Pharmaceutical Industry Competitiveness Task Force

Final Report – March 2001

Websites – Department of Health: www.doh.gov.uk/pictf

– Association of the British Pharmaceutical Industry: www.abpi.org.uk

Foreword by the Prime Minister

A successful pharmaceutical industry is a prime example of what is needed in a successful knowledge economy. The UK's pharmaceutical industry has an outstanding tradition and has contributed very substantially to our economy and to the welfare of our citizens. It has provided tens of thousands of high quality jobs, substantial investment in research and development, and a massive contribution to the UK's balance of trade. UK patients and people around the world have benefited from the early introduction of new and improved medicines that would not have been discovered without work undertaken in UK laboratories.

We must work together to ensure that the future of the UK pharmaceutical industry is even brighter. This is a truly global industry, whose companies have more choice than ever before when deciding where to place new investment. I am committed to ensuring that the UK retains the features that have made it an attractive location for investment – features such as the availability of a high quality scientific workforce, protection of intellectual property, a supportive regulatory framework, and an environment conducive to the research needed to discover the cures of the 21st century.

A key feature in maintaining the UK's attractiveness will be effective partnership at the highest levels between Government and industry. That is why I am delighted at the work and outputs of the Pharmaceutical Industry Competitiveness Task Force. It has addressed some important issues. There is more work to do, but a continuation of the spirit and approach of PICTF will offer the most effective means of rising to future challenges. I look forward to future partnership and to the pharmaceutical industry continuing to make a significant contribution to the health and prosperity of the UK.

Preface

By the Co-chairmen, Lord Hunt and Dr Tom McKillop

The Pharmaceutical Industry Competitiveness Task Force (PICTF) has provided a structured, action-oriented platform for effective dialogue between Government and the pharmaceutical industry. The involvement of Ministers from a number of Government Departments and senior industry executives, who are able to reflect both UK and global perspectives, has been of great benefit. PICTF has strengthened industry-Government relationships, significantly increased mutual understanding and delivered some valuable outputs. The commitment and hard work of all those involved in PICTF should be acknowledged and applauded.

PICTF is an important and timely initiative. The pharmaceutical industry is one of the UK's most successful industrial sectors, but the global business environment is changing. The traditional factors that underpinned the UK's past success in pharmaceuticals are no longer on their own sufficient to guarantee good performance, and we need to work together to ensure that the UK retains its competitive edge. 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.

This report from PICTF reflects many positive outputs. PICTF has addressed a number of important areas, including protection for intellectual property, tensions in the EU Single Market for Pharmaceuticals, overcoming impediments to competitive clinical research, and improving the competitiveness of the pharmaceutical and biopharmaceutical research sector. It has also engaged in a much more strategic debate about future developments in the UK pharmaceuticals market.

PICTF has demonstrated the importance of ensuring that 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. We have agreed competitiveness and performance indicators for the pharmaceutical sector that should allow us to test future major changes to the pharmaceutical regulatory environment for their likely impact on industry competitiveness.

PICTF has allowed us to take important steps towards ensuring that the UK remains a competitive location for the continued development of a vibrant pharmaceuticals sector. There are issues – such as market access for new products, and the environment for animal research – where further dialogue is required and where industry and Government continue to work together to identify effective ways forward. We are delighted that a high level successor mechanism to PICTF has been identified and that a plan of future action has been drawn up. We are confident that the key strengths of PICTF will be inculcated into future dialogue, and that the benefits of partnership for the UK and the industry will be delivered.

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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 Medicine 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)[1]

Industry

Sir Richard Sykes	(Glaxo Wellcome)[2]
J-P Garnier	(SmithKline Beecham)[3]
Bill Fullagar	(ABPI President and Novartis)
Vincent Lawton	(APG Chairman and Merck Sharp & Dohme)[4]
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.

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

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.

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).

Section I

Introduction

1.1 The pharmaceutical industry based in the UK – whether domiciled in the UK with majority British ownership, or domiciled overseas – is one of the most successful in the world. It is a prime example of what is needed in a successful knowledge economy.

1.2 This can bring direct benefits to UK patients from faster introduction of therapeutically beneficial new medicines because development work for them is undertaken here. They also may benefit from treatments that might never have been discovered but for work in UK laboratories. Many of our most valuable medicines – used by patients in the UK, Europe and around the world – including the developing world – would simply not have existed were it not for the UK-based industry.

1.3 Companies based here maintain a significant presence in all the major markets in the world and the UK has consistently "punched well above its weight" since the 1940s. The UK market itself is relatively small, maintaining a share by value of the world ethical market[1] of around 3% – this compares to an equivalent figure of nearly 40% for the USA. In terms of overall competitiveness, the UK is second only to the US and well ahead of its main European competitors.

1.4 The UK-based industry generates valuable and significant foreign trade income; since the mid-1990s it has consistently contributed over £2 billion trade surplus. The Task Force estimates[2] (see Box 1) that the UK resources currently employed in the pharmaceutical industry produce greater economic benefits of around £0.7–2.0 billion a year than they would if employed elsewhere in the economy and the "terms of trade" benefit may be between £1.0 and 2.0 billion a year.

1.5 Pharmaceutical companies in the UK spent around £2.7 billion in 1997 on research and development (R&D), which represented 23% of all expenditure on manufacturing R&D in this country[3]. And around 60,000 people are employed directly in the pharmaceutical industry in the UK, a great proportion of whom are in high quality jobs, with many others (up to 250,000) in jobs dependent on the industry's presence here.

1.6 However these figures are looked at, the pharmaceutical industry is clearly a jewel in the industrial crown of the UK. It contributes very substantially indeed to the economy of the country and to the welfare of its citizens.

1 The market for prescription medicines.
2 PICTF report "The Value of the Industry".
3 OECD data – see also Figure 5.1 – 1997 is the most recent year for which data is available across OECD countries. In 1999, the most recent year for which data is available for the UK, comparable figures are £2.85 billion and 22% respectively.

1.7 But the conditions required for the industry to retain its competitive position are changing in the face of significant shifts in the global business environment. Rapid globalisation of markets, the ease of global communications and the existence of an increasingly international and mobile pool of scientific and commercial talent mean that firms can serve more markets from fewer locations, while at the same time they have greater choice than ever before about where to locate new investments. At the same time, competition in product markets, cost-containment policies, the emergence of new customers around the world, and the shortening of product life cycles are altering the economics of the industry.

1.8 These factors are driving pharmaceutical firms to take a much closer look at what each locale offers in terms of access to required skills, proximity to technical partners (what Michael Porter[1] has called technology "clusters"), attractiveness of local market conditions, operational costs and taxation rates. Locations are increasingly decided from the perspective of their effect on the overall competitiveness of the global firm. The factors that have underpinned UK success in the pharmaceutical industry are no longer in themselves sufficient to guarantee good performance.

Box 1 – The Value of the Pharmaceutical Industry to the UK Economy

The UK resources currently employed in the pharmaceutical industry produce greater economic benefits than they would if employed elsewhere in the economy. The net benefits currently total around £0.7–2.0bn a year although this sum can only be a very rough estimate. There is also a "terms of trade" effect the benefit of which we estimate at £1.0–2.0bn per year.

The UK benefits in the following ways from the pharmaceutical industry owned by UK residents or based in the UK:

- benefits to patients from having a UK supplier of medicines;
- returns to UK shareholders;
- tax revenues accruing to the UK Exchequer;
- wages and salaries received by UK employees;
- benefits arising from the terms of trade;
- "spillover" benefits from R&D i.e. those not captured by the industry itself but by universities, the NHS and other industries.

UK patients may benefit from speedier introduction of therapeutically beneficial new medicines to the UK market because development work for them is undertaken in the UK, and may possibly benefit from the introduction of treatments which might never have been discovered but for work in UK laboratories.

1 Porter, ME (1998) The Competitive Advantage of Nations, Macmillan.

1.9 The UK can no longer count on securing 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. In the new global economy the pharmaceutical industry faces difficult strategic decisions about where best to invest for the future.

1.10 For the industry to continue to invest in this country over others, and for the industry to maintain its presence here and its contribution to a vibrant knowledge economy, the UK in turn must continue to offer a supportive and competitive business environment compared to other viable locations.

1.11 However, the Government needs to ensure that in supporting a vibrant and profitable pharmaceutical industry it also supports a vibrant, modern, high-quality National Health Service (NHS). The NHS is very largely funded directly by the UK taxpayer rather than through public and private health insurance funds as is the case in many other advanced economies. Providing an efficient and effective NHS costs money – expenditure on medicines consistently forming a rising element of overall costs. However, there is no doubt that good health, and the part medicines play in providing it, are important factors in generating a vibrant UK economy. A healthy economy in turn – of which a successful pharmaceutical industry is an important part – will provide the resources to deliver a world class health service in this country. There is an important balance to get right in supporting both the NHS and the industry, but it is a balance that stands to benefit all.

1.12 Getting this balance right was the challenge delivered to the Pharmaceutical Industry Competitiveness Task Force by the Prime Minister when it was established in March 2000. The Task Force brought together key decision makers from Government and from industry to assess where UK comparative advantage lies – or might lie – and to formulate a joint action plan to ensure that the UK continues to offer a competitive environment for pharmaceutical companies to do business. Success would bring benefits to the industry and, above all, to the health and welfare of Britain.

PICTF Approach and the Structure of this Report

1.13 The structure of this report – the Task Force's main report – largely follows the approach to work taken by PICTF itself. The Task Force quickly identified the key areas of UK competitiveness where progress might usefully be made and established six high-level working groups to deal with discrete areas:

i. *Developments in the UK Market:* the Government has introduced a wide range of policies to modernise the NHS. This is against a background of increasing globalisation and consolidation of the pharmaceutical industry as well as rapid and significant advances in science expected to lead to new treatments and approaches to healthcare. A working group chaired jointly by Dr Tom McKillop, Chief Executive of AstraZeneca plc, and Health Minister Lord Hunt examined how these developments interacted and brought forward actions to improve partnership between industry and Government in meeting the challenges of the future.

ii. *Intellectual Property Rights:* intellectual property rights (IPRs) are the life-blood of the innovative pharmaceutical industry. Sir Richard Sykes, Chairman of Glaxo Wellcome plc[1], chaired a working group considering how industry and Government might work together to secure appropriate protection of IPRs in the UK, in the European Single Market, an enlarged European Community, and worldwide.

iii. *Science Base and Biopharmaceuticals:* the UK science-base enjoys an enviable international reputation and in order to maintain this we need a good supply of the right skills, effective links between industry and academia, and an environment of encouragement for research. Science Minister Lord Sainsbury chaired a working group addressing these and other issues, including how the UK might promote a vibrant biopharmaceuticals sector.

iv. *Medicines Licensing:* licensing procedures have evolved substantially since the introduction of the 1968 Medicines Act and new developments continue to bring new challenges. Dr George Butler, Vice President, Head of Worldwide Regulatory Affairs for AstraZeneca plc, chaired a working group considering how the industry and Government could ensure that the current European Commission-led review of medicines delivered a high level of protection of human health and restored UK and EU competitiveness against other major markets.

v. *Clinical Research:* the NHS presents a unique environment for properly conducted clinical research with proper arrangements in place for informed consent. Sir John Pattison, Director of NHS Research, and Vincent Lawton, Managing Director of Merck, Sharp and Dohme Ltd, led a group considering what steps might be taken to make the UK a more competitive location for clinical research by speeding up start-up times, improving quality and improving transparency in NHS costing, thus accelerating access to effective new medicines for NHS patients and cutting industry's development costs.

vi. *The Wider Economic Climate:* Financial Secretary, Stephen Timms MP, led a working group considering how wider economic policies affected the competitiveness of the UK for the pharmaceutical industry – and industry's performance in the UK market.

1.14 The conclusions of discussion in each of these groups are presented in separate sections of this report. In most cases PICTF took concrete steps to improve UK competitiveness in the area concerned. Performance and competitiveness indicators were agreed and joint action plans formulated to address areas where further progress might be made. All the key indicators are brought together in Section VIII and will be monitored and reviewed regularly by industry and Government, providing a benchmark against which future major policy initiatives can be tested.

1.15 Substantial progress has been made in PICTF in cementing a unique partnership between Government and industry that should benefit all those interested in the effective delivery of healthcare within the UK. The Government and the industry agree that every effort should be made to ensure that this partnership continues and grows.

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

Section IX of this report sets out how the partners intend to deliver on this, as well as arrangements for monitoring progress on the agreed action plans.

1.16 PICTF intends to publish a number of reports covering different aspects of their work. A full list of PICTF publications is at Appendix II.

Section II

Developments in the UK Market

Co-chaired by Lord Hunt and Dr Tom McKillop

Summary

- Research confirmed the very strong performance of the UK-based industry in terms of global competitiveness. Only the US generally outperforms the UK and after the US, the UK is the least regulated market at the pre-launch stage. At the post-launch stage, NHS physicians are subject to many influences to encourage cost-effective prescribing and the industry remains concerned about the possible effect of NICE guidance on uptake of new medicines. A review of NICE planned for July 2001 will take account of ongoing detailed discussions with the industry on the question of NICE.

- The potential impact of proposed changes to the regulatory environment need to be considered carefully.

- Arrangements are in place to involve the industry in the development of future National Service Frameworks (NSFs) and in existing NSFs on diabetes, older people, and mental health.

- A mechanism is to be set up to take forward discussions on how industry might use NHS databases as an R&D information source.

- An action plan is agreed on how better information on medicines might be made available to patients.

- An action plan is agreed to develop arrangements for handling access to the market for medicines not available on the NHS.

- Better partnership working will be developed with the pharmaceutical and biopharmaceutical industry to maximise the benefits of genetics to the discovery and targeted use of medicines.

Introduction

2.1 The key issue for consideration was the relationship, and perceptions of the relationship, between the UK-based industry and the UK market. What are the key features of the UK market and the industry's relationship with it that affect the global

competitiveness of the UK-based industry? How does the UK market and the UK market/industry relationship compare to other countries' markets and their relationships with the industry (eg other EU countries, the US, Australia, New Zealand, Canada)?

2.2 A working group was established to tackle these issues under the joint chairmanship of Health Minister Lord Hunt and the Chief Executive Officer of AstraZeneca plc, Dr Tom McKillop. The terms of reference for the working group were:

"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."

How Does the UK Market Compare to Other Major Economies?

2.3 Pharmaceutical companies based in the UK – both those domiciled here and foreign-owned companies with a significant base here – maintain a significant presence in all major markets in the world except perhaps Japan. The UK market itself is relatively small, maintaining a share by value of the world ethical market throughout the nineties of around 3%. However, the world market is dominated by the USA – nearly 40% of ethical medicines by value, with corresponding figures for Japan and the EU being 16% and 24% respectively.

Table 2.1 – 1999 Pharmaceutical Market Statistics for Selected Countries

				Share of sales by corporate nationality 1999			
	Market size US$M 1999	Growth 1998–99 %	Deflated growth %	Locally based	US Corps	Eur Corps	UK Corps
Australia	3,143	15%	13%	9%	40%	51%	15%
Canada	5,510	11%	8%	12%	48%	38%	10%
France	17,751	0%	-1%	37%	24%	75%	8%
Germany	18,500	1%	1%	45%	22%	76%	6%
Japan	53,548	23%	24%	78%	8%	13%	10%
Netherlands	2,391	3%	3%	na	na	na	na
New Zealand	471	3%	3%	8%	30%	58%	20%
Sweden	2,102	7%	6%	21%	38%	61%	11%
Switzerland	1,824	6%	4%	30%	27%	71%	12%
UK	11,029	8%	6%	24%	32%	56%	24%
USA	130,069	17%	14%	63%	63%	33%	12%

Source: OECD

2.4 The UK spends less *per capita*, and as a proportion of income, on healthcare and pharmaceuticals than many other advanced nations. Looking simply at headline expenditure makes no allowance for differences in efficiency of expenditure between countries or in variations in unit price or between private and public sector markets. However, regardless of the level of regulation, the size of the budget for pharmaceuticals expenditure will have a significant impact on uptake of medicines within any particular market.

2.5 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* (see Appendix II) and selections of key findings are interspersed throughout this report.

2.6 The UK scored second overall only to the US on measures of innovation, and surpassed the US in terms of patent productivity (see Figure 2.1).

2.7 On regulation and access to the market, the group found that national systems display widely differentiated characteristics, across both supply and demand sides, all of which have the potential to influence the availability of medicines within a market.

2.8 Historically, the UK has offered relatively rapid initial access to market due to an efficient registration system and the absence of any pricing and reimbursement procedures applied after market authorisation is granted, which may delay launch of new products.

2.9 However, although the UK market has been comparatively free from regulation in the period between gaining marketing approval and launch, 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.

2.10 The way in which demand-side influences are used post launch in the UK differentiates it from both the price-controlled markets and the other free price markets.

Figure 2.1 Index (UK = 0) of Pharmaceutical Expenditure, Health Expenditure and GDP *per capita* for Selected Countries

Source: CMR

2.11 In particular, NICE differs from similar organisations in other countries in the way in which it uses pharmacoeconomics. PICTF's analysis has shown that where other countries use pharmacoeconomic submissions, they are normally in the context of setting prices. Most countries allow or encourage cost-effectiveness data to be submitted as part of the pricing dossier, but it is not clear how much weight is given to the data in determining the final price or reimbursement status. Only Australia to date has made it mandatory for all products.

2.12 The UK is alone in using cost-effectiveness analyses at national level to inform guidance to physicians 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 on to what the industry considers already a heavy burden of control on physician prescribing decisions in the UK.

2.13 The Government's view is that:

- except for scheduled products, clinicians retain complete freedom to prescribe whatever they believe their patients need;
- physicians and the NHS more generally need and welcome advice on clinically and cost-effective prescribing;
- they receive much of this already from pharmaceutical companies;

- when new medicines are introduced, central guidance helps to avoid duplicative evaluation regionally and locally and helps eliminate unacceptable variations in prescribing practice;
- Central guidance from NICE is helping to encourage the faster uptake of new medicines that demonstrate evidence of clinical and cost-effectiveness.

2.14 Existing UK market conditions, including the traditional conservatism of many UK prescribers, mean that sales of new products are limited in the years immediately following launch and thus impose little burden on the overall drugs budget.

2.15 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. Allied to this is the industry's view that any inequality in access will only become apparent once the product has achieved wide-scale use. Taking these factors together, it is the industry's contention that the appropriate time to do any economic evaluation is after a new product has had the opportunity to build broad market penetration through clinical proof of therapeutic value.

2.16 The Government's view is that the evidence available at launch is often the best, and sometimes the only, reliable information on clinical and cost-effectiveness that comes to light. The Government also sees great difficulty in changing prescribing behaviour once doctors and patients have become accustomed to a pattern of medication. This is intended to speed up uptake of cost-effective new medicines and prevent "postcode prescribing" from gaining a foothold. The Government considers that, in the vast majority of cases so far, appraisal by NICE has promoted greater use of innovative medicines.

2.17 Evidence from markets which allow launch of a product pending the conclusion of reimbursement discussions (eg Canada, France, Australia) suggests that physicians consistently are unwilling to prescribe products for which the eventual reimbursement status is unknown, not wishing to start patients on a treatment which they may subsequently be forced to discontinue. The industry believes this has implications for the UK, for example, in cases where there is a delay between the announcement of NICE's intention to review a new product or product class and the final issuing of guidance. From the evidence of other markets the industry considers that this will lead to product 'blight' with doctors unwilling to prescribe the new treatment in advance of a decision from NICE. The relatively short track record of NICE has not, as yet, enabled demonstration of the new picture for the UK, either confirming the industry's or Government's view.

National Institute for Clinical Excellence

2.18 The industry and Government respect and understand one another's viewpoint on NICE. The industry side recognises the existence and importance of NICE for the NHS and the Government's overall strategy for the service but considers that there are a range of important issues to be addressed with regard to how NICE operates

and its impact on the UK-based industry in an international context. On its part the Government side of the Task Force recognises the industry's concerns and the importance it attaches to this issue.

2.19 These concerns are being addressed outside PICTF in preparation for the Review of NICE in July 2001. Initially discussion is focusing on the key issues of:

- Timing of appraisal in relation to availability of data, and opportunities and limitations of modelling with reference to particular case studies;
- How topics are selected for NICE appraisal.

2.20 A number of other issues will also be reviewed including effects on the rate of access of new medicines to the market, assessment of resources used as a result of NICE's activities, and the monitoring of NICE recommendations and assessment of NICE's 'added value'. The Department has also agreed to provide clarification of the role of NICE with regard to affordability.

2.21 This programme of work is intended to inform the review of NICE in July 2001. The outcome of this review should shape the development of NICE in the future. The Government will report and discuss progress on the review to the industry (as part of the follow-up arrangements for PICTF) as well as to other stakeholders.

2.22 It is agreed the preparatory work will be completed by May/June 2001.

Future Market Directions

2.23 The Access and Competitiveness Study revealed the UK as a historically competitive market with considerable strengths. However, the industry is concerned that changes to how the market operates as a result of Government policy will diminish overall competitiveness.

2.24 Both industry and Government were determined that the Task Force took 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.

2.25 Five specific issues were considered to be priorities:

i. Industry involvement in development and implementation of National Service Frameworks

ii. Potential for greater industry use of the NHS clinical information data base for research and development

iii. Information for patients and concordance (improving patients' use of medicines)

iv. Access to the market for products not available on the NHS or not recommended for NHS use ("non-reimbursed" medicines)

v. Developments in genetics and implications for medicines and health services.

Industry Involvement in Development and Implementation of National Service Frameworks (NSFs)

2.26 National Service Frameworks (NSFs) are a key part of the Government's strategy for modernising the NHS. 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. PICTF recognised the potential benefit to both industry and the NHS of industry involvement in the development and implementation of NSFs.

2.27 Industry will be involved in all key stages of development and implementation:

i. *Development* – industry will have the opportunity, alongside other key players, to put in its views at an early stage to identify potential future developments as well as the future role of pharmaceuticals and medical systems.

ii. *External Reference Group (ERG)* – industry may be able to offer necessary expertise through future membership of ERGs and Topic Working Groups (TWGs). Decisions on membership will be taken by Ministers on a case-by-case basis.

iii. *Emerging Findings* – further, more focused, discussion with the industry will take place once ERGs have reported to test industry views on the issues that are emerging.

iv. *Implementation and Delivery* – effective implementation and delivery of NSF standards and key interventions are dependent on fundamental cultural change and changes in clinical practice. The industry has both expertise (and, in some areas, resource capacity) to bring to bear in the professional development of GPs, primary health care teams and other clinicians. Industry involvement in delivery of the NSFs will be of significant benefit where a pharmaceutical or medical system intervention has been identified in the NSF.

2.28 In practice, industry involvement will be largely on a 'NSF by NSF basis' with detailed involvement tailored to the particular subject. Priority areas for industry involvement to date have been on diabetes, older people, and mental health. The Government is committed to positive industry involvement in the NSF programme.

Potential for Greater Use by Industry of NHS Information

2.29 The NHS Plan commits the Government to ensuring the NHS has "the most up to date information technology systems to deliver services faster and more conveniently to patients". The need is for good quality, consistent and compatible data as each patient moves along his or her own unique care pathway. Such information is essential to high quality care. Substantive progress is being made on setting up the necessary infrastructure including setting and securing quality standards. For example by 2002 all GP practices will be computerised and connected to NHSnet. The systems will be collecting real, valid and accessible data.

2.30 Security and confidentiality of patient data are paramount. However, given that the necessary safeguards are in place, information derived from patient records is essential both to performance monitoring and to health service and medical research and development. Because of the single nature of the NHS, its various data sources already provide invaluable information for research and development. The improvements in NHS information set out above have the potential to develop NHS information as a world leader as a source of health information.

2.31 This potential applies as much to those working on research and development on new medicines in the pharmaceutical industry as to other researchers. The pharmaceutical industry is already making significant use of the NHS' existing – and often unique – data resources in particular of the General Practice Research Database (GPRD). These resources are highly valued by the industry and well used by them. There is however potential for significantly greater use – to the mutual benefit of both the NHS and the industry – as the quality of NHS information and the data bases that generates improves.

2.32 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. The Task Force's main conclusions from that discussion are:

- That subject to the necessary safeguards in relation to security of access and confidentiality, there is significant further potential for the NHS and industry to work together to develop data sources that will significantly improve the quality of data available for research and development of 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. The availability of high quality clinical information databases in itself encourages R&D investment.
- The industry use of existing databases is well recognised. But each has its limitations. The significant improvements in patient based NHS information collection that are taking place provide an opportunity to improve and develop data bases that are both comprehensive and disease specific, record as many medical events as possible, and provide appropriate linkage and quality of life data.
- Major issues remain to be explored further. In particular: the extent to which existing databases can be improved and built on and to which new databases are needed; and the question as to the extent to which the NHS will develop a single comprehensive health information source which can be used pro-actively as well as re-actively as opposed to a collection of specific databases for specific purposes. There is an immediate need for better information about existing databases and record linkages (and about gaps in coverage links between primary and secondary care and between health information and genotype).

2.33 PICTF has started this dialogue. The issues to be addressed are substantial. 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.

2.34 To this end it has been agreed that:

- there will be discussion between DH and industry at the same time as discussions with other 'stakeholders' on confidentiality issues and implementation of Clause 67 of the current Health and Social Care Bill (subject of course to Parliamentary approval);
- following further internal DH discussions on policy in relation to development of databases (in the light of NHS Plan developments on both information and services), agreement to develop an appropriate mechanism to take forward substantive discussions over the coming year between industry and DH on how relevant NHS databases might be used and developed for use for appropriate research and development activities by the pharmaceutical industry, including options for public/private partnerships; and report progress as part of PICTF follow-up. On its part the industry will seek to ensure the participation of those involved in global R&D decisions to ensure that the full potential for use of NHS information is discussed with those responsible for decisions about location of global R&D and what information systems best support such work.

Information for Patients and Concordance

2.35 In today's information society, the desire of patients for reliable and balanced information about their health needs and the options available for treatment have never been greater and increase day-by-day. Information is now much easier to get hold of, whether from trusted sources like family GPs and NHS Direct, or more 'hit-and-miss' sources like the world-wide web. The Government very much encourages better patient information and sees clear benefits to public health if patients are well informed by accurate, balanced material.

2.36 A better-informed patient is more likely to complete his or her course of treatment and thus derive the maximum benefit from medicines. This theme is revisited later under "Concordance" (improving patients' use of medicines).

2.37 However, a key problem facing the industry is the extent to which it can legitimately (and legally) participate in this information revolution. This is perhaps particularly a problem for companies planning to launch medicines into the small non-NHS UK market, where awareness of products is low. But it is also a problem for medicines used widely in the NHS where patients can sometimes see large amounts of information from a variety of sources on the Internet (not all of which are reliable) though not from the manufacturer.

Information for Patients

2.38 Industry and Government therefore explored ways to improve public access to good quality information on licensed medicines. Industry has an important role to play in meeting this objective and has greater flexibility in the approach it can adopt to doing so in some markets outside the EU.

2.39 There is no easy answer to these issues, but 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 takes into account, where possible, the potential for differentiating between information that is passively received by the general public and information that they actively seek.

2.40 In the short term, the aim is to agree UK Guidance on disease awareness programmes. Other agreed actions will be for the medium term, with the exception of establishing a practical definition of the distinction between advertising and information which, given the likely need for European guidelines, must, necessarily, be a longer term objective.

Action Plan

2.41 Industry and the Government are agreed that, subject to the requirements of EU legislation, disease awareness programmes are an acceptable way of communicating information on diseases to the public. However, it is not clear to what extent the legislation applies to these programmes where there is only one main treatment available or where reference is made to the fact that treatment options are available.

- MCA will aim to agree guidelines with ABPI on disease awareness programmes, including establishing scope for programmes where there is only one treatment available, by Quarter 2 in 2001.

2.42 The Internet is increasingly becoming a primary source of information for the public on many subjects including medicines and may be regarded as providing a library of reference materials as well as a medium for electronic trading. There is a need for clarity on what may be included on pharmaceutical company websites under EU law. The scope for providing patient information already available in packs electronically in a more user-friendly way should be examined.

- The ABPI will provide a ‘model’ company website as a basis for discussion in this area by Quarter 3 in 2001. ABPI will also provide examples of company generated information material they would like to be able to provide directly to the public by Quarter 2 in 2001. Taking proposals agreed during this discussion into account, the MCA will actively seek clarification within Europe on information that can be included on websites by Quarter 2 in 2002.

2.43 One of the main difficulties in establishing the scope of EU law is the lack of a clear internationally agreed understanding of the borderline between advertising and information.

- The MCA and industry will work together to 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. As a basis for discussion, industry will provide suggested working interpretations by Quarter 2 in 2001. The MCA and industry will aim to finalise working definitions by Quarter 2 in 2002 which could form the basis for discussions on European guidelines

2.44 Although licensed over-the-counter medicines can be advertised to the public there are a number of diseases for which advertisements are prohibited.

- The MCA will review the list of diseases on the basis of proposals received from the industry and others by Quarter 2 in 2002.

2.45 This work-plan represents a helpful package of measures. However, in the industry's view, the prohibition on advertising prescription medicines to the public is unsustainable in the longer term, particularly with the expected growth in e-commerce, use of the Internet, and development of more significant European private markets for some products, and changes to legislation will be required to deliver a truly rational package and bring accurate information on their products to the market. The Government's view is that the European ban on direct to patient advertising of prescription medicines should remain and it sees no appetite amongst other Member State governments for any change to this position.

Concordance

2.46 Concordance is a new approach to the prescribing and taking of medicines. It recognises that patients are not passive recipients of prescribing decisions. They have their own beliefs about medicines, how they work and how they are best used. Moreover, medicine taking has to fit within their normal daily living. Concordance involves a range of strategies to determine whether, when and how medicines are taken.

2.47 Concordance seeks two outcomes: health gain in terms of the pharmacological intention of the treatment and health gain in terms of patient satisfaction. It has advantages for all those involved in the delivery of healthcare in that it reduces:

- avoidable ill-health
- premature death
- wasted medicines
- potentially avoidable admissions to hospital
- other consequent social and welfare costs

and offers the potential to yield significant savings from the achievement of optimum medicines taking. Industry and Government are committed to working together, and

with others, to explore ways of improving the efficiency and effectiveness of medicine taking in the UK.

Joint Concordance Task Force

2.48 Within the Pharmacy Programme, *Pharmacy in the Future – Implementing the NHS Plan*, the Government announced its intention to establish a Joint Task Force, involving the professions, the pharmaceutical industry and patient groups, to lead the implementation of a national strategy on partnership in medicine taking.

2.49 The Joint Task Force's work programme will include:-

- development of a series of best-practice concordance models
- education and training for health professionals
- raising public awareness.

2.50 The focus will be on medicines and medicines taking, driven from a patient and carer perspective. The aim will be to ensure that all players engage in a partnership in medicine taking which is reflected in health policy, NHS service development and delivery, professional practice and patient/carer expectations and participation.

2.51 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, eg research and development, communications, education and training;
- ensure, through the Task Force and supporting infrastructure, the establishment and maintenance of collaboration and sharing of information on activities inspired by the Task Force, other partners and the pharmaceutical industry;
- ensure partnership in medicine taking is reflected in key policy initiatives, such as National Service Frameworks, the development of medicines management and self-management programmes flowing from the Expert Patient Programme;
- contribute at least £1m over the next two years specifically to work on partnership in medicines taking.

2.52 The project infrastructure and initial work programme is expected to be established by the end of March 2001.

2.53 To complement and support the work of the Joint Task Force, the pharmaceutical industry is proposing a parallel programme of activity to:

- establish ABPI policy and endorsement of concordance (Q2 2001)
- Compile a core list of industry executives with experience or an interest in medicine taking/compliance issues
- Develop a programme of communication within industry

- Develop a programme of consumer communication
- Develop monitoring and performance indicators.

Access to the Market for Products Not Available on the NHS or Not Recommended for NHS Use ("non-reimbursed medicines")

2.54 Discussions in the Task Force concluded that not all medicines developed in the future will necessarily be appropriate for use in the NHS – the receipt of a licence for Propecia for male-pattern baldness clearly demonstrated this.

2.55 The pharmaceutical industry would like to see easier access to the small part of the UK market which is outside the NHS and easier subsequent accessibility to patients.

2.56 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.

2.57 Discussion in PICTF concentrated on the manner in which GPs' NHS activity is regulated under their statutory terms of service. The current terms of service contain a number of detailed schedules, two of which list those medicines that GPs are barred from prescribing on the NHS (Schedule 10) and those that can be prescribed only in specific circumstances, but not otherwise on the NHS (Schedule 11). The male baldness treatment, Propecia, is on Schedule 10. The impotence treatment, Viagra, is on Schedule 11. The manufacturers of Propecia instigated its inclusion on the schedule to enable them to develop a private market.

2.58 For those medicines included on Schedules 10 or 11, GPs terms of service allow them to issue private prescriptions to their NHS patients though they are barred from charging for the private prescription. For medicines that are not scheduled, but not recommended for use by, say, NICE, GPs are prevented from issuing private prescriptions to patients on their NHS list or those of their partners. Their NHS patients have to consult with a GP outside their NHS practice, giving rise to potential problems of continuity of care and inconvenience.

2.59 Adding a medicine to Schedule 10 or 11 is achieved by amending the relevant statutory instrument in the four respective administrations of the devolved UK. This requires a period of public consultation with interested parties, including the manufacturer(s), the British Medical Association, other professional representatives and patient groups. The process is subject to requirements laid down in European legislation. Consultations have to be undertaken separately by the four respective administrations. The processes can be onerous and time-consuming.

2.60 Industry and Government are agreed that there a number of aspects inherent in the current arrangements that must remain as "givens":

i. medicines will continue to be prescribeable 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 white-list system similar to those operated in most European countries;

ii. the devolved administrations retain responsibility for deciding what medicines will be available on the NHS in Wales, Scotland and Northern Ireland and, if they wish, will continue to conduct separate consultations;

iii. 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);

iv. advertising of POMs to the public is banned under an EU Directive. However, there are ways in which disease awareness campaigns offer scope to inform potential patients, though it is then up to patients to seek further information, eg, via a website.

2.61 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:

i. the scope to speed up the process for placing products on schedules 10 or 11, and potential alternatives, including a voluntary mechanism which does not involve amending regulations each time a product is added to the list;

ii. streamlining the processes for reclassifying medicines from POM to P;

iii. 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, eg, pharmacists;

iv. the provision of guidance to remind GPs about the rules on private prescribing and the status of NICE.

2.62 The timetable for proceeding on the various actions is:

i. *Speed up the scheduling process and explore a "voluntary mechanism"*, aiming to complete the process and, if appropriate, issue guidance to the NHS by the end of 2001.

ii. *Streamlining classification from POM to P:* the first step is to develop a detailed work programme and timetable for action in early 2001.

iii. *Routes of access to non-reimbursed medicines:* an overall aim to have agreed arrangements in place by the end of 2001.

iv. *GP guidance on prescribing Schedule 10 & 11 drugs:* the aim is to have guidance issued by summer 2001.

NHS Developments in Genetics

2.63 Hardly a day passes without further new announcements on the startling progress being made in the fields of biotechnology and biosciences. These advances create enormous opportunities and challenges both for the pharmaceutical and biotechnology industries and for the NHS.

2.64 In discussions under the broad Task Force umbrella, industry and Government agreed:

- Advances in genetics will lead, to (a) an increasing ability to assess an individual's risk of developing a disease, (b) better prediction of the likelihood of an individual responding to a pharmaceutical (pharmaco-genomics) and, ultimately (c) to the development of new drugs and therapies.
- There is much less certainty about the time scale of these developments but some advances (mainly in single-gene disorders and pharmacogenomics) will become available during the next five years whilst others (e.g. gene therapy) may be 10–20 years away.
- The NHS will need to build on current examples of good practice to strengthen informal networks and ensure equity of access to genetics services while starting to build up an infrastructure flexible enough to deal with further advances.
- 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.

2.65 How best to deliver this last action needs to be considered further and the PICTF follow-up mechanism is expected to return to the issue later this year.

Section III

Intellectual Property Rights

Chaired by Sir Richard Sykes

Summary

- Government and industry partnership to improve access to medicines in developing countries and promote appropriate protection of international intellectual property rights.
- Agreement that European Community rules on data exclusivity provisions needs to be clarified, harmonised and strengthened.
- An agreed joint long-term vision of developments needed in the European Single Market in pharmaceuticals taking an incremental approach to market liberalisation.
- Close partnership in delivering UK inputs to Community-wide discussions on enlargement of the European Union as it affects the pharmaceutical industry.

3.1 Nothing characterises the R&D based industry as much as its drive to generate new intellectual property – which is essential to the continued flow of newer and better medicines.

3.2 The UK has a long history of protecting intellectual property rights (IPRs). Some of the most significant developments today are happening at the international rather than solely the national level. The UK has an important role to play in these wider discussions though it cannot alone determine their outcome.

3.3 Hence, it is the UK's negotiating position in Europe and internationally that most impacts on industry boardroom perceptions.

3.4 The Task Force considered that intellectual property rights were one of the key issues in its discussions. A working group was established under the leadership of Sir Richard Sykes, Chairman of GlaxoSmithKline plc[1].

3.5 The specific objectives the IPR working group set itself were to:

i. agree an approach on international intellectual property rights that contributed to the improvement of access to medicines in developing countries;

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

ii. agree a UK negotiating position on data exclusivity in the context of the current European Commission-led review of the European medicines licensing system;

iii. develop, promote and pursue EU-level policies towards completion of the Single Market in pharmaceuticals; and

iv. develop and keep under review a UK position on EU enlargement negotiations as they concern pharmaceuticals.

International IPRs and Access to Medicines

3.6 Over the last year, the international community (G8, European Community and United Nations) has been looking at ways to harness a significant increase in political commitment to address communicable diseases of poverty. These focus on but are not limited to HIV/AIDS, TB and Malaria.

3.7 In its December 2000 White Paper, "Eliminating World Poverty: Making Globalisation Work for the Poor", the Government set out its commitment to working with other interested parties to improve research and development of and access to medicines for use in developing countries.

3.8 The industry has recently entered into a new and exciting phase of evolving relationships with the international community to improve access to medicines. Initiatives such as the Medicines for Malaria Venture and GAVI aim predominantly at developing new products for diseases of poorer countries. The recent Accelerating Access Initiative, with UNAIDs, WHO and others, aims at reducing the cost of – and improving access to – existing medicines for those in developing countries.

3.9 These initiatives and others like them require effective partnership between governments, the international community and the global pharmaceutical industry. The UK – both Government and industry – is committed to playing a leading role in developing such partnerships. There are, of course, numerous dimensions to this partnership and much going on to cement it. PICTF focused on the role that protection of IPRs play in improving access to medicines.

3.10 Government and industry agree 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 attempts to weaken it would be counter-productive.

International Exhaustion of Trademarks

3.11 There has been much discussion over the last two years within the European Community about the balance between benefits to European consumers and the continued ability of trademark owners to control supply of consumer goods into the

European Single Market (clothing is a prime example). This discussion has led to calls – including from the UK – for the development of policies in the European Community to introduce international exhaustion (rather than just Community exhaustion) of trademarks.

3.12 However, such a move on medicines has the potential for impacts on consumers that may be detrimental rather than beneficial – and there exists at least the theoretical potential for harm. For this and other reasons, industry and Government are agreed that pharmaceuticals should not be included in any moves within the European Community to introduce international exhaustion of trademarks.

3.13 These two agreed positions – on international IPRs and access to medicines, and on international exhaustion of trademarks, are summarised in a joint position agreed by the Task Force, set out in Box 2.

Box 2 – International intellectual property rights

The UK Government and the UK pharmaceutical industry agree that effective intellectual property rights for pharmaceuticals are an essential pre-condition for sustained investment in the R&D of new and improved medicines. They 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. They recognise the need for further assistance with capacity building for TRIPS implementation in a number of developing countries.

The UK Government and the UK pharmaceutical industry recognise the pressing need to address the situation whereby many people in developing countries do not have ready access to basic healthcare services, including safe and effective medicines. They are also acutely aware of the growing HIV/AIDS epidemic in Africa and their responsibilities in responding to it. There is much that can be done to reduce the impact of AIDS and to improve access to medicines. However, intellectual property protection is not per se a barrier to access to medicines, and attempts to weaken it would be counter productive. The Government and industry will work together to explore the scope to address the issues around access to medicines through public-private partnership solutions, such as the new UN-industry endeavour to accelerate access to HIV/AIDS-related care, the UNAIDS Treatment Access Initiative, and the Medicines for Malaria Venture. The Government and the industry will work together to increase R&D into major health problems in developing countries and jointly consider what incentives are needed to reflect this.

The UK Government and the UK pharmaceutical industry agree that pharmaceuticals should not be included in any move towards international exhaustion of trademarks, and that there should be no moves to extend international exhaustion to patents.

Data Exclusivity Within the European Community

3.14 The basic principles the Government pursue on seeking the appropriate balance between protection of pharmaceutical IPRs and availability of medicines are: to reward innovation, providing reasonable reward for products in which there is an innovative step; and to maximise competition between older products to drive choice up and costs down.

3.15 In the European Community data exclusivity is provided for information given in support of licence applications in circumstances provided for in Council Directive 65/65 EEC (as amended). The scope of this Directive has become increasingly uncertain and the 1998 ECJ Generics judgement cast the appropriateness of current legislative arrangements in some significant doubt.

3.16 The ongoing European Commission-led review of the European medicines licensing system provides an opportunity for data exclusivity arrangements to be re-cast in a coherent and sustainable manner.

3.17 During the latter stages of the work of PICTF, the Government encouraged the European Commission to bring forward proposals to redefine what data exclusivity is available within the Community. Initial proposals are expected in summer 2001.

3.18 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. Disclosing the likely UK position in forthcoming negotiations would – of course – be counter-productive, but the key points on data exclusivity agreed by industry and Government include:

i. a 10-year period of exclusivity harmonised across the European Community is appropriate for data supporting first applications to market new medicines in the Community;

ii. European Community law should be clear so that a further period of exclusivity is available for data supporting changes to licences to include new indications for existing medicines;

iii. other data on safety and efficacy supporting amendments to licences should be given additional periods of exclusivity as for data justifying new indications;

iv. the concept of “essential similarity” as defined in Council Directive 65/65 EEC (as amended) needs clarification to ensure that it continues to appropriately assess risk to patient safety. Products where there is a significant change to the delivery mechanism of which utilised different salts, esters or other derivatives of an active substance should not be considered to be essentially similar;

v. within the context of the same Directive 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.

The Single Market in Pharmaceuticals

3.19 Industry and Government are committed to work together to advance the European Single Market in pharmaceuticals. It has the potential to bring substantial benefits to UK, European and industry competitiveness and, above all, to patients in the European Community. However, despite significant efforts in the 1990s involving the European Commission, Member States and the pharmaceutical industry, the Single Market in this sector is still some way off realisation.

3.20 Industry and Government are agreed that:

i. completion of the Single Market in pharmaceuticals should improve the competitiveness of the European Community for the innovative R&D based industry;

ii. an efficient and effective European medicines licensing system should be part of the completed Single Market in this sector;

iii. steps towards completing the Single Market should seek to enhance, not undermine the competitiveness of the innovative industry operating in the Community;

iv. progressive and incremental steps towards lifting price controls from medicines not purchased by State health services represent a viable and sustainable way forward;

v. the UK will aim to ensure that domestic policies applied as the Single Market progresses seek both to benefit the NHS and the competitiveness of the UK-based industry.

3.21 Lord Hunt, co-chairman of the Task Force, pressed these points of principle at the round table on European pharmaceutical industry competitiveness hosted by Enterprise Commissioner Erkki Liikanen in Brussels in December last year. These discussions are expected to lead to the creation of a European-level Task Force on pharmaceutical industry competitiveness.

3.22 Industry and Government are agreed that efforts need to be made to promote a more competitive dynamic within the Single Market and have developed an agreed way forward. They foresee the pursuit of this agreed way forward both in bilateral and Community-level discussions over the course of 2001/02.

3.23 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.

3.24 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.

EU Enlargement

3.25 Enlargement of the European Union offers real potential for benefit for the citizens of the UK and other EU Member States, for the citizens of the countries that join the EU, and in expansion of markets for industry.

3.26 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.

3.27 Many of the current candidate countries, particularly in Central and Eastern Europe, made considerable advances after they emerged from Soviet influence in the 1990s in bringing their rules, norms and practices governing IPR protection towards European Community standards.

3.28 The basis of the UK position – agreed between industry and Government – in negotiating how the IPR regime in candidate countries might operate upon accession to the European Union is that they afford an equivalent level of protection to that available within the current EU15.

3.29 As negotiations continue, industry and Government in the UK will continue to work in partnership to seek a fair outcome from this part of a complex set of negotiations which brings benefits to all principal stakeholders.

Conclusions

3.30 The UK has a long history of leading international developments in intellectual property protection for innovation.

3.31 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, given the shared industry/Government view that appropriate IPR protection stimulates investment and innovation.

3.32 Key areas of agreement include:

- the pressing need to develop yet more partnerships to help improve access to medicines in developing countries, noting the important contribution effective protection of IPRs makes to access;

- European Community legislation on data exclusivity provisions needs to be clarified, harmonised and strengthened;
- a joint long-term vision of developments needed in the European Single Market in pharmaceuticals taking an incremental approach to market liberalisation;
- commitment to continued close partnership in delivering UK inputs to Community-wide discussions on enlargement of the European Union as it affects the pharmaceutical industry.

3.33 Industry and Government expect progress in each of these areas to be kept under review by the successor mechanism to PICTF described in Section IX.

Section IV

Regulation of Medicines Licensing

Chaired by George Butler

Summary

An important element of the UK regulatory environment has been the Medicines Control Agency and the leading role it has played in the past in EU medicines regulation. However, other Member States have learned from the example of the MCA, and the Task Force concluded there was scope to re-establish the MCA as an agency of choice. 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 resulting in more predictable regulatory decision making, globally competitive approval times and the possibility of more rapid availability of innovative medicines to European patients. Industry is concerned that the MCA commits to European assessment procedures on a forward looking partnership basis with other regulators in the community to deliver high quality single EU assessments and optimally uses resources.

4.1 The current system of medicines' control in the European Community has evolved over 30 years. The complexities of the current procedures are far from ideal resulting in unnecessary difficulties for national agencies, Community structures and the regulated pharmaceutical industry. There is an urgent need to change, streamline and improve the efficiency of the current medicines regulatory system prior to enlargement of the Community when more national systems will be added.

4.2 The MCA has historically had a leadership role in European procedures and has been a major contributor to the development of the mutual recognition system. The industry has until recently routinely chosen MCA to assess the first application for a licence under the mutual recognition procedure. However, industry has been choosing other Member States' Agencies to assess important new products. MCA and industry are committed to finding ways of re-establishing the benefits of their previous working relationships. This could be achieved by:

- closer liaison between companies and the regulatory agency;
- routine dialogue between the agency and industry during drug development;
- RMS acting as advocate where appropriate for the product during the mutual recognition procedure.

4.3 An opportunity for change is created by requirements placed on the European Commission to review in 2001 the operation of the current system. The UK regulatory agency's primary obligation – as set out in the Medicines Act 1968 – is the protection of public health. However, the aim of this workstream was also to establish the MCA as a driving force to provide a European assessment of new drug submissions of high scientific quality, in a timely but collaborative way, based on centres of excellence. The Review also provides an opportunity for the development of a UK environment that, by establishing the MCA as an agency of choice, will foster a strong, competitive pharmaceutical Industry in the UK. In terms of competitiveness, the US regulatory environment has made some forward steps which the EU needs to match as well as seeking global best practice whilst maintaining the high standards of public health.

4.4 A working group under the chairmanship of Dr George Butler, Head of Worldwide Regulatory Affairs, AstraZeneca plc, was established with an objective to:

Consider the future development from a competitiveness point of view of the European licensing system in relation to the respective roles of the EMEA and national agencies.

4.5 Its aim was to establish the MCA as a leading regulatory agency within the EMEA context and to drive a new regulatory partnership with academia and the industry to help improve the rapid availability of pharmaceutical products to citizens of the Member States of the European Union.

European Commission 2001 Legislative Review

4.6 The European Commission is leading a review of the EU medicines licensing system during 2001, with a view to national implementation of revised legislation by 2005. Any proposals made by PICTF need to be updated as the Commission's proposals are developed; the issues referred to here will be returned to under the auspices of the PICTF successor mechanism at least during the rest of 2001.

Goals Agreed by Industry and Government

4.7 Government and industry have agreed that any revision to the EU licensing system should:

- provide a high level of protection and promotion of public health;
- utilise high quality, scientific European Community-wide competence;
- provide a single, high quality assessment of safety, quality and efficacy;
- provide for dialogue between companies and agencies during drug development to facilitate greater predictability of the regulatory outcome;

- deliver Community co-ordinated pharmacovigilance EU opinions based on the local collection of high quality standardised pharmacovigilance data;
- operate on timelines for approvals that are competitive with present US performance or international best practice;
- facilitate the development of a centre of excellence in regulatory affairs at UK MCA;
- provide for optionality in the selection of rapporteurships for centralised applications;
- deliver a more streamlined mutual recognition procedure;
- operate sharing of Community knowledge via common standards and state of the art data, information and knowledge management systems;
- establish effective European co-ordination of national manufacturing inspection and enforcement activity;
- provide legitimate business freedoms for the industry;
- be more efficient, conserve resource and limit costs.

In addition, it was recognised that industry should facilitate provision of better, more robust applications.

Industry considers that the evolution of Centres of Excellence would bring together the benefits of regulatory expertise and experts from several Member States to assess applications, including appropriate dialogue with industry, to produce a single European assessment, thus avoiding multistep reviews.

Action Plan

4.8 Government and industry have agreed a detailed workplan to deliver these goals.

Section V

Science Base and Biopharmaceuticals

Chaired by Lord Sainsbury

Summary

The competitiveness of the pharmaceutical and biopharmaceutical research sector will be improved by agreed measures including:

- An application for a "Faraday" project on biopharmaceutical manufacturing
- An industry secondee to DTI to advise on sector inward investment
- Training and support for Industrial/Academic Liaison Officers
- Improvement in the application processes for postgraduate training schemes such as CASE
- A Corporate Venturing Symposium for senior directors and managers
- A review of Animals Scientific Procedures licensing processes so as to promote animal welfare by using resources to best effect

Introduction

5.1 The UK Science Base has a world-wide reputation for excellence and historically, the strategic business environment in the UK has supported high levels of R&D investment and innovation by the UK's pharmaceutical and biopharmaceutical industries.

5.2 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 UK share of world pharmaceutical R&D is just under 10% despite realising only 3% of global sales. The UK has a comparative advantage in pharmaceutical R&D – it accounts for a larger share of national R&D than in any other industrial country.

5.3 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.

5.4 A working group was established under the guidance of the Science Minister, Lord Sainsbury to address these issues with the terms of reference:

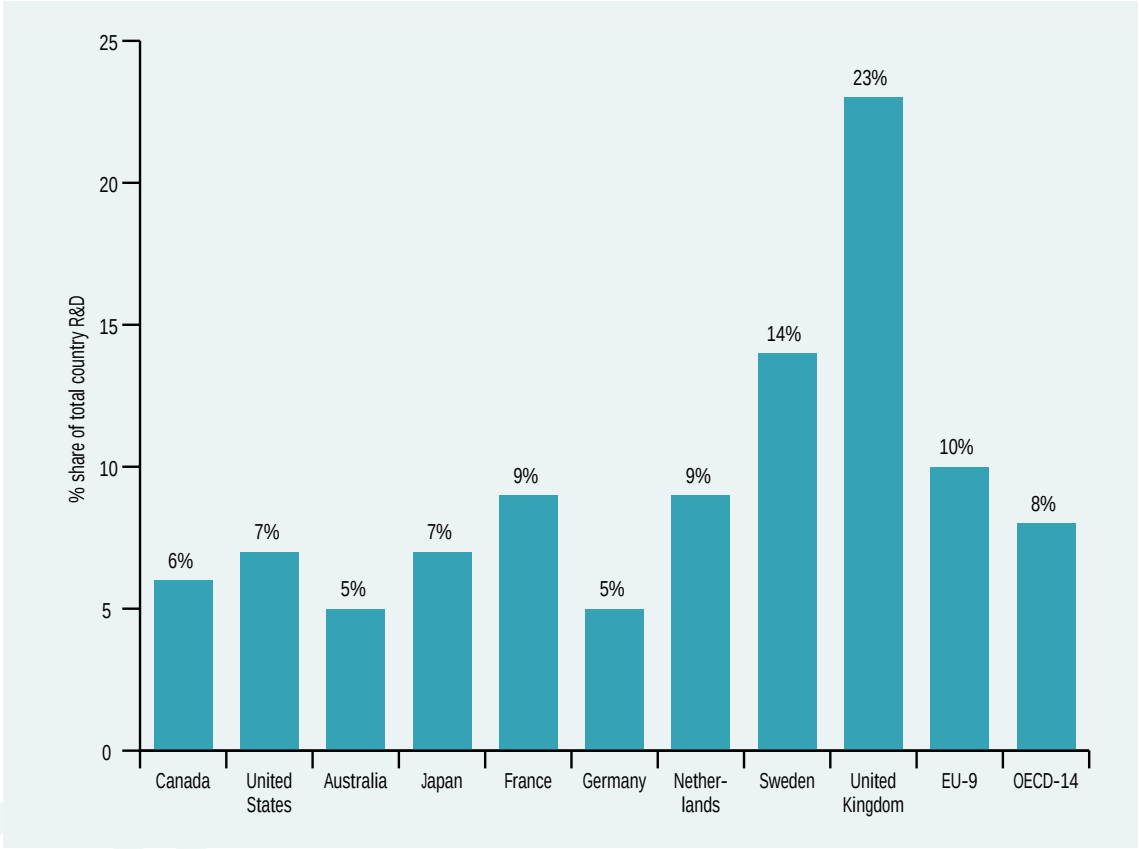
- to identify further steps that might be taken to foster the development of a vibrant biopharmaceuticals sector, including examination of the potential for technology clusters to develop, taking into account the interface with land use planning;
- to identify the potential for promoting further partnership between the industry and academia and industry and Government.

5.5 In discussion, industry and Government quickly concluded that recent progress in other areas (such as publication of the Genome Valley and the Biotechnology Clusters Reports) meant that not all of the issues encompassed by the terms of reference were priorities for action. Industry and Government therefore agreed revised priorities.

The UK Environment for Innovation

5.6 The UK-based pharmaceutical industry invests heavily in R&D in comparison both to other UK industries and to pharmaceutical industry in the rest of the world.

Figure 5.1: Share of pharmaceutical R&D as a per cent of total manufacturing industry R&D

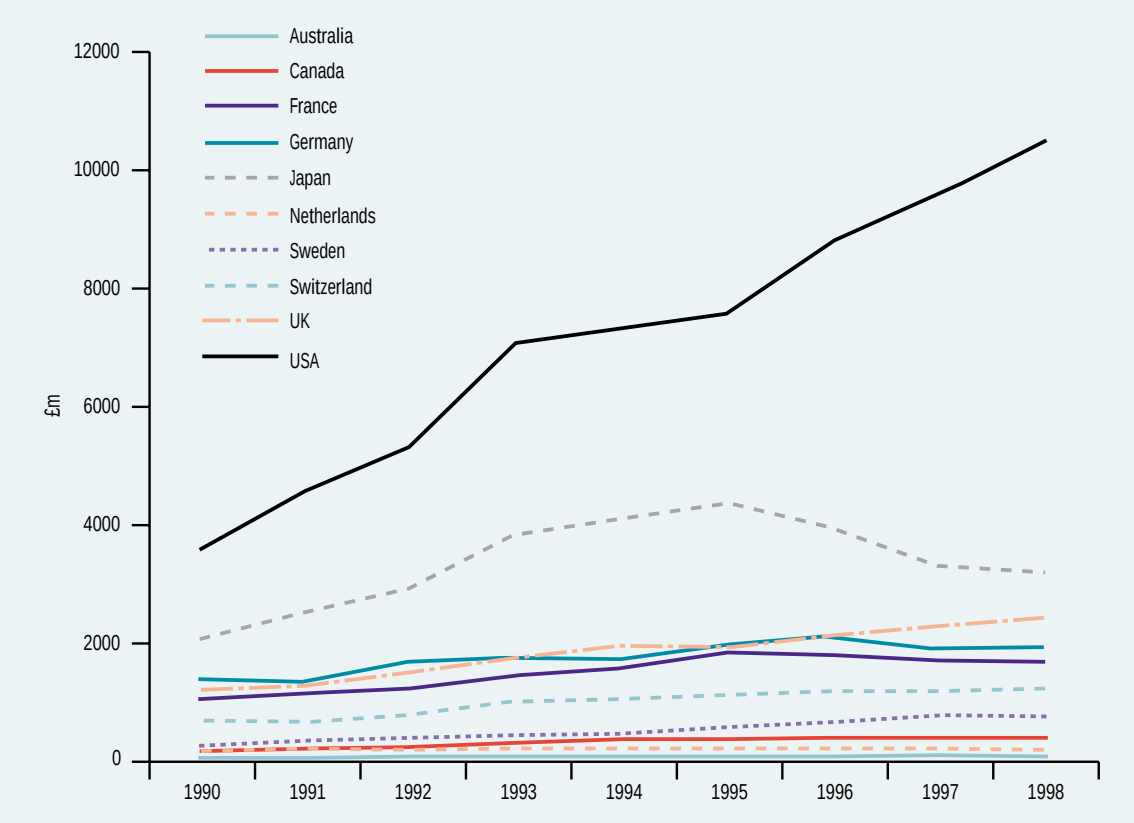


Source: OECD, 1997

5.7 Pharmaceutical R&D expenditure in the UK accounts for 23% of all commercial R&D (see figure 5.1). This figure is much higher than our main competitors.

5.8 Whereas the UK market accounts for about 3% of global pharmaceutical sales, R&D expenditure by UK pharmaceutical manufacturers has accounted for around 8% of the global total during the 1990s. Moreover, growth in UK R&D over this period has outstripped that of all other significant producer countries by a considerable margin, although it has not kept pace with the USA (Figure 5.2 and table 5.1).

Figure 5.2 Expenditure on Pharmaceutical R&D



Source: ABPI

Table 5.1: Growth in R&D expenditure 1990-1998

USA	195%
UK	108%
France	64%
Germany	41%
Japan	57%
Switzerland	87%

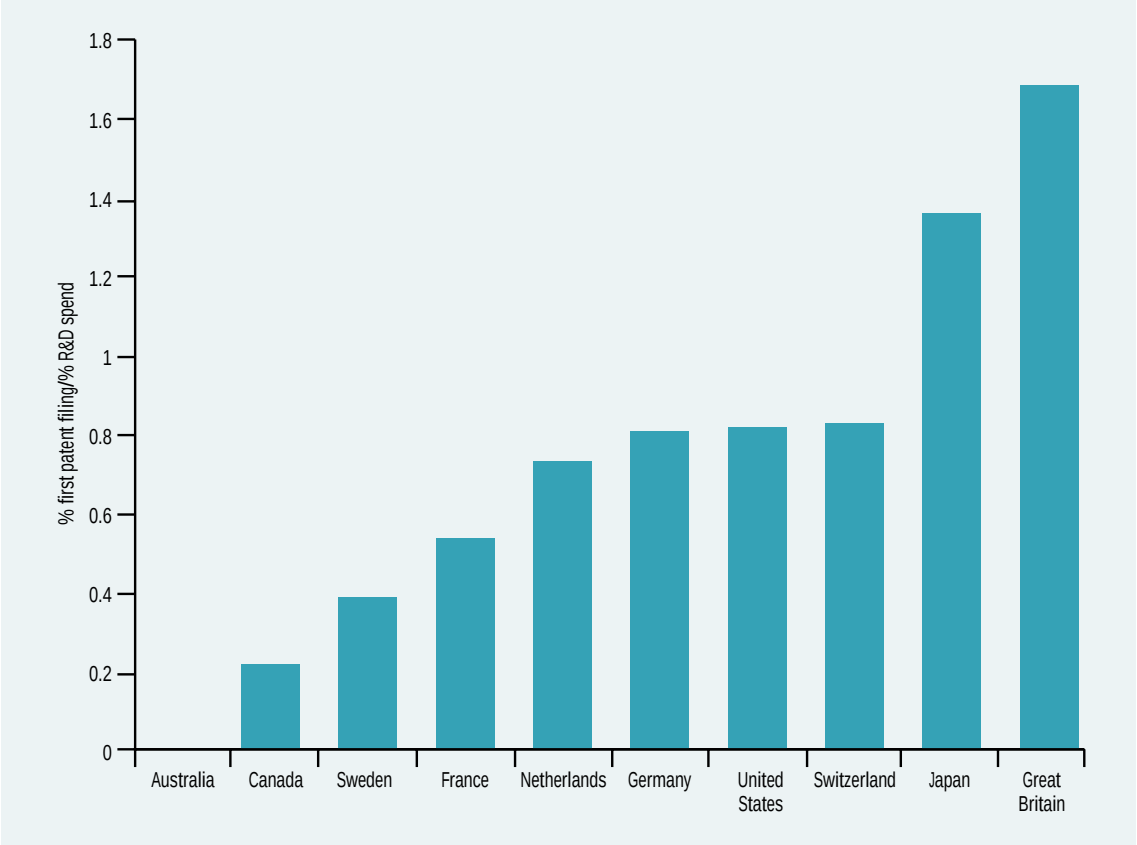
Source: OECD

5.9 Pharmaceutical R&D can usefully be divided into the discovery phase, in which compounds are identified, and the development phase which includes clinical trials. The discovery phase may be particularly important because it is at this stage that patenting gives rise to valuable intellectual property. The UK share of global expenditure on this phase is higher than on both phases combined, at around 10%.

5.10 In order to measure innovative performance it is necessary to combine a number of indicators covering R&D expenditure, success in filing patents, success in launching new products, success in penetrating global markets and, ultimately, success in capturing a large share of the biggest markets. PICTF found 10 such indicators detailed in the ACSG Report. The UK ranks second or third on 9 of the 10 indicators and on average ranked second.

5.11 The UK ranks number one for productivity of drug discovery measured in terms of patents filed per £ invested (Figure 5.3, where a score of one is equal to world average productivity).

Figure 5.3 Pharmaceutical Patent Productivity



Source: CMR International

5.12 Products from UK research perform relatively well in penetrating the global market. For example, although the UK produces fewer new products than Japan, companies are more innovative and their products sell more widely across the globe. Over 95% of UK products are sold in one or more leading overseas markets whereas 85% of Japanese products are not.

Industry/Government Key Issues

5.13 Industry and Government identified the following issues as key elements of a competitive environment for the pharmaceutical and biopharmaceutical research sectors:

- manufacturing
- the UK skills base
- industry/Academia Links
- big Pharma/SME Relationships
- animal experimentation and the climate for research in the UK.

5.14 The value of genetic databases to the research based pharmaceutical industry was also considered.

Issues Affecting Competitiveness

Manufacturing

5.15 The future of pharmaceutical and early stage biopharmaceutical manufacturing in the UK has been the subject of continued discussion between the industry and Government. A sub-group considered proposals to a) help maintain pharmaceutical industry manufacturing investment in the UK, b) help limit further disinvestment and c) help facilitate an increase in the availability in the UK of early stage biomanufacturing and the related skills required.

Key achievements:

- An application for a “Faraday” project to help work on early-stage biopharmaceutical manufacturing
- Agreed Terms of Reference for an industry secondee to advise Government on inward investment by the pharmaceutical industry.

The UK skills base

5.16 The strengths of the pharmaceutical industry’s R&D activities in the UK are largely dependent upon the quality of the graduates and post-graduates arising from the country’s universities.

5.17 At one level, the pharmaceutical industry shares many skills needs with other sectors. Many new recruits are often lacking, at appointment, in such transferable skills as basic communication, contextual use of IT, problem-solving capabilities, time-management, presentation skills, report writing and scientific writing. More specifically, the pharmaceutical industry has particular requirements for high-level specialist skills. This is particularly the case for science and technology graduates

and post-graduates with specialist research skills. A sub-group reviewed current skill needs by the pharmaceutical and biopharmaceutical industry and identified ways of addressing shortcomings. Further work will be needed to develop the actions suggested by this sub-group.

Key achievements:

- Recognition 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.
- Agreement that application processes for postgraduate training schemes such as CASE should be reviewed and improved as necessary to ensure their maximum relevance to industry.

Industry/Academia Links

5.18 Beyond the quality of the graduates and postgraduates arising from UK universities, the competitiveness of the industry's R&D activities is also heavily dependent upon the quality of the research carried out in British universities, research institutes and clinical centres. It was acknowledged that the pharmaceutical industry/academic interface in the UK has never been stronger. However, both industry and academia recognise that they are operating in a rapidly changing environment. The cost of research continues to increase, stimulating further mergers and acquisitions amongst the larger companies and the need to seek partners, in academia and through external contract activities. At the same time, the more forward looking universities are recognising that they, like the pharmaceutical industry, operate in a global market and need to identify and promote what they feel are their strengths in leading edge research. Technology driven companies will fund world-class research irrespective of location. A sub-group considered areas of particular strength in the UK and made proposals to build on these strengths.

Key achievement:

- Agreement that there should be training and support for Industrial/Academic Liaison Officers in universities and industry to foster increased professionalism for this vital work.

Big Pharma/SME Relationships

5.19 The value of a strong and sustainable SME community in the UK, active in key technology fields of relevance to the established pharmaceutical sector, and effective technology transfer/collaborative mechanisms between these industries are acknowledged as important contributors to the competitiveness of the pharmaceutical sector. A sub-group considered the following key issues of a) innovatory research in SMEs b) access to key data, personnel, expertise c) finance: shared risks and income streams for SMEs d) clusters of companies in the same or complementary fields and e) external influences to university sites, planning and staff recruitment constraints.

Key achievement:

- A Corporate Venturing Symposium for senior directors and managers in the pharmaceutical and biopharmaceutical sectors on 22 February 2001.

5.20 The symposium, chaired by Lord Sainsbury, explored ways in which pharmaceutical companies might benefit through using corporate venturing to spin out companies to research and develop innovative ideas and drags and provide platform technologies to enhance mainstream research programmes. The symposium was attended by senior representatives from pharmaceutical and biotechnology companies.

5.21 The symposium concluded that corporate venturing was beneficial to and in the best interest of pharmaceutical companies. The benefits of corporate spin-outs were to enhance assets, particularly intellectual property that would otherwise remain untapped, equity in a spun-out company and continued access to skilled scientists whilst offering them flexibility and the opportunity to be entrepreneurial. The symposium heard that spin-outs often lead to increased internal motivation within the new company, spurring further innovation and leading to additional spin-outs in non-core research areas.

5.22 During discussions, the symposium reached the conclusion that the main reasons for failure of spun-out companies were likely to be failures in management. The ability to recognise different management needs, according to the stage of life of a spun-out company, was always of paramount importance. Failure could be minimised through corporate venturing by providing potential entrepreneurs with access to the business skills they needed, such as advice on preparation of business plans and legal advice on start-ups.

5.23 The outcome of the symposium, together with the presentations from speakers, will be published in a short report.

Animals Welfare and Research

5.24 The increasing complexity of the regulatory processes 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 essential research involving animals. There is a danger that, as a result, research may be moved abroad. If this were to happen, there would be implications for the welfare of animals used in research: most markets offering animal testing facilities fail to match the UK's scrupulous standards. The working group considered these issues and what might be done about licensing processes. Streamlining the licensing process will enable administrators and researchers to put more resources into improving animal welfare.

Key achievements:

- 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.

- Proposals to amend the Criminal Justice and Police Bill, the Malicious Communications Act and the Companies Act to tackle harassment and intimidation by animal rights campaigners, and to restrict access to the residential addresses of Directors of companies engaged in animal research and testing. Amendments were brought forward by the Government.

Future Action

5.25 Industry and Government considered some key factors of importance to maintaining a vibrant research environment for the pharmaceutical and biopharmaceutical industry in the UK. A number of actions were identified which, if implemented, should help to ensure the UK remains an attractive place for innovative scientific research and development. A monitoring system will track and progress these actions. Their impact will then be measured against the relevant competitiveness and performance indicators described in Section VIII of this report.

5.26 The system for monitoring will comprise ad hoc groups drawn from industry and relevant Government departments.

Section VI

Clinical Research

Co-chaired by Sir John Pattison and Vincent Lawton

Summary

- 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.
- Collaboration between the industry and the Department of Health/NHS has identified strengths, but also some impediments, to internationally competitive clinical research sponsored by the industry in the NHS.
- An action plan to address these includes:
  - Work by industry, the DH and the NHS to significantly improve start up times on clinical trials from April 2001.
  - Development of a Research Governance Framework by the Department of Health which defines quality standards and clarifies responsibilities for all research involving patients in the NHS.
  - Development of a partnership agreement which defines the working relationship between industry and the NHS.
  - Work to improve transparency in costing and hence reduce transaction costs for commercial clinical trials.
  - Agreement of performance indicators to monitor progress and ongoing competitiveness of the UK in industry sponsored clinical research.

Scope

6.1 The Task Force established a working group under the chairmanship of Sir John Pattison, Director of NHS R&D, and Vincent Lawton, Managing Director of Merck Sharp and Dohme Ltd, to work on reviewing the opportunities and costs associated with the clinical research infrastructure in the NHS as a base for research by pharmaceutical companies, in tandem with promoting and supporting R&D of value to patients and the health service.

6.2 The Terms of Reference given to the group were:

"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."

Introduction

6.3 The UK has long been regarded as a good place to conduct research. The presence of highly motivated and educated investigators, a strong academic base, a comprehensive health service committed to research and development, well organised and funded medical research organisations and strong networks of General Practitioners, have historically resulted in an efficient infrastructure for the conduct of clinical research.

6.4 In its turn, industry sponsored clinical research plays an important role in the NHS in developing patient services and is essential for a sound, research based, pharmaceutical industry within the UK. Clinical research has direct benefits to patients who participate and also contributes towards improved take-up rates of beneficial treatments through the close involvement of researchers and clinicians. Other important benefits include improved health outcomes and reduced morbidity that new medicines provide for participating and non-participating patients alike. Also the NHS as an organisation benefits through the financial support that industry sponsored research brings with it. Clinical research also improves patient care through the development of treatment protocols and by stimulating other research through the education of participating staff.

6.5 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.

6.6 The main objective industry and Government agreed for this working group was to identify ways of maintaining and improving the competitiveness of industry sponsored clinical research in the United Kingdom. Having benchmarked UK clinical research against its main competitors in Western Europe and North America, the group went on to identify 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. None of these parameters is independent and the final decision as to whether or not to place research within the UK will depend on a judgement about overall cost-effectiveness for a particular project and company.

6.7 The working group considered how both industry and the NHS can have a positive influence on these factors. It successfully identified solutions to a number of important issues.

Issues Affecting Competitiveness

Start up time

6.8 In the international arena there is considerable pressure on the pharmaceutical industry to reduce product development times. An important element in this is the time taken for studies to start after protocols have been finalised. The working group sought to identify areas in the underlying framework for clinical research in the UK where delays might occur and provided an action plan to remove both current and anticipated impediments to research.

6.9 Two major issues were identified:

i. Currently, clinical research protocols in the UK may undergo up to four review processes before implementation. This is higher than in other European Union countries. Regulatory review takes up to seven weeks for completion and runs in parallel to Multicentre Research Ethics Committee review. This is followed sequentially by Local Research Ethics Committee review and NHS review. In extreme circumstances these processes can take up to 9 months to complete. The average time is less, but frequently longer than other European countries.

ii. The European Directive on Clinical Trials aims to provide an EU-wide standard for regulatory and ethics review. Whilst it may have a beneficial impact on start up times within the UK overall, it may be counter-competitive in some specialised areas of research such as human pharmacology (Phase I) trials where speed is of the essence and which do not currently require regulatory approval prior to starting.

Recruitment and Research Quality

6.10 Quality of research falls under two broad headings. Organisational quality encompasses the ability of UK centres to recruit participants efficiently. Internal quality amounts to the ability to conduct research in a proper and ethical fashion to agreed standards. The latter has always been high in the UK but recent high profile and wholly atypical cases of research fraud and mismanagement have reduced public confidence in research. A number of issues were identified that reduce the ability of the UK pharmaceutical industry to recruit willing investigators and of these investigators to recruit sufficient patients to trials.

6.11 The application of the ICH Tripartite Guideline for Good Clinical Practice has increased the administrative burden associated with clinical research. This in turn reduces the time available to investigators to recruit and examine trial participants. Trusts and their employees are, as a result, less willing to take part in industry-sponsored research. Overall, 30% of UK sites fail to recruit a single patient and only 70% of agreed recruitment targets are met. The UK is falling behind other European countries in these respects.

6.12 Errors in the conduct of research by any type of sponsor adversely affects all research. To maintain public confidence and participation in research, people have to be confident that the research process is scientific, ethical and in their best interest.

6.13 Medical mistakes and the few clinical trials that go wrong dominate public discussion and the media. Also, some scientific concepts like random allocation can be difficult. So, clinicians and patients sometimes shy away from participating in a trial because they lack confidence in the scientific basis and safety of a trial and understanding of the terminology. Better tools are needed to communicate the benefits of participating in trials as well as the risks, that trials are well regulated and good for patients, and to enable people to make sound choices confidently.

6.14 Training is fundamental to the quality of research. Changes across the world in the way in which doctors are trained and accredited are putting pressure on curricula, including in the medical specialities such as clinical pharmacology. It is important to enhance the profile of research in basic and post-graduate training for doctors, nurses and other healthcare professions, so as to sustain the pool of suitably trained individuals.

Research Costs

6.15 Surveys across many companies suggest that between 1993 and 1998, the costs of Phase II-III clinical research in the UK increased by 50%. Compared with our close European partners, the UK is more expensive and the gap appears to be widening.

6.16 The cost of each clinical trial is a compilation of a series of different procedures. Western European countries usually only charge for those parts of a trial which are in addition to normal treatment and investigations for the condition, whereas in the UK there is evidence that charges may include all investigations and treatments in some cases. In February 1999, the ABPI used the DataEdge database to price Phase III studies in Acute Myelogenous Leukaemia (AML) and reversible airways obstruction, and to compare the costs across nine European countries and the USA. These showed the UK to be most expensive country in Europe in which to conduct clinical research on these topics and rapidly approaching the cost of such studies in the USA. Since then the low value of the Euro has exacerbated the position.

6.17 However, in their analysis for PICTF, the access and competitiveness study group (see Section II – details of full report in Appendix II) looked at numbers of patients recruited to trials (rather that direct cost data) in the major economies. The data for 1996-99 show a decline in the UK, Germany and France in contrast to North America, though the available data is insufficient to tell whether this represents a longer-term trend.

6.18 Different hypotheses could account for the data. Cost does not appear to explain recent movements, since costs are highest in the US, although it is thought to be a factor that firms consider alongside the growth rate of each market.

Research Partnership

6.19 The NHS has its own research needs. Much of the infrastructure for this research is common with that required by the industry for its research. Currently, the NHS hosts industry sponsored research but collaborates infrequently with industry. During discussion the working group identified a number of areas where the interests of both the NHS and the pharmaceutical industry would be better served by closer collaboration and where a clear understanding of the responsibilities of both parties might improve the efficiency and therefore the competitiveness of the research process.

Actions Agreed by The Working Group and Implemented

6.20 The Department of Health has published a Research Governance Framework, taking on board comments from the industry, and setting out standards and responsibilities for all research conducted within the NHS. Adherence to the framework will be monitored. For its part, the ABPI has published recommendations to companies on the registration of commercial clinical trials.

6.21 The Medicines Control Agency (MCA) will maintain its high standard and speed of review of clinical trial protocols by allowing a maximum of 35 calendar days for review and a further 25 days where there are queries on the protocol. The MCA will measure adherence to this using the time taken from application to final CTX (Target ≤60 days). The industry will maintain its high standard of submission to MCA, and industry and the MCA will work together to ensure that the proportion of CTXs approved within 35 days does not fall.

Actions Agreed Awaiting Implementation

6.22 In implementing the EC Directive on Good Clinical Practice, serious consideration should be given to a procedure which regulates human pharmacology (Phase I) studies in an appropriate manner, taking into account the perceived low risk to subjects in these studies and maintaining the UK's competitive edge.

6.23 The Department of Health will clarify Trust responsibilities in approving industry-sponsored research. This will provide that the Trust R&D review should run in parallel with Research Ethics Committees' (REC) review and be completed within a 60-day time limit. Guidelines will be issued by 01/06/01.

6.24 The Department of Health will develop new guidance clarifying Research Ethics Committees' responsibilities, including the requirements of the European Clinical Trial Directive. Timeline: By 01/04/01.

6.25 As a result of this, Multi-centre and Local Research Ethics Committees will consider applications in parallel and complete their review within 60 days from initial submission in accordance with the European Directive. This procedure will be

implemented by the recently established Central Office for Research Ethics Committees (COREC) by 01/07/01.

6.26 The initial review by Multi-centre Research Ethics Committees (MRECs) of valid applications to conduct studies will be completed within 45 calendar days, with no more than one extension to resolve questions, and the total review not to exceed 60 days. This procedure will be implemented by COREC by 01/04/01.

6.27 Industry and the NHS are to set up joint training initiatives for commercial applicants, to improve the quality of submissions to RECs. This procedure will be implemented by the ABPI and COREC by 30/6/01.

6.28 The members of the ABPI will record average (range) industry cost of UK-recruited patients (target: EU major market average). These data will be compiled in summary form by the ABPI and sent to the Department of Health to inform its own pricing assessment project (outlined in the next paragraph). This process will be completed by 31/05/01.

6.29 The Department of Health will review its guidance on the relationship between prices charged by the NHS and the cost of studies with the intention of improving the transparency and consistency of pricing. The review will be informed by evidence of variations in NHS approaches to pricing and the cost to industry of conducting its research in other major markets. The overall aim will be, within the constraints of EC law and Government policy for public services, to minimise impediments to the UK's competitiveness for clinical trials when compared with major EU and North American markets. This review will be completed by 30/06/01.

Performance Indicators

6.30 The above actions will be progressed over the coming months against appropriate performance indicators listed in Section VIII.

Ongoing Discussions

6.31 A Research Partnership Agreement is to be drawn up between the UK pharmaceutical industry represented by the ABPI and the Department of Health/NHS, that acts as a framework for continued interaction. It will parallel that for non-commercial (charity) funded research (this to cover issues of mutual interest and arrangements for collaborative work, funding, timeliness, communication between companies and NHS bodies and the quality of research in the wider public interest). Following the development of a Research Partnership agreement, industry and Government will establish a formal mechanism to continue discussion.

6.32 The ABPI and the NHS, working in partnership, are to encourage the development of Clinical Research Networks and Centres, using the Cancer Research Network announced in the NHS Plan as an example of "best practice".

6.33 COREC will continue looking at the feasibility of novel processes, such as prior certification schemes, whereby the consideration of the local research environment might be streamlined.

6.34 The ABPI and DH will explore ways of working with other key stakeholders to promote public engagement with the relevance of clinical trials.

6.35 The industry believes that to maintain the UK's competitive position with regard to Phase I (human volunteer) studies notification by letter of intention to carry out such a study should be pursued as sufficient by the MCA within the relevant European Regulations.

6.36 The mechanism and extent to which the Research Assessment Exercise recognises industrially sponsored research needs to be clarified and Good Publication Policy needs to be defined, particularly in the area of early phase (I and IIa) studies where registration and early publication may breach the need for commercial sensitivity in drug development. Industry will consider ways of encouraging broader adoption of Good Publication Policy with a key aim of addressing investigators' concerns regarding their autonomy over their research results.

6.37 Variations in pricing are compounded by some Trusts' practice of including provisions for normal NHS treatment in the prices to industry. The Working Group, however, agrees that the most appropriate costs falling to industry for commercial research hosted by the NHS should be those that are extra to the standard costs of treatment that trial participants would receive as patients under the NHS. Industry welcomes the review proposed in paragraph 6.29 and seeks assurance that the review will consider whether the approaches currently applied in the NHS are all consistent with the Government's wider policy, eg on fees and charges, and on recovering the costs of services provided by the public sector in wider markets.

6.38 The Department of Health has undertaken to initiate discussions with the higher education funding council and university representatives about joint NHS/university arrangements for improving transparency in pricing and charging industry for clinical work arising in teaching hospitals, including a unified overhead where charged.

6.39 Industry and Government members of the Working Group support the further exploration of issues around access, by clinical investigators, to genetic and population databases to assist in patient recruitment.

Future Direction

6.40 Joint industry/NHS monitoring of the agreed performance indicators should take place on a regular basis. A joint Department of Health/ABPI mechanism will be established to monitor the indicators and disseminate the results overseen by the Medical Director of the ABPI and the Director of Research and Development at the Department of Health. Details of data collection are still to be agreed for each indicator. In the context of a formal partnership between industry and the DH, there will be periodic meetings between the two parties at a high level to review progress on these and other issues.

Conclusion

6.41 Working Group 5 has 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 has arrived at a number of recommendations which, if adopted, will help to ensure that the UK remains at the forefront of clinical research. To monitor this, the Group has proposed a number of performance indicators and targets.

Section VII

Wider Economic Climate

Chaired by Stephen Timms MP

Summary

- The Government attaches great importance to making the UK a good place to do business by creating a stable and competitive economic environment.
- The pharmaceutical industry agrees that the UK is in general is a good place for them to do business.
- A key determinant of where R&D is carried out, however, is the availability of staff of the right quality.
- It is important for the industry, therefore, that investment in the UK science base and education is maintained.
- Other factors such as the tax regime and exchange-rate exposure can have an important effect at the margin.
- 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.

7.1 The Government attaches great importance to making the UK a good place to do business by creating a stable and competitive economic environment.

7.2 The economic climate working group was established under the leadership of Stephen Timms MP, the Financial Secretary to the Treasury, to consider the aspects of the economic climate in the UK which foster or constrain the competitiveness of the innovative pharmaceutical industry. The specific objectives the economic climate group set itself were to:

i. identify why the UK is a good place for business in general; and

ii. identify what additional specific factors about the UK economic climate are important to the pharmaceutical industry.

The UK Economic Climate

7.3 There are a number of reasons why the UK economic climate is a good place for business in general:

i. Economic growth has averaged 2.7% per year since 1997 and forecasts for this year are in line with estimates of trend.

ii. Inflation has remained stable and close to the Government's target for RPIX (Retail Price Index excluding mortgage interest payments) inflation of 2½%.

iii. Interest rates are lower and more stable than in the past – official rates are less than half levels seen in the late 1980s and early 1990s. Long-term market rates are at their lowest levels for thirty years and are down to levels of other major European economies.

iv. Business investment has risen strongly in recent years, rising to a record high of 14.3% of GDP in 1999 which was the second highest amongst the G7 countries.

v. Employment has risen by over one million since 1997 (on the Labour Force Survey measure).

7.4 This platform of economic stability has led to economic conditions favourable to investment and trade. The UK has long been an open and outward looking market, with deep and enduring economic linkages with the rest of the world. These links include the UK's significant role in world trade, its strong record in attracting inward investment as well as its own position as a large investor overseas. There is a high level of inward foreign direct investment in the UK and this partly reflects the importance to overseas investors of the UK's flexible workforce, good labour relations and the relatively light level of regulation faced by businesses.

7.5 Permanently low inflation is an essential platform for achieving the Government's objectives of high and stable levels of growth and employment. The Government has a clear commitment to price stability. This has been demonstrated by giving independence to the Bank of England and having a monetary framework that provides a credible, transparent and accountable long-term approach to achieving consistently low and stable inflation.

7.6 The UK has a history of liquid capital markets which UK and international companies can readily access to finance growth. The London domestic equity market is the largest in absolute terms in the European Union, enabling a wider range of companies to raise long-term capital. The UK also has a vibrant private equity market, which provides access to risk capital for a wide range of companies from start-ups through to substantial management buy-outs. Within the venture capital sector the UK is still the deepest market across Europe, although other countries, notably Germany and France, are gaining a greater share of European venture investment.

7.7 The UK markets have for some time enabled technology-based companies, particularly in the biotechnology sector, to come to the market at an early stage in their development. This has helped finance the long-term research and development investment programmes for companies to bring products through to commercialisation.

7.8 The Government is taking steps to facilitate universities establishing fruitful links with industry and exploit research through such initiatives as the University Challenge Fund (UCF), the Science Enterprise Challenge (SEC), the Higher Education Reach Out to Business and the Community (HEROBAC) Fund and Faraday Partnerships. Greater partnership working and sharing of information will benefit both industry and the university sector through knowledge transfer and direct financial benefits.

Key Issues for the Industry

The industry identified the following key elements that contribute to a competitive environment for the pharmaceutical sector:

- global perspective
- science base
- education
- fiscal climate
- capital markets
- corporate venturing.

7.9 Pharmaceutical companies operate globally and have bases in a number of countries, which makes investment, especially at the margin, very mobile. The continuing restructuring in the industry has brought with it both the requirement and the opportunity to review the scale and location of activities to ensure that they are carried out in the best available environment world-wide.

7.10 A key determinant in any investment decision for the pharmaceutical industry is the availability of appropriately skilled staff. To carry out R&D it is necessary to have access to highly specialised skills and as such barriers to R&D tend to be practical rather than financial. 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.

7.11 Investment must also, however, continue to flow into primary and secondary, as well as tertiary, education. Emphasis should be placed on supporting a conducive environment for science in secondary schools, which will lead to an increase in the numbers choosing science at university, and ultimately the resource base of

scientists qualified to carry out R&D. It will also be important that the industry is able to draw on the skills base of other countries to allow R&D to be maintained in the UK if there is a shortage of specialist skills, so visa arrangements are important. This issue has been identified for further review in the Science Base and Biopharmaceuticals working group.

7.12 The tertiary infrastructure must be sustained as companies will invest where there is scientific excellence and access to new technologies. The US inevitably offers most in this regard, but the US universities' approach to ownership of intellectual property rights, leading to premature spin-out and commercialisation at too early a stage, can sometimes make collaboration more costly for businesses. The mechanisms for collaboration with universities in the UK have improved over the last few years and these need to continue to be developed.

7.13 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.

7.14 The UK capital markets have liquidity, breadth and the ability to handle large financial transactions. This is of great importance to the pharmaceutical industry as increasing numbers of transactions are cross border, and the ongoing restructuring of the industry requires capacity in the City to handle huge equity sales.

7.15 Access to new ideas and technology through links with the academic research base and with biotechnology SMEs is important to the competitiveness of the UK pharmaceutical companies. As companies seek to reduce the risk and increase the productivity of their R&D activities, it is possible that more focus will be placed on the opportunities to use corporate venture capital to make strategic investments. Corporate venturing and other measures can enable large pharmaceutical companies to develop specialist technology in partnership with SMEs, thereby pulling in extra management capacity; and can enable SMEs to develop technology that flows out from the big pharmaceutical companies because it is marginal to their product portfolios.

Section VIII

Competitiveness and Performance Indicators

8.1 This section looks to the future beyond the life of the Task Force. It sets out an agreed set of competitiveness and performance indicators that industry and Government might draw on after completion of the current initiative to assess how the UK stands up as a competitive environment for the industry to do business in.

8.2 The terms of reference for PICTF envisaged that the Task Force would approach its work by first agreeing a series of key factors that affect the competitiveness of the UK as a base for the global R&D-based pharmaceutical industry. The substantive work was to involve an assessment of how the UK performed against these factors and to take action to improve matters where practicable. Finally, the Task Force was to review the extent to which its work had addressed the competitiveness factors.

8.3 This section of the final report is intended to discharge the last of these functions and gathers together a set of broad indicators agreed by industry and Government economists together with specific output or performance measures agreed within the different working groups the work of which has been reported in Sections II to VII.

Why Have Competitiveness Indicators?

8.4 An agreed set of indicators will be used in the future to consider whether the UK competitive environment improves, stays broadly the same or deteriorates – both as a result of the current exercise and as a result of other subsequent changes to the UK business environment including, but not only, proposals for change to regulation of the market.

8.5 As recommended in the Access and Competitiveness Study Group report, agreed indicators give Government and industry a baseline against which to consider the foreseeable implications of future policy proposals.

8.6 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 by the PICTF follow-up mechanism at least annually, and results published as industry and Government agree is appropriate.

The Indicators

8.7 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. The list is at Tables 8.1 and 8.2 below. Where not already

done, a baseline of current values for these indicators will be established and consideration will be given to setting agreed targets as appropriate for future improvement in them. All of the indicators are based on published data.

8.8 The indicators have been drawn from those suggested by the various PICTF Working Groups and from the literature on the competitiveness of nations. The DTI (2001) publication *UK Competitiveness Indicators: Second Edition* has been a particularly useful reference.

Categories of indicators

8.9 In order to clarify the structure of the range of competitiveness and performance factors the list of indicators has been divided under three main headings and several sub-headings:

- 'Supply conditions' – cover factors affecting the availability, cost and quality of the labour and capital inputs required by the pharmaceutical industry, and the strengths and weaknesses of the UK's research infrastructure;
- 'Demand and regulatory conditions' – concern the rate of uptake of valuable new medicines in the UK compared with elsewhere, the nature of price/profit regulation in force, and the relative efficiency and reputation of the UK's medicines regulation system;
- 'Industry outputs' – reflect not only the attractiveness of the UK as a base for the pharmaceutical industry but also the extent to which the industry uses that capacity. Of particular importance is the extent of innovative activity achieved by the industry, as well as its general contribution to the UK economy.

8.10 Forty-six indicators will be applied to a number of countries for comparison, which represents a large set of data. For ease of assimilation, they will be divided into a list of 12 main indicators and a secondary list of supporting indicators (see Tables 8.1 and 8.2).

Caveats

8.11 The inclusion of an indicator in the list implies that it scores well on the following criteria:

- relevant to PICTF's terms of reference;
- easy to interpret;
- likely to be readily available internationally;
- responsive to change.

8.12 No one indicator dominates as a representation of competitiveness or performance. It is important, therefore, not to focus on individual indicators without reference to the wider picture demonstrated by the indicator set as a whole. Furthermore, although the specified indicators measure many aspects of the pharmaceutical industry, they do not encompass all matters of importance. For example, the overall demand and regulatory environment is very important but some of the key factors identified during

the Access and Competitiveness Study described in Section II are difficult to capture in objective indicators. These are presented in the grid shown in Table 8.3 at the end of this chapter. The factors making up this environment provide the background for an overall assessment of UK competitiveness. Commentary on them will inform future discussions of competitiveness and should accompany future publication of the competitiveness and performance indicators:

- the complexity of pricing and reimbursement procedures in the UK compared with other countries;
- the extent of conditions on reimbursement that narrow the market for medicines;
- use of pharmacoeconomics in national guidelines;
- use of pharmacoeconomics in pricing and reimbursement decisions;
- how health care purchasers attempt to influence prescribing.

8.13 Many of the indicators listed in Tables 8.1 and 8.2 are affected by both Government and industry actions. For example, the speed with which a particular new medicine is developed and brought to market may depend on the decisions and the efficiency of industry, as well as on the nature of the regulatory regime imposed and the efficiency or otherwise with which regulators undertake their tasks.

8.14 Also, it is important to acknowledge that the inclusion of an indicator does not necessarily imply agreement on its interpretation or the policy implications of any change.

8.15 The implementation plan for collecting, reviewing and reporting on the competitiveness and performance indicators will be agreed by the Department of Health and the ABPI by the end of June 2001. This will cover:

- responsibility for collection of baseline data for all indicators and future updating;
- means of sourcing data within available resources;
- the way in which indicators are to be presented for publication; and
- the frequency with which they will be updated.

Table 8.1 Main Competitiveness & Performance Indicators

Supply Conditions:
Labour:
i. Number of new graduates with degrees in sciences relevant to the pharmaceutical industry
Capital:
ii. Venture capital invested in the pharmaceutical/biotechnology industry
Basic Research Infrastructure:
iii. Government expenditure on R&D in medical and biological sciences
iv. Scientific research publications per head
v. Clinical Research infrastructure: UK % of patients enrolled in international studies, normalised for population
Demand & Regulatory Conditions:
vi. Uptake: Population adjusted standard units sold per month of a sample of major new NHS-reimbursed products launched within last 5 years, monthly sales measured at 1 year and 3 years after launch in the UK and comparator countries
vii. Price/Profit Regulation: Companies free to set the launch prices of new medicines? (Y/N)
Research and Medicines Regulation:
viii. Overall time taken from first submission of protocols to final medicines regulatory approval (CTX), REC approval and NHS hospital approval to proceed with clinical trial at first site
Industry Outputs: Innovation:
ix. Proportion of world first patents filed for marketed NMEs divided by proportion of world R&D spend
x. UK-based companies' number of 'global top 75' NASs
xi. % of world pharmaceutical R&D spend
Macroeconomic Contribution:
xii. Gross value added

Table 8.2 – Full List of Competitiveness and Performance Indicators

Competitiveness & Performance Indicators	Possible Data Sources
SUPPLY CONDITIONS	
Labour	
*1 Number of new graduates with degrees in sciences relevant to the pharmaceutical industry	Higher Education Statistics Agency
2 Business executive perceptions of labour regulation	International Institute for Management Development's (IMD) *World Competitiveness Yearbook* survey
3 Total hourly labour costs in UK versus comparator countries	US Bureau of Labor, Eurostat, various other
Capital	
*4 Venture capital invested in the pharmaceutical/biotechnology industry	British Venture Capital Association published data
5 Marginal rate of Corporation Tax	HM Treasury
6 Market capitalisation of pharmaceutical, including biotechnology firms, on second tier capital markets	AIM, NASDAQ, EASDAQ, Neue Markt
7 Number of new pharmaceutical/biotech businesses created minus existing such businesses closed	Small Business Service (DTI Agency) – data based on VAT registrations
8 Foreign direct investment as % of GDP	UN World Investment Report
Basic research infrastructure	
*9 Government expenditure on R&D in medical and biological sciences	DoH, OST
*10 Scientific research paper citations per head	OST
11 Scientific research publications per head	OST

Clinical research infrastructure	
*12 UK % of patients enrolled in international studies, normalised for population	ABPI
13 Proportion of studies completed within planned timelines	ABPI
14 Average industry grant cost per patient recruited to clinical trials	ABPI
15 % of international studies undertaken partially or wholly in the UK	ABPI
DEMAND & REGULATORY CONDITIONS	
(For the wider demand and regulatory context see Table 8.3 presenting the grid of features of health care systems influencing access to markets and patient access to medicines.)	
Uptake	
*16 Population adjusted standard units sold per month of a sample of major new NHS-reimbursed products launched within last 5 years, monthly sales measured at 1 year and 3 years after launch in the UK and comparator countries	IMS
17 Population adjusted standard units sold per month of a sample of new non-reimbursed products launched within last 5 years, monthly sales measured at 1 year and 3 years after launch in the UK and comparator countries	International Medical Statistics (IMS)
18 Pharmaceutical sales as % of GDP	OECD
19 % (by value) of national pharmaceuticals market accounted for by NMEs launched within last 5 years	IMS
20 % (by value) of national pharmaceuticals market accounted for by generics	IMS, pharmaceutical trade associations
Price/profit regulation	
*21 Companies free to set the launch prices of new medicines? (Y/N)	Published details of countries' regulatory regimes

Research and Medicines Regulation		
*22	Overall time taken from first submission of protocols to final medicines regulatory approval (CTX), REC approval and NHS hospital approval to proceed with clinical trial at first site	ABPI
23	Proportion of studies approved by Research Ethics Committees (MRECs and LRECs) without deferral	RECs
24	Average approval time for licence for animal experimentation	Home Office (with industry input)
25	Average time from first world application for market authorisation to application in the particular market	CMRI
26	Average time from application for market authorisation to approval, in the particular market	CMRI
27	Average time from approval to launch, in the particular market	CMRI
28	Number of regulatory and scientific advice opportunities between the MCA and the pharmaceutical industry	ABPI
29	In the mutual recognition procedure, the number of times the MCA is chosen as the Reference Member State (RMS)	Mutual Recognition Facilitation Group
30	In the mutual recognition procedure, the number of times applications to other EU member states are withdrawn from the procedure following a positive UK opinion when the MCA is the RMS	Mutual Recognition Facilitation Group
31	In the centralised procedure, the number of times the MCA is nominated by industry as the rapporteur	EMEA
32	In the centralised procedure, the number of times the MCA is nominated as rapporteur to provide European scientific advice	EMEA

INDUSTRY OUTPUTS	
Innovation	
*33 Proportion of world first patents filed for marketed NMEs ÷ proportion of world R&D spend	CMRI
*34 UK-based companies' number of 'global top 75' NASs	CMRI, IMS
*35 % of world pharmaceutical R&D spend	ABPI
36 Number of NMEs launched in the world by UK-based companies	CMRI
37 % of sales by UK-based companies attributed to NMEs first launched during the previous 5 years	CMRI, IMS
38 UK-based companies' % of global sales of 'top 75' NASs	CMRI, IMS
39 Number of UK-based companies' NMEs that were first or second launches in class (by mechanism of action)	CMRI
40 UK-based companies' share of the US market	IMS
41 Number of UK-based companies' NMEs launched in all of the 'top 4' markets: US, Germany, France, UK	CMRI
42 Number of UK-based companies' NMEs launched that received FDA priority review	CMRI
Macroeconomic contribution	
*43 Gross value added	ONS, Eurostat, OECD
44 Pharmaceutical trade balance	DTI, US Census Bureau, pharmaceutical trade associations
45 Share of world pharmaceutical industry production	DTI, US Census Bureau, pharmaceutical trade associations
46 Pharmaceutical industry employment	ONS

Note: * denotes main competitiveness indicators (see Table 8.1)

Table 8.3 Features of Healthcare Systems Most Likely to Influence Access to Markets and Patient Access to Medicines

This table outlines a number of factors which make up the demand and regulatory environment. As a package, they have a bearing on overall competitiveness.

Key: 3 = High potential for impact on access 2 = Some potential to affect access 1 = Unlikely to significantly affect access
N/A Not applicable (ie not a feature of this market) ? = Not known

Influencing Factors	Australia	Canada	France	Germany	Japan	Netherlands	NZ	Sweden	Switzerland	UK	US
Speed of regulatory approval	2	2	1	1	3	1	2	1	2	1	1
Complexity of p/r procedure	3	3	3	N/A	2	3	3	1	2	N/A	N/A
Downward pressure on launch prices	3	2	2	N/A	2	2	3	1	1	N/A	N/A
Conditional/limited reimbursement	3	2	1	1	1	3	3	1	1	2	2
Level of generic penetration	?	?	Growing	High	Low	High	High	Low	Low	High	High
National guidelines using pharmacoeconomics	No	No	No	No	No	No	?	No	No	Yes	No
Pharmacoeconomics used in p/r decision	Yes	Some Provinces	Possibility	No	Not usually	Some products	Yes	Some times	Some times	Not directly	?
Drugs budget funded by:	National	Provincial	National	National	National	National	National	Local	Local	National	Mix
% of population covered	1	2	1	1	1	1	1	1	1	1	3
Copayment culture exists	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Level of copayment	2	1	1	1	1	1	2	1	1	1	3
Capped budgets for GPs	1	?	1	3	1	1	3	1	1	3	1
Influencing of GP prescribing	1	2	1	2	1	2	3	2	1	3	2
Capped profits/sales – rebates	No	No	Yes	No	No	No	Yes	No	No	Yes	No
Private market: 'lifestyle' drugs	1	?	1	?	3	?	2	2	1	3	1
Private market: other drugs	3	?	3	?	3	3	2	3	2	3	1
DTC advertising allowed	No	?	No	No	No	No	Yes	No	No	No	Yes

The combination/aggregate policy mix is unique to each country

Note: p/r = pricing and reimbursement

Section IX

Conclusions and Taking the Relationship Forward

9.1 The UK-based pharmaceutical industry is world class and a jewel in the crown of the British economy, second only in innovative capacity to the US-based industry. The Government is determined to do what it can to help the UK industry maintain its competitive advantage in the face of industry consolidation and increasing globalisation.

9.2 The UK has built up considerable comparative advantage in the field of pharmaceuticals compared to all other major producers except the USA. Even the US is unable to out-compete the UK in all respects despite having the largest pharmaceuticals market in the world. The Task Force's Access and Competitiveness Study revealed the UK as a relatively open market where the PPRS offers a liberal pricing regime and quick access to the NHS market. Market uptake is relatively slow, however, and UK demand side measures are better developed and have more impact than in many other major markets.

9.3 The Government is seeking considerable change in the way the UK market functions. Considerable efforts are being made to modernise the NHS, to encourage uptake of clinically and cost effective medicines, and to eradicate "post-code prescribing". This is in the context of a recently re-negotiated PPRS that confirms the rapid access and freedom of pricing at launch valued so much by the industry.

9.4 However, the impact of policies to modernise the NHS and, in particular, the impact of the introduction of NICE, on uptake of new medicines will remain uncertain until sufficient empirical data can be gathered. Government's view is that market responsiveness will improve as a consequence of these policies and that a more discriminating UK market will – if anything – serve to increase the competitiveness of the UK-based industry. The industry, on the other hand, remains very concerned that NICE in particular will delay access to the UK market and much reduce the overall competitiveness of the UK.

9.5 So far, experience confirms neither view. Time will tell, but despite the overall excellent outcomes from the Task Force's deliberations, the industry's *perception* of the UK as a market in which to invest is under some threat.

9.6 One of the principal outputs of the Task Force, therefore, is the commitment from Government to explore fully and jointly the detail of the industry's concerns. This will culminate in a review of NICE's performance and way of working planned for July of 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.

9.7 One of the key points reaffirmed by the Task Force process is that the probable impact of new policy directions on competitiveness ought to continue to be considered – with the pharmaceutical industry – prior to implementation. The policy of "no surprises" will be delivered by a much stronger and more senior ongoing relationship between Government and industry. This is set out in more detail later in this section.

9.8 The agreed competitiveness and performance indicators set out in Section VIII provide a benchmark against which to test new major policy directions – both before and after implementation.

9.9 The Task Force process has itself already introduced a more forward-looking strategic relationship between Government and industry. The work programmes considering how patients can be better informed about new medicines and treatments and on creation of more efficient approaches to reaching the market for products outside the compass of the NHS are challenging and far-sighted. Each 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 at least some steps down the respective paths are agreed – is in itself unique in Europe and demonstrates the Government's commitment to creating a competitive environment for the innovative industry.

9.10 Industry and Government have each long called for more strategic engagement on possible future policy directions. PICTF has delivered that and both industry and Government are determined that this will continue after winding up the current task force initiative.

Research and Innovation in the UK

9.11 The Task Force has confirmed the UK's first-rank science base and record in innovation. In the pharmaceuticals sector it remains first in Europe and globally second overall to the USA. The UK returns more by way of intellectual property gained per pound spent on pharmaceutical R&D that any other major economy in the world.

9.12 The Task Force has agreed workable plans to improve the competitiveness of the UK as a base for clinical research reflecting the new EU Directive on Clinical Trials – by addressing in particular issues of timeliness, quality, and cost to the industry. Communication and understanding between large pharmaceutical companies, biotechnology SMEs, and regulators has been significantly improved to the benefit of all. Agreed plans to streamline the implementation of the Animals (Scientific Procedures) Act should mean improved animal welfare as well as improved UK competitiveness.

9.13 Taken together, these developments are expected to increase the UK lead within Europe in biotechnology – which is set to be the engine that will drive many of the drug discoveries of tomorrow.

The UK in Europe and Beyond

9.14 The Task Force produced some significant outputs by way of agreed positions for the UK in international fora dealing with discussions on intellectual property rights and the future of the medicines licensing system.

9.15 Much of the legal basis for policies that underpin UK and European competitiveness is determined at a European rather than national level. A close industry-Government partnership, and subsequent concerted activity, on issues like data exclusivity, EU enlargement, and steps towards incremental liberalisation of the Single Market in pharmaceuticals stand a better chance of delivering benefits than independent action.

9.16 The Task Force process has developed a clear understanding between both partners on these and other issues that stands to benefit European, not just UK, competitiveness. The UK Government and industry will pursue a similar understanding in the expected European-level pharmaceutical industry competitiveness task force.

9.17 Nowhere is the new partnership between industry and Government more important than on the issue of improving access to medicines for the world's poor. New medicines are needed to meet the diseases of the poor and current barriers to access overcome. The UK seeks to play a leading role in developing international initiatives to combat disease in developing countries and the agreements reached in PICTF discussions present a solid basis for the industry to work with Government in rising to one of the most daunting but important challenges in the public health field so far this century.

The Industry–Government Relationship

9.18 Unlike many other countries, the UK Government has long maintained a positive relationship with its pharmaceutical industry. In recent years, this has take the form of frequent informal contacts as well as the formal Industry Strategy Group (ISG) which brings together senior officials from the Department of Health, the Department of Trade and Industry and the Treasury along with senior industry representatives from the Association of the British Pharmaceutical Industry (ABPI).

9.19 This group – the ISG – has continued to meet during the life of the Task Force, but PICTF has raised the profile of the industry-Government relationship considerably and has lifted the dialogue to a far more strategic level than hitherto.

9.20 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.

Taking The Relationship Forward

9.21 The Task Force's Terms of Reference included the requirement to:

"identify the potential for promoting further partnership between the industry and government".

9.22 The way forward builds on the structures already in place prior to the creation of the Task Force, on the experience gained in PICTF on joint-working and on the need to set in place mechanisms that will

i. monitor progress on action agreed in PICTF;

ii. allow proper monitoring and scrutiny over time of the competitiveness indicators for the UK-based R&D pharmaceutical industry identified in PICTF;

iii. address any other strategic issues which may arise.

9.23 The Department of Health remains "sponsor" of the UK-based R&D pharmaceutical industry, though contact with other Departments on specific issues continues to be encouraged (one of the specific outcomes of PICTF, for example, is to strengthen the pharmaceutical industry capabilities of Invest. UK). DH Ministers are however responsible for the 'totality' of the industry's relationship with Government and for main formal contact arrangements.

9.24 The Department sponsors the whole of the UK-based R&D pharmaceutical industry regardless of where companies are domiciled.

9.25 The ABPI remains the lead industry organisation for formal representation of the views of the UK-based R&D pharmaceutical industry to Government. But – as before – the Government also needs to maintain significant contact both with other relevant trade associations and groups that represent specific industry sectors and with individual UK-based companies.

9.26 The following arrangements have been agreed:-

i. future dialogue between Government and industry will be maintained through the Industry Strategy Group (ABPI meeting with DH, DTI and HMT officials) and a Ministerial Industry Strategy Group, which will comprise Ministers (DH, HMT, DTI etc) and senior industry executives. Both Government and industry sides in the Ministerial Industry Strategy Group will therefore reflect PICTF composition.

ii. the **Ministerial Industry Strategy Group** will meet at least once a year (possibly more frequently in the immediate follow-up to PICTF). Its focus will be discussion of strategic issues. It will consider in particular overall progress on action agreed in PICTF (and any subsequent strategic tasks/issues identified after PICTF) and on competitiveness indicators, and will set the direction of activity. In order to reflect the structure of PICTF it will be co-chaired by the relevant DH Minister and a

company Chief Executive. The first Ministerial ISG follow-up meeting to take stock of progress on PICTF issues will be held in October 2001.

iii. the **Industry Strategy Group** will be the forum for general follow-up to PICTF business. Although it will embrace discussion of strategic issues, both industry and Government recognise that it will inevitably be used to take stock of some "issues of the moment". On the Government side representatives from Departments (in addition to DTI and HMT) will be brought in as agenda items require. It will meet three times a year. It will be chaired jointly by the ABPI President and the Head of the Department's Medicines, Pharmacy and Industry Division.

iv. the existing DH/ABPI Industry Strategy Group secretariat will serve both Ministerial and regular ISG meetings.

v. DH Ministers and officials – working with other Government departments as relevant – will maintain regular individual contact with the main UK-based R&D pharmaceutical companies and other relevant groups.

9.27 These arrangements will be reviewed as necessary to ensure that the momentum, trust and partnership developed in the Task Force remain for the future.

Appendix I

Agreed Action Plan

ACTION (with Leads)	TIMING
Developments in the UK Market	
NATIONAL SERVICE FRAMEWORKS	
1 Summit on industry specific issues (eg adherence) on *diabetes.* (DH)	(March 2001)
2 Industry membership of *Diabetes* NSF Implementation Task Force. (DH)	
3 DH/Industry meeting on options for industry involvement in implementation of NSF for older people. (DH/Industry)	April/May 2001
4 DH/Industry meetings to collaborate on the NSF on mental health. (DH/Industry)	April 2001
POTENTIAL FOR GREATER USE BY INDUSTRY OF NHS INFORMATION	
5 Discussions to be held with industry on confidentiality issues in connection with implementation of Health and Social Care Bill. (DH)	
6 Mechanism to be set up to take forward discussions on how relevant data bases might be used and developed for use for appropriate R&D pharmaceutical industry. (DH)	March 2001 – 2002
INFORMATION FOR PATIENTS	
7 MCA aim to agree guidelines with ABPI on disease awareness programmes, including establishing scope for programmes where there is only one treatment available. (MCA/ABPI)	by June 2001
8 The ABPI will provide a 'model' company website as a basis for discussion of what might be allowed on company websites. (ABPI)	by September 2001
9 ABPI will provide examples of company generated information material they would like to be able to provide directly to the public. (ABPI)	by June 2001
10 The MCA will actively seek clarification within Europe on information that can be included on websites. (MCA)	by June 2002
11 The MCA and industry will work together to 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. As a basis for discussion, industry will provide suggested working interpretations. (MCA/Industry)	by June 2001
12 The MCA and industry will aim to finalise working definitions, which could form the basis for discussions on European guidelines. (MCA/Industry)	by June 2002

ACTION (with Leads)	TIMING
13 The MCA will review the list of diseases in respect of which advertisement of OTC medicines to the public is prohibited on the basis of proposals received. (MCA/Industry)	by June 2002
CONCORDANCE	
14 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, eg research and development, communications, education and training. Project infrastructure and initial work programme to be established. (DH)	by end April 2001
15 The Department of Health will ensure, through the Task Force and supporting infrastructure, the establishment and maintenance of collaboration and sharing of information on activities inspired by the Task Force, other partners and the pharmaceutical industry. (DH)	
16 The Department of Health will ensure partnership in medicine taking is reflected in key policy initiatives, such as National Service Frameworks, the development of medicines management and self-management programmes flowing from the Expert Patient Programme. (DH)	
17 The Department of Health will contribute at least £1m specifically to work on partnership in medicines taking.over the next two years. (DH)	
18 To complement the work of the Task Force ABPI will *inter alia* establish ABPI policy and endorsement of concordance; identify industry 'leaders' in this area; develop a communication programme with industry and a programme of consumer communication. (ABPI)	June 2001
"NON-REIMBURSED MEDICINES"	
Speeding up the scheduling process and exploring a voluntary mechanism:	
19 DH and industry to obtain a definitive legal opinion on options. (DH/Industry)	by end April 2001
20 Complete consultation and discussion with interested parties, including professions. (DH)	by end June 2001
21 Resolution of implementation issues with industry and other stakeholders. (DH)	by end September 2001
22 Guidance to NHS. (DH)	by end December 2001
Streamlining classification from POM to P:	
23 The Medicines Control Agency will convene a meeting with interested parties to discuss this issue, including a detailed work programme and timetable for action. (MCA)	April 2001
Routes of access to non-reimbursed medicines: Overall aim to have agreed arrangements in place.	
24 DH and industry to obtain a definitive legal opinion on options. (DH/Industry)	by end April 2001
25 Complete consultation and discussion with interested parties, including professions. (DH)	by end June 2001
26 Resolution of implementation issues with industry and other stakeholders. (DH)	by end September 2001

ACTION (with Leads)	TIMING
27 Guidance to NHS. (DH)	by end December 2001
28 *GP guidance on prescribing Sch 10 & 11 drugs:* acknowledging that this action is dependent on the progress of consultation on impotence treatment, DH aims to have guidance issued. (DH)	by end June 2001
ADVANCES IN GENETICS	
29 Agreement to producing proposals on how to work in partnership with pharmaceutical and bio-pharmaceutical industry to maximise the likelihood of mutually beneficial advances from new developments in genetics. (DH/Industry).	will be developed over the coming months
Intellectual Property Rights	
INTELLECTUAL PROPERTY RIGHTS	
30 Wide dissemination of an agreed position on international Intellectual Property Rights (IPR) and access to medicines. (DH)	March 2001
31 Development of industry/Government partnership to improve access to medicines in developing countries. (DH/DTI/DFID/Industry)	Ongoing. First outputs required by July 2001
32 Agreement of a UK position for forthcoming EC discussions on data exclusivity and related issues, and partnership in delivering an acceptable overall outcome. (DH/Industry)	Position agreed. Otherwise timing dependent on Community processes
33 Agreement to promote and pursue a long-term programme of actions at EU level to develop an incremental approach to the liberalisation of pricing of non-reimbursed medicines. (DH/Industry)	Ongoing
34 Agree UK position for EU enlargement negotiations on protection of intellectual property rights in an enlarged Community. (DH/DTI/FCO/Industry)	Position agreed. Deliver acceptable overall outcome by end June 2001

ACTION (with Leads)	TIMING
Regulation of Medicines Licensing	
35 Develop MCA as leading community regulator involving wider community expertise	
• Define strategy for gaining agreement from other interested parties regarding Centre of Excellence (CoE) concept. (MCA/Industry)	End June 2001
• MCA to offer CPMP rapporteurship for scientific advice questions consistent with areas encompassed by CoE. (MCA)	Ongoing
• Industry to promote CoE concept in Europe. (Industry)	End September 2001
• Industry to improve quality of submitted dossiers. (Industry)	End September 2001
36 Increased early dialogue to gain a European regulatory perspective	
• Propose framework for regulatory dialogue at predetermined development milestones. (MCA/Industry)	December 2001
37 Full optionality for applicant in choice of filing route for all types of product	
• Pursue at EU level. (MCA/Industry)	December 2001
38 Full optionality for applicant in choice of rapporteur	
• Pursue at EU level. (MCA/Industry)	December 2001
39 Earlier dialogue between MCA and industry on post-marketing issues	
• Define procedures for engagement. (MCA/Industry)	June 2001
40 To develop ISIT strategy within Europe	
• Define strategy for progression of ISIT initiatives. (MCA/Industry)	June 2001
• Agree longer term initiatives and define strategy and plan for progression, including performance measures. (MCA/Industry)	April 2001
• Establish mechanism and funding for electronic submission of dossiers. (MCA)	By June 2001
• Electronic submission of ADRs. (Industry)	End 2001
• Establish suitable system & funding for secure email. (MCA)	End 2001
• Promote transparent tracking processes. (MCA)	Ongoing
• 100% ADRs submitted electronically to MCA. (Industry)	December 2004
41 EU regulatory environment that enables commercial flexibility and makes it more attractive for UK based industry and protects public health	
• Industry to define requirement to not restrict normal commercial practices and that simplifies the system to allow multiple trade names, product licences and marketing agreements for new products. (Industry)	June 2001

ACTION (with Leads)	TIMING
Science Base and Biopharmaceuticals	
MANUFACTURING	
42 To attract and retain more pharmaceutical and biopharmaceutical companies to the UK. Appoint a secondee and dedicated team to assist Invest.UK (DTI).	June 2001
43 BIA to review current biomanufacturing needs of the UK to identify gaps. (BIA)	April 2001
Use results of this survey to determine what action (e.g.enhancement of current Government support for biomanufacturing) needs to be taken to ensure that the UK is a competitive location for biomanufacturing investment. (DTI/Industry)	by December 2001
44 Greater facility/technology transfer and exploitation of UK biomanufacturing R&D. BIA to make an initial submission for funding for Faraday Centre. (BIA)	Completed
45 Follow-up with a full proposal for funding a Faraday Centre. (BIA)	April 2001
SKILLS BASE	
46 Industry to identify to Research Councils key fields for further implementation of MRes scheme. (DTI)	June 2001
47 Monitor impact of level of stipend on quality and uptake of PhDs. (DfEE)	Ongoing
48 Review likely impact of latest immigration regulations on the employment by the industry of overseas specialist R&D experts in the UK. (Home Office/Industry)	April 2001
49 Industry/Research Council review of industry's current needs and availability of specific modular university courses. (Industry/Research Councils)	Ongoing
50 Review barriers (regulations, funding etc) to the establishment and maintenance of whole animal pharmacology courses in the UK and make recommendations to DfEE on how these barriers might be addressed. (Industry)	June 2001
INDUSTRY/ACADEMIC LINKS	
51 To have in place more focused schemes to enhance technology transfer. (DTI)	September 2001
52 Develop Government guidelines on consultation with users which ensure greater consultation around the proposed introduction of new schemes. (DTI & DfEE)	June 2001
53 Develop policy statements to clarify most appropriate approaches to knowledge transfer. (DTI/DfEE)	September 2001
54 Develop and obtain funding for suitable training programmes for Industrial and Academic Liaison Officers in universities and industry. (DfEE)	September 2001
55 Develop clear and supportive guidance on the most effective management of IP arising from industry sponsored collaborative research with academia. (DTI)	June 2001
56 Consultation between the Government and industry on any proposals to change the arrangements for the management of IP arising out of collaborative research. (DTI)	Ongoing
57 Research Councils to review current procedures for application review and for conversion of CASE and industrial CASE schemes. (Research Councils)	June 2001

ACTION (with Leads)	TIMING
BIG PHARMA/SMEs	
58 BIA to consider and report on the likely logistics and costs involved in creating a database/internet portal on SME research that could be used by large pharmaceutical companies to identify suitable SME partners and to seek (as appropriate) funding for the establishment of databases. (BIA)	December 2001
VIOLENT HARASSMENT and ANIMAL RIGHTS EXTREMISTS	
59 To take action against intimidatory behaviour of extremist animal rights activists targeted at individuals and companies. Government amendments to the Criminal Justice and Police Bill aimed at tackling harassment and intimidation by animal rights campaigners. (Home Office)	April 2001
60. Review need for retention of Section 24 of the Animals (Scientific Procedures) 1986 Act. (Home Office)	June 2001
Clinical Research	
61 Implementation of the EC Directive of Good Clinical Practice, will regulate human pharmacology (Phase 1) studies in an appropriate manner. (MCA)	
62 The Department of Health will clarify Trust responsibilities in approving industry sponsored research. This will provide that the Trust R & D review should run in parallel with Research Ethics Committees' (REC) review and be completed within a 60-day time limit. (DH)	Guidelines will be issued by June 2001
63 The Department of Health will develop new guidance clarifying Research Ethics Committees' responsibilities, including the requirements of the European Clinical Trial Directive. (DH)	by April 2001
64 Multi-centre and Local Research Ethics Committees will consider applications in parallel and complete their review within 60 days from initial submission in accordance with the European Directive. This procedure will be implemented by the recently established Central Office for Research Ethics Committees (COREC). (COREC)	by April 2001
65 The initial review by Multicentre Research Ethics Committees (MRECs) of valid applications to conduct studies will be completed within 45 calendar days, with no more than one extension to resolve questions, and the total review not to exceed 60 days. This procedure will be implemented by COREC. (COREC)	by April 2001
66 Industry and the NHS are to set up joint training initiatives for commercial applicants, to improve the quality of submissions to RECs. This procedure will be implemented by the ABPI and COREC. (ABPI/COREC)	by end June 2001
67 The members of the ABPI will record average (range) industry cost of UK-recruited patients (target: EU major market average). These data will be compiled in summary form by the ABPI and sent to the Department of Health to inform its own pricing assessment project. (ABPI)	This process will be completed by end of May 2001

ACTION (with Leads)	TIMING
68 The Department of Health will review its guidance on the relationship between prices charged by the NHS and the cost of studies with the intention of improving the transparency and consistency of pricing. The review will be informed by evidence of variations in NHS approaches to pricing and the cost to industry of conducting its research in other major markets. The overall aim will be, within the constraints of EC law and Government policy for public services, to minimise impediments to the UK's competitiveness for clinical trials when compared with major EU and North American markets. (DH)	This review will be completed by end June 2001
Competitiveness and Performance Indicators	
69 Competitiveness and performance indicators will be agreed by the Department of Health and the ABPI. This will cover: • responsibility for collection of baseline data for all indicators and future updating; • means of sourcing data within available resources; • the way in which indicators are to be presented for publication; and • the frequency with which they will be updated. (DH/ABPI)	by end June 2001

Appendix II

Planned Future PICTF Publications

- Access and Competitiveness Study Group Report
- Value of the Industry Report
- Report of Working Group on Clinical Research

Glossary and Notes

ABPI	The Association of the British Pharmaceutical Industry	Represents companies in Britain producing prescription medicines, other organisations involved in pharmaceutical R&D and those with an interest in the pharmaceutical industry operating in the UK.
APG	American Pharmaceutical Group	Association of US-owned research based pharmaceutical companies operating in the UK.
BPG	British Pharaceutical Group	Association of UK-owned research based pharmaceutical companies.
CASE	Co-operative Awards in Science and Engineering	Research Council studentships where PhD students are linked with a company.
CTX	Clinical Trail Exemption Certificate	An exemption from holding a Clinical Trials Certificate granted by the UK Regulatory Authority (MCA) following review of evidence to support the quality and safety of a medicine for use in a clinical trial. This has to be obtained prior to starting Phase II to III clinical trials but is not currently required for Phase I (human pharmacology) studies in healthy volunteers.
DETR	Dept for Environment Transport & the Regions	UK Government Department.
DfEE	Dept for Education & Employment	UK Government Department.
DFID	Dept for International Development	UK Government Department.
DH	Department of Health	UK Government Department.
DTI	Dept of Trade & Industry	UK Government Department.
“Faraday” project		DTI-financed programme to encourage technology transfer & collaboration between academia and industry.
GAVI	Global Alliance for Vaccines and Immunisation	Initiative to protect children against vaccine-preventable diseases of public health concern. Involves WHO, UNICEF, the World Bank, UNDP and the Rockefeller Foundation.

GCP	Good Clinical Practice	An international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials.
HMT	Her Majesty's Treasury	UK Government Department.
ICH GCP	International Conference on Harmonisation for Good Clinical Practice	A conference set up to harmonise research standards around the world. Prior to the issuance of its guidelines, there were 3 recognised GCP standards to which clinical trials to support a marketing authorisation (product licence) could be conducted. The ICH guidelines were approved by EU regulators (CPMP) in 1996 and came into effect in 1997.
LREC	Local Research Ethics Committee	A committee established by, and accountable to, a Health Authority specifically for the purpose of ethical review of research. Its favourable opinion on (a) the ethics of the research proposal, and (b) the local issues (including the suitability of the researcher and of the research environment, and any special requirements of the local population) is required before research can be conducted within the boundaries of that Authority. If a favourable opinion on the ethics of the proposal has already been obtained from an MREC, its remit is limited purely to the local issues.
MREC	Multi-centre Research Ethics Committee	One of a number (currently 10) of committees established by UK Health Departments specifically to consider the ethics of research proposals which would otherwise require review by five of more LRECs. The opinion of any one MREC covers the whole of the UK.
"Net contribution" to the economy		The "net contribution" refers to the estimated additional value that pharmaceutical industry adds over and above what would be produced by the same resources if they were transferred to the rest of the economy.
"Prodigy"	Prescribing Rationally with Decision-support In General Practice Study	A computer decision-support system integrated with GPs' clinical systems. It provides guidance on prescribing, treatments, therapies, referrals, investigations and patient advice leaflets.

Schedule 10 & Schedule 11	Schedules 10 & 11 to the NHS (General Medical Services) Regulations 1992	Schedule 10 is a list of drugs which GPs may not prescribe on the NHS, and Schedule 11 is a list of drugs which GPs may prescribe on the NHS only in specified circumstances, and/or for specified patient groups. GPs may write a private prescription, without charge, for their own NHS patients for any Schedule 10 drug, and may write a private prescription for a Schedule 11 drug providing the patient is not eligible for an NHS prescription because of his or her condition. These lists of drugs are published by The Stationery Office in Part XVIII of the Drugs Tariff.
"Terms of trade"		The "terms of trade" benefit refers to the loss of UK purchasing power that would result from sterling depreciation if pharmaceutical production ceased for some reason without any countervailing improvement in the competitiveness of other sectors of the economy.
TRIPS	Trade-related aspects of intellectual property rights	Multilateral agreement establishing minimum standards in the field of intellectual property in states which are members of the World Trade Organisation.
WTO	World Trade Organisation	Organisation for regulating international trade set up in 1995. States which decide to become members of WTO undertake to abide by its rules.