



Better health through partnership:

a programme for action

Better healthcare through partnership: a programme for action

**Healthcare Industries Task Force
Final report
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Foreword

By the co-chairmen, Lord Warner and Sir Christopher O'Donnell



The Healthcare Industries Task Force (HITF) has been the most important initiative to date between Government and the healthcare products industry. The UK-based healthcare products industry plays a significant role in contributing to patient care, public health and the national economy. It is highly diversified and innovative, capturing a wide range of technological advances for application in the medical field. There is considerable potential for growth in this knowledge-intensive sector, leading to expansion of manufacturing activities and job creation. Focusing on this industrial sector reflects the Government's agenda by stimulating innovation as a means to maintain the UK's edge as a market leader in science- and technology-intensive markets.

The domestic and global business environment is evolving rapidly, and both Government and the industry need to be able to keep pace with new technological advances so that we can provide a modern health service. The needs and preferences of patients are changing too, with greater life expectancy, the emergence of different disease patterns and increasing demand for information and choice. All these factors suggest that a closer working relationship between Government and the private sector is necessary to ensure that there is a better understanding of how industry can help Government meet its objective of a stronger patient-centred focus within the public health agenda.

HITF was established to explore issues of common interest and identify opportunities for co-operation that would bring benefits for patients and service users, health and social care services, and industry. The results of our deliberations have exceeded our initial expectations. We have been able to propose an ambitious work programme involving continuing co-operation at all levels, with some specific developments to be taken forward as a matter of urgency. In particular, from 1 April 2005 we are aiming to start



the development of the existing Device Evaluation Service into a new service managed by the NHS Purchasing and Supply Agency, to better inform purchasing decisions. Such a service will be critical to the success of the proposed Collaborative Procurement Hubs, a new regional focus for purchasing decisions with significant clinician involvement.

A new Innovation Centre in an appropriate organisation is planned to spread best practice in promoting and supporting

development of new healthcare technologies. A new concept for the development of Healthcare Technology Co-operatives as centres of excellence will be piloted, and training and education for health professionals will be developed to improve skills and spread best practice in the use of medical devices. Steps to maximise the UK's influence in international regulatory matters are in hand and a focused export strategy is under development.

We believe that these proposals represent significant improvements that will deliver considerable benefits to patients and service users, to the NHS and the social care system, and to industry.

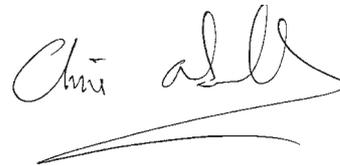
This report reflects some of the complexities which the Task Force faced. The vision that was missing at the beginning emerged as the Task Force's work gained momentum. Although not documented formally, this vision has been expressed as "to capture the best that the NHS, social care and industry together can provide for the benefit of the health of the nation". The Task Force has produced effective and practical proposals for improving arrangements for the future. It has managed to do this on the basis of consensus on the proposed ways forward. This report is an agreed document owned by all participants.

HITF was a very timely initiative. The Task Force agenda was challenging and at the outset it was difficult to predict what would come of it – it was certainly a steep learning curve for us all. But the result is testimony to the consistent, high-quality contributions made by participants throughout the exercise. The key outputs are wide-ranging and involve radical changes. We are confident that the actions planned will deliver the benefits envisaged. In addition, in bringing together the key players from Government and industry, HITF has fostered a better understanding between both parties and has provided the basis for a strong ongoing working partnership in future.

We would like to acknowledge the valuable contribution made by all who participated in HITF, including those behind the scenes who gave their time and expertise, and the trade associations, in particular the Association of British Health-Care Industries which co-ordinated industry's representation. Our thanks also go to NHS representatives, and to those in public-sector groups at regional and local levels and in the Devolved Administrations who contributed at various levels, keeping the Task Force in touch with the real world. Without their efforts, HITF would not have achieved so much.



Lord Warner



Sir Christopher O'Donnell

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Key outputs

1. Device evaluation

Inform procurement decisions, and encourage and support the uptake of useful, safe, innovative products and procedures used in health and social care:

- develop a new device evaluation service to integrate and strengthen horizon scanning, and the assessment of value and effective performance of new and enhanced healthcare technologies, devices and related procedures
- develop nationally accepted methodologies and toolkits for device evaluation that can be used locally to ensure consistency of approach whilst facilitating decision-making at the appropriate level
- consider how best to ensure speed of evaluation, a ‘once only’ approach and prompt sharing of outputs with stakeholders throughout the health and social care system and industry

To help effect these changes, the existing Device Evaluation Service, currently sited in the Medicines and Healthcare products Regulatory Agency, will move to the NHS Purchasing and Supply Agency (PASA) with effect from 1 April 2005 (subject to legislation) and will be developed over time.

2. Innovation

Stimulate more innovation and encourage a more entrepreneurial culture in industry and the NHS:

- work towards the development of a new Innovation Centre in an appropriate organisation to promote and support the rapid development, dissemination and commercialisation of a pipeline of innovations coming from the NHS, academia or the global healthcare industry; the role of this centre would be to:
 - co-ordinate and develop the activity of the existing network of NHS Innovations Hubs
 - improve interactions and promote the exchange of knowledge between the NHS, industry, financiers and other key stakeholders, utilising online knowledge exchange and communication tools
 - play a brokerage role between industry, financiers and the NHS, fostering partnership and collaboration opportunities
 - promote successes and facilitate innovation uptake in the NHS
 - introduce an ‘innovation fund’ to promote the development and exploitation by the NHS of innovative products and procedures

- establish collaboration between the Medical Devices Faraday Partnership, other appropriate partners and the new Innovation Centre networks, covering the supply industry, academic departments, business and finance organisations, and NHS and DH bodies, to:
 - promote the exchange of knowledge between the networks
 - deliver an online ‘integrated routemap’ guiding stakeholders on product development, business planning and manufacturing, regulatory and marketing procedures, through to entry into NHS and world healthcare markets
 - when appropriate, promote co-ordination of respective brokerage activities
 - work to increase both public and private funding for translational research in developing new products from proof of concept to commercialisation

This proposal is subject to ongoing work to secure funding and a detailed analysis of its impact on the NHS.

3. Procurement processes

Embed modern approaches to procurement in the NHS to deliver better value for the service of patients through:

- nationally-agreed/accepted best practice models, including early communication with industry on workplans (eg the Supply Chain Excellence Programme (SCEP)) to provide clarity on levels of market access and to ensure capture of innovative solutions
- a focus for regional procurement with significant clinician involvement to provide the platform for an informed approach to procurement decision-making
- ensuring that the role of procurement in supporting the timely uptake of new technologies identified as providing benefit to patients is embraced

The above will be incorporated into the redesign of NHS PASA, the proposed model for Collaborative Procurement Hubs under SCEP and the continuing development of Supply Management Confederations.

- regular dialogue between the NHS and industry to encourage input into policy-making generally and specifically (eg National Service Frameworks and Payment by Results initiatives)

4. Building R&D capacity

Through the UK Clinical Research Collaboration (UKCRC) DH will:

- incorporate devices into the disease hubs/networks (starting with five initial disease areas: mental health, diabetes, new medicines for children, stroke, and Alzheimer's)
- develop a capacity-building programme, including fellowships
- increase commitment to the new and emerging technologies R&D programme (New and Emerging Applications of Technology (NEAT))

UKCRC will provide a platform for harnessing the quality and expertise of the NHS for all stakeholders by:

- building up the clinical research infrastructure in the NHS
- building up the research workforce (through improved training opportunities and career structures)
- developing incentives for research in the NHS
- streamlining the regulatory and governance processes
- co-ordinating funding (through a strategic analysis of current portfolios which will also reveal 'orphan' areas for discussion)

5. Healthcare Technology Co-operatives (HTCs)

Government and industry will work together to develop a suitable academic centre of excellence as a pilot HTC to pioneer specialist techniques in patient treatments in order to inform future development.

6. UK as the regulatory lead in the EU and internationally

Maximise UK influence in regulatory matters in the EU and other international forums, in consultation with industry, across all relevant issues to:

- help ensure regulation and enforcement are appropriate
- maintain high standards of patient safety
- provide a stable legislative framework in the UK



7. Export strategy and international trade

Whilst continuing to service healthcare exporters in all markets, UK Trade and Investment will focus its strategic activities and resources in favour of the USA, Germany, France, Japan and China in relation to the devices industry. A watching brief will be maintained on developments in India. A range of key supporting initiatives have also been identified to promote export opportunities.

8. Communication with patients/public to improve understanding of benefits and risks of medical devices

Increase the general understanding and appreciation of the role medical devices and technologies play in public health, by more effective communication to health professionals, social care personnel, patients, service users and the public of the risk:benefit profile and the regulatory system for devices.

9. Training and education

Work towards improving training and education on medical devices for NHS staff and strengthening linkages between the NHS, its education partners, purchasers, device evaluation staff and industry, to support the spread of best practice in the competent and safe use of medical devices through:

- consideration of initial and ongoing training and education needs as part of the procurement process where appropriate, eg for new technologies
- exploration with Skills for Health of how to raise the profile of competencies in the use of medical devices and technologies
- consideration of the development and use of learning programmes/tools
- in the longer term, the introduction of electronic staff records to ensure that records of key skills are transferable as staff move around the NHS

1. Executive summary

Establishing the Task Force

- 1.1 The Healthcare Industries Task Force (HITF), was announced on 23 October 2003 by the co-chairmen, Lord Warner, Under Secretary of State (Lords) for the Department of Health, and Sir Christopher O'Donnell, Chief Executive of Smith and Nephew plc. The aim of the Task Force was to identify opportunities where closer co-operation between Government and healthcare companies would bring about benefits for patients and service users, the NHS and social care, whilst also helping to improve the industry's performance.
- 1.2 There was thought to be considerable potential for closer working. The Government is keen to support the growth of innovative industrial sectors as part of its commercial agenda, and to encourage industry to take full advantage of the UK's strengths in science and technology in creating a vibrant, competitive environment. The healthcare industries represent an important sector which has the potential for growth, increasing its contribution to the knowledge-based economy through manufacturing, R&D activity and job creation.
- 1.3 The Task Force members came from wide-ranging backgrounds to reflect the scope of the agenda and included ministers responsible for health and social care, trade, overseas markets and inward investment; senior decision-makers and advisers from the public sector; patient groups; and leaders of industry. The Task Force had one year to deliver its conclusions and produce its report.

Key issues

- 1.4 The Task Force identified four key areas for investigation:
 - **market access** – how to increase and speed up NHS adoption of useful new products and procedures
 - **R&D and the industrial base** – how to improve support for innovation in the home market and enhance the UK's reputation as an attractive location for healthcare manufacturers
 - **regulatory issues** – building on the existing working relationship between the UK regulator and industry, and maximising the UK's influence in regulatory matters in the EU and overseas
 - **international trade** – working together to improve opportunities in overseas markets for UK-based companies

- 1.5 The Task Force set up Working Groups in each of these four areas. Working Group members were drawn from experts and advisers from relevant public sector organisations and industry. Each Group was charged with exploring its respective area in detail and agreeing recommendations to improve the existing arrangements, for consideration by the Task Force.
- 1.6 The Working Groups produced an extensive list of over 50 recommendations and actions (see table of recommendations at **Annex E**). Their full reports can be found at www.advisorybodies.doh.gov.uk/hitf.

Focusing the Working Group recommendations

- 1.7 The Task Force decided to focus on key areas where the development of practical, workable measures would bring about the improvements envisaged. The following are the nine areas which emerged as priorities for the Task Force:
 - improving device evaluation
 - more support for innovation
 - improving procurement processes through regional focus and significant clinician involvement
 - building R&D capacity
 - developing a pilot for Healthcare Technology Co-operatives based on existing centres of excellence within the NHS
 - maximising the UK's regulatory influence
 - developing an agreed export strategy
 - improving public understanding of the safety and value of medical devices
 - improving training and education on medical devices for NHS staff

Developing implementation strategies

- 1.8 The Task Force went on during the late summer and autumn of 2004 to develop proposals for translating these aspirations into actions.
- 1.9 The results of HITF's efforts are summarised in the key outputs (see pages 1–4). These represent a major achievement for the Task Force. They are fully aligned with the HITF goals and objectives, and propose pathways for implementation. In some cases, implementation is already under way. Where more detailed investigation is necessary before any actions can be agreed, the Task Force has commissioned the necessary work. Progress on implementing and developing the outputs during the time that the Task Force was in operation is detailed in **Section 5** 'Taking things forward – proposed strategies and implementation plans'.

Data on the healthcare industries and inward investment

- 1.10 In addition, the Task Force concluded that two further areas needed more detailed explanation. In the area of **data on the healthcare industries**, it developed proposals for collecting statistics and deriving indicators from them which will enable meaningful industry metrics information to be published on an annual basis (see para 5.19 *et seq* and **Annex D**). In the area of **inward investment**, the Task Force proposed that a cross-government strategic dialogue should be arranged to consider the opportunities for further action to attract R&D and manufacturing investment in medical devices to the UK.

Conclusion

- 1.11 HITF's work does not end with this report. The commitment to ensure that the outputs are carried through into actions means that government and industry representatives will need to come together to oversee the ongoing work. At its final meeting, the Task Force requested that a new joint committee be formed to review progress for a period of two years, and Lord Warner and Sir Christopher O'Donnell agreed to co-chair the new group. There is clearly a mutual wish to maintain the momentum initiated by this first strategic collaboration between Government and the healthcare technology industry, and a strong determination to ensure that HITF really does continue to make a difference.

2. Introduction – what the Task Force set out to do

Background

- 2.1 This report is an account of the Task Force’s activities and findings. It represents the culmination of HITF’s work over its twelve-month period of operation, including the process followed, the key stages in developing conclusions and the final outcome. It is supplemented by reports from each of the four Working Groups which were established by the Task Force to examine key areas in depth and submit their findings for consideration. The Working Groups each produced a report of their activities and these may be accessed on www.advisorybodies.doh.gov.uk/hitf.
- 2.2 The Task Force considers that the key outputs outlined on pages 1–4 represent a significant step forward for all stakeholders. It hopes this report will engage a broad readership, from those with a professional interest in the delivery of our health and social care services, to people who would just like to know more about opportunities to improve patient treatments.

Why the need for a Task Force ?

- 2.3 The Healthcare Industries Task Force (HITF) was the first joint venture of its kind between the healthcare industries and Government in this country. It came about following discussions late in 2002 between industry representatives and Lord Hunt, the then Health Minister with responsibility for the Government’s sponsorship of the healthcare products industry. In April of that year, Sir Derek Wanless had published a report,¹ commissioned by HM Treasury, which examined future health trends and the resources necessary to run a publicly funded, comprehensive and high-quality health service over the next 20 years. Wanless emphasised that the NHS was a “late and slow adopter of medical technology”. This raised important issues for Government and industry alike, and there was a shared interest in trying to improve this situation.
- 2.4 Of particular concern were how to facilitate introduction into the NHS of beneficial new technologies and, as the industry’s main customer, how our health and social care system could present a more attractive but discerning market for companies

1 *Securing our Future Health: Taking a Long-Term View*, accessible on the HM Treasury website www.hm-treasury.gov.uk

operating in the UK. The Government recognised the added value of supporting more timely adoption of innovative medical technologies – a modern health and social care service, better outcomes for patients and service users and a vibrant, competitive industrial environment.



- 2.5 Likewise, industry was keen to see what could be done to improve uptake of its products in the domestic market. Easier access to the NHS and the social care system would not only help companies reduce their marketing overheads, a significant problem for the many smaller companies operating in this sector, but would also help increase their share of export markets – being able to showcase their products already in use in the NHS is a distinct advantage for exporters.
- 2.6 Some of the difficulties encountered by companies trying to introduce new, innovative products into the NHS are illustrated in Case Study 1 at the end of this section.
- 2.7 There was a clear need for collaborative working. However, it was acknowledged at an early stage that the issues were complex and there were no instant solutions. A think-tank approach was adopted as the best way to ensure a detailed and wide-ranging exploration of the issues and a constructive output. During 2003 government and industry representatives therefore worked closely together in developing the scope of a joint task force and identified four areas for in-depth study which, if agreed solutions could be found, would bring significant benefits to all stakeholders.
- 2.8 Lord Warner agreed that a joint strategy would be the best way forward and in October 2003 HITF was launched.

Context

- 2.9 HITF could not have happened at a better time. The reforms emanating from the Government's NHS Plan² were beginning to take effect, and were carried further forward by commitments made by Government under the NHS

2 *The NHS Plan: A Plan for Investment, a Plan for Reform* – www.dh.gov.uk/publications

Improvement Plan³ announced in June 2004. These reforms are underpinned by high levels of government spending on health (an average of 7.6 % growth for the last four years), increases in the NHS's capacity and investment in the world's largest health-related IT programme. They are producing a more flexible approach to delivery of public health services, reducing waiting times, and increasing patient choice and the provision of modern, readily accessible treatments to meet the changing health needs and preferences of the population.

- 2.10 The Department of Trade and Industry (DTI) also restated its commitment to support a thriving, knowledge-based economy in its Innovation Review published in December 2003⁴ (see also para 2.13). DTI is continuing to make major investments in industrial science and technology through its Technology Strategy and other funding programmes. As part of its contribution to HITF, DTI commissioned an independent study of competitiveness factors in six key areas in the medical technology field. Its report is due to be published before the end of 2004. This will provide useful information for companies and for Government.
- 2.11 Sir Peter Gershon's Efficiency Review of the Public Sector,⁵ published in July 2004, required government departments and services to improve efficiency through, for example, reducing bureaucratic overheads, aligning resources with priorities and introducing new ways of working. The aim of these changes is to release resources to front line staff. In DH this means that health and social care services are better able to provide an effective and responsive service to patients.
- 2.12 DH was already involved in a central restructuring programme which aligned with the Gershon Review. This was followed by a review of its arm's length bodies (ALBs). The results of the ALB review were announced on 22 July,⁶ ie in the final stages of the Task Force's deliberations. The implications of these restructuring exercises need to be taken into account in giving effect to HITF's key outputs.

3 *The NHS Improvement Plan: Putting People at the Heart of Public Services* – www.dh.gov.uk/publications

4 *Competing in the Global Economy: The Innovation Challenge* – www.dti.gov.uk/innovationreport/index.htm

5 *Releasing Resources to the Front Line: Independent Review of Public Sector Efficiency* – www.hm-treasury.gov.uk

6 *Reconfiguring the Department of Health's Arm's Length Bodies* – www.dh.gov.uk/publicationsandstatistics/publications/publicationspolicy

- 2.13 The Task Force wished to ensure that its conclusions fitted in with wider government plans and also wanted to avoid duplicating the work of others. The Task Force noted that the following government reports were particularly relevant to its work:
- *Competing in the Global Economy: The Innovation Challenge*⁷ (December 2003) (see also para 2.10)
 - the Office of Government Commerce (OGC) report to the Chancellor of the Exchequer *Increasing Competition and Improving Long-term Capacity Planning in the Government Market Place*⁸ (December 2003)
 - the OGC and Cabinet Office report *Making a Difference – Reducing Bureaucracy in Central Civil Government Procurement*⁹ (December 2003)
 - the Better Regulation Task Force and Small Business Council review *Government: Supporter or Customer?*¹⁰ (May 2003)
 - OGC’s *Capturing Innovation: Nurturing Suppliers’ Ideas in the Public Sector*¹¹ (May 2004)
- 2.14 The characteristics of the UK-based industry, its potential for growth and a shared desire to develop a better understanding of its drivers also indicated that a collaborative venture would produce a worthwhile output. The UK hosts a highly innovative healthcare industry that is adept at capturing new and emerging technologies and applying them in the medical field. More details about the size, structure and dynamics of the healthcare industry are outlined in **Section 3** ‘The healthcare industries and the NHS market – an overview’. The Government’s health agenda increasingly provides opportunities for the private sector and recognises the benefits of collaborative working at all levels, especially in the areas where manufacturers based in the UK play a leading role, such as orthopaedics, biomedicine, diagnostic imaging, advanced wound management, operating theatre equipment and hospital beds.

7 DTI’s innovation report – www.dti.gov.uk/innovationreport/index.htm

8 www.gov.uk/embedded_object.asp?docid=1001394

9 www.ogc.gov.uk/embedded_object.asp?docid=1001426

10 www.brpf.gov.uk/reports/smeprocurement.asp

11 www.ogc.gov.uk/embedded_object.asp?docid=1001717

Working methods

2.15 One of the founding principles of the Task Force was that it would produce jointly agreed conclusions. This required recruiting a balanced membership that genuinely represented the key stakeholders, and making decisions by consensus throughout the process. The Task Force adhered strongly to this precept and succeeded in delivering proposals and actions that are supported by all those involved. Task Force membership was drawn from key players in the relevant areas, from patient groups and the public and private sectors. Terms of reference are at **Annex A** and a list of participants is at **Annex B**.

2.16 At its first meeting in November 2003, the Task Force set up four Working Groups, one to cover each key area:

- market access (Working Group 1)
- R&D and the industrial base (Working Group 2)
- regulatory issues (Working Group 3)
- international trade (Working Group 4)

The Working Groups' role was to study their respective areas in detail, identify the issues and make recommendations to the Task Force.

2.17 The Working Groups were extremely active during the first half of 2004 and presented over 50 recommendations to the June meeting of the Task Force, a reflection of the scope and intensity of their deliberations (see **Annex E** for a composite list of Working Group recommendations).

2.18 These recommendations were then focused into nine key areas and proposals for implementation developed. The issues were selected on the basis that they aligned with the Task Force's strategic goals, and that if effective solutions could be found to improve the status quo, there would be significant benefits for all stakeholders. The areas cover the re-focusing of market access for companies through the development of a new and better device evaluation service which will have strong working partnerships with other health technology networks and industry; development of more support for the introduction of innovation; and a more informed approach to procurement. Also included are measures to maximise the influence of the UK Medicines and Healthcare products Regulatory Agency (MHRA) in matters affecting the legislative framework for medical devices; more focused support for companies involved in international trade; raising awareness of the valuable role that devices

play in public health; and consideration of additional training and education for NHS staff. Further details are given under the key outputs on pages 1–4.

- 2.19 The work does not end here. Government and industry have undertaken to continue to work together to oversee implementation in those areas where concrete actions have been agreed, and to refine proposals where work is ongoing. This collaboration is a valuable achievement in itself and will pave the way for future partnership working in the interests of all stakeholders.



Case Study 1 – The challenges in marketing innovative medical technologies

Background

As part of its Artificial Intelligence Neural Network Programme, DTI funded original research into analysing ECG which was carried out at Brunel University. This became the subject of a Technology Transfer Agreement with a new company, founded to develop the research and bring it into widespread medical use.

Product development

The technology was incorporated successfully in a medical device. This was CE-marked under the EU regulatory system and also meets the requirements of the US Food and Drug Administration.

Clinical validation was carried out at St George's Hospital, London, with the assistance of a grant from the British Heart Foundation. Wide area performance and clinical governance trials were successfully carried out in Berkshire and Lancashire, and published in the *British Journal of Cardiology*. These included a cost-benefit assessment, described below. User trials have recently been carried out in India.

Benefits of the new device

Based on the results of the Berkshire trials and using published figures from the Personal Social Services Research Unit, the University of Kent, the company demonstrated that the device was cost-effective, offering the following benefits:

- reduction in referrals from primary care of 60%
- 100% increase in identification of patients at high risk
- 80% reduction in the cost of diagnosis per patient
- investing approximately £30 million could result in savings of £72 million annually

The company also identified the following benefits for the NHS and patients:

- more effective diagnosis at primary care
- significant improvements in patient care and patient quality of life
- a reduction in the demand for scarce cardiac resources
- shorter waiting times as a result of reducing unnecessary referrals

In addition, the innovation meets the requirements of:

- the National Service Frameworks for improved cardiac diagnostics
- the NHS Cardiac Collaboratives
- the new initiative to improve effectiveness in primary care – the first point of contact for most patients

Challenges

- the company is relatively unknown with no track record or reputation
- the technology is innovative and causes a major disruption to current practices
- GPs/practice nurses are required to acquire new skills, and training is required
- the new approach needs cardiologist buy-in to changes in procedures
- the product is innovative – it has no competition and is single-sourced – making competitive tendering difficult
- savings are made in secondary care, but the purchase is made at primary care, and the NHS budgeting system effectively hinders adoption

Current position

The company has over 300 devices in use in primary care to date, representing only about 1% of all GPs.

3. The healthcare industries and the NHS market – an overview

The data in this section was originally compiled for the first meeting of the Task Force to give a clearer picture of the characteristics of the industry and its main drivers. As there is little reliable data on the industry, the figures used came from a number of different sources. As a result, there are inconsistencies which cannot be easily reconciled. The difficulty in producing the paper illustrated to the Task Force the need for better data collection and analysis, and gave rise to the decision to produce new industry metrics (see para 5.19 and Annex D).

Introduction

- 3.1 The healthcare industries play a vital role in meeting the needs of an increasingly health-aware population. They constitute a dynamic sector which has grown out of a range of other industries, such as engineering, informatics, biotechnology, etc and produce an array of devices, equipment and consumables for use in health and social care. The composition of this sector is diverse and it is clear that its profile is little understood by many, despite the number of products in use by the population – it is estimated that more than half the population of the UK have contact with a medical device in any one day.
- 3.2 The healthcare industrial sector is relatively young, highly diversified and does not have a cohesive structure. These factors have all contributed to a lack of hard data about the industry and its products, and have made it difficult to gain an accurate picture of its size, structure and dynamics. The Association of British Health-Care Industries (ABHI)¹² surveyed its member companies in 2001 to gain a better understanding of its characteristics (see *A Competitiveness Analysis of the Healthcare Industry in the United Kingdom*, often referred to as CoMap II). There are other sources of data, but few that are comprehensive and consistent – edges are blurred and overlaps inevitable. This section draws on such studies and existing data where relevant. The data has not been further validated and is used in this report as illustrative only, to gain a better understanding of the UK industry and how it relates to our health and social care services.

¹² A leading UK trade association of companies providing medical devices and related services

Scope

3.3 'Healthcare industries' in the context of HITF means manufacturers of all products, except medicines, used in diagnosis, prevention, monitoring or treatment of illness or handicap in humans. The range of products is extensive, covering consumables, hospital supplies and equipment, and devices used in the community. The kinds of products covered range from plasters, syringes and mobility aids, to diagnostic test kits, pacemakers and high-technology scanners. All these products are regulated under the European Medical Devices Directives. Hospital buildings, their construction and design, and related services such as consultancies are outside the remit of HITF. Examples of products covered are given in **Annex C**.

Size and composition

3.4 The healthcare industries comprise a series of sub-sectors, loosely grouped together around product types and technologies. There are estimated to be about 7,000 medical technology companies in Europe. The ABHI's database includes around 4,800 companies operating in the UK. The industry contains a large number of small organisations – 85% of healthcare companies in the UK are estimated to have a turnover of less than £5 million per year. Larger UK companies have sales typically between £500 million and £1 billion or more a year, and there are also a few major foreign-owned companies, mainly American.¹³ According to a recent survey published by Eucomed¹⁴ more than 80% of the medical technology legal entities in Europe (a total of 9,345) are small and medium-sized enterprises. However, each of the sub-sectors tends to be dominated by a small number of big companies.

Market breakdown

3.5 The US Advanced Medical Technical Association (AdvaMed)¹⁵ breaks down the key world markets as follows:

World market: €170 billion in 2001

Europe	€47 billion
USA	€73 billion
Japan	€24 billion

¹³ Source of figures: ABHI's *A Competitiveness Analysis of the Healthcare Industry in the United Kingdom*

¹⁴ The European medical technology trade association

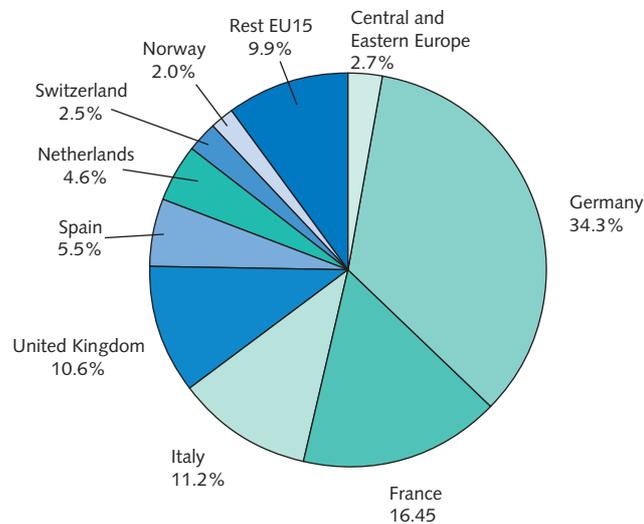
¹⁵ The main healthcare technology trade association in the USA

European market: €47 billion in 2001

Germany	€18 billion
France	€7.6 billion
Italy	€6.2 billion
UK	€3.9 billion

3.6 On the other hand, Eucomed reports that from the latest available figures from 2001 and 2002, the total value of the industry in Europe is about €54.8 billion. Germany is the leading country for medical technology with a market share of 34.7% (€19 billion), followed by France with 16.4% (€9 billion), Italy with 11.2% (€6 billion), the UK with 10.6% (€5.8 billion) and Spain with 5.5% (€3 billion). These five EU countries account for 78% of the market, with 51% coming from Germany and France (see Figure 1 below).

Figure 1 – The European medical technology industry by market share



The NHS

3.7 The NHS is the world’s largest healthcare delivery organisation and the main UK customer for healthcare products. The role of independent healthcare providers is unusually low (15% compared with an OECD average of 28%). In 1999 private acute hospitals had a total turnover of £3 billion compared to a total NHS expenditure of £52 billion. Spending on healthcare technology per capita in the UK is half, or less than half, that of North America, Switzerland, Scandinavia and Germany.

- 3.8 However, while most healthcare systems around the world are trying to constrain expenditure, the UK Government has committed itself to substantial growth in NHS expenditure in the coming years. The 2002 Budget provided for the largest ever sustainable increase in NHS funding – total investment will rise year on year to over £90.2 billion by 2007/08, averaging 7.3% growth in real terms over the five-year period.
- 3.9 The Wanless Review,¹⁶ which provided the analysis underpinning the 2002 Budget decisions, examined what the NHS's use of medical technology in future years might be. In the last 20 years, medical technology has accounted for around 2% of the annual growth of NHS spending. The Wanless Review projected that under the scenario it refers to as “fully engaged”, that figure would rise to 3%. It also stated that this growth in spending on medical technology could help achieve a growth in NHS productivity of 3%.

NHS procurement

- 3.10 It is estimated that the NHS spends around £15 billion on goods and services (revenue) each year. This includes all non-capital purchases, from energy and food to medical consumables and equipment. For 2004/05 £4 billion is covered by contracts negotiated by the NHS Purchasing and Supply Agency (PASA). The 28 Strategic Health Authorities (SHAs) have a role in ‘strategic capital’ expenditure (£7.6 billion for 2004/05), though ‘operational capital’ (about £1 billion in 2004/05) is now allocated directly to Primary Care Trusts (PCTs) and NHS Trusts. In 2004/05 78.5% of the NHS budget was allocated to PCTs and they therefore have a key role in purchasing services. PASA is modernising its approach to purchasing and in co-operation with the Department of Health Commercial Directorate is developing collaborative procurement hubs (consortia of NHS organisations within an SHA boundary) to provide a regional focus for procurement.
- 3.11 As the NHS develops greater diversity of providers to help improve patient access, choice and quality of care, including services provided by the independent sector such as Independent Treatment Centres (ITCs), there will be an impact on the shape and nature of the market for healthcare products.

¹⁶ *Securing our Future Health: Taking a Long-Term View*, accessible on the HM Treasury website www.hm-treasury.gov.uk See also para 2.3.

Contribution by the healthcare industry to the UK economy

3.12 The UK-based healthcare industries contribute positively to the economic environment in a number of ways.

3.12.1 Employment

Based on current knowledge and data from major countries, Eucomed estimates that the UK is the second-largest employer in the European medical technology industry, which employs around 350,000 people (Germany 110,000; UK 50,000; France 35,000; Switzerland 30,000 including downstream suppliers).¹⁷

Eucomed also reports that, based on the limited data available, the European industry invested an average 6.35% of its sales on R&D (the UK spent 5%), against 12.9% for the USA and 5.8% for Japan. This means that the EU healthcare industry spent on average a little over half that spent by US companies on R&D, but slightly more than Japan.

3.12.2 R&D and manufacturing

Traditionally, US and other foreign companies have often selected the UK as their European operational base. The UK has a worldwide reputation for R&D and there is a significant number of affiliate companies here. The NHS, as a major public health provider, is also a major attraction.

Recent economic analyses suggest that business investment in Europe is, however, beginning to decline. There is a close link between R&D and manufacturing and it is often the case that if R&D is reduced, the industrial base will be similarly affected.

3.12.3 Exports

UK exports are valued at around £3 billion in goods supplied annually, to a global market that is growing rapidly as individual expectations rise and political pressure grows in many countries to improve services and facilities. Exports from the EU are dominated by a few countries: Germany, Ireland, Italy and the UK. Twenty per cent of UK production is exported outside the EU; Germany exports 17% to third countries, and Ireland 35% of its €385 million output. In vitro diagnostic devices companies and electromedical and anaesthetic/respiratory equipment manufacturers are the major exporters.

¹⁷ Eucomed's *Industry Profile 2003*

The main markets are the USA, Japan, Central and Eastern European countries and Australasia. According to Eucomed and Medistat,¹⁸ in 2002 there was a positive balance of trade in the UK healthcare sector, with imports in the region of €1.6 billion and exports €2 billion. The new exercise to collect data (see para 3.14 below) will put these figures to the test and is likely to reveal a negative trade balance in this sector.

Conclusion

- 3.13 It is clear that the healthcare industries provide a valuable contribution to the UK's economy and that the NHS is a major element in stimulating the home market. The absence of accurate, consistent data is a significant drawback to formulating a future strategy of co-operation. A clearer understanding of the key drivers and trends within the UK-based industry will inform the implementation of HITF outputs and the ongoing dialogue between Government and industry.
- 3.14 The Task Force therefore agreed proposals drawn up by DTI, in consultation with DH and industry, for a new system of data collection, analysis and production of key indicators about the industry and its activities (see para 5.19 *et seq.* and **Annex D**).
- 3.15 In addition, during 2004 DTI commissioned a sector competitive analysis study in six key areas covered by the industry with the aim of assessing performance better and helping to identify how to improve it. This study should be published before the end of 2004. Both these exercises will contribute towards a more complete understanding of the UK's strengths in this sector and will help shape future decisions on industrial healthcare issues.

18 Medistat is part of Espicom, a market research organisation that provides data on healthcare

4. Changing patterns of health and social care – a vision for the future

Introduction

- 4.1 Throughout the world, economic and social models are changing more rapidly than ever, spurred on by interconnected physical and virtual technologies. These are redefining whole fields of human activity. It is those societies which understand and master these knowledge-based opportunities that will lead the world in the 21st century. Nowhere is this more true than in healthcare. As we understand more of the origins of disease, both genetic and environmental, we realise that we are on the verge of a new model. This will be based upon helping individuals understand and maintain their health throughout their lives, rather than simply treating disease after it has taken hold. The emphasis will shift from 'late' to 'early' and will expand from treating disease to maintaining health.
- 4.2 Technology has a central role to play in enabling this vision, but its success will be critically dependent on establishing the right mechanisms of interaction and partnership between scientific innovators, the healthcare industries, the NHS and individual patients. To be successful, we must look more holistically at this supply chain of innovators, developers, deliverers, patients and service users to ensure that it is vigorous, innovative and based upon world-leading best practice. Above all, it is only as strong as its weakest link. This section therefore addresses practical measures to improve short-term connectivity in some of these areas. Further consideration of the strategic opportunities in healthcare by Government, relevant industrial sectors, and other stakeholders may be worthwhile.
- 4.3 Twenty years ago, the economy was recovering from a world recession and the drive for business to re-establish its viability gave rise to important industrial advances. The rapid expansion of microelectronics had a major impact on the medical, computer, communications and other industries, and the development of glass optical fibre significantly increased phone messaging capacity, while computers began increasingly to appear in the workplace and in the home.
- 4.4 The leading medical news at the time was the discovery of the viral cause of AIDS, and experimental medical procedures involving organ transplantation, mechanical implants, cultured skin, human fertilisation and embryology were in their infancy.

- 4.5 Today, mobile phones are commonplace, the internet has revolutionised global communication and business, and automation has significantly changed the face of industry. The increasingly fast pace of scientific and technological progress has impacted on all aspects of our daily life, not least on health and social care. We are living longer, travelling more widely and our lifestyles bear little resemblance to those of our grandparents.
- 4.6 All these factors have an impact on health – disease patterns and health needs are changing faster than ever before. It is therefore important for longer-term public health strategies to take account of opportunities afforded by new and emerging technologies so that the health and general well-being of the population can start to benefit from these advances now and in the future.
- 4.7 The healthcare industries, the use of new technologies, the NHS and wider government policy all have critical parts to play in moving the health agenda forward to deliver progressive, relevant services in the future.
- 4.8 Some thoughts on the challenges facing future health and social care and some developments already in train are outlined below.

Earlier diagnosis

- 4.9 The current model of healthcare, whereby the NHS's main role is in treating the sick, is becoming ever more difficult to sustain as people are living longer (in part due to improvements in healthcare) and the cost of long-term care for an ageing population spirals. The case for an alternative model which focuses on early diagnosis and prevention is gaining momentum. The combination of strategies to promote healthy lifestyles, increasing expenditure on screening programmes to detect disease early and providing prophylactic treatments for predictive conditions could be used more extensively to avoid ill health. This requires a change away from the current NHS approach of treating those who are suffering ill health, to working towards an 'early health' model which is aimed at preventing and mediating disease and disability.
- 4.10 Greater use of in vitro diagnostics and imaging technologies will allow earlier and more precise identification of disease. This means that management can begin earlier, and often in a lower-cost environment than for managing later-stage disease. New modalities in imaging, such as PET/CT combinations, novel applications of ultrasound and molecular imaging will allow disease to be identified at a far earlier stage and therapies to be more precisely targeted and monitored.

- 4.11 All of the imaging modalities, current and novel, are being revolutionised by digital technology coupled with computer enhancement and sophisticated analysis and manipulation of images.
- 4.12 Novel biosensors could radically change the precision of laboratory profiling of patients and, more importantly, take diagnosis into the general practitioner's office and the home. Complex conditions which currently require the involvement of hospital specialists could be easily diagnosed and treated in the community, on the basis of very much more refined diagnostic information, and acted upon at an earlier stage in the disease process. For example, a diagnostic chip on a mobile phone which could identify common diseases could entirely eliminate the need for visits to doctors for infections such as colds and influenza.
- 4.13 Pharmacogenomics, pharmacogenetics and genetic screening will have an enormous impact on our ability to identify those members of the population who are at increased risk of disease. Genetic screening can already identify those at increased risk of breast and other cancers. New diagnostic tests can identify specific types of tumour which then allows the most appropriate drug treatment to be offered. Pharmacogenomics can identify those at risk of particular adverse events and can help to define drug dosages more effectively.
- 4.14 The building blocks of a more satisfactory early health model are already coming into place. Instead of waiting until symptomatic late-stage disease has taken hold, when the only options available are expensive, unpleasant and sometimes ineffective, the early health approach will allow individuals to understand their own genetic propensity to key treatable diseases, so that they can receive regular selective screening. Upon identification of early pre-disease changes, in vivo molecular imaging may show the location and extent of early-disease activity, allowing rapid intervention through surgery, drugs or lifestyle improvement.
- 4.15 Healthcare technologies will also produce major changes in the number and type of drugs that we need to take. We now understand that common cancers in reality consist of many distinct forms of the disease, which require entirely different drug types. Also, many of today's drugs have been developed to treat late-stage disease. Earlier identification will open up opportunities for new types of drugs, which may also be more effective, particularly if more cancers become detected before they metastasise throughout the body.

Community care and assistive technologies

- 4.16 With an increasingly ageing population, the management of chronic conditions in large numbers of people will become an increasing priority. Keeping people out of hospital and active has huge benefits for people and for the economics of healthcare delivery. The ability to manage chronic disabilities via assistive technology will increase as devices get smaller, lighter and more manageable because of the use of advanced materials, engineering and IT developments. Such technologies as the intelligent wheelchair will develop and become more accessible as volumes of use facilitate cost reductions.

Technologies for supporting an ageing population

- 4.17 Orthopaedic implants have already transformed the lives and long-term care costs of large sections of the population and will continue to develop as materials technology improves both function and reliability. In the longer term, technologies will address nerve regeneration and treatment of paralysis in stroke patients. Already implants have been applied to the management of tremor associated with Parkinson's disease and medical devices will increasingly address conditions where pharmaceutical solutions are not available. The emergence of such technologies offers to reduce dramatically the burden of care in the community.

Device/drug combinations

- 4.18 Device/drug combinations are emerging at a pace. These range from drug eluting stents, which enhance the performance of the essentially mechanical function of the stent, to closed-loop insulin management systems incorporating blood sugar sensors and delivery pumps. These systems are already demonstrating efficacy in eliminating many of the effects of diabetes such as blindness, ulcers and the need for amputation. This technology is merely the forerunner of many closed-loop therapeutic systems that are in development and will be applied to a wide range of chronic conditions. Other drug eluting platforms will facilitate the localised delivery of therapeutic agents, for example stents that deliver chemotherapy or vascular proliferative antagonists in the treatment of cancer.

Tissue engineering

- 4.19 The field of tissue engineering covers a wide field of both allogeneic and autologous tissue applications with materials derived from human and animal sources. Early examples of tissue engineering developed in the UK include autologous cartilage culture and repair and the processing of porcine skin to create a collagen material that can be used for surgical tissue repair. With an ageing population, the demand for materials which can be used for tissue repair and either remain intact or are metabolised following use, depending on the body's own repair capabilities, will increase. These materials will facilitate enhanced quality of life and reduce re-working of existing mechanical devices. Other examples include replacement of corneal tissue and, in the longer term, nerves and blood vessels. More complex organ replacement engineering will emerge as kidney, liver and pancreas replacements become possible.
- 4.20 Combinations of biological and electromechanical technologies will be captured in devices such as bionic eyes and implanted digital hearing aids.

Nanotechnology

- 4.21 'Nanobiotechnology' is emerging as a discipline where very specialised 'nano' surfaces encourage tissue organisation (applied to tissue sourced from animals and to humans). Nanotechnology is also being applied to the generation of particles that are targeted at specific tumour tissue and activated by microwave to deliver heat, which destroys tumour cells without the collateral damage caused by conventional radiotherapy.

Robotics

- 4.22 Surgery will be steadily transformed by the introduction of robotics. The skills of the surgeon are limited by the capabilities of the human body. Robots can perform with much greater precision than even the most accomplished surgeon. In areas such as orthopaedics and neurosurgery, robotic assist devices are delivering precision which minimises the scope for re-worked surgery and collateral damage to delicate tissues surrounding the surgical target.

Information and communications technology

- 4.23 Information technology will steadily become more pervasive as an integral part of medical devices. This will allow people to control the management of their own health much more than at present. Already mentioned above are the impact of IT on implantable devices such as pacemakers, defibrillators, etc. Microcomputers are also at the heart of much imaging and diagnostic apparatus as well as life support and monitoring equipment.
- 4.24 In the future, there will be an acceleration of the impact of IT on medical devices. Activity will be captured on integrated systems and these could be used much more effectively for the benefit of both practitioners and the patient. Remote monitoring technologies will allow the health of at-risk patients to be monitored as they go about their daily lives and treatment to be provided when there is an indication of need emerging. All of this will be done via intelligent systems which analyse streams of data, looking for patterns which indicate if intervention is required.
- 4.25 Telemedicine will increase and be applied in its many forms to deliver service re-engineering and allow the quick turn-around of patients in the community setting. This will mean fewer referrals and more rapid turn-arounds at general practitioner level. It will also allow more care to be provided locally where community hospitals and health centres can be transformed into intermediate-tier centres. Telemedicine will also support the rapid referral of those patients at risk.
- 4.26 With people's agreement, personal data will be stored securely and confidentially in much greater quantity and be accessible to authorised medical professionals. It will be derived from medical devices used in diagnosis and therapy in both the hospital and the community.

Maximising the benefits of the 'technology explosion'

- 4.27 The Government is conscious of the accelerating pace of scientific and technological advances and is committed to harnessing these for the benefit of the health and wealth of the nation. The Department of Health's strategic goals in improving healthcare delivery were specified in the NHS Plan¹⁹ and were developed further under the NHS Improvement Plan²⁰ published in June 2004. DH has increasingly

19 *The NHS Plan: A Plan for Investment, a Plan for Reform* – www.dh.gov.uk/publications

20 *The NHS Improvement Plan: Putting People at the Heart of Public Services* – www.dh.gov.uk/publications

invested in a range of initiatives in line with these objectives to modernise our public health services. Patients are at the heart of services, along with new ways of tackling the causes of ill health and preventing the onset of disease, reflecting the Government's policy of preparing for future health needs today.

4.28 Some of the key initiatives are set out below.

4.28.1 **Screening**

In recognition of the need to diagnose disease early, DH has set up the UK National Screening Committee to advise on screening policy and assess programmes to ensure that there is good evidence that they will be effective. In priority areas such as cancer, diabetes, heart disease, and other key areas of child and adult health, pilots and full screening programmes have been introduced to implement this policy. For example, following pilots of new tests for bowel cancer, DH is investing £37.5 million over two years in a national screening programme which will begin in April 2006. MRI and CT scanners have been the subject of a centralised replacement programme to help ensure that a high-quality, readily accessible service can be offered to at-risk patients. New screening programmes have been rolled out to make greater use of existing tests, new tests introduced where these offer improvements on previous products, and unreliable methods phased out. For example, introduction of a new mammography technique is increasing the number of breast cancers detected, including small but invasive tumours which are unlikely to be found otherwise. Deaths from cancer in this country are falling significantly as services are improved and extended.

4.28.2 **The National Programme for IT (NPfIT)**

As the eHealth market is set to develop at a rapid pace, driven by new IT, telecommunications and medical devices, DH has invested in a new electronic system for England's NHS which will provide a platform for major expansion in this area. NPfIT has a number of components. The Care Record is an integrated electronic record management service which will support a revolution in health and care. It includes electronic prescribing of medicines, booking of appointments (by 2005) and personal records – with patient access (by 2005). All health services will have facilities for telemedicine by 2005. For the first time information about patients will be mobile and over time this will bring benefits for patients, clinicians (particularly in patient safety, diagnostic procedures and in early detection) and the NHS. An electronic infrastructure will facilitate care delivery across

different health communities, the increased use of telemedicine, smart medical and diagnostic devices for near patient testing, and consumer-friendly home care services. Electronic auto-identification of medical devices will become more widespread, which will not only improve management of the supply chain, but also enable devices to be tracked in use and linkage made to individual patient data, improving procedures in the event of a safety concern.

4.28.3 **Integration of health and social care and use of assistive technologies**

DH recognises that increasingly it is beneficial for patients and service users to receive health and social care services in the community where appropriate. For instance, in the management of chronic disease and to support older people, which is a growing need as the age profile of the population lengthens, solutions often need to be implemented in the community or home environment to meet people's expectations and enable them to live as normal a life as possible, maintaining their independence. Increasing emphasis on home care has meant closer co-operation between health and social care and an expansion of resources in this area. By 2006 a further 100,000 people each year will be supported to live independently at home. Whilst there are a number of issues to resolve in delivering integrated services, caring for people close to their home environment is a pressing objective for the future.

4.28.4 The scope for advanced assistive technology products to support this change in focus is therefore expanding. This is a very diverse sub-sector of the medical devices industry which supplies a varied range of products, from home gadgets, rehabilitation products, customised artificial limbs and appliances, to state-of-the-art personal transport and mobility aids. The industry's contribution to the development of care standards and promotion of active living is key to the closer integration of care services.

4.28.5 **Supporting innovation**

In recognition of the paramount importance of developing new medical therapies to meet the challenges of new diseases and the changing health needs of the population, DH invests over £550 million a year in research, working with other stakeholders to sustain and develop the science base, develop research infrastructure and capacity, support programmes to meet the research priorities and needs of the NHS, and commission research to inform the development and implementation of policy. DH funds a range of

national R&D programmes that develop new devices for health and social care, undertake health technology assessment, and consolidate and develop the evidence base on the organisation, management and delivery of services. DH also funds the National Horizon Scanning Centre to provide advance notice of significant new and emerging health technologies that might require urgent evaluation, consideration of clinical and cost impact, or modification of clinical guidance.

4.28.6 DH is committed to helping the NHS become an innovative organisation.²¹ A key tenet of this policy is the continuing development of a network of NHS Innovations Hubs.

4.28.7 **Cost-effectiveness**

Government and industry have become more focused on using and developing products and systems which have the potential to reduce costs whilst maintaining effectiveness and safety. Another consideration is easing the burden of treatment on the individual patient. Current examples include:

- increasing use of stents to reduce highly invasive and cost-intensive coronary artery bypass treatments
- heart valve replacement, which is now increasingly being performed percutaneously, avoiding the need for open-heart procedures

Not only do these developments eliminate a great deal of expensive hospital activity but they also allow the patient to be treated without a major impact on their life.

- microwave endometrial ablation has the potential to eliminate a large proportion of the hysterectomies performed, with little more than day-case inconvenience for patients
- emerging spinal navigation technologies offer to reduce dramatically the cost and invasiveness of neurosurgery

4.28.8 The Task Force debated value and cost-effectiveness extensively. The development of a more transparent collaborative approach between the National Institute of Clinical Excellence (NICE), Health Technology Assessment (HTA) and the new Device Evaluation Service will enhance the flow of information along a continuum of evaluation from clinical guidelines

²¹ *The NHS as an Innovative Organisation* – see www.innovations.nhs.uk

through technology assessment to expert evaluation of individual products by users. The new service will inform NHS procurement and help ensure that value for money considerations are at the centre of purchasing decisions.

4.28.9 **Business support**

DTI provides substantial support for UK-based businesses through its various funding programmes and advice schemes to encourage economic growth and investment. In particular, it acknowledges that a dynamic small business community is central to enterprise in the UK, generating 52% of private sector turnover, and employing 12.6 million people. The Government's Action Plan for Small Businesses, published January 2004, aims to make the UK the foremost location to start a small business and builds on existing government support for small business.

4.28.10 **New service models**

DH is already meeting the challenges of introducing disruptive technologies and in so doing, helping to ensure that patients receive better treatments more quickly in more convenient locations:

- **NHS Direct**, which began as a pilot offering medical advice at the end of a telephone 24 hours a day, has become a successful innovation and is now an integral part of the NHS. It is professional, reliable and accessible, saving a large number of patients a wait for a GP appointment or hospital visit. Similarly, the ongoing introduction of **NHS Walk-in Centres** in convenient locations has brought ease of access right across the patient population, as well as to specific groups. The **independent sector Treatment Centre programme**, which began in October 2003, is providing speedy local access for diagnostic and elective procedures. This new model of service delivery is increasing the capacity of the NHS, particularly in areas where there are bottlenecks, and speeding up treatment for patients – when fully operational (end 2005) an additional 144,000 patients a year will be treated. The NHS is increasingly adopting a flexible approach to services and partnership arrangements.
- Some surgical procedures, with the spread of minimally invasive techniques and devices, are being performed on a day case basis and DH, the Modernisation Agency and the NHS are working closely together to facilitate an expansion of **day surgery**. This is increasing NHS efficiency and allowing patients to recover in their own homes, without the need for hospitalisation.

- **Foundation Hospitals**, whose aims are to be responsive and accountable to the local community, are beginning to have an impact on the market for equipment and services. Patients have a big say in directing and shaping these new organisations, and additional investment is being made year on year to support their development. Financial decisions and priorities are driven by local health needs and NHS professionals responsible for providing the services at ground level, rather than by a central hierarchy, while at the same time the hospitals remain fully part of the NHS. Twenty Trusts currently have foundation status and this number is expected to rise to around 40 by the end of 2004/05. By 2008, all NHS Acute Trusts in England will be in a position to apply to become NHS Foundation Trusts, working as independent public benefit corporations, modelled on cooperative and mutual traditions. These radical reforms are still at an early stage and it is not as yet clear what impact they will have on the supply of services and equipment. The current Foundation Trusts are being reviewed by the Healthcare Commission, which will also consider their impact on the local health economy. DH aims to publish the findings during summer 2005.

Future plans and the move to a patient-centred approach

4.29 DH believes that prevention of ill health is better than cure and agrees that measures supporting screening, early detection and intervention are a sensible way forward. Existing services in this area will be extended over time where supported by evidence. Making health services more patient-focused and ensuring they are easily accessible is a fundamental aim of the NHS Plan and the subsequent NHS Improvement Plan. A significant investment has been put into IT applications and redesigning services so that they meet people's needs and personal preferences. This has fostered the development of a range of new service delivery patterns which will continue to develop away from the traditional institutions to more flexible, convenient locations, including a patient's home environment where applicable. The expert patient programme is supported by DH to promote and expand self-management skills amongst people living with long-term conditions. Access to their own electronic records will empower patients to become more involved in decisions about their health and make informed choices.

- 4.30 DH's plans need to be developed in consultation with all stakeholders. The NHS needs to be supported by a skilled and flexible workforce. There also needs to be an ongoing dialogue with the industry about its capabilities to develop medical products and technologies to meet health and social care needs of the future. Genetic science, tissue engineering, information technology and nanotechnology will give rise to a range of new materials, systems and products which can be applied in the medical field. Clearly, industry and its products have a key role in shaping future healthcare services in this country.

Patient and public involvement (PPI)

- 4.31 DH is committed to making services genuinely responsive to people's needs and preferences. Whilst many parts of the NHS are involving patients and the public in service design and delivery, and in improving and monitoring the quality of care, the output of this process still needs to be embedded more widely into practice so that communities have greater influence over the way their local resources are spent and patients have greater control over their own care.
- 4.32 The NHS is working towards treating people as partners – recognising the contribution they can make towards improving their care, listening to them and making changes as a result.
- 4.33 The ethos of DH's policy for the changing NHS is to put patients at the heart of services, championing patient involvement. There are many examples of good practice and successful projects involving patients and the public, and work is in progress to spread this ethos through the wider NHS.

Conclusions

- 4.34 The explosion of healthcare technologies is a global phenomenon and the UK is in a position to benefit from the changes ahead. Innovation, entrepreneurship and evaluation are key elements in driving forward improvements in health and social care, and are essential ingredients in a thriving economy. The UK has unique advantages in terms of academic and industrial competences in the key areas of information technology, biosciences and engineering. These are complemented by a venture capital environment which is better developed than anywhere else in Europe.
- 4.35 Our largest asset is the NHS itself, which needs to drive change and innovation in healthcare delivery more strongly. No other country has a single system with the NHS's resources and links to academia. An NHS that looks to innovate can capture

the benefits of the emerging technologies and, in so doing, provide an engine for industrial development based on the knowledge economy.

- 4.36 Viewed holistically, the healthcare ‘supply chain’ – from innovation in academia, through product and service development in industry, to delivery in the NHS and social care system – is already one of the largest activities in the UK economy. It could, however, become its major long-term growth engine. With a strong biomedical science base and increased investment in healthcare capacity, the UK has the potential to become a lead adopter of the ‘early health’ model.
- 4.37 Achieving recognition as the world’s leading environment for healthcare innovation, development and delivery could become the cornerstone of the 21st-century UK economy, attracting in further sources of academic, industrial and clinical excellence. Healthy societies have been proven to be more economically productive, and have a greater sense of well-being and cohesion.²² The macro-economic benefits of a focus on healthcare are therefore very great.
- 4.38 The Task Force recognised the unique strengths and potential which the UK possesses as a leading nation in the provision and development of healthcare. Government and industry have taken a significant step forward towards integrating progressive technologies and procedures into health and social care services, as part of a broader aspiration to maximise the benefits that can be derived from achieving the Government’s strategic goals in improving healthcare delivery. The patient experience needs to be factored in to future service developments to help ensure that we are not just caring for the sick, but promoting good health throughout the population.

22 OECD Health Project, *Towards High-Performing Health Systems* (Summary Report), 2004

5. Taking things forward – proposed strategies and implementation plans

Two-phased approach

5.1 The Task Force adopted a two-phased approach to delivering its conclusions. Phase 1 focused on the activities of the four Working Groups in examining the key areas in depth and bringing forward recommendations for improvements. Phase 2 involved honing the Working Group recommendations into an integrated framework for action to optimise their impact across the spectrum of HITF's remit, and developing workable strategies for implementation.

Phase 1 – the Working Groups

5.2 The Working Groups began their activities very quickly after the inaugural meeting of the Task Force in November 2003. They agreed their respective terms of reference (see **Annex A**) and drew up their work programmes. Although each Working Group had a different area to investigate, mechanisms to ensure effective communication between them were put in place because of the emergence of common and cross-cutting themes.

5.3 The Working Groups were very productive, identifying barriers and devising agreed ways of overcoming or reducing them. At the June 2004 meeting of the Task Force, each group presented a set of conclusions and recommendations for the Task Force to consider. There were over 50 recommendations and proposals for action at that stage. These are listed in the table at **Annex E**.

Phase 2 – development of an integrated framework for action

5.4 The Task Force felt that the scope and creativity of the Working Groups' recommendations represented a considerable achievement, particularly in view of the complexity and diversity of issues addressed. However, there was clearly a need to prioritise the recommendations and to focus on those which would not only be effective but would also be deliverable.

- 5.5 During the summer the Task Force therefore turned its attention to distilling the suggestions put forward by the Working Groups into a coherent set of proposals. Nine key areas were selected. Each subsumes a range of initiatives originating from the various Working Group recommendations.
- 5.6 The next step was to develop recommendations for implementing the proposed measures, ensuring full integration with existing arrangements and future developments where appropriate. The intention was to ensure that the recommendations would be effectively translated into action, and not left to wither on the vine or be overtaken by other changes.
- 5.7 The key outputs are summarised on pages 1–4. Details of what they are intended to achieve and proposals for implementation, including updates on progress already made where applicable, are given below. These outputs represent the agreed conclusions of the Task Force. They encompass to a large degree the recommendations first proposed by the Working Groups. Only a small number of Working Group recommendations are not covered by these key areas, as indicated in the table at **Annex E**.
- 5.8 The Working Groups have each produced a report of their activities, and these reports, together with other documents relating to the Task Force’s work, may be accessed at www.advisorybodies.doh.gov.uk/hitf.
- 5.9 The main points of the strategy and progress towards implementation are summarised below.

Proposed strategies and implementation plans for key outputs

5.10 **Device evaluation – key output 1**

Inform procurement decisions, and encourage and support the uptake of useful, safe, innovative products and procedures used in health and social care:

- *develop a new device evaluation service to integrate and strengthen horizon scanning, and the assessment of value and effective performance of new and enhanced healthcare technologies, devices and related procedures*
- *develop nationally accepted methodologies and toolkits for device evaluation that can be used locally to ensure consistency approach whilst facilitating decision-making at the appropriate level*
- *consider how best to ensure speed of evaluation, a ‘once only’ approach and prompt sharing of outputs with stakeholders throughout the health and social care system and industry*

To help effect these changes, the existing Device Evaluation Service (DES), currently sited in the Medicines and Healthcare products Regulatory Agency (MHRA), will move to the NHS Purchasing and Supply Agency (PASA) with effect from 1 April 2005 (subject to legislation) and will be developed over time.

Plans to deliver the first stage of this proposal are being developed. The current DES will provide the foundation for developing an extended evaluation service as required by the Task Force. In line with the conclusions of the DH Arm's Length Bodies (ALB) Review,²³ plans are in hand to transfer DES from MHRA to PASA, where it will have close links with NHS procurement. This will involve an amendment to MHRA's Trading Fund Order which is a Statutory Instrument. The aim is for the transfer to take effect from 1 April 2005, subject to this legislative amendment. DES will take with it all the expertise it has developed during nearly 30 years of operations, as well as the networks and working partnerships it has established with other relevant agencies and industry. It will also build a working relationship with the new Innovation Centre, as described in para 5.11 below. Its main function will be to inform purchasing decisions and give independent expert advice, particularly on the application of innovative products and procedures in the NHS, facilitating the adoption and diffusion of new medical technologies. Case Study 2 depicts some of the advantages for patients and healthcare that accrue from effective evaluation.

Case Study 2

Rapid exclusion of diagnosis of deep vein thrombosis

Blood tests are now available to rapidly exclude a diagnosis of deep vein thrombosis (DVT). The evaluation report produced by DES (MHRA 03088) helped NHS laboratories by enabling them to select suitable products for the implementation of this new way of working.

The study of eight test kits from seven manufacturers demonstrated that this method benefited patients by the reduction of the need for unnecessary, time-consuming and sometimes invasive imaging techniques by up to 35%.

With an estimated 250,000 suspected cases of DVT in the UK annually, this represents a potential saving to the NHS of up to £5 million and better service for patients.

²³ The ALB Review was undertaken by DH as part of its wider restructuring programme. It covered Non-Departmental Public Bodies and other agencies sponsored by DH. The report was published in July 2004 (see www.dh.gov.uk/publications) and included a recommendation that MHRA's DES should be located within a more appropriate part of the DH organisation as its function was not regulatory.

5.11 Innovation – key output 2

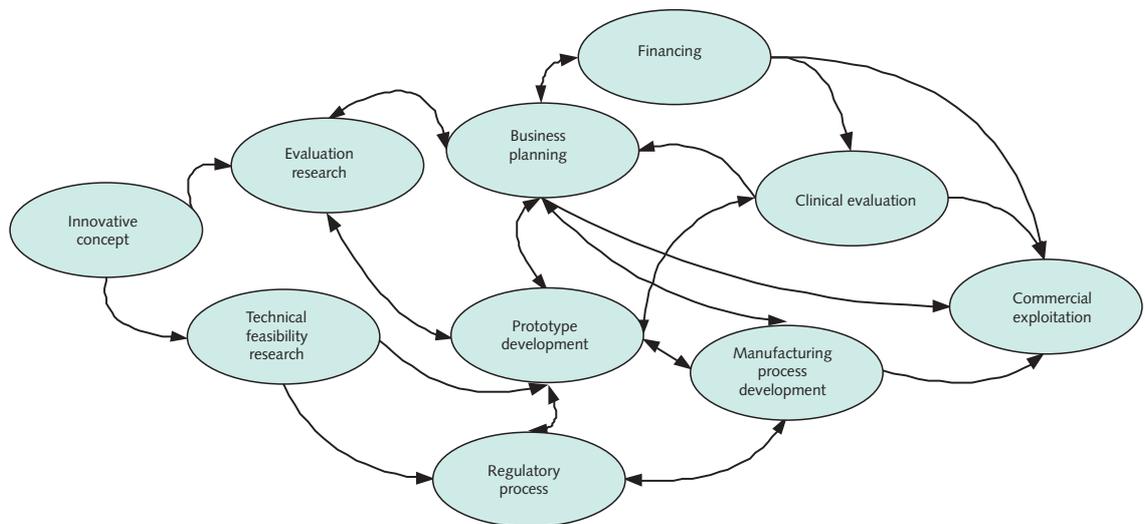
Stimulate more innovation and encourage a more entrepreneurial culture in industry and the NHS:

- *work towards the development of a new Innovation Centre in an appropriate organisation to promote and support the rapid development, dissemination and commercialisation of a pipeline of innovations coming from the NHS, academia or the global healthcare industry; the role of this centre would be to:*
 - *co-ordinate and develop the activity of the existing network of NHS Innovations Hubs*
 - *improve interactions and promote the exchange of knowledge between the NHS, industry, financiers and other key stakeholders, utilising online knowledge exchange and communication tools*
 - *play a brokerage role between industry, financiers and the NHS, fostering partnership and collaboration opportunities*
 - *promote successes and facilitate innovation uptake in the NHS*
 - *introduce an ‘innovation fund’ to promote the development and exploitation by the NHS of innovative products and procedures*
- *establish collaboration between the Medical Devices Faraday Partnership, other appropriate partners and the new Innovation Centre networks, covering the supply industry, academic departments, business and finance organisations, and NHS and DH bodies, to:*
 - *promote the exchange of knowledge between the networks*
 - *deliver an online ‘integrated routemap’ guiding stakeholders on product development, business planning and manufacturing, regulatory and marketing procedures, through to entry into NHS and world healthcare markets*
 - *when appropriate, promote the co-ordination of respective brokerage activities*
- *work to increase both public and private funding for translational research in developing new products from proof of concept to commercialisation*

This proposal is subject to ongoing work to secure funding and a detailed analysis of impact on the NHS.

The Task Force recognised that product development in the medical devices field is an iterative process (see Figure 2 below) and that a clear pathway from initial idea through to effective diffusion in the health and social care services is needed if industry and NHS innovations are to be successfully commercialised. Understanding clinical requirements and priorities is also a key element. This was reflected in the thinking of Working Groups 1 and 2 (Market Access, and R&D and the Industrial Base). As well as introducing new structures and practices, effective linkages with other relevant organisations are also essential.

Figure 2 – stages of product development



Developing a national innovation service presented a significant challenge for the Task Force in terms of devising a new structure that could manage the complete innovation agenda for the NHS. However, the Government considers this to be a desirable step in the sequence of stimulating innovation in the industry and the NHS, and successfully bringing useful new products and techniques to market. Government has therefore agreed to work towards the development of a new Innovation Centre in an appropriate organisation. Its primary function will be to bring together in a single unit advice for the NHS and for industry on exploiting and commercialising new products and technologies used in health and social care. Its remit will go beyond medical devices. Clear links with the new Device Evaluation

Service (see para 5.10), the research community, clinical networks and other interested parties will be embedded in its objectives to ensure effective transitional support for products from early development through to marketing. Although further work is required before plans for the new centre can be finalised, there are many gains for the NHS to be realised from this proposal.

5.12 Procurement processes – key output 3

Embed modern approaches to procurement in the NHS to deliver better value for the service of patients through:

- *nationally-agreed/accepted best practice models, including early communication with industry on workplans (eg the Supply Chain Excellence Programme (SCEP)) to provide clarity on levels of market access and to ensure capture of innovative solutions*
- *a focus for regional procurement with significant clinician involvement to provide the platform for an informed approach to procurement decision-making*
- *ensuring that the role of procurement in supporting the timely uptake of new technologies identified as providing benefit to patients is embraced*

The above will be incorporated into the redesign of the NHS PASA, the proposed model for Collaborative Procurement Hubs under SCEP and the continuing development of Supply Management Confederations.

- *regular dialogue between the NHS and industry to encourage input into policy-making generally and specifically (eg National Service Frameworks and Payment by Results initiatives)*

During the period when HITF was active, a number of changes were simultaneously taking place in connection with NHS procurement policy and practice. As this key recommendation emerged from the Task Force, steps were already being taken to ensure that HITF objectives were also incorporated into these new proposals. In addition, a commitment was made to continue dialogue with industry on procurement issues, building on the model and membership of Working Group 1 (Market Access). This would provide a mechanism for making industry aware at an early stage of the various aspects of modernising the procurement function, which would be formally embedded into the NHS PASA through the ALB Review.²⁴

²⁴ Accessible on DH's website at www.dh.gov.uk/publications/

5.13 **Building R&D capacity – key output 4**

Through the UK Clinical Research Collaboration (UKCRC) DH will:

- *incorporate devices into the disease hubs/networks (starting with five initial disease areas: mental health, diabetes, new medicines for children, stroke and Alzheimer's)*
- *develop a capacity-building programme, including fellowships*
- *increase commitment to the new and emerging technologies R&D programme (New and Emerging Applications of Technology (NEAT))*

UKCRC will provide a platform for harnessing the quality and expertise of the NHS for all stakeholders by:

- *building up the clinical research infrastructure in the NHS*
- *building up the research workforce (through improved training opportunities and career structures)*
- *developing incentives for research in the NHS*
- *streamlining the regulatory and governance processes*
- *co-ordinating funding (through a strategic analysis of current portfolios which will also reveal 'orphan' areas for discussion)*

The Task Force recognised the significant government investment in UKCRC²⁵ (an initial £24 million for Alzheimer's, stroke, diabetes, mental health and children's medicine, plus £7 million for additional research and to strengthen the infrastructure for clinical trials in these areas) and its potential to drive forward a coherent research programme in collaboration with all health R&D industrial sectors. DH therefore

25 The UK Clinical Research Collaboration (UKCRC) is tasked with speeding up the development of new medicines and treatments from the laboratory to the patient by expanding the number and range of clinical trials. Its aim is to help bring together clinical teams, Primary Care Trusts, the voluntary sector and industry to increase the number of patients participating in clinical trials. Its work will initially be targeted on five therapeutic areas. It is chaired by the Director of R&D of DH and the Board comprises representatives of the main UK funding bodies for clinical research (Departments of Health – England, Scotland, Wales and Northern Ireland, the Office of Science and Technology (OST) and the Medical Research Council (MRC), the Association of Medical Research charities, the Wellcome Trust, UK Cancer Research, related industry sectors, the Academy of Medical Sciences and the Academy of Medical Royal Colleges), the NHS Confederation, a Strategic Health Authority (SHA), MHRA, the National Institute of Clinical Excellence (NICE) and the public.

took the opportunity provided under HITF to invite the healthcare industries to join the Board of this new body, established in June 2004 as part of the Government's response to the conclusions of the Academy of Medical Sciences report²⁶ and the Bioscience Innovation and Growth Team (BIGT) report.²⁷ Innovation in this sector plays its part in the workstreams supported by this new body. UKCRC's work is just beginning and it will have an increasingly influential role in health research in this country. Industry has already taken up the offer to appoint a representative to UKCRC.

The Task Force is keen to ensure that the healthcare industries fully engage with this new initiative. UKCRC aims to create a thriving R&D environment in the UK that will attract international interest and investment. Active participation by the healthcare industries will help ensure that there is a better understanding of the conditions needed for clinical trials with medical devices, and that opportunities for trialling innovative products and procedures are maximised.

5.14 Healthcare Technology Co-operatives (HTCs) – key output 5

Government and industry will work together to develop a suitable academic centre of excellence as a pilot HTC to pioneer specialist techniques in patient treatments in order to inform future development.

The Task Force considered that the concept of bringing together leading experts from clinical practice, academia and industry to collaborate on innovative procedures was very worthwhile. Government and industry will explore this further and undertake work leading to a pilot exercise.

5.15 UK as the regulatory lead in the EU and internationally – key output 6

Maximise UK influence in regulatory matters in the EU and other international forums, in consultation with industry, across all relevant issues to:

- *help ensure regulation and enforcement are appropriate*
- *maintain high standards of patient safety*
- *provide a stable legislative framework in the UK*

²⁶ *Strengthening Clinical Research* (October 2003) – www.dh.gov.uk/publications

²⁷ The BIGT report *Improving National Health, Increasing National Wealth*, published in November 2003 (see www.dti.gov.uk/bio-igt/bio-igt-index.html), included a number of recommendations aimed at improving the UK environment for the development of bioscience. One of the recommendations was for a national clinical trials agency to support better quality and more effective trials in the NHS. DH has taken this work forward through the establishment of UKCRC.

The MHRA, as the UK regulatory body for devices, is the main focus for the development of this key recommendation with the appropriate involvement of industry. The legislative framework for devices emanates largely from the EU and developments in this area are therefore generally governed by progress at a European level. It is important that the regulatory environment is appropriately balanced, giving priority to public health and patient safety while not stifling innovation. This balance is particularly relevant with regard to new and emerging technologies. Good communication between industry and MHRA is essential to the development of an effective UK position. MHRA will continue to develop its dialogue with industry on key issues such as the European Medical Devices Directives, the regulatory aspects of clinical investigations, human tissue engineering.

5.16 **Export strategy and international trade – key output 7**

Whilst continuing to service healthcare exporters in all markets, UK Trade and Investment (UKTI) will focus its strategic activities and resources in favour of the USA, Germany, France, Japan and China in relation to the devices industry. A watching brief will be maintained on developments in India. A range of key supporting initiatives have also been identified to promote export opportunities.

An **international export strategy** document has been developed and agreed. This will form the centrepiece for helping companies improve their performance in export markets by collectively galvanising efforts towards the priority countries. The strategy has already been circulated to government officials stationed overseas who deal with commerce, and the focus of activity is beginning to shift. UKTI has also confirmed that under recent plans healthcare will remain a priority area for development.

Improvements have been made to **co-ordination** within Government on export trade matters in the medical devices sector. Following discussions with the Department for International Development (DfID), mechanisms have been put in place for information on international development programmes of interest to medical device companies to be passed to UKTI to share with industry.

British Healthcare is developing a **map of regional activities** involving medical devices. This will be available on its website and will be kept up to date.

UKTI is to pilot a new template for **collecting and communicating healthcare sector information in target markets overseas** and has also arranged a briefing course for commercial staff from key markets during March 2005 to develop their knowledge of the UK healthcare industry.

DH International will put in place a mechanism to proactively **promote the NHS overseas** and disseminate positive news about the health and social care services.

The **indicators** to be compiled as part of a broader HITF exercise to collect data on the industry include exports and will provide valuable information in future on the industry's performance in overseas markets (see paras 5.19 *et seq.* and **Annex D**).

5.17 **Communication with patients/public to improve understanding of benefits and risks of medical devices – key output 8**

Increase the general understanding and appreciation of the role medical devices and technologies play in public health, by more effective communication to health professionals, social care personnel, patients, service users and the public of the risk:benefit profile and the regulatory system for devices.

MHRA has incorporated this into its new Agency communications strategy and implementation will be effected through various activities to be developed by the Agency in liaison with industry and other stakeholders. The Task Force was mindful of the Government's policy to provide information to patients about their healthcare choices and the move towards increasing patient power. The Task Force recommends involvement by the National Patient Safety Agency (NPSA) and clinicians to enhance the credibility of information programmes with the public.

5.18 **Training and education – key output 9**

Work towards improving training and education on medical devices for NHS staff and strengthening linkages between the NHS, its education partners, purchasers, device evaluation staff and industry, to support the spread of best practice in the competent and safe use of medical devices through:

- *consideration of initial and ongoing training and education needs as part of the procurement process where appropriate, eg for new technologies*
- *exploration with Skills for Health of how to raise the profile of competencies in the use of medical devices and technologies*
- *consideration of the development and use of learning programmes/tools*
- *in the longer term, the introduction of electronic staff records to ensure that records of key skills are transferable as staff move around the NHS*

This is a wide-ranging recommendation that requires the involvement of many stakeholders. It emerged in general terms from Working Groups 1, 2 and 3 and is important because it underpins progress on HITF objectives in a number of key areas, in particular supporting the safe use of novel products and technologies in the NHS. Companies make a valuable contribution to training NHS staff, particularly where innovation is involved, but there is only limited information available about the scale or nature of this contribution. The Task Force emphasised the need for company training to be generic and impartial, not associated with commercial marketing strategies. It acknowledged that more detailed development was needed to clarify the way forward, recognising that there are many stakeholders. DH will work with industry to analyse a specific area, so as to gain an understanding of sources of training and education as a precursor to establishing future needs.

Industry metrics

5.19 During the time that the Task Force was developing its outputs, DTI was working with DH and industry to put forward proposals for some meaningful metrics on the healthcare sector. All were agreed that the resources required for data collection would be kept to a reasonable level and that initially the metrics should be kept as simple as possible. On the basis of DTI's findings, the Task Force agreed that the following data should be collected annually (source of information is in brackets beside each indicator):

Output and economic profit

- UK production (Office for National Statistics (ONS) data)
- exports (ONS data)
- economic profit (ONS data plus DTI estimate of cost of capital)

Value added and productivity

- sector employment (ONS data)
- value added per employee (ONS data)

R&D and innovation

- total R&D spend (leading companies only – DTI data)
- R&D as a percentage of sales (leading companies only – DTI data)
- number of patents awarded (database search – DTI/Patent Office)

- number of clinical investigations approved by MHRA (MHRA data)
- number of licensing and spin-out agreements signed by the NHS (to be collected by the new Innovation Centre when it comes into operation)

Size and quality of market

- total size of UK market (ONS data)

In addition the new Device Evaluation Service could contribute to data collection on technology uptake, once it is operating within the NHS PASA.

- 5.20 DTI will assist ABHI and DH with the collection of this data in future years. DTI will assemble these metrics once a year. There should be no need for new business surveys or use of external contractors to collect this data. More details are in Annex D and its appendices.

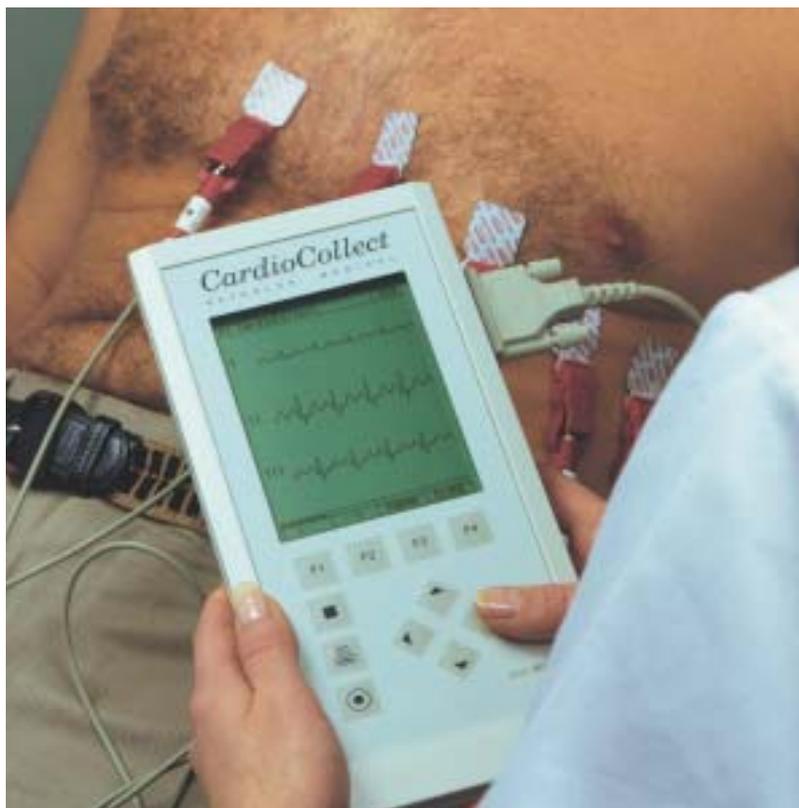
Inward investment and international trade

- 5.21 UKTI is committed to encouraging greater innovation within UK industry and has a number of activities aimed at attracting high-quality inward investment, including partnerships which can inject, quickly, the benefits of global innovative product and practice into health and social care service delivery.
- 5.22 DTI has commissioned an independent study analysing the relative competitiveness of six leading sub-sectors of the medical device industry to coincide with HITE. The six sub-sectors are:
- orthopaedics and implantables
 - respiratory and electromedical equipment
 - advanced wound management
 - radiotherapy equipment
 - imaging equipment
 - in vitro diagnostics

- 5.23 The study seeks to identify the current status of the UK supply side and its competitive position when compared against international benchmarks. The report is expected to be published before the end of 2004 and will provide for the first time valuable data that could be used to inform future trade policy in the medical devices sector. The Task Force would therefore like to see the creation of a government strategy group, made up of senior representatives from DH, UKTI and DTI, to take forward the assessment of the current UK medical devices supply sector and identify potential areas for further inward investment from the global supply market.

Summary

- 5.24 The position on developing and implementing the key outputs is summarised in the table opposite.

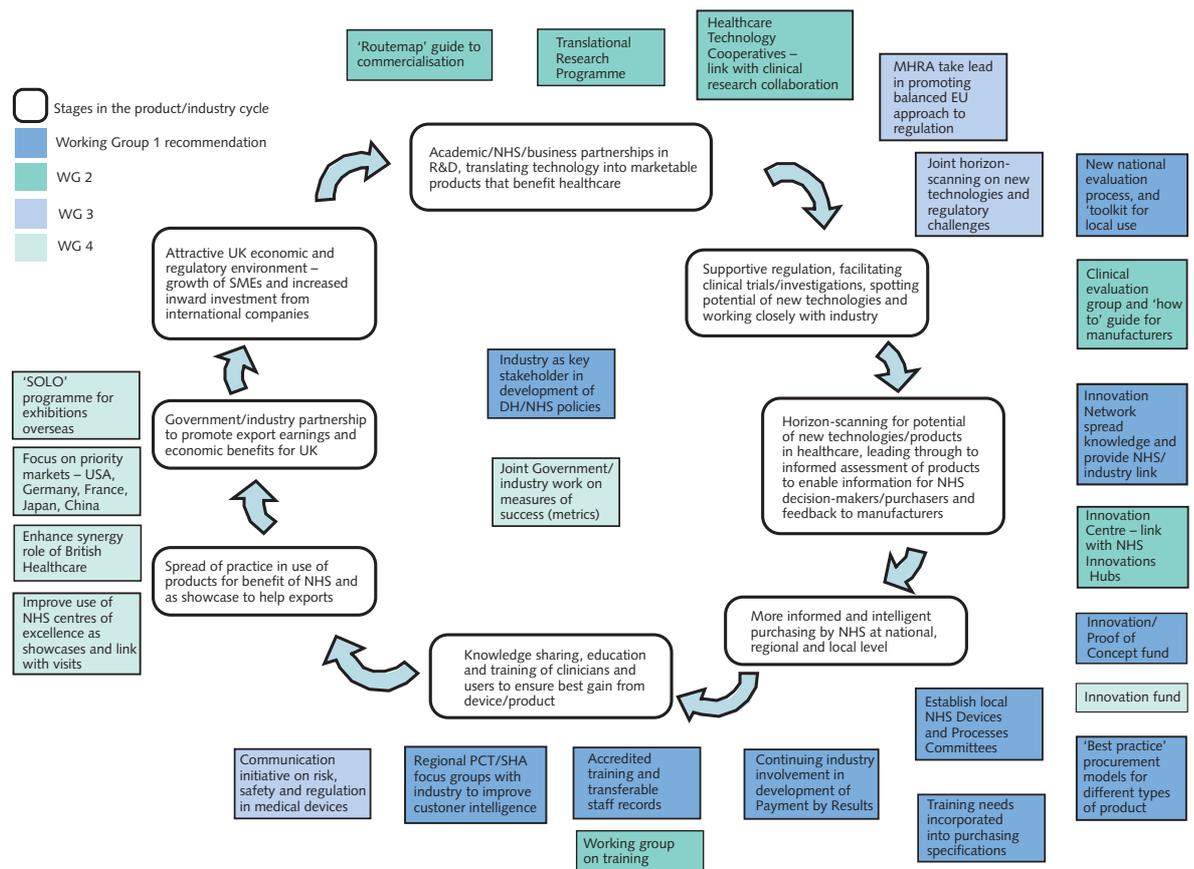


Key output	Current status	Outstanding issues – lead responsibility
1	Preparations underway to transfer existing DES from MHRA to PASA (including amendment to Trading Fund Order)	Development of future service – DH and other key stakeholders
2	Plans to work towards the development of a new Innovation Centre in an appropriate organisation agreed in principle with key stakeholders	Structural detail, governance and funding arrangements to be defined – Government and industry to consider Analysis of impact on NHS to be produced by DH
3	Procurement processes being adapted	To be incorporated in the design and working arrangements of new PASA and collaborative procurement hubs – DH
4	Forms part of UKCRC programme	Work programme to be defined and implemented – UKCRC Board Industry to engage proactively
5	Preliminary work to identify pilot agreed	Existing centres of excellence to be identified and suitable candidates selected for pilot – DH Funding arrangements – Government and industry to determine
6	MHRA and industry dialogue to develop UK position developing	Strengthen existing dialogue – MHRA and industry trade associations
7	Export strategy developed and disseminated and work on other supporting initiatives underway	Discussions to be arranged on best ways to focus UKTI's resources – Government
8	Incorporated into the objectives of MHRA's new strategy on communications	Specific actions to deliver to be defined – MHRA in liaison with industry and other stakeholders
9	Work in progress to develop improvements	To be incorporated as best practice for NHS – DH Engage with Skills for Health on occupation standards – DH Define industry's contribution by examination of training in a specific therapeutic area – DH and industry

6. Conclusion

6.1 Looking back at what has been achieved over the last year, the Task Force believes that it has achieved a major step forward. The HITF agenda was an exacting one and it would have been easy to produce a list of aspirations rather than proposed solutions. It is to the Task Force’s credit that it did not allow this to happen, but instead focused on translating the recommendations put forward by the Working Groups into proposals for action. Figure 3 below captures the key elements and illustrates how they will be integrated together to support the various stages of product development through to an improved and more personalised service for patients and service users.

Figure 3 – Integration of key recommendations



6.2 Because it adopted a practical approach, the Task Force has achieved a set of workable proposals which encompasses the vast majority of recommendations from the Working Groups and shapes them into a rational strategy within an integrated framework. This includes some major changes to existing procedures and introduction of new structures at operational and central levels. In addition, regular dialogue and sharing of information between all stakeholders will be at the heart of new working

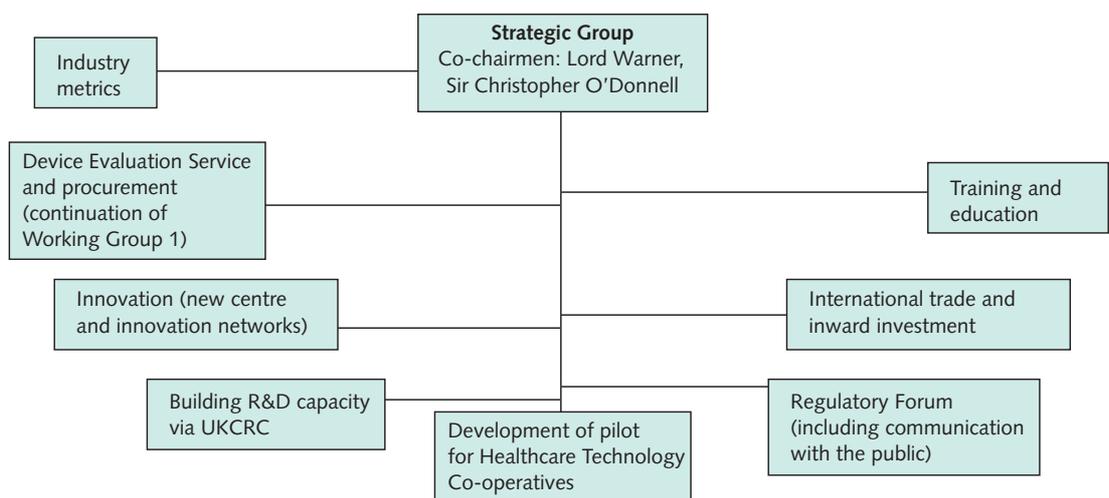
arrangements. The commitment to collect and publish metrics about the industry is a first for this sector. It will provide valuable commercial data for Government and for companies, and facilitate the evaluation of the development of the sector.

- 6.3 Although it will inevitably take some time to have the expected impact, the Task Force is confident that benefits for patients, the NHS and the social care system, industry and the economy will ensue.

Next steps

- 6.4 The strategy that has been proposed and the actions already taken to progress these demonstrate the Task Force’s commitment to see through the changes that have been recommended. To underpin this, both Task Force co-chairmen, Lord Warner and Sir Christopher O’Donnell, have agreed to preside over a new joint group which will oversee the continuing progress of implementation for a period of two years (see Figure 4 below). Participants will be drawn from key decision-makers in Government, industry and other interest groups as appropriate. Its remit will be to oversee and progress the work programme arising from HITF.
- 6.5 Information on these developments will appear on the DH website (www.advisorybodies.doh.gov.uk/hitf) in due course.
- 6.6 Far from being the end of the exercise, the Task Force believes this is the start of the development of relationships and networks at strategic and operational levels. Similar initiatives are under way or being contemplated in other countries and there is very keen international interest in HITF and its achievements. The Task Force hopes it has provided a good model for others to follow.

Figure 4 – HITF review and monitoring arrangements



Annex A

HEALTHCARE INDUSTRIES TASK FORCE (HITF)

Terms of reference

The Healthcare Industries Task Force (HITF) will bring together government and industry leaders to identify steps to develop, stimulate the growth and performance of the UK healthcare industry and maximise the benefit to patients from healthcare products, in particular to:

- increase healthcare professionals' and patients' access to appropriate and innovative medical technology across all healthcare services
- foster and facilitate an improved environment for product research, development, clinical evaluation and related manufacturing investment
- provide a clear framework of regulation and information that serves patients
- promote international trade in products in this sector

Co-chaired by a Government Minister and a leading Chief Executive, HITF will within a year report and deliver recommendations which should benefit patients, encourage the best use of NHS resources and stimulate science and industry in the UK to improve growth in manufacturing, investment, employment and exports. The Task Force will be assisted by working groups bringing together experts on each area. Four Working Groups are planned, each with co-chairs from Government and industry. The Task Force will produce a report and recommendations within a year.



WORKING GROUP 1 – MARKET ACCESS

Terms of reference

The Market Access Working Group will consider the factors around the UK market for products from the healthcare industries, specifically to:

- assess the trends in NHS use of healthcare technology, particularly new technology
- consider ways in which industry and Government/NHS might work together more effectively to assess the clinical and cost effectiveness of new medical devices and equipment, and facilitate their increased uptake in order to improve healthcare outcomes for patients
- identify specific barriers preventing optimum use of new technologies, such as training or procurement processes, and propose steps to overcome any such barriers
- consider the impact of changes planned or under way in the NHS (eg PCTs' purchasing role, greater plurality of provision, introduction of "Payment by Results"), and cast recommendations in the context of these changes

WORKING GROUP 2 – R&D AND INDUSTRIAL BASE

Terms of reference

The R&D and Industrial Base Working Group's objective is to consider and make recommendations on how to strengthen the UK as an attractive location for R&D and manufacturing investment in the healthcare sector. In particular, the working group will:

- identify the strengths and weaknesses of existing arrangements for promoting R&D partnerships between the NHS, academia and industry to bring promising new technologies to market
- develop proposals for encouraging clinical trials in the NHS, building on experience as appropriate in the pharmaceutical and biotech fields
- consider whether the UK's areas of industrial strength in this sector are sufficiently aligned with the science and research base, and what steps might be taken
- assess the UK's position as a base for industry investment in R&D and manufacturing, and consider steps to attract greater levels of investment
- assess skills issues which have an impact on innovative performance in the UK healthcare industry and options available to improve the situation

WORKING GROUP 3 – REGULATORY ISSUES

Terms of reference

The Regulatory Issues Working Group will look at the regulatory environment for medical devices and public health in the UK, identify any issues which would benefit from joint working between Government and industry, both currently and in light of forthcoming regulatory developments, and agree a joint approach. In particular this will require consideration of:

- the developing relationship between the recently established Medicines and Healthcare products Regulatory Agency (MHRA) and the industry
- the UK's contribution to the EU and other international institutions on legislative proposals and discussions, particularly in connection with tissue engineering, the recent review of the Medical Devices Directives and promotion of standards
- regulatory issues posed by emerging technologies and advances in information technology
- transparency and provision of information about medical devices

WORKING GROUP 4 – INTERNATIONAL TRADE

Terms of reference

The Working Group will consider how Government, in conjunction with British Healthcare, can assist the healthcare manufacturing industry in particular to improve their international trade performance and to submit recommendations for possible inclusion in the operational plan. Key objectives are:

- to deliver a clear and cohesive strategy to promote greater co-ordination between export organisations
- to prioritise key markets, with a view to developing market strategies and galvanising resources towards specific countries
- to develop robust and effective mechanisms to enhance market penetration of priority country markets

Annex B

HITF MEMBERS AND PARTICIPANTS

Douglas Alexander	Minister of State for Trade, Investment and Foreign Affairs (from September 2004)
Ameer Ally	ConvaTec Ltd UK
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Theresa Ashford	Association of British Health-Care Industries (ABHI)
Bob Atwill	Corin Ltd
John Atwill	Philips Medical Systems UK Ltd
Gordon Aylward	Association of British Health-Care Industries (ABHI)
Ruth Baillie	Becton Dickinson UK Ltd
David Ball	Gyrus International Ltd
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Tony Bates	NHS Innovations
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Jo Billingham	ConvaTec Ltd UK
Bob Bish	Healthcare Sector – Global, UK Trade and Investment (UKTI)
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Paul Brice	Medicines and Healthcare products Regulatory Agency (MHRA) (Devices)
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David Brown	Tyco Healthcare UK Ltd
Paul Brown	Technovent/Medilink
Malcolm Carlisle	Eschmann Equipment
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Dr Iain Chambers	Institute of Physics and Engineering in Medicines (IPEM)

Philip Charlton-Smith	Sumed International (UK) Ltd
Michael Clancy	Hill-Rom Ltd
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Graham Collyer	Shiloh plc
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Geoff Cox	Huntleigh Technology plc
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Professor Sir Ara Darzi	Department of Health Advisor on Surgery
Professor Sally Davies	Director of Research and Development, Department of Health
Tony Davis	Medilink West Midlands
Dr Paul Debenham	LGC Ltd
Professor Dave Delpy	Vice Provost, University College London, Department of Medical Physics and Bioengineering
Lindsay Dibden	HG Capital
Andrew Dillon	Chief Executive, National Institute of Clinical Excellence (NICE)
Alan Driver	Partnerships UK
Gunter Dombrowe	Siemens Medical Solutions
Sue Dunkerton	Medical Devices Faraday Partnership
Duncan Eaton	Chief Executive, NHS Purchasing and Supply Agency (PASA), Co-chair of Working Group 1
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Peter Ellingworth	ConvaTec Ltd UK
John Emanuel	Pax Technology Transfer Ltd

Andrew Ferguson	Blease Medical Equipment Ltd
Professor Martin Ferguson-Pell	Foundation for Assistive Technology (FAST)
Dr Patrick Finlay	Armstrong Healthcare Ltd
Clement Fitzgerald	Randox Laboratories Ltd
Bernard Flynn	Scarborough & NE Yorkshire Healthcare NHS Trust
Richard Foggie	Department of Trade and Industry (DTI)
Elizabeth Fothergill	Pennine Healthcare Ltd
Chris Francis	Cardionetics Ltd
Sally Fryer	Office of Government Commerce (OGC)
Shaun Gallagher	Former Head of Industry Sponsorship, Department of Health
Sam Gallop CBE	emPower (patient representative)
Katrina Gatley	Association of British Health-Care Industries (ABHI)
David Gilbert	Renal National Service Frameworks
Dr Helen Glenister	Director, National Patient Safety Agency (NPSA)
Jacqui Gray	Wales Office of R&D
Stephen Gray	Multi-Ed Medical
Dr Peter Greenaway	Co-chair of Working Group 2
Nic Greenfield	Workforce Directorate, Department of Health
Adrian Griffin	Johnson and Johnson Medical Ltd
Brian Godfrey	Medical Devices and Equipment Northern Ireland
Andy Goldberg	Medical Futures
Dr Nigel Gough	Huntleigh Technology plc
Graeme Hall	Brandon Medical Co Ltd
Martin Hall	Sector Manager, Healthcare, UK Trade and Investment (UKTI)
Paddy Hall	Microsulis Medical Ltd
Professor Aidan Halligan	Deputy Chief Medical Officer, Department of Health
Mike Halworth	Association for Clinical Biochemists (ACB)
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Dimitrios Hatzis	Commercial Directorate, Department of Health
Kate Hinks	DH International
Dr Christopher Hodges	CMS Cameron McKenna, Co-chair of Working Group 3
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Dr Emily Horwood	Engineering and Physical Sciences Research Council (EPSRC)
Dr Jennifer Houghton	Engineering and Physical Sciences Research Council (EPSRC)
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Philip Kennedy	Eschmann Equipment
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Mike Kingston	Cuxson Gerrard and Co Ltd
Dr Louise Knight	Centre for Research in Strategic Purchasing and Supply, University of Bath
Mike Kreuzer OBE	Association of British Health-Care Industries (ABHI)
Dr Peter Lawes	Apatech Ltd
Geoff Lee	GE Healthcare

Berenice Levenez	Commercial Directorate, Department of Health
Professor Richard Lilford	Birmingham University
Les Lindsay	KCI Medical Ltd
Colum Lowe	National Patient Safety Agency (NPSA)
Professor Gareth Lloyd-Jones	Medilink Yorkshire and the Humber
Dr Susanne Ludgate	Medicines and Healthcare products Regulatory Agency (MHRA) (Devices)
Dr Linda Magee	North West Regional Development Agency
Naseem Mahtey	Industry Sponsorship, Department of Health
Maynard Marwhinney	Northern Ireland R&D Office
Darian McBain	NHS Purchasing and Supply Agency (PASA)
Mark McIntyre	Boston Scientific Ltd
Judith Mellis	Association of British Health-Care Industries (ABHI)
Colin Morgan	Johnson and Johnson Medical Ltd, Co-chair of Working Group 1
Janet Morgan	National Assembly for Wales
Dr Steve Morgan	University of Nottingham, Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH)
Geoff Morris	Medtronic Ltd and ABHI Chairman
Galvin Mould	Intavent Orthofix Ltd
Phillip Needham	Cardionetics Ltd
Ken Newnham	British Healthcare (BH)
David Nixon	NHS Purchasing and Supply Agency (PASA)
Mike O'Brien	Minister of State for Trade, Investment and Foreign Affairs
Sir Christopher O'Donnell	Chief Executive of Smith and Nephew plc, Co-chair of Task Force
Margaret O'Donovan	National Patient Safety Agency (NPSA)
Sue Osborn	Joint Chief Executive – National Patient Safety Agency (NPSA)
Vince Osgood	Engineering and Physical Sciences Research Council (EPSRC)
Mark Outhwaite	NHS Modernisation Agency (MA)

Steve Owen	Medicines and Healthcare products Regulatory Agency (MHRA) (Devices)
Dr Claire Packer	National Horizon Scanning Centre, University of Birmingham
Ian Parker	NHS Purchasing and Supply Agency (PASA)
Margaret Parton	Department of Trade and Industry (DTI)
Professor Sir John Pattison	Department of Health, Director of Research (retired)
Colin Pearson	Clinical and Cost Effectiveness, Department of Health
Liz Pearson	NHS Purchasing and Supply Agency (PASA)
David Peddy	Surgical Instruments Group Holdings Ltd
Trevor Perry	GE Healthcare
Andrew Phair	Craven, Harrogate and Rural District Primary Care Trust
Martin Phelan	UK Trade and Investment (UKTI)
Richard Phillips	Medtronic Ltd
Dr Wendy Phillips	Centre for Research in Strategic Purchasing & Supply, University of Bath
David Pink	Chief Executive, Longterm Medical Conditions Alliance
Ian Pinn	Beckman Coulter UK Ltd
Richard Pitt	University Hospitals of Leicester NHS Trust
Dr Klaus Pollmann	Roche Diagnostics
Clive Powell	Association of British Health-Care Industries (ABHI)
Alan Press	Kimal plc
Professor Chris Price	Bayer
David Purnell	Association of British Health-Care Industries (ABHI)
Suzanne Raymond	GE Healthcare
Clive Ridgwell	Zimmer Inc
Eileen Robertson	Financial Flows, <i>Payment by Results</i> project, Department of Health
Andrew Rudd	NHS Purchasing and Supply Agency (PASA)
Andrew Rumble	Brandenburg UK
Lord Sainsbury	Minister for Science and Innovation, Department of Trade and Industry (DTI)

Philip Salt	Salts Healthcare Ltd
Evi Salvanou	Association of British Health-Care Industries (ABHI)
Dr George Sarna	Medical Research Council (MRC)
Liz Scanlon	Leeds NHS Trust
Julian Schild	Huntleigh Technology plc
Dr Sandeep Shah	SSL International plc
Dr Julie Shelton	Queen Mary College, London University
David Schild	Huntleigh Technology plc
Paul Sim	Association of British Health-Care Industries (ABHI)
Peter Simpson	British Association of Day Surgery (BADs)
Barry Skeet	Tyco Healthcare UK Ltd
Stuart Smalley	DH International, Co-chair of Working Group 4
Mike Stevens	Scottish Executive Health Department
Philip Stimpson	Mediwatch
Bob Stock	Scottish Executive Health Department
Graham Stokoe	Guidant Ltd
Daniel Storey	HM Treasury
Professor Robert Stout	R&D Office Northern Ireland
Andrea Sutcliffe	National Institute for Clinical Excellence (NICE)
Steve Swanscott	Beckman Coulter UK Ltd
Chris Theaker	NHS Purchasing and Supply Agency (PASA)
Jim Thompson	Mediwatch plc
Dr Gary Thorpe	Birmingham University
Tim Torlot	Technology and Sector Partnership, UK Trade and Investment (UKTI)
Paddy Turnbull	TriVirix International Ltd
Stuart Tyson	Department for International Development (DfID)
Bob Urie	Mediplus Ltd
Dr Helen Walker	Centre for Research in Strategic Purchasing & Supply, University of Bath
Jonathan Wackett	Vida Capital

Emma Ward	Department of Trade and Industry (DTI)
Lord Warner	Under Secretary of State for Health (Lords), Co-chair of Task Force
John Warrington	NHS Purchasing and Supply Agency (PASA)
Lila Webley	Association of British Health-Care Industries (ABHI)
Oliver Wells	Association of British Health-Care Industries (ABHI), Co-chair of Working Group 2
Chris Widnall	Bibby Sterlin Ltd
Amanda Wilde	ConvaTec Ltd UK
Sue Wilkin	Medicines and Healthcare products Regulatory Agency (MHRA) (Medical Device Evaluation Service and Publications)
John Wilkinson	Association of British Health-Care Industries (ABHI)
Michael Wilkinson	Department of Health (Joint Secretariat)
Rachael Willey	NHS Purchasing and Supply Agency (PASA)
Alun Williams	QinetiQ
Doris-Ann Williams	British In Vitro Diagnostics Association (BIVDA)
Professor David Williams	Loughborough University
John Williams	Vice-President, Royal College of Surgeons/Chairman, Committee on the Safety of Devices
Susan Williams	Joint Chief Executive, National Patient Safety Agency (NPSA)
Mark Willcox	Sidhil Ltd
Professor Kent Woods	Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA)
John Wotton OBE	Chiltern Invadex Ltd
Dr Dennis Wright	The North West London Hospitals NHS Trust
Sylvia Wyatt	NHS Confederation
Professor Jeremy Wyatt	National Institute for Clinical Excellence (NICE)
Carwen Wynne-Howells	National Assembly for Wales
Mike Yon	Smiths Medical
Dr George Zajicek	Axis-Shield plc

Annex C

EXAMPLES OF MEDICAL DEVICES AND EQUIPMENT

Anaesthetic machines and monitors
Apnoea monitors
Artificial eyes
Artificial limbs
Blood transfusion and filtration devices
Breast implants
Cardiac monitors
Cardiopulmonary bypass devices
Clinical thermometers
Condoms
Contact lenses and prescribable spectacles
CT scanners
Defibrillators
Dental equipment and dentures
Dental material and restoratives
Diagnostic imaging equipment
Diagnostic kits and tests
Dialysers
Electrosurgery devices
Endoscopes
Enteral and parenteral feeding systems
Equipment for disabled people
Examination gloves
Foetal monitors
Hearing aids and inserts
Heart valves
Hospital beds
Hydrocephalus shunt
Incontinence pads
Infusion pumps and controllers
Intra-uterine devices

Intravascular catheters and cannulae
Laboratory equipment (as covered by Regulations)
Lithotripters
Medical lasers
Medical textiles, dressings, hosiery and surgical supports
Orthopaedic implants
Operating tables
Ostomy and incontinence applicances
Pacemakers
Physiotherapy equipment
Prescribable footwear
Pressure sore relief devices
Radiotherapy machines
Resuscitators
Scalpels
Special support seating
Sphygmomanometers
Stents
Suction devices
Surgical instruments and gloves
Sutures, clips and staples
Syringes and needles
Ultrasound imagers
Urinary catheters, vaginal speculae and drainage bags
Ventilators
Walking aids
Wheelchairs

This list is not exhaustive, but is intended to illustrate the range of products manufactured by the healthcare industries.

Annex D

HEALTHCARE INDUSTRY METRICS

The Department of Trade and Industry (DTI), the Department of Health (DH) and the Association of British Health-Care Industries (ABHI), who acted on behalf of the industry as a whole) agreed that it was important to come to a shared understanding within HITF of what constituted the medical device industry, and how to measure its performance and progress. It was agreed to use the definition in the European Medical Devices Directive (MDD) to determine what manufacturers should be included.

It was agreed that the metrics for measuring progress should be as helpful as possible in measuring the industry's progress. Success indicators for this sector were to include a growing, profitable business base with high value output per employee, a high level of R&D and innovation, rapid introduction of new innovative products to the market and an expanding, demanding and intelligent customer. The metrics should therefore seek to measure:

- output and economic profit
- value-added and productivity
- R&D and innovation
- size and quality of market

Because statistics are not collected nationally on the basis of the legal definition of medical devices, some work to identify the appropriate data would be required. However, it was agreed by all parties that the burdens imposed by data collection for the metrics should be kept as low as possible.

DTI, DH and ABHI successfully developed a limited number of informative metrics for the sector. Although the data will not be perfect and will depend on certain estimates and corrections being made, it should be accurate enough to illustrate trends and give indications of the size and economic importance of the sector.

DTI will collate the necessary figures from official sources for 9 of the proposed 11 measures once a year. It will discuss and agree with ABHI and DH any estimates and corrections to be used in its calculations. This will be done annually in November. DH will provide data on clinical investigations, and on NHS licensing and spin out agreements once the new Innovation Centre comes into operation. Other data thought to be useful may be included in the exercise at a future date. There should be no need for industry surveys or external data collection agencies, though ABHI may choose to ask some of its members for information to verify the estimates and corrections being used. The metrics will then be distributed to all HITF participants by e-mail every December.

Current data for 9 of the proposed 11 metrics can be found in appendices to this annex.

Definition

DH, DTI and ABHI agree that the most appropriate definition of medical devices for the purposes of this exercise is that contained in the European Medical Devices Directive (Council Directive 93/42 of 1993). The Directive states in Article 1(2):

‘medical device’ means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

This definition has the advantage of being broad and inclusive for all manufacturers of diagnostic, therapeutic and assistive devices and materials. It is also common to all European Union countries. It does **not** cover suppliers of healthcare services or pharmaceuticals. It **only** covers suppliers of laboratory equipment, IT equipment and services and raw materials such as chemicals, metals and plastics to the extent that their products are incorporated into diagnostic, therapeutic or assistive devices, which are caught by the EU Directive(s). It does **not** cover distributors or retailers of medical equipment and materials.

Sources of data

Office for National Statistics (ONS)

ONS collects a range of statistical data from UK companies. This is divided into industry data and product data.

a) Industry data

Heading 33.1 is entitled “manufacture of medical and surgical equipment and orthopaedic appliances”, which covers most manufacturers of medical devices. All companies registered under heading 33.1 can be considered manufacturers of medical devices.

Heading 35.43 is entitled “manufacture of invalid carriages”. All companies registered under this heading can be considered manufacturers of medical devices.

Heading 24.42/2 is entitled “manufacture of pharmaceutical preparations – manufacture of non-medicaments”. It covers vaccines and antiseras, on the one hand, which are not medical devices, and on the other hand, in vivo diagnostic reagents, dental cements, surgical gels, dressings, waddings, bandages, surgical catgut and first aid kits, which arguably should fall within the medical device definition. Unfortunately, industry data is not available from ONS at the more detailed level, but using product data from ONS and company data available to DTI from other sources, it is possible to calculate what proportion of UK output under heading 24.42/2 consists of vaccines and antisera. DTI thus calculates that 66.25% of the output under this heading is “medical devices” and the rest is not.

Heading 24.66 is entitled “other chemical products not elsewhere classified”. Within this category, two sub-headings cover potential medical devices – diagnostic and laboratory reagents and dental pastes and impression compounds respectively – but amongst a plethora of other sub-headings for other chemical products. Industry data is therefore not available from ONS for the in vitro diagnostics sector. Product data indicates that sales of medical device manufacturers under this heading reached £429m in 2003, 27.34% of total sales under the 24.66 heading.

Industry data offers figures on (inter alia) number of companies, employment, turnover, cost of purchases of goods, services and materials, gross value added, taxes paid, capital expenditure, gross value added per head.

b) Product data

ONS product data uses the same broad classifications as industry data but information is made available at a much more detailed level. An attempt is also made, for each broad heading, to estimate ‘net carry-in’ of products manufactured by companies classified under other headings. For the 33100 heading, for example, this adds a considerable 16% to the UK sales figures for the sector.

Product data offers figures for UK sales, imports and exports and the size of the UK market.

Patent databases

Commercial databases provide information on the numbers of patents awarded in different fields of activity, by country. DTI and any other subscribers can search through Dialog and the Derwent World Patents Index for total numbers of patents granted in priority countries in areas of medical diagnostics, medical equipment and medical supplies.

DTI

DTI tracks R&D investment across all sectors, in absolute terms, on a per employee basis and as a percentage of sales. The analysis only covers the top 700 UK companies across all sectors, but this includes the top 32 healthcare technology companies, who probably account for the vast bulk of industrial R&D in the sector and should be representative.

The figures show healthcare R&D expenditure in the 32 companies rising to £331m in 2002/03, amounting to 6.8% of sales or £9,000 per employee. This was 2.0% of the R&D of the top 700 companies in the UK as opposed to 1.9% for healthcare in 2001/02. The £331m constituted an increase of 10% over the previous year and a rise of some 150% over the 1997 figure.

The figures may not fully incorporate all R&D carried out by foreign-owned companies in the UK, however, and in some cases medical device R&D is counted under another sectoral heading (eg R&D by Johnson & Johnson is recorded under the pharmaceuticals and biotechnology heading). Privately-owned companies may also not record their R&D expenditure in their annual accounts or it may not be picked up by the DTI trawl. However, with adjustments, the DTI figures offer an approximation of the picture for R&D in the medical device sector and permit a tracking of progress.

DTI similarly analyses value-added across a range of sectors for the top 800 UK companies. This analysis only covers five healthcare companies, however, so is not representative for this sector.

Independent analysis

Various City analysts have tried to pull together statistics for the medical equipment sector. They mainly focus on market growth trends by sub-sector and corporate development trends – which companies are growing, in which product areas – but also estimate UK market size, production figures and import and export data. The figures rarely cover the full range of medical device manufacturers covered by the EU definition. Most of the raw data is drawn from national statistics anyway.

Useful performance indicators

All parties are anxious not to preside over the collection of data and statistics for their own sake. The objective is to collect meaningful figures, which actually elucidate the state of the sector and map its progress. A balance must be struck between the value of statistical indicators and their ease of collection, but there is no point in collecting meaningless or misleading data.

DTI believes that the profile of long-term success in a sector such as medical devices would involve companies investing in R&D, becoming highly productive with strong value-added per employee, innovating and rapidly bringing new goods to market, and working with demanding, forward-looking and innovative customers to drive innovation further and faster in future. The following five categories of data are therefore proposed as offering a good insight into industry performance at reasonable cost in terms of data collection obligations.

a) Output and 'economic profit'

UK output figures give an indication of scale of activity in the sector. These figures should be easy to gather through ONS product and industry data.

Export data can also be gathered fairly easily and helps to track UK firms' ability to seize market opportunities outside the NHS.

It would be valuable to assess the economic value of UK output, rather than just its size. This can be done using industry data and adding a figure for estimated cost of capital. UK sales, minus operating costs minus cost of capital, would be a good metric for 'economic profit'. Most of this data is available through National Statistics, but it would require calculation, judgements over cost of capital and estimates for those parts of the industry only covered by subheadings in the industry data.

b) Value-added and productivity

'Value-added' measures sales minus cost of inputs. It can then be analysed on a per employee basis to measure productivity. National Statistics industry data gives a figure for value-added per employee, but estimates would have to be made for those parts of the industry only covered by sub-headings in the industry data.

Average wage is another useful indicator for productivity and economic value. When the average wage for a sector is compared with the average wage elsewhere in a full employment economy, this can indicate the extra value a sector is delivering compared with the value that would be offered by alternative employment. This indicator is relatively easy to produce, requiring only employment numbers and employment cost data.

c) R&D investment and innovation

DTI data on R&D across industry includes analysis of the 32 biggest spenders on R&D in the medical devices sector. This should be reasonably representative, although it may not capture the full R&D spend of private companies or non-UK multinationals, which may take place in the UK. The DTI figures on total R&D spend, on R&D as a percentage of sales, on a per employee basis and as a proportion of total UK industry are collectively useful indicators for the quantity of R&D in the sector.

An alternative is therefore to look at measuring rates of innovation by reference to the patent register. The number of UK patents awarded to those companies for whom R&D is being measured should, over time, give some indication of whether the R&D is leading to innovation.

A further useful metric would be the number of technology licensing agreements and spin-out company agreements signed by the NHS in any given year. This would offer some measurement of NHS innovation and capacity to commercialise such innovation, with obvious implications for the UK medical devices sector. The Innovation Centre being proposed under HITF could be tasked with collecting these figures from the NHS Innovations Hubs.

d) Quality and size of market

Industry states that the volume of purchases by the NHS, the willingness and ability of the NHS to collaborate on product development and technology validation and testing, and the willingness of the NHS to purchase innovative and high value-added products for patient benefit are important determinants of their global success. It therefore makes sense to try to measure trends in at least NHS product testing and procurement to assess how favourable such movements are.

The total size of the UK market is the first obvious indicator. This should be relatively easy to measure using product data from National Statistics, which measure output and imports and exports.

e) Other NHS metrics

Finally industry would benefit from any improvement to NHS performance indicators. Improved NHS metrics for enhancing patient outcomes and cost-effectiveness would lead to enlightened decisions about the cost-effectiveness of investment in new medical devices, which industry would welcome. For example, how to measure whether purchasing decisions about value are leading to optimal patient outcomes, how to measure the value of improved quality of life for patients and the impact on quality of life of purchases of medical devices, how to measure whether investment in clinical trials capacity is cost-effective in the long run, etc. These are complex metrics, which go beyond the HITF context, but which may be critical measurements of HITF's success in the longer term.

Appendix 1 Sales of medical devices*

	2000 (£m)	2001 (£m)	2002 (£m)
In vitro diagnostics and dental materials (ex category 24.66)**	781	761	738
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc (ex category 24.42/2)***	772	489	583
Invalid carriages (ex category 35.43)	181	173	200
Medical and surgical equipment (ex category 33.1)	2,411	2,531	2,993
TOTAL	4,145	3,954	4,514

*Total turnover, excluding VAT, of UK manufacturers

**27.34% of total sales in this category

***66.25% of total sales in this category

Appendix 2 Exports*

	2000 (£m)	2001 (£m)	2002 (£m)
In vitro diagnostics and dental materials (ex category 24.66)	448	501	648
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc (ex category 24.42/2)	411	521	502
Invalid carriages (ex category 35.43)	41	36	38
Medical and surgical equipment (ex category 33.1)	1,531	1,683**	1,869**
TOTAL	2,431	2,741	3,057

*Value of products exported from the UK

**Estimated that intra-EC exports increased at same rate as extra-EC exports as exact figures for intra-EC exports not available

Appendix 3 Economic profit from sales of medical devices*

	2000 (£m)	2001 (£m)	2002 (£m)
In vitro diagnostics and dental materials (ex category 24.66)**	109	96	61
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc (ex category 24.42/2)***	43	(21)	31
Invalid carriages (ex category 35.43)	10	20	8
Medical and surgical equipment (ex category 33.1)	331	322	446
TOTAL	493	419	546

*UK sales minus operating costs (cost of purchases of goods, materials and services plus employment costs) minus weighted average cost of capital applied to operating costs. Cost of capital is estimated here for the sake of argument to be 8%

**Calculated estimating 27.34% of total operating costs for this heading

***Calculated estimating 66.25% of total operating costs for this heading

Appendix 4 UK manufacturers' employment in the medical device industry in UK*

	2000	2001	2002
In vitro diagnostics and dental materials (ex category 24.66)	5,000	5,000	4,000
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc (ex category 24.42/2)	7,000	5,000	6,000
Invalid carriages (ex category 35.43)	1,000	2,000	2,000
Medical and surgical equipment (ex category 33.1)	31,000	37,000	34,000
TOTAL	44,000	49,000	46,000

*Does not include employment in sales, marketing and service operations of companies not manufacturing in the UK

Appendix 5 Value-added per employee*

	2000 (£000s)	2001 (£000s)	2002 (£000s)
In vitro diagnostics and dental materials (ex category 24.66)	60.8	54.5	52.8
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc (ex category 24.42/2)	40.2	28.5	36
Invalid carriages (ex category 35.43)	43.3	39.6	35.4
Medical and surgical equipment (ex category 33.1)	37.3	31.7	39.9
TOTAL (weighted average of above)	40.3	34.4	42.2

*Also excludes importers/service providers

Appendix 6 Total R&D spend

	2000/01 (£m)	2001/02 (£m)	2002/03 (£m)
'Healthcare' companies (as per DTI scoreboard)	256	300	332
Other sectors' spending on medical device R&D (estimated)*	25	42	49
TOTAL	281	342	381

*20% of total for Smiths, plus
60% of UK total for Johnson & Johnson, plus
25% of UK total for Bristol Myers Squibb, plus
100% of total for Axis Shield

Appendix 7 R&D as a percentage of sales

	2000/01 (%)	2001/02 (%)	2002/03 (%)
'Healthcare' companies (as per DTI scoreboard)	6.2	6.5	6.8
Other sectors* investing in medical device R&D (weighted average)	N/A	4.6	7.4
TOTAL (weighted average)	6.2	6.3	6.9

*as at Appendix 6 above

Appendix 8 Number of patents awarded

Total numbers of patents granted in priority application countries in areas of medical diagnostics, medical equipment and medical supplies:

Country of priority application	2000	2001	2002	2003
US	2,138	2,534	3,416	3,685
GB	180	183	198	211
Germany	663	703	750	727
France	168	157	167	193

Source: Dialog (Derwent World Patents Index)

Appendix 9 Size of UK market*

	2000 (£m)	2001 (£m)	2002 (£m)
In vitro diagnostics and dental materials (ex category 24.66)	675	742	656
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc (ex category 24.42/2)	765	399	549
Invalid carriages (ex category 35.43)	209	220	255
Medical and surgical equipment (ex category 33.1)	3,525	4,095**	4,547**
TOTAL	5,174	5,456	6,007

*Equals UK sales plus net balance of imports over exports. Import figures from trade data are adjusted to take account of sales, general, administrative (SGA) and service costs in the UK as well as profit. It is estimated that SGA, service costs and profit should reach about 40% of the total price of a medical device on the UK market, so basic import figures have been increased by 66.67% before calculating trade balance

** Estimated that intra-EC exports increased at same rate as extra-EC exports as exact figures for intra-EC exports not available

Annex E

TABLE OF WORKING GROUP RECOMMENDATIONS (JUNE 2004)

Working Group 1 – Market Access		Addressed by key output (see pages 1–4)
1	Develop a nationally agreed/accepted evaluation methodology and toolkit that can be used locally to ensure consistent decision-making	1
2	Ensure that evaluation methodology recognises the different approaches necessary for evaluating ‘disruptive/transformational’ compared to ‘incremental’ innovations	1
3	Ensure evaluation results are shared throughout the NHS	1, 2, 3
4	The DH and NICE should develop a ‘stronger’ work-stream on medical device appraisals via a focused organisation	1
5	Develop nationally agreed/accepted best practice models for procurement processes	3
6	Establish Trust Medical Devices and Processes Committees (based on the current Drugs and Therapeutics Committee model) to include stakeholders from within local healthcare communities	3
7	Raise the ‘professional’ profile of procurement in the NHS	3
8	Improve communications between the NHS and industry on NHS requirements and procurement work-plans	3
9	Develop a nationally agreed/accepted methodology and toolkit for introducing new technologies that can be used locally to ensure consistent decision-making	1, 2, 3
10	Develop a nationally agreed approach to new technologies that require a co-ordinated approach higher than at Trust level or that appear to add significant cost to the NHS	1, 2, 3
11	Consider the need for an ‘innovation fund’ or a ‘proof of concept fund’ to fast-track selected innovations	2
12	Develop PCT/SHA regional focus groups with industry to improve the ‘informed customer’ approach	3

Working Group 1 – Market Access		Addressed by key output (see pages 1–4)
13	Develop an ‘innovation network’ or ‘knowledge brokerage hub’	2
14	DH should commission research to define best practice models in adoption and implementation	N/A
15	Create a transferable staff record of training/skills for the use of medical devices	9
16	Create nationally accredited training schemes for the use of medical devices	9
17	Emphasise employers’ responsibilities with regard to ensuring staff are appropriately trained and qualified	9
18	Ensure education/training requirements are incorporated into purchase specifications	3, 9
19	Scope the requirements for introducing e-learning/e-training for device usage	9
20	Industry should be considered a key stakeholder and appropriately represented for the Healthcare Resource Group (HRG), National Innovations Classification (NIC) and clinical language (snomed) development processes of the <i>Payment by Results (PbR)</i> programme	3
21	DH should develop a clear, transparent process for enabling stakeholders to contribute suggestions for incorporating innovations or new technologies into the national tariff	3
22	SHAs should be encouraged to undertake, influence and manage the communication of <i>PbR</i> within the NHS and, in particular, their clinical community	3
23	Evaluation and monitoring of <i>PbR</i> should consider the impact on technology uptake investment, patient outcomes and quality of care	3
24	Industry should be considered a key stakeholder and involved in development of DH/NHS policies as a matter of course	1, 2, 3, 4

Working Group 1 – Market Access		Addressed by key output (see pages 1–4)
25	A national workshop should be held involving the NHS, users, DH and industry to discuss the role and opportunity for commissioners to influence and drive the uptake of new services	N/A
26	A report should be commissioned to show how medical technologies can assist the NHS to deliver National Service Frameworks	3
27	DH should work with the Modernisation Agency and other stakeholders to ensure that best practice in commissioning specialised services can be shared across the NHS	N/A

Working Group 2 – R&D and the Industrial Base		Addressed by key output (see pages 1–4)
28	Develop Healthcare Technology Co-operatives as effective clinical, industrial and academic collaboratives from existing NHS centres of excellence	5
29	Establish long-term clinical and cost-effectiveness device evaluation group run from within DH	1
30	Establish a National NHS Innovation Centre to integrate the network of English NHS Innovations Hubs and corresponding organisations in the other home countries	2
31	Develop a comprehensive web-based route map from existing guidance to identify all the steps required to bring an innovative product to market	2
32	Support translational research through more focused and increased public funding	2
33	Increase education and training for professionals and key private sector staff, particularly in clinical research, on the use of new technologies and related skills	6

Working Group 3 – Regulatory Issues		Addressed by key output (see pages 1–4)
34	UK to continue to take the lead in EU medical device regulatory matters	6
35	Dialogue between MHRA and industry to be further strengthened and NPSA involved	6
36	Strengthen horizon scanning to identify systematically useful new and emerging technologies	1
37	Develop UK negotiating position on EU regulation of tissue engineered products to ensure appropriate regime	6
38	Maximise UK influence in EU negotiations on revisions to the MDD to ensure the quality of clinical trials regulation in other Member States and improve controls on Notified Bodies	6
39	MHRA and industry to continue to support the use of voluntary standards (in the context of the New Approach Directives) and to streamline and strengthen the standards making process, also including global considerations	6
40	Improve public and clinicians' understanding of risk, safety and regulation of medical devices	8
41	Ensure proper linkage of auto-identification systems with patient systems to improve traceability and support post-marketing surveillance and vigilance of medical devices	MHRA/NPSA to work with DH in taking forward in close liaison with industry
42	Promote better understanding of the regulatory regime with SMEs	MHRA to organise occasional seminars; establish dedicated SME advisory function and develop 'e-regulatory' system

Working Group 3 – Regulatory Issues		Addressed by key output (see pages 1–4)
43	Consider how to support the developing market for ‘over the counter’ medical devices and IVDs	MHRA to take forward with stakeholders and produce action plan to support developing market
44	Improve awareness of manufacturers of the importance of good design and explore ways of feeding back information to them on design issues identified on products and systems in use	MHRA and NPSA to take forward and produce agreed action plan

Working Group 4 – International Trade		Addressed by key output (see pages 1–4)
45	Promote ‘SOLO’ and SESA programmes to support medical device companies exhibiting at overseas trade fairs	9
46	In return for specific services, government should support British Healthcare at a level of £200k per year over 5 years to develop its role	Further discussions to be arranged
47	Greater use of NHS as showcase of medical device excellence for overseas visitors	7, 5
48	Consideration of re-introduction of an Innovations Fund to accelerate the uptake of British products and processes in the NHS	2
49	UKTI to focus its strategic activities and resources for the medical devices industry on the USA, Germany, France, Japan and China (in key order) whilst continuing its support for healthcare exports in all overseas markets	7
50	Department of Health International to put in place mechanisms to capture and disseminate abroad good news stories about the NHS	7
51	Steps to be taken to integrate DfID programmes into supporting UK healthcare exporters	7 – Agreement reached on sharing of information

Working Group 4 – International Trade		Addressed by key output (see pages 1–4)
52	British Healthcare to maintain and publish details of healthcare export activities nationally and in the regions	7
53	UK Trade and Investment to pilot a template for basic market intelligence with a view to its universal adoption by overseas posts in target markets	7
54	In conjunction with the Office for National Statistics, consideration to be given to improving sector metrics	Covered by DTI-led project to gather and publish data on industry metrics
55	The Association of British Health-care Industries should develop appropriate guidance on the sector’s strengths and update it regularly so that overseas posts can promote these to buyers	ABHI to take forward in conjunction with other trade associations, UKTI and DH International

Annex F

GLOSSARY

ABHI	Association of British Health-Care Industries
ACARD	Advisory Council for Applied Research and Development
ACLM	Association of Contact Lens Manufacturers
ACOST	Advisory Committee on Science and Technology
AIME	Association of Institutions with interests in Medical Engineering
ALB	Arm's Length Bodies
AMDS	Active Medical Devices Section (ABHI Special Interest Section)
AMRC	The Association of the Medical Research Charities
AMS	Academy of Medical Sciences
ASDEM	Association of Steriliser and Disinfector Manufacturers
AXrEM	Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care
BBSRC	Biotechnology and Biological Sciences Research Council
BHTA	British Healthcare Trades Association
BIGT	Biosciences Innovation and Growth Team
BIVDA	British In Vitro Diagnostics Association
BSI	British Standards Institution
CD	Commercial Directorate (Department of Health)
CE mark/markings	Mark denoting conformity with an EU New Approach Directive, eg the Medical Devices Directive
CEN	European Committee for Standardisation
CENELEC	European Committee for Standardisation (Electrical)
CHD	coronary heart disease
CID	cardiac interventional devices
COCIR	The European Co-ordination Committee of the Radiological and Electromedical Industry
CoMAP	Competitive Analysis of the Healthcare Industry in the United Kingdom
COREC	The Central Office for Research Ethics Committees
CPD	Continuing Professional Development

CRM	cardiac rhythm management
CSR	corporate social responsibility
CT	Computerised Tomography or CAT (computerised axial tomography) Scan
CVD	cardio vascular disease
CWG	Core Working Group
DfID	Department for International Development
DH	Department of Health
DH Industry sponsorship	Part of the Medicines and Pharmacy Industry Group of the Department of Health
DLA	Dental Laboratories Association
DNA	deoxyribonucleic acid
DRG	Diagnosis Related Group
DT	Drug Tariff
DTC	Diagnosis and Treatment Centre
DTI	Department of Trade and Industry
ECDL	European Computer Driving Licence
ECG	electrocardiograph
EDMA	European Diagnostics Manufacturers Association
EMS	Emergency Medical Systems
EPSRC	Engineering and Physical Sciences Research Council
ESI	elimination of sharps injuries
ESRC	Economic and Social Research Council
EU	European Union
Euromed	European Medical Technology Industry Association
EUROM VI	European Federation of Precision Mechanical and Optical Industries
EUROPA	Europa is the portal site of the European Union
EV	environmental values
FARADAY	A multidisciplinary research partnership organisation
FDA	(US) Food and Drug Administration
FRG	Funding and Reimbursement Group (of Euromed)
GAMBICA	Association for Instrumentation, Control, Automation and Laboratory Technology

GHTF	Global Harmonisation Task Force
H BUS	Healthcare Business
HCC	Healthcare Challenge Centre
HEFC	Higher Education Funding Council
HITF	Healthcare Industries Task Force
HTA	Health Technology Assessment
HTD	Health Technology Devices
HRG	Healthcare Resource Group
IEC	International Electrotechnical Committee
IMechE	Institution of Mechanical Engineers
INTELLECT	Information Technology Telecommunications and Electronics Association
IntHeTech	Integrated Healthcare Technologies – a source of funds for industry-led collaborative research projects in strategically important sectors of the British manufacturing industry
IP	intellectual property
ISO	International Standards Organisation
IT	information technology
IVD	in vitro diagnostics
LMCA	Longterm Medical Conditions Alliance
LWG	Little Working Group
MATCH	Multidisciplinary Assessment of Technology Centre for Health (at Brunel)
MDA	Medical Devices Agency (now part of MHRA)
MDD	Medical Devices Directive
MEDICA	Trade fair and information portal
MEDILINK	Medilink Network
MEDIWALES	The Welsh medical technology and bioscience sectors
MED TECH	medical technology
MHRA	Medicines and Healthcare products Regulatory Agency
MPIG	Medicines and Pharmacy Industry Group, Department of Health
MRA	Mutual Recognition Agreement
MRC	Medical Research Council

MTG	Medical Technology Group
MRI	magnetic resonance imaging
NEAT	New and Emerging Applications of Technology
NHS	National Health Service
NHSIA	NHS Information Authority
NHS MOD AGENCY/NHS MA	NHS Modernisation Agency
NHS PASA	NHS Purchasing and Supply Agency
NHS SID	NHS Supplier Information Database
NIC	Net Ingredient Cost
NICE	National Institute for Clinical Excellence
NIP	New Information Paradigms
NIRAG	NHS Industry Research Advisory Group
NPfIT	National Programme for IT
NPSA	National Patient Safety Agency
NSF	National Service Framework
OECD	Organisation for Economic Co-operation and Development
OFT	Office of Fair Trading
OST	Office of Science and Technology
OTC	over the counter
PASA	Purchasing and Supplies Agency
PbR	Payment by Results
PET/CT	Positron Emission Tomography/Computerised Tomography (or CT-Cat Scan)
PCT	Primary Care Trust
PICTF	Pharmaceutical Industry Competitiveness Task Force
PMS	Post-marketing surveillance
Pr Pr	Processes and Procurement
PVC	polyvinyl chloride
QMS	Quality Management System
R&D	Research and Development
RAE	Royal Academy of Engineering
RCP	Royal College of Physicians

RDA	Regional Development Agency
RDD	Research and Development Directorate of DH
RFID	Radio Frequency Identification
RTO	Research and Technology Organisation
SDMA	The Surgical Dressings Manufacturers Association
SDO	Service Delivery and Organisation
SEEDA	South East England Development Agency
SESA Programmes	Support for Exhibitions and Seminars Abroad
SHA	Strategic Health Authority
SIS	Special Interest Section (of ABHI)
SISIS	Surgical Instruments Special Interest Section (of ABHI)
SMEs	small and medium-sized enterprises
Solo	The Solo Show Support Scheme is a pilot initiative aimed at helping experienced exporters develop new markets
TA	trade association
ToR	Terms of Reference
TPUK	Trade Partners UK
TSE	Transmissible Spongiform Encephalopathies
TTO	Technology Transfer Organisation
UCL	University College London
UKCRC	UK Clinical Research Collaboration
UKTI	UK Trade and Investment
VFM	Value for Money
VGO	Virtual Global Organisation
WEEE	Waste Electrical and Electronic Equipment
WKG	Working Group
WKG1	Working Group 1 – Market Access
WKG2	Working Group 2 – R&D and the Industrial Base
WKG3	Working Group 3 – Regulatory Issues
WKG4	Working Group 4 – International Trade
Y&H	Yorkshire and the Humber

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