UK Market

- 6.1 The Task Force commissioned a major assessment of the key features of the relationship between the UK based industry and the home market. This was done on the basis of international comparisons to identify, and then compare and contrast, the advantages and disadvantages of the different market arrangements in 11 countries to see how they related to innovation and competitiveness of the local research based industry and its attractiveness to global R&D investment. The full results are reported in *The PICTF Access and Competitiveness Study*.
- 6.2 The UK scored very highly (second overall only to the US) on measures of innovation. On regulation and access to the market, the UK has historically offered relatively rapid initial access to market due to an efficient registration system and the absence of pricing and reimbursement procedures, after marketing authorisation is granted, which may delay launch of new products.

- 6.3** However, once on the market products in the UK are subject to a more diverse range of influences which potentially affect physicians' prescribing practices, than in almost any other country examined. GP prescribing habits are influenced by indicative budgets, prescribing guidelines (including the use of Prodigy) which together encourage clinically and cost-effective options, by monitoring and evaluation of prescribing patterns and costs, and by encouragement to prescribe generically. The introduction of NICE has reinforced demand-side influences on NHS prescribing.
- 6.4** With the introduction of NICE, the UK also differs in the way in which it uses pharmacoeconomics. The UK is alone in using cost-effectiveness analyses at national level to inform guidance to doctors on selected medicines. This represents a significant difference from practice in other countries, where it is primarily used to affect reimbursement decisions. It is seen by the industry as adding another layer to what they consider an already heavy burden of control on physician prescribing decisions in the UK.
- 6.5** There are existing demand-side controls in the UK, and uptake of new products is limited in the years immediately following launch and thus imposes little burden on the overall drugs budget (in 2000 less than 5% of medicines expenditure on products up to three years old). The industry believes that this evidence of slow uptake in the UK demonstrates the need for care in changing the regulatory environment in the peri-launch period lest such change prevents the rapid launch after grant of marketing authorisation, which has hitherto been a positive feature of the UK market. The Government believes that NICE is helping speed up the rate of uptake of new medicines, deliver consistency across the NHS on clinical and cost-effective prescribing and reduce inequity in access to medicines. The Government considers that GPs, and the NHS more broadly, are generally supportive of NICE and that it is helping to deliver high quality services and – in the vast majority of cases – promote greater use of innovative medicines.
- 6.6** PICTF considered the different viewpoints of the various parties on NICE. The impact of policies to modernise the NHS, and in particular the impact of the introduction of NICE on market access for new medicines in the UK, remains uncertain in that insufficient empirical data is yet available to determine its effects. Experience with NICE is accumulating and will help us to address these different viewpoints.
- 6.7** One of the principal outputs of the Task Force is a commitment from Government to explore fully and jointly the detail of the industry's concerns about how NICE operates. These discussions will address broader impacts on market access and the resulting competitiveness of the UK as a global player, as well as NHS perspectives. Discussions are focusing on the key issues of: timing in relation to the availability of data, opportunities

and limitation of modelling with reference to particular case studies, and how topics are selected for NICE appraisal. A number of other issues will also be reviewed. The discussions will culminate in a review, involving all stakeholders, of NICE's performance that is planned for July this year. Industry and Government have understood one another's concerns and positions in the course of the Task Force discussions and the challenge now is to resolve the remaining differences as quickly as possible.

- 6.8** The UK market has historically enjoyed considerable comparative advantage in the field of pharmaceuticals compared to all markets except, recently, the USA. However, the Government is seeking considerable change in the way the UK market functions. In this context, both Government and industry are agreed on the need to ensure that any proposed changes to the pharmaceutical regulatory environment are considered very carefully in terms of their potential to impact on the UK based industry. New policy measures should not be viewed in isolation, but as part of the overall environment. The probable impact of new policy directions on UK (including industry) competitiveness will be considered – with the pharmaceutical industry – prior to implementation. The policy of “no surprises” will be delivered more effectively by a much stronger and more senior ongoing relationship between Government and industry.

## **Future Market Directions**

- 6.9** Both industry and Government were determined that the Task Force take the opportunity to look forward to how developments in technology, policy, and industry pipelines might be dealt with in a manner consistent with overall competitiveness. The specific issues outlined below were considered to be priorities.
- 6.10 Industry involvement in development and implementation of National Service Frameworks (NSFs)** – national standards for fair access and high standards of care are being set by the Department of Health through NSFs in key areas of clinical priority identified in the NHS Plan. The Government is committed to positive industry involvement in the development and implementation of the NSF programme. In practice, industry involvement will be largely on a ‘NSF by NSF basis’ with detailed involvement tailored to the particular subject.
- 6.11 Potential for greater use by industry of NHS information** – given the necessary safeguards on security and confidentiality of patient data, there is potential for the NHS and industry to work together to develop data sources that will significantly improve the quality of information available for research into medicines. This potential applies across the whole range of pharmaceutical issues – health economics and outcomes research, clinical trials evaluation, epidemiology, safety, education and concordance.

Developing this potential is to the mutual benefit of the NHS as it facilitates the better clinical and cost-effective use of medicines and to the industry in its search for improved use of medicines and the development of new medicines. That in turn benefits both public health and industry competitiveness. Availability of high quality clinical information databases in itself encourages R&D investment. Under the auspices of PICTF, a workshop was held in January 2001 to discuss how better access to NHS data for pharmaceutical research and development purposes could be secured. Major issues remain to be explored further, but both industry and Government are committed to working together to find solutions that meet the legitimate needs of the NHS and its patients and improve the competitiveness of the UK in attracting investment from the global research-based industry.

- 6.12 Information for Patients and Concordance** – the desire of patients for reliable and balanced information about their health needs and the options available for treatment has never been greater. The Government very much encourages better patient information and sees clear benefits to public health if patients are well informed by accurate, balanced material. A key problem facing the industry is the extent to which they can legitimately (and legally) participate in this information revolution. Industry and Government therefore explored ways to improve public access to good quality information on licensed medicines.
- 6.13** An action plan is agreed between industry and the Medicines Control Agency (MCA) to look at the scope for moving forward within existing EU law. This will cover guidance on disease awareness programmes, including establishing scope for programmes where there is only one treatment available; will offer clarity on what could be included on pharmaceutical company websites under EU law and the scope for providing patient information already available in packs electronically in a more user-friendly way; and seek a practical definition of the distinction between advertising and information in Europe, with a view to the European Commission publishing guidance in this area. This work-plan represents a helpful package of measures.
- 6.14** However, in the industry's view, the prohibition on the advertising of prescription medicines to the public is unsustainable in the longer term. Industry considers that changes to legislation will therefore be required to deliver a truly rational package and bring accurate information on their products to the market.
- 6.15** Concordance is a new approach to the prescribing and taking of medicines. It involves a range of strategies to determine whether, when and how medicines are taken, and seeks two outcomes – health gain in terms of

the pharmacological intention of the treatment and health gain in terms of patient satisfaction. Industry and Government are committed to working together, and with others, to explore ways of improving the efficiency and effectiveness of medicines taking in the UK. Within the Pharmacy Programme, *Pharmacy in the Future – Implementing the NHS Plan*, the Government announced its intention to establish a Joint Task Force to lead the implementation of a national strategy on partnership in medicines taking. The Department of Health will invite pharmaceutical industry representation on the Joint Task Force and supporting infrastructure, including working groups on specific areas of action, such as research and development, communications, education and training.

- 6.16 Access to the market for non-reimbursed medicines** – discussions in the Task Force concluded that not all medicines developed in the future will necessarily be appropriate for use in the NHS. The pharmaceutical industry would like to see easier access to the part of the UK market which is outside the NHS and easier subsequent accessibility to patients. Specifically, the pharmaceutical industry seeks arrangements allowing NHS clinicians using NHS facilities to prescribe prescription only medicines (POMs) privately to their NHS patients, if the medicines are appropriate for their clinical need. The principal focus is on General Practitioners (GPs) to enable them to prescribe privately to patients on their NHS lists.
- 6.17** Industry and Government are agreed that there a number of aspects inherent in the current arrangements that must remain as “givens”. First, medicines will continue to be prescribable on the NHS once they receive a marketing authorisation (though, subsequently, they may be listed on Schedule 10 or 11); there is no question of moving to a system similar to those operated in most European countries under which medicines would have to be “approved for reimbursement” before becoming prescribable on the NHS. Second, the devolved administrations retain responsibility for deciding what medicines will be available on the NHS in Wales, Scotland and Northern Ireland. Third, a clear distinction should be maintained between the circumstances when private prescribing is allowed and when it is not (with clear rules for prescribers which are understood by them). Finally, advertising of POMs to the public is currently barred under an EU Directive.
- 6.18** Within these constraints industry and Government agree that a market for medicines not reimbursed by the NHS, which involves NHS prescribers, should be developed. There are a number of opportunities on which it should be possible to move forward. These fall into four areas. First, speeding up the scheduling process and exploring a voluntary mechanism which does not involve amending regulations each time a product is added to the list. Second, streamlining the processes for reclassifying medicines from POM to P (pharmacy only). Third, exploring the range of potential

alternative routes of access to non-reimbursed medicines, in particular the use of patient group directions and the extension of prescribing rights to other health professionals, such as pharmacists. And fourth, providing guidance to remind GPs about the rules on private prescribing and the status of advice from NICE and the position in the absence of any advice from NICE.

- 6.19 NHS developments in genetics** – it is agreed that a new partnership between Government and the pharmaceutical and biotechnology industries is needed so that we can maximise the likelihood of mutually beneficial advances from new developments in genetics. How best to deliver this needs to be considered further and the PICTF successor mechanism is expected to return to the issue later this year.

## Intellectual Property

- 7.1** Effective intellectual property rights (IPRs) are essential to the continued flow of innovative medicines, and PICTF considered that IPRs were one of the key issues in its discussions. The UK has a long history of efficient protection of IPRs but some of the most significant developments today are happening at the international rather than the national level. The UK clearly has an important role to play in these wider discussions though it cannot alone determine their outcome. Discussions between industry and Government on IPR issues within the Task Force focused on how the UK might maintain its international reputation as a champion of IPR protection within the pharmaceuticals sector. There are a number of key areas of agreement.
- 7.2 A joint industry-Government position on international IPRs and Access to Medicines in developing countries** – the UK, both Government and industry, is committed to playing a leading role in developing partnerships to improve access to medicines in developing countries. Much is being done but a great deal more is required if the significant difficulties facing the poor are to be overcome. Within PICTF, the industry and Government agreed that the protection of international intellectual property rights is a necessary prerequisite for investment in R&D for new medicines. Protection of IPRs is and should remain a key plank in a sustainable way forward. They are agreed that intellectual property protection is not *per se* a barrier to access to medicines and that attempts to weaken it would be counterproductive. The Government and industry support the complete implementation of the current TRIPS agreement by all WTO member countries – although there will be a need for a pragmatic approach where individual countries have genuine implementation problems.

- 7.3 International Exhaustion of Trademarks** – Government and industry agree that pharmaceuticals should not be included in any European Community moves to international exhaustion of trademarks and that there should be no moves to extend international exhaustion to patents.
- 7.4 Data Exclusivity** – industry and Government are agreed that data supplied in support of applications for licences for medicines within the European Community – which is often difficult and expensive to generate – should be protected and that robust, harmonised data exclusivity provisions are an appropriate way to achieve this.
- 7.5** On data exclusivity, the UK will argue within the EC for a harmonised period of 10 years for first authorisations and a further harmonised period for data for new indications and for other data on safety and efficacy supporting amendments to licences. It is also agreed that the current Community definition of “essential similarity” is inadequate and that practice needs to be harmonised – essential similarity should not apply for any change of salt, ester or other derivative of an active substance. Also, within the context of EU rules, the term “is marketed” needs to be interpreted (if necessary, as a result of a change in European law) to mean “has been authorised” for abridged licences for copy products.
- 7.6 The Single Market in Pharmaceuticals** – industry and Government are committed to working together to advance the European Single Market in pharmaceuticals. There is potential to bring substantial benefits to Member State economies, to UK, European and industry competitiveness and, above all, to patients in the European Community.
- 7.7** Industry and Government have agreed a long-term programme of actions at EU level to develop an incremental approach to the liberalisation of pricing of non-reimbursed medicines. This programme envisages removal of controls where they still exist in the Single Market on OTC prices, price liberalisation for non-reimbursed medicines, and price liberalisation for all sales of medicines in the private sector.
- 7.8** Industry and Government are also agreed that efforts need to be directed to ensuring that the full benefits of the Single Market, as it currently exists, are harnessed in a way that both benefits the NHS and contributes to industry competitiveness. Both are agreed more progress is needed to take the Single Market forward.
- 7.9** More broadly, the Task Force agreed five principles to help guide the way to completion of the Single Market in this sector. UK industry and Government representatives to the new European task force on pharmaceuticals will pursue these principles in that forum.

- 7.10 EU Enlargement** – the challenges facing the pharmaceutical industry from EU enlargement are considerable, but so are the opportunities enlargement creates, most importantly for the public health of the enlarged Community.
- 7.11** The basis of the UK position – agreed between industry and Government – in negotiating how the IPR regime in candidate countries might need to operate upon accession to the European Union is that they afford an equivalent level of protection to that available within the current EU15.

## Regulation of Medicines Licensing

- 8.1** There is a good measure of agreement between industry and Government on the vision of the elements of the EU regulatory system that would improve EU competitiveness. There is also agreement on the nearer term needs with regard to improvement of pre-submission dialogue and enhancements in regulatory dossier quality and processes to result in more predictable regulatory decision making, globally competitive approval times and the possibility of more rapid availability of innovative medicines to European patients.

## Science Base and Biopharmaceuticals

- 9.1** The UK Science Base has a worldwide reputation for excellence. Historically, the strategic business environment in the UK has supported high levels of R&D investment and innovation by the UK's pharmaceutical industry. Research by PICTF concluded that the UK remains a highly favoured site for R&D activity and has performed strongly as a location for pharmaceutical innovation. The challenges facing the Task Force were first how to maintain and where possible build on that comparative advantage and second, how to ensure that it carried over to a vibrant biopharmaceuticals sector.
- 9.2** Industry and Government identified a number of actions to maintain the UK as a competitive environment for the pharmaceutical and biopharmaceutical research sectors.
- 9.3** On **Manufacturing**, the Task Force agreed an application for a DTI "Faraday" project (to fund technical development and its transfer to industry) to help work on early-stage biopharmaceutical manufacturing, and agreed Terms of Reference for an industry secondee to advise Government on inward investment by the pharmaceutical industry.

- 9.4** On the **UK skills base**, the Task Force recognised that a further review of the immigration regulations inhibiting the employment by the industry of overseas specialist experts in the UK may be necessary when the impact of recent changes to the regulations is clear. It also agreed that application processes for postgraduate training schemes such as CASE should be reviewed and improved as necessary to ensure their maximum relevance to industry.
- 9.5** On **Industry/Academia Links**, it was agreed that there should be training and support for Industrial/Academic Liaison Officers in universities and industry to foster increased professionalism for this vital work.
- 9.6** On **Animal Welfare and Research**, it was agreed that the increasing complexity of the regulatory process involved in obtaining licences to carry out animal studies, the activities of extremist animal rights activists, and the possible implications of the new Freedom of Information Act, have meant that the UK is increasingly perceived by industry as an unfavourable environment in which to conduct research involving animals. There is a danger that, as a result, future research may be moved abroad.
- 9.7** The Task Force agreed substantial actions to streamline licensing procedures thus enabling some of the resources currently devoted to administration to be reassigned to promoting and supporting animal welfare. It also suggested amending the Criminal Justice and Police Bill, the Malicious Communications Act and the Companies Act to tackle harassment and intimidation by animal rights campaigners. Amendments have subsequently been brought forward by the Government.

## Clinical Research

- 10.1** Clinical trials are essential to the development of beneficial treatments for NHS patients as the consumers of medicines and healthcare. Clinical trials supported by the pharmaceutical industry in the NHS play an important part in keeping the NHS at the forefront of modern treatments and research.
- 10.2** Significant changes in the external environment governing clinical research are occurring at the global and European level with the introduction of ICH Guidelines on Good Clinical Practice, the European Directive on Clinical Trials, and the development of high quality infrastructure for research in a wider range of countries, often at relatively low cost. Clearly the UK needs to adapt to these changes if it is to maintain and improve upon its attractiveness as a base for industry sponsored clinical research.

- 10.3** The Task Force considered those factors that are important in maintaining a thriving, research based pharmaceutical industry, and a productive relationship between the industry and the NHS. It identified the three main parameters used when deciding where to place clinical studies: speed (in terms of start up times of clinical research), cost and quality of research. The Task Force identified strengths underpinning, but also some impediments to, internationally competitive clinical research sponsored by the industry in the NHS. It agreed an action plan that will help to ensure that the UK remains at the forefront of clinical research. The key elements are as follows.
- 10.4** First, work by industry, the Department of Health (DH) and the NHS significantly to improve start up times on clinical trials from April 2001. Second, development of a Research Governance Framework by DH which defines quality standards and clarifies responsibilities for all research involving patients in the NHS. Third, development of a partnership agreement which defines the working relationship between industry and the NHS. Fourth, work to improve transparency in costing and hence reduce transaction costs for commercial clinical trials. And fifth, agreement of performance indicators to monitor progress and ongoing competitiveness of the UK in industry sponsored clinical research.
- 10.5** Some actions have already been implemented, though there is still more to do and on other issues further dialogue is planned.

## Economic Climate

- 11.1** The Government attaches great importance to making the UK a good place to do business by creating a stable and competitive economic environment. The Task Force considered the aspects of the economic climate in the UK which foster or constrain the competitiveness of the innovative pharmaceutical industry.
- 11.2** There are a number of reasons why the UK economic climate is good for business. These include steady economic growth, stable inflation rates, and low and stable interest rates. In addition, the UK has long been an open and outward looking market, with deep and enduring economic linkages with the rest of the world.
- 11.3** A key determinant in any investment decision for the pharmaceutical industry is the availability of appropriately skilled staff. Availability of scientific research skills and infrastructure will always outweigh financial incentives or a low tax climate, although financial factors may be decisive in a choice between two locations with the necessary science base. It is

critically important to future investment in R&D that the Government continues to invest in the science base. Investment must also, however, continue to flow into primary and secondary, as well as tertiary education.

- 11.4** Subject to the availability of the necessary science base, financial considerations will also influence decisions on location of R&D. Continued fiscal support for R&D allowances, credits, and the modernisation of tax legislation on Intellectual Property will help to ensure international competitiveness is maintained.

## Competitiveness and Performance Indicators

- 12.1** Agreed indicators give Government and industry a baseline against which to consider the foreseeable implications of future policy proposals. A list of internationally comparable competitiveness and performance indicators has been drawn up to form the basis of joint future monitoring and comparison by Government and industry.
- 12.2** It will also be important to monitor future trends in these factors and to continue to compare how the UK is doing relative to its main competitor countries. The indicators will therefore be reviewed annually, and will be published periodically.

## Future Partnership

- 13.1** The UK-based pharmaceutical industry is world class and a jewel in the crown of the UK economy, and the Government is determined to do what it can to help the UK industry maintain and enhance its competitive advantage.
- 13.2** Unlike many other countries, the UK Government has long maintained a positive relationship with its pharmaceutical industry. PICTF has raised the profile of the industry-Government relationship considerably and has lifted the dialogue to a far more strategic level than hitherto. In both the industry and the Government's view, this more strategic debate has raised mutual understanding to a much higher degree than ever before. Better understanding has helped engender real trust between the partners, which will help to condition perceptions of top decision makers in both industry and Government. This is expected to bring both tangible and intangible benefits to both partners.

- 13.3** The Task Force process has itself already introduced a more forward-looking strategic relationship between Government and industry. Some of the work programmes are challenging and far-sighted. Much of the debate has a long way to go, and there is no guarantee that there will always be agreement between industry and Government. But the mere fact that the dialogue has begun at a more senior policy level – and that some steps down the respective path are agreed – demonstrates the Government’s commitment to creating a competitive environment for the innovative industry.
- 13.4** An important output from PICTF is agreement on a successor mechanism that will capture the key strengths of PICTF and inculcate them into future dialogue; agreement on the tracking of UK competitiveness through agreed competitiveness and performance indicators is also a very helpful step forward. Both sides are now committed to taking the spirit and attitude of the PICTF discussions into future dialogue.

## TERMS OF REFERENCE

The Task Force was established in March 2000 with the following terms of reference:

The Pharmaceutical Industry Competitiveness Task Force will bring together the expertise and experience of the industry leaders in the UK with Government policy makers to identify and report to the Prime Minister on the steps that may need to be taken to retain and strengthen the competitiveness of the UK business environment for the innovative pharmaceutical industry.

The Task Force will:

- I. Identify all the criteria for maintaining and developing the competitiveness of the UK as a successful and effective base for an innovative pharmaceutical industry in a global market.
- II. Address the following specific issues:
  1. Given the role of NICE in relation to judgements about clinical and cost-effectiveness and other measures intended to improve the quality of prescribing in the NHS, consider how the home market can best support the international competitiveness of innovative medicines produced for the home and international market by the R&D industry in the UK;
  2. The recognition of intellectual property for pharmaceuticals in the context of:
    - resolution of the tensions caused by national pricing of medicines and the free movement of goods within the European Single Market
    - global trade in pharmaceuticals;
  3. Evaluate the importance of the clinical research infrastructure of the NHS and the benefits and costs of its use by industry as a location for clinical studies;
  4. Consider the aspects of the economic climate in the UK which foster or constrain the competitiveness of an innovative pharmaceutical industry, and identify any changes which would significantly strengthen that environment for the industry;
  5. Identify further steps that might be taken to foster the development of a vibrant biopharmaceuticals sector, including examination of the potential for technology clusters to develop, taking into account the interface with land use planning;

6. Identify the potential for promoting further partnership between the industry and academia, and industry and Government;
  7. Consider the future development from a competitiveness point of view of the European medicines licensing system, especially in relation to the respective roles of the EMEA and national agencies.
- III. Assess in the light of the Task Force's work, how well the UK is currently meeting the criteria identified at I above and what further action is needed.

## MEMBERSHIP

*Co-chairmen:* Lord Hunt of Kings Heath (Parliamentary Under Secretary of State for Health)  
Tom McKillop (AstraZeneca)

*Members:* **Government**

Lord Sainsbury of Turville (Minister for Science and Innovation)  
Baroness Blackstone (Minister of State for Education and Employment)  
Nick Raynsford MP (Minister for Housing and Planning)  
Stephen Timms MP (Financial Secretary)  
Nigel Crisp (Permanent Secretary/Chief Executive DH)<sup>1</sup>

**Industry**

Sir Richard Sykes (Glaxo Wellcome)<sup>2</sup>  
J-P Garnier (SmithKline Beecham)<sup>3</sup>  
Bill Fullagar (ABPI President and Novartis)  
Vincent Lawton (APG Chairman and Merck Sharp & Dohme)<sup>4</sup>  
Trevor Jones (ABPI Director-General)

*Attendees*

- a. Observer: Prime Minister's Policy Unit
- b. Officials from DH, HMT, DTI, DETR, DfEE, DFID and other representatives from industry will attend meetings as and when necessary.

1 Chris Kelly, DH Permanent Secretary, until 31 October 2000.

2 Sir Richard is now Chairman of GlaxoSmithKline plc. He was Chairman of Glaxo Wellcome plc until 27 December 2000.

3 J-P Garnier is now Chief Executive of GlaxoSmithKline. He was Chief Executive of SmithKline Beecham until 27 December 2000.

4 Ken Moran, ABPI Vice-President and Pfizer until June 2000.

## **SECRETARIAT**

An appropriate and adequate secretariat will be provided jointly by industry and the Department of Health.

## **METHOD OF WORK AND WORK PROGRAMME**

The Task Force is expected to meet regularly over a period of one year, beginning April 2000. The frequency and location of meetings will be determined by the co-chairmen. The Task Force will work and reach agreement by consensus.

The Task Force will set the detail of its work programme and priorities therein at its first meeting. The work programme will be developed from within the framework of topics set out in these Terms of Reference. Further items can be put forward for inclusion in the work programme with the consent of the two co-chairmen. Decisions on whether to incorporate further items will be taken by consensus.

The Task Force will commission specific work from such joint industry-Government working groups that it sees fit to establish. Representatives of these working groups (senior officials and industry representatives) will join the Task Force meetings as appropriate to report on activity and progress. Agreed action will be taken forward during the course of the year. A report will be published setting out the achievements of the Task Force after consideration by the Prime Minister.

PICTF was established in March 2000 and met for the first time on 13 April. It drew its business to a close on 1 March 2001. Section IX describes the PICTF successor mechanism which will be the principal forum for continued industry-Government high level discussion.

The joint secretaries were Chris Strutt (GSK) and Iain Gillespie (Department of Health).

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