



**Medicines and Healthcare products
Regulatory Agency**

**Corporate Plan
2007/2008 to 2011/12**

The MHRA is an Executive Agency of the Department of Health. It carries UK-wide responsibility for the regulation of medicines and is the Competent Authority for the UK in regulating medical devices. In 2005, the Agency also took on the role of Competent Authority for Blood in the UK which added to its responsibilities and widened the range of stakeholders to include NHS blood banks and blood establishments. Under the devolution agreements, responsibility for enforcement of medical devices regulation is reserved. Medicines regulation policy is also generally reserved, although enforcement functions are the responsibility of the Scottish Executive and the Welsh Assembly. When not suspended, all aspects of medicines control are the responsibility of the Northern Ireland Assembly. In practice the MHRA carries out many of these functions on behalf of and in regular close consultation with the devolved administrations.

This Corporate Plan is produced within the context of the Agency's Framework Document which sets out the relationship between the MHRA, the Department of Health and its Ministers. The plan covers five years from 2007/08 to 2011/12 and is updated each year. An annual Business Plan, including key targets, is also published and sets out what the Agency expects to do in the year ahead.

FOREWORD

The Medicines and Healthcare products Regulatory Agency has been in existence for four years, safeguarding public health through the regulation of medicines and medical devices. This revision of its Corporate Plan sets out the strategic direction of the Agency for the next five years. The Agency's strategy for the future is being reviewed and it is likely that the Corporate Plan for future years (from 2008 when the Agency will have been in existence for five years) will be revised more fully.

The objectives and activities described here have been formulated by the Board of the Agency, which consists mainly of non-executive members. The Board not only has responsibility for determining the Agency's corporate objectives and approving its business strategy but also for advising Ministers on their implementation.

The primary role of the MHRA is to protect public health through regulation, to promote it through communication, and to improve it by supporting beneficial developments in medicines and medical devices sectors. The next five years will see further integration of the sectors of the Agency and work to maintain it as a leading regulatory agency in Europe, addressing the many scientific challenges that will continue to emerge. The MHRA also has an important role to play in ensuring that key ministerial objectives for the health service are achieved, including the wider availability of medicines and the provision of authoritative and objective information about medicines and devices for the public and other stakeholders.

The Agency has undergone considerable change within the last couple of years. Significant new legislation has come into force, the major medicines operational divisions have been restructured to allow more integrated oversight of medicines throughout their lifecycle, and the Agency has introduced a major new information system that supports Agency-wide decision-making and electronic working. A key priority for the Agency in the early years of this plan is to ensure that we gain the full benefits of all these changes, not only in faster and more efficient handling of applications but in supporting all our objectives.

The next five years will be just as important and challenging for the MHRA as the first four, and also potentially very rewarding. I look forward to working with the Board and the staff of the Agency to ensure success.

Sir Alasdair Breckenridge

Chairman of the MHRA Board
March 2007

THE AIMS OF THE MHRA

Protecting public health

... through regulation, with acceptable risk:benefit profiles for medicines and devices.

Promoting public health

... by helping people who use these products to understand their risks and benefits.

Improving public health

... by encouraging and facilitating developments in products that will benefit people.

To achieve these aims we will:

- maintain rigorous authorisation and inspection programmes;
- maintain and develop pro-active surveillance and enforcement programmes;
- communicate authoritative and reliable information and advice to improve public and professional awareness;
- shape and influence the future regulatory framework, working with other Government bodies and European and worldwide regulators;
- support innovation and product development, offering constructive and impartial advice to scientific communities and health services;
- minimise the burden of regulation so far as is compatible with our public health role; and
- run a successful business with a skilled and equipped workforce dedicated to the Agency's aims.

1. KEY INITIATIVES, ESPECIALLY FOR THE NEXT TWO YEARS

The Business Plan for 2007/8 sets out the key priorities for the coming year, with key targets identified to support those priorities.

Following a period of change, the Agency will, in particular, be focussing on ensuring it gains the full benefits of those changes, including more timely handling of medicines licence applications in those areas where improvements are needed.

The Agency will make efforts to encourage the industry to embrace electronic applications, particularly those in eCTD format, for which the Agency's new IT system was designed, and will work to achieve an agreed design across Europe.

In addition, the Agency will continue to work in support of Government priorities, improving the availability of medicines licensed specifically for treating children through implementation of the Paediatric Regulations, and empowering people to make

informed choices about their healthcare with more over-the-counter medicines and devices.

We will continue to implement EU legislation to regulate devices, traditional herbal medicines and clinical trials, and playing a key role in developing EU regulations and national controls for tissue based therapies.

We will work to enhance surveillance systems – for adverse drug reactions, adverse incidents involving devices and the General Practice Research Database – and exploiting the information they gather. This will include working closely with the National Patient Safety Agency as it redesigns its National Reporting and Learning System, to ensure that MHRA and NPSA responsibilities are clear and mutually supportive in assuring safety.

We will continue to make efforts to raise the Agency’s public profile, disseminating authoritative and impartial information and advice, and providing guidance to meet the needs of healthcare professionals.

We will develop a longer term financial strategy for the Agency and will take forward work already begun on the Better Regulation initiative.

We will carry out extensive consultation with our stakeholders on the Agency’s forward strategy, to be reflected in a revised Corporate Plan from April 2008.

Financial Outlook to 31 March 2012

Total income	£442 m
Total costs	£436 m
Operating surplus	£6m
Dividends	£4m
Projected surplus at 31/3/12	£2m

2. SERVING CUSTOMERS AND STAKEHOLDERS

To summarise the aims and aspirations of this plan we set out here how we intend to serve our main groups of customers and stakeholders to the best of our ability.

For patients, their carers and the public, we will:

ensure that beneficial products meeting appropriate standards of safety and quality are brought to the market without unnecessary delay on our part and with stringent safeguards for those on whom they are tested; ensure that those who use products have adequate instructions for doing so safely;

take action to protect them when products in use are found to pose unacceptable risks;

help them understand both the risks and the benefits of medicines and devices and provide reliable and authoritative advice to help them to make more choices about treatment;

listen carefully to their concerns and those of their representative organisations; and

be accountable to them in the provision of information under the Freedom of Information Act and in the impartiality of our dealings with the pharmaceutical and devices industries.

For health and social care professionals, and their representative organisations, we will:

help them make appropriate choices about treatment for their patients by providing reliable information, including about the safe usage of medicines and devices;

urge and facilitate training in the safe use of products and encourage the adoption of good practices; and

listen to their concerns, not least in their reporting of adverse reactions and incidents.

For manufacturers, distributors and retailers, we will:

endeavour to ensure that science leads and influences regulation which, while affording appropriate standards of public health protection, does not become overly burdensome and inhibit development;

offer constructive and impartial advice about the development and testing of new products; and

maintain and develop regular and appropriate contacts with their trade associations and other bodies.

For our EU Partners, we will:

demonstrate the effective operation of European Directives for the regulation of medicines and devices, learning from our partners' experiences and offering them the benefit of ours; and

continue to play a leading role in the development of new EU legislation.

For our staff, we will:

value all their contributions and maintain a culture in which they are proud to work for the Agency in serving the public; and

equip them with all the knowledge, skills and facilities they need to discharge their roles effectively.

For Government Ministers we will:

provide sound and objective advice and timely contributions to relevant ministerial business; and

continue to contribute to the implementation of Government policies on health.

3. PROTECTING PUBLIC HEALTH: RIGOROUS AUTHORISATION AND INSPECTION

This section describes many of the core functions of the MHRA: regulating clinical trials and investigations; authorising the marketing of medicines and inspecting their manufacture and distribution; and auditing the bodies which assess manufacturers' compliance with the medical device regulations. Though there are some fundamental differences between the ways medicines and devices are authorised, the Agency operates under European legislation for both categories of products.

Medicines

For MHRA, the lifecycle of a medicinal product starts with the regulation of its clinical trials. Then, when manufacturers believe they are ready to market medicines for human use in the UK which do not need mandatory centralised EU authorisation, the Agency assesses their claims for safety, quality and efficacy. If satisfied, it issues marketing authorisations. Later changes to reflect scientific, technical and therapeutic advances are achieved by variations to the original marketing authorisations, which are also evaluated by the Agency. The UK authorisations may also be used to gain further authorisations in other Member States by a process of "mutual recognition".

Medicines which have been authorised by the EU centralised procedure can be marketed throughout the European Union. The Agency will continue to play an active part in evaluating centralised marketing authorisations for medicines, as well as in the mutual recognition of authorisations of other Member States and in the licensing of products authorised by them and imported into the UK.

Medicines must reach acceptable standards of quality. The Agency inspects the manufacturing and distribution processes for medicines and issues licences to manufacturers and wholesale dealers where it is satisfied that companies are complying with relevant practice standards. It also undertakes good practice inspections of companies' clinical, laboratory and pharmacovigilance activities.

We will:

- only allow clinical trials which have adequate safeguards for patients and have

been approved by an ethics committee, seeking external expert opinion where necessary;

- apply rigorous standards to ensure that claims for quality, safety and efficacy are justified and that residual risks are commensurate with potential benefits;
- vet the advertising of all new active substances, setting and policing high standards in the control of medicines advertising;
- ensure that medicines licensed outside the UK are authorised for marketing here to the same standard that applies to products originating in the UK;
- ensure that manufacturers and distributors operate systems which safeguard quality, and that companies comply with regulatory guidelines in clinical and laboratory practice and in pharmacovigilance; and
- assess reports of suspected defective medicines, advise on appropriate action and communicate details of this action to recipients of the products and other interested parties.

Devices

The lifecycle of some medical devices starts with clinical investigations, which are regulated by the MHRA. But authorisation for marketing is different from that for medicines. For devices posing higher levels of risk, independent certification bodies – Notified Bodies – verify that they comply with the Medical Device Directives. Only after this can the manufacturer CE-mark a device and place it on the European market. UK Notified Bodies are however designated and audited by the MHRA. Devices CE-marked after assessment by Notified Bodies can be marketed throughout the Union regardless of where the Notified body is based; the Agency therefore has a lively interest in the standards of authorisation throughout the EU. We will:

- only allow clinical investigations which have adequate safeguards for patients and have been approved by an ethics committee;
- ensure that rigorous standards are applied by UK Notified Bodies to ensure the safety and performance of devices; and
- press for consistently high standards throughout the EU in the operation of Notified Bodies for devices.

Human Blood and Blood Components

As the interim Competent Authority for human blood and its components, the Agency authorises and inspects blood establishments, including national blood services. We also receive reports from hospital blood banks about their compliance with regulations and, if necessary, inspect their sites.

4. PROTECTING PUBLIC HEALTH: PRO-ACTIVE SURVEILLANCE AND ENFORCEMENT

The Agency operates post-marketing surveillance systems for recording, monitoring and investigating adverse reactions to medicines and adverse incidents involving medical devices. Where there are problems, the Agency takes any necessary action to protect public health, for example through safety warnings, or through action to remove or restrict the availability of products or improve designs.

This kind of surveillance has traditionally been largely reactive. We have relied mainly on professional users to report suspected problems voluntarily, using Yellow Cards for medicines and adverse incident reports for devices. Recognising the need to become more pro-active in soliciting reports of problems, we will:

- make these reporting systems as accessible and straightforward to use as possible and encourage fuller reporting, especially from the relatively undeveloped resource of patients and the public. In particular, we will be extending current electronic reporting facilities for both drugs and devices.

A valuable and increasingly utilised, but still under-exploited resource is the Agency's General Practice Research Database (GPRD). Continuously updated, it holds 46 million patient-years of information about the diagnosis, treatment and progress of diseases and conditions recorded in general practice. It is widely used outside the Agency to assess, amongst other things, the safety and efficacy of prescribed medicines. While of great value, this research does not necessarily focus on the most significant issues that confront the Agency. We will therefore:

- exploit the GPRD to ensure that key questions on the safety, efficacy and use of medicines are rigorously researched, whether through internal or commissioned studies.

New legislation in 2005 heralded a major change in emphasis towards proactive pharmacovigilance involving specific risk management plans for new medicines. These changes will supplement traditional pharmacovigilance and will have a major impact on our work. We will continue to:

- undertake targeted, proactive reviews on existing therapeutic classes of medicines for which the risk:benefit has changed significantly and which may no longer reflect best therapeutic practice; and
- develop risk assessment practices to maximise the benefits of proactive pharmacovigilance and, using new information technology, improve our drug safety signal detection and tracking process to introduce new indicators of potential signals and better methods for prioritising and tracking work.

Following the European Commission's response to the consultation on the community system for pharmacovigilance, we will work closely with EU colleagues on development and implementation of proposals to strengthen the pharmacovigilance system covering better implementation of the existing framework and a change in the legal framework.

In November 2005, the Agency launched SABRE, a major new on-line reporting system in support of MHRA's role in respect of blood safety. It allows UK blood establishments and hospital blood banks to report notifications and confirmations of serious adverse reactions and events. We will:

- use this surveillance data to monitor reporting compliance and follow-up action, submitting annual reports to the EU Commission; and
- review the effectiveness of the new UK haemovigilance system and address any issues identified.

Pro-active surveillance also includes the sampling and testing of medicines for quality defects. The Agency will maintain robust systems for this activity, discussing any anomalous results with the companies concerned and, where necessary, issuing alerts or taking other corrective action.

Much of the Agency's surveillance is of products whose manufacture or use is well-regulated. However, there is an increasing threat from potentially unsafe medicines and devices reaching the public through internet websites. We will:

- continue to prioritise the illegal advertising, sale and supply through the Internet, and will take action, where appropriate, against sites being operated or controlled within the UK;
- continue to closely co-operate with domestic law enforcement agencies and our international counterparts to tackle illegal medicines and devices available online.

We will continue to focus activity against the availability of counterfeit medicines, thoroughly investigating all reports, and prioritising those that pose a threat to the regulated and licensed supply chain.

We will develop the capability of the Enforcement and Intelligence Group to lead investigations of suspected breaches of medicines and associated legislation. Enforcement will be conducted in accordance with the Government Enforcement Concordant, working with manufacturers and wholesalers to achieve compliance, but without hesitating to enforce compliance where necessary.

5. AUTHORITATIVE AND RELIABLE COMMUNICATION

The Agency needs to develop further its communications with patients, carers and the wider public, as well as the NHS, healthcare professionals and industry. Public expectations for impartial, accessible and authoritative information and advice have grown significantly over recent years. Information presented through the media and on the Internet is increasingly accessible, but not always authoritative or impartial, and may present serious safety concerns. People want to play a more active role in decisions affecting their health and need access to reliable information on the risks and benefits of available treatments.

The Agency can make an important contribution to public understanding of the issues

surrounding medicines and devices, but to be effective its work must be understood and trusted by the wider public as well as by health professionals. Our scientific and regulatory work, widely acknowledged to be of the highest quality, will only be translated into the best public health outcomes if prescribers, suppliers, professional users, patients and carers have access to and take notice of sound information and advice. We will:

- help maintain confidence in the regulation of medicines and medical devices by providing timely, necessary and helpful information to healthcare professionals, to the public and to industry, and by ensuring that people know who to turn to if they are concerned;
- help healthcare professionals, patients and the public to understand both the risks and the benefits of medicines and devices, enabling them to make more informed choices about treatment and use of products safely;
- raise standards in information for patients and maximise the impact of user testing of patient information;
- raise awareness for patients of the patient information leaflet and work closely with the Department of Health to maximise patient benefits of their Information Prescription initiative;
- provide more accessible and targeted high quality information to healthcare professionals, promoting good practice in the management of medication and use of devices;
- encourage and assist those responsible for the education and training of healthcare professionals to provide high quality guidance about the regulation and safe use of medicines and devices; and
- meet the information needs of the pharmaceutical and medical devices industries, including information about regulatory systems.

We will use whatever medium is most appropriate for the task, using for example general or specialist news media and our print publications. Our website is of increasing importance. We will continue to develop and maintain the new site, using it to publish up-to-date information, including about new technologies. We will also continue to promulgate standards for medicinal products through the British Pharmacopoeia, develop some for herbal products and help set international standards for the manufacture of medical devices.

6. OPENNESS

The Agency is committed to open government and the release of as much information to the public as is consistent with the provisions of the legislation under which we operate. We will:

- respond helpfully and positively to all requests made under the Freedom of

Information Act, continue to publish the advice provided to us by our advisory committees, and encourage the industries towards greater degrees of openness.

Recent amendments to pharmaceutical legislation introduced the concept of public assessment reports detailing decisions about the licensing of medicines. These aim to give transparency to the regulatory process and to provide information on the product and the data supporting its authorisation or refusal. We will:

- continue to publish the assessment report on the Agency's website, together with the reasons for our opinion and a lay summary, after deletion of any information of a commercially confidential nature.

7. ADVICE TO MINISTERS

As an Executive Agency of the Department of Health we have a responsibility to support Ministers who are accountable to Parliament for what we do. This includes giving timely and accurate advice and information, effectively managing the Agency's Parliamentary business and providing responses to correspondence Ministers receive about medicines and devices. We will:

- provide high quality briefs and advice to Ministers;
- provide effective management of the Agency's Parliamentary business;
- provide responses to Ministerial correspondence aiming to meet Ministers targets for speed and quality.

8. WORKING WITH OTHERS TO SHAPE AND INFLUENCE THE REGULATORY FRAMEWORK

The Agency has a responsibility not only for implementing the existing regulatory system for medicines and devices, but also for developing policy on how regulation should evolve to meet changing needs. In doing this, we work with colleagues across Government, with external stakeholders, and with European and international partners to ensure that our policy advice to Ministers is underpinned by a sound evidence base of both scientific knowledge and stakeholder views.

European legislation underpins most aspects of the regulation of medicines and devices in the UK. The Agency is responsible on behalf of Ministers for negotiating legislative proposals from the European Commission. In the pharmaceutical sector the Agency makes a significant contribution to both the centralised and decentralised procedures and is recognised as a leading player. It is also widely recognised for its leading role in the development and implementation of the devices regulatory regime.

We expect the next five years to bring significant changes not only to the way products are developed but also to the way that they are regulated. It will be important to ensure that appropriate regulatory methods are developed in parallel with the advancing

science. In particular we expect to see the introduction of a single regulatory framework for advanced therapy medicinal products (gene therapy products, somatic cell therapy products and tissue engineered products).

We aim to maintain our influence in negotiating legislation and to retain our position as a leading regulatory Agency in the recently enlarged EU by:

- ensuring that we continue as a centre of excellence in Europe, playing a leading role in the development of EU legislation and maintaining a high UK profile in the key decisions and influencing fora of the EU;
- helping and where necessary leading our European partners in devising and adopting European regulatory regimes that respond to developments in the types or uses of products;
- continuing to offer knowledge and expertise to other Member States, particularly the new ones; and
- pressing for similar high standards of authorisation, inspection and enforcement throughout the EU.

Recognising that there are global markets for both medicines and devices, the Agency will continue to play a leading role on the wider international stage. In particular we will:

- actively support the harmonisation of regulation in the International Conference on Harmonisation (ICH) for medicines and the Global Harmonisation Task Force (GHTF) for devices.

Part of the Department of Health's policy is to widen or secure the availability of new and existing products. We advise Ministers about whether that can be done with a reasonable degree of safety We will:

- fulfil what was set out for the Agency to do in the Government's response to the Health Select Committee's report on the influence of the pharmaceutical industry; and
- continue to support and share several of the Department's policies and initiatives, mainly concerned with the availability of products such as:
 - nicotine replacement therapy to reduce smoking,
 - vaccines, with the fast-tracking of licence applications where a vaccine is developed to meet a new threat,
 - medicines over the counter, to help widen choice for patients and involve them in their own treatment,
 - products made more available through the introduction of further non-medical prescribing responsibilities.

There are a number of other Government bodies whose responsibilities interact with those of the MHRA. They include the National Patient Safety Agency (NPSA), the

Health Protection Agency (HPA), the National Institute for Health and Clinical Excellence (NICE), the NHS Purchasing and Supply Agency (PASA), the Food Standards Agency (FSA), and the Veterinary Medicines Directorate (VMD). We will:

- maintain close working relationships with the Department and other Government bodies to achieve a comprehensive and integrated approach in the UK to enhancing and safeguarding health and social care.

9. SUPPORTING INNOVATION AND PRODUCT DEVELOPMENT

The Agency operates in a highly innovative scientific environment. We expect to see the discovery and development of new medicines and new devices, more new drug/device combinations and a further blurring of the boundaries between medicines, medical devices and other health-related technologies. We expect the following scientific developments to be significant for our work over the period of this plan:

- an increase in products derived from biotechnology and the use of new techniques that have the potential to shorten the development time for new medicinal products;
- advances in molecular biology, genomics, gene therapy, cell therapy and elsewhere that are likely to lead to a new generation of medicines and an increasing number of specialised and “niche” pharmaceuticals;
- developments in pharmacogenetic tests and in screening services to identify patients who will gain the greatest benefit from a particular medicine or who may have a heightened risk of adverse reaction – developments which are likely to lead to more personalised medicines;
- better understanding and control of manufacturing processes which improve the quality of medicines by reducing batch to batch variation, including process analytical technology;
- significant developments in both targeted and controlled drug delivery systems, with the introduction of sophisticated drug/device delivery products;
- the convergence of advances in a range of disciplines including nanotechnology, biomaterial science, microelectronics, digital technology and software developments that would revolutionise the development of healthcare technologies extending across the spectrum of medical device applications;
- developments in devices specifically designed for use in the home or a community setting; and
- rapid developments in human tissue engineering.

The GPRD database is already used by many research companies to help with an understanding of disease, the patient journey, unmet need as well as the profiles of existing treatments. New linkages to disease registers will further enhance the value of such data analysis. A new methodology for running large scale highly cost-effective real world clinical trials is also in development.

Having brought together a wide range of expertise from the devices and medicines sectors, the Agency is in a very strong position to become a leading European Centre in responding to these scientific developments. We will:

- develop strategies to ensure that the Agency and the UK can play a leading role in the application of new technologies in the field of medicines and devices.

There are many product developments that rely on new uses for existing technologies rather than on innovations. Particularly important developments, in line with Government priorities, are the increasing availability of both medicines and devices over the counter, the licensing of medicines specifically for use in children, and the development of new forms and uses for well-established drugs. We will:

- encourage and support such developments so far as is consistent with public safety and ensure that the public is provided with adequate instructions for safe use and warnings about unsafe use.

Whether innovative or evolutionary, it is in the public interest that product developments reach the market as soon as their risks and benefits can be properly established. There is a cost to society if potentially beneficial products are unnecessarily delayed. We will:

- strive to ensure there are no unnecessary delays in the ways that we operate under existing regulations and “best practice” guidance; and
- continue to offer constructive and impartial advice to scientific communities and healthcare professionals who develop and test new products, to help such products bring benefits to patients as soon as possible.

The completion of the Agency’s Sentinel programme for IT in the medicines sector, coupled with a realignment of staff across three of the Agency’s Divisions IN 2006/2007, is expected to lead to improvements in the services we provide, by:

- accelerating and enhancing decision-making processes at all levels within the Agency and improving the quality of work we do and the services we provide;
- establishing an information infrastructure that can evolve to meet the changing needs of the Agency and better provide data or knowledge to external bodies; and
- improving the process of communicating with the Agency.

10. MINIMISING THE BURDEN OF REGULATION

The Agency’s medical devices operations are funded by central Government under a Service Level Agreement with them while its regulation of medicines is funded by fees from industry. In addition, both sectors of industry bear the costs of complying with EU and UK regulations. Most of the fee and compliance costs are recouped by industry from purchases of their products by Government or the public. It is therefore

in the public interest that, while protecting public health by ensuring appropriate standards are met, the Agency should minimise these burdens. We will:

- minimise the burdens of regulation subject to our duty to protect public health through necessary regulation.

As a Government Trading Fund, the MHRA's target is to break even, taking one year with another, after taking account of HM Treasury's requirement to earn an average real terms' return on capital employed of 3.5% within five year cycles set by HM Treasury. The current cycle ends in 2007/8 and the Agency expects to meet its financial duty to the end of 2007/8. The Agency's financial outlook for the next five years is set out in the Annex. The aim is to achieve financial stability by operating a balanced budget that generates a small surplus as a reserve for future investment or as a margin against contingencies. An important element of the strategy to achieve this aim is to ensure that income from fees is aligned with appropriate costs.

The Agency's costing model is continuously updated in line with changes in the organisation's activities. We will continue to review how the Agency earns and recognises its income, with fee arrangements designed to reflect the Agency's work. This is likely to see a continuation of the trend of annual service fees representing an increasing share of medicines income.

Meanwhile we expect to consolidate the changes introduced by the implementation of the Sentinel IT system for processing medicines licences and variations, with improvements in the backlogs from 2006. The Sentinel system provides for a fully electronic data repository, which will make the Agency's use of information more transparent and more efficient. The smooth submission of licensing applications through an electronic portal drastically reduces paper handling and when electronic standards are fully adopted by applicants, Sentinel will speed up the processes following receipt of applications. In addition, electronic reporting of adverse drug events will help to drive efficiencies. We will therefore:

- work closely with industry and other European regulatory partners to encourage the take-up of electronic submission of applications and adverse drug event reports;
- understand the lessons learned from the implementation of the Sentinel system and the experience of using the new capabilities. Apply these to system and/or process changes in order to maximise the efficiencies of both the system and the associated processes; and
- work across the Agency to address outstanding questions of data quality, originating from prior systems, or from the Sentinel migration.

We will also follow the Agency's restructuring of its key operational divisions by ensuring that we keep the efficiency of our operational processes under review, seeking to leverage opportunities that are provided by the Sentinel implementation as well as other opportunities for process improvement.

In addition to fees from industry and funding from the Department of Health for our work on devices, the Agency will also continue to develop other revenue sources to augment its income, for example through the provision of conferences and education events. Sentinel may also afford new opportunities for generating revenues.

The operational costs set out in the Annex are only indicative since much of the Agency's work is reactive and many caseloads and the resources needed for them are difficult to predict. For example, the rate at which new medicinal products are put forward for authorisation by manufacturers is highly variable from one year to the next. In view of large uncertainties in many elements of the Agency's work, detailed projections of business volumes for the coming five years would be misleading.

We want to avoid all unnecessary bureaucracy that might increase the burdens to industry of complying with our requirements. To do this we will:

- continue to consult with industry about the impact of regulatory changes on them, taking note of their views and wherever possible reducing the prospective burden;
- be fully committed to the Government's initiative to simplify and lighten, wherever possible, the cost and administrative burdens that regulation imposes on industry. We will continue to work with industry representative bodies to identify burdens that can be reduced, while still protecting public health; and
- in particular, lead the Better Regulation of Medicines Initiative (BROMI) to deliver lighter touch regulation that is proportionate and risk based with the aim of delivering benefits for the public, industry and other stakeholders.

11. A SUCCESSFUL BUSINESS WITH SKILLED, EQUIPPED AND DEDICATED STAFF

Our staff – over 800 of them – are our key resource. We need people dedicated to continue delivering the commitments set out in this plan. The challenge is to maintain that dedication in the face of significant culture change within the Agency as well as those changes involving new IT systems and a restructuring of part of the organisation.

While seeking to capitalise on synergies which will lead to improved efficiency and effectiveness, we will continue to recognise the diverse contributions of staff with highly developed specialist knowledge of two distinct sectors. We recognise also the need to develop a culture of serving patients and the public as well as industry and the NHS. We will:

- grow as an organisation by building on our existing strengths, valuing the contributions of all our staff, sharing and learning from diverse backgrounds and experiences in a trusting, blame-free environment and establishing a common organisational culture for serving our stakeholders.

To maintain and equip our highly skilled workforce, we will:

- recruit and promote only those who are best fitted to the specialist, administrative and managerial roles that fall vacant or are newly needed;
- provide wide opportunities for learning and development for all staff, actively supporting continuing professional development, dedicated skills training and management and leadership programmes, to keep skills up to date and prepare people for new roles; and
- provide a good working environment and the tools people need, especially IT equipment and information, accommodation and opportunities to balance their work with their life.

Retaining valuable people is as important as recruiting the right ones. Staff should see the Agency not only as a successful organisation with a reputation for excellence but also as a good employer which encourages and values where the contributions of staff. We expect to hold a third staff satisfaction survey in 2008, measuring progress since the previous surveys in 2004 and 2006. Another useful benchmark is the series of assessments to maintain our valued status as an Investor in People, which we will use to measure performance in the areas of staff involvement, development and leadership and to compare this with other employers. We will:

- ensure that the contributions of staff are adequately recognised and rewarded; and
- seek to improve the well-being of our staff and our organisational focus by learning and applying the lessons of liP assessments and of successive surveys of staff's views about working in the Agency.

12. THE QUALITY OF OPERATIONS AND DECISIONS

However expert our staff, they need to operate within systems and under external scrutiny that can demonstrate to the increasingly informed public and media that the Agency takes high quality regulatory decisions and provides a good service to all of the Agency's customers and stakeholders. For several years one part of the Agency has operated within a Quality Management System. Over the next few years that approach will be adopted throughout the Agency. The Agency has also benefited from a pan-EU exercise to identify and share best practices across a range of regulatory and organisational areas. The Agency was central to the development of this exercise and it now has the potential to yield long-term benefits to all Member States.

An increasing number of expert advisory bodies support the work of the Agency. The Commission on Human Medicines (CHM) will continue the work of its predecessors (the Medicines Commission and the Committee on Safety of Medicines), together with the Advisory Board on the Registration of Homoeopathic Products and the Committee on Safety of Devices. These bodies provide valuable advice on decisions

related to regulatory, scientific and surveillance issues. The Commission will be supported by Expert Advisory Groups (EAGs). A Herbal Medicines Advisory Committee has also been established.

It is essential that the new bodies for medicines and their counterpart for devices operate independently of the interests of industry and are trusted by the public to act independently. To ensure that they consider risk and benefits from a broader perspective, the CHM now includes two lay members and each EAG will have a minimum of one. The other bodies also have lay members. To support them and help maximise their valuable contribution, a new panel will regularly bring together all of the lay representatives. We will:

- keep under review the composition of our advisory bodies to ensure that they maintain their scientific excellence and can adapt to changes in the regulatory environment; and
- continue to enforce the new Code of Practice for chairs and members dealing with the pharmaceutical industry to help assure the public that the advice on which regulatory decisions is based is impartial.

Annex

Financial Estimates

£m	2007/8	2008/9	2009/10	2010/11	2011/12	Total
Income	90.1	87.9	87.9	87.9	87.9	441.7
Expenditure	87.1	87.1	87.1	87.1	87.1	435.5
Operating Surplus/(deficit)	3	0.8	0.8	0.8	0.8	6.2
Interest & Dividends	-0.7	-0.8	-0.8	-0.8	-0.8	-3.9
Carried forward surplus	2.3	2.3	2.3	2.3	2.3	2.3