MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

BUSINESS PLAN FOR 2009/2010

The Medicines and Healthcare products Regulatory Agency (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. The Agency also has the role of Competent Authority for Blood Safety and Quality in the UK. Though some powers and functions for medicines are devolved to Scotland, Wales and Northern Ireland, the Agency carries out many of them on behalf of and in close consultation with the devolved administrations.

This Business 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 Agency also has a Corporate Plan which covers five years from 2009/10 to 2013/14 and is updated each year.

INVESTORS IN PEOPLE

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

BUSINESS PLAN FOR 2009/2010

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1. Foreword from the Chief Executive

Since the Agency's creation six years ago, our priorities have been to protect, promote and improve public health through the whole range of our responsibilities across medicines and medical devices regulation.

Enhancing communication with our diverse stakeholders has been a key theme of the MHRA's development and this year is no exception. As well as continuing and expanding our existing media relations, targeted stakeholder communications, and website activity, we are also investing in engagement activity to understand and respond more fully to the needs of patients and the public. The need to do so emerged strongly as a theme in the Agency's consultation on strategic priorities in 2007, and identifying and taking appropriate opportunities for patients and the public to input meaningfully into our work is a key development area for the coming months.

We serve the interests of the UK population, but a great deal of how we do that is through action at European and international level. Important changes have been proposed to the EU regulatory framework for medicines, and a high priority for us this year will be to ensure that we are influential in shaping these changes, covering counterfeit medicines, drug safety monitoring, and information for patients on medicines. We expect changes also to the regulatory framework for medical devices, and we will be working throughout the year to influence proposals that may be published in 2010. Our aim in all these areas will be to improve safeguards for patients whilst meeting the principles of better regulation. Beyond Europe, we will strengthen our international links, in particular with China and India, source countries for a significant proportion of medicines and devices used here in the UK.

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Action to tackle counterfeit medicines and devices is one of our most high-profile activities, and we will continue to devote resources to this. We have had significant successes in prosecutions in the last year and aim to continue to disrupt and prosecute counterfeiting operations so that we can prevent this threat from taking hold in the UK.

In all our work, we rely on our staff and their skills and expertise. Our reputation for scientific excellence is evidenced by our leading position among European regulators for licensing and scientific advice work. But we must continue to build our capability to keep pace with technology, and in our plans for the year we will be investing in regulatory science and in staff training and development to ensure that we have the right expertise not just for our current needs, but also for the future.

As an accountable public authority, the MHRA is subject to scrutiny and review from a variety of sources. During the year the Agency underwent a review of its compliance with the Hampton principles of better regulation, and we were pleased with the very positive report from this review. As this Business Plan is published, we expect shortly the outcome of the Department of Health review of the MHRA. I am grateful to our stakeholders who have taken the time to contribute to both these reviews, to help ensure that their findings reflect the views and expectations of those with whom we work. This Business Plan will be adjusted as necessary to enable us to respond to any recommendations that flow from the Department's review.

Professor Kent Woods
Chief Executive
March 2009

2. The MHRA's Strategic Aims and Objectives

Our plans for 2009/10 are derived from our strategic aims and objectives, along with the priorities identified in the Corporate Plan. The Agency's aims are:

Protecting public health through regulation, with acceptable benefit-risk 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.

The Agency's strategic objectives are to:

- **Safeguard public health** through our primary role in ensuring that the products we regulate meet required standards, that they work and are acceptably safe;
- Carry out our **communication** role through the provision of accurate, timely and authoritative **information** to healthcare professionals, patients and the public;
- Support **research,** ensuring through the application of **Better Regulation** principles that regulation does not stifle **innovation**;
- Influence the shape of the future regulatory framework through use of our effective **European and International** relationships;
- Run an **organisation** with a skilled and equipped workforce that is **fit for the future**.

3. Key priorities for 2009/2010

The priorities of the Agency for 2009/10 are derived from the longer term Corporate Plan. The targets are developed to cover the Agency's key functions and development work, and contribute to the Agency's strategic objectives as outlined above.

The Business Plan includes relevant key and high-level targets that support the Agency's objectives and priorities for the coming year. We have presented these in this plan in line with the balanced scorecard model with the four quartiles for our organisation identified as being: Safeguarding Public Health; Communicating Effectively; Shaping a Balanced Regulatory Framework; and Running a Successful Organisation.

This year there are 10 key targets and 14 high level targets which can be found in Section 8.

4. Safeguarding public health

Safeguarding public health remains our fundamental purpose, and everything we do contributes to this overall goal. Specific areas of activity in the coming year are set out below.

Reporting systems:

Our reporting systems – for adverse events involving medicines, medical devices, and blood – remain a cornerstone of our work to safeguard health. We have challenging targets for ensuring that all reported adverse drug reactions and adverse incidents involving medical devices are captured and entered on relevant databases as quickly as possible to allow urgent action to be taken in order to protect health. Similarly, we will continue to get urgent safety messages out to the right people within a timescale that is proportionate to the level of risk involved. We will also build further on the campaign launched in early 2008 to promote patient reporting of adverse drug reactions, and promote the web-based reporting system that allows direct entry to our pharmacovigilance database.

In addition, we will this year be introducing new on-line reporting and alerting systems for medical devices;

- New format electronic Medical Device Alerts - these new alerts will be circulated using the recently introduced Central Alerting System to email a single summary sheet to recipients; and
- MORE 2 (Manufacturers On-line Reporting Environment) – this enables medical device manufacturers to submit information to other European Authorities who have compatible systems.

Tackling counterfeits

Continuing to tackle the threat of counterfeit medicines and devices remains a high priority for the Agency. We will continue to take forward the Agency's Anti-counterfeiting strategy which will contribute to an 'Internet Awareness' campaign to highlight the dangers in obtaining medicines from unregulated websites. We will also work closely with stakeholders including industry, law enforcement and other regulatory bodies both in the UK and internationally to secure the regulated supply chain. There are also important changes to UK and EU legislation, described below.

Clinical trial/ investigation applications

We will continue to consider rigorously all clinical trial applications for both medical devices and medicines, ensuring that all trials meet the necessary standards to protect participants, and are subject to tight time targets so that research into beneficial new treatments is not delayed.

We will work further with clinical researchers – particularly in the non-commercial sector – to identify opportunities for regulatory simplification and to assist the understanding of, and compliance with, standards to protect trial participants.

Medicines licensing

Workload on medicines licensing has increased significantly over the last year, in large part due to the continuing increase in applications for EU-wide licences under the Decentralised Procedure. New applications through this route continue to grow, and we have recruited additional assessment staff

to ensure we can maintain high assessment quality standards and improve achievement of assessment time targets. Whilst Decentralised Procedure applications are of high priority – enabling new medicines to be made available across Europe – we will also pay particular attention to national licensing work, and will establish a new assessment unit focused on the particular needs of "over the counter" medicines available without prescription.

Making more medicines available without prescription

We will continue to work with stakeholders on reclassification of medicines to be available without a prescription, ensuring that any reclassification is acceptably safe, and thereby will enable wider access to medicines while safeguarding public health. Over the course of the coming year we will strengthen and streamline the processing of reclassification applications, working with key stakeholders to develop new procedures and implementing these by the end of March 2010.

Medicines for Children

The EU Regulation on paediatric medicines came into force in January 2007 with the objective of improving the availability of suitably formulated medicines authorised for use in children. The UK has fully supported the implementation of the regulation over the last two years and has shown a strong commitment to the assessment of paediatric investigation plans and paediatric studies at European level. Now that the procedures introduced by the Regulation are becoming fully embedded, it is time to reflect on the next stage of the UK strategy in ensuring better medicines for children. We will develop a renewed strategy, focussing on the challenges which healthcare professionals, patients and their carers still face in this area and taking advantage of the new European and, indeed, global climate for advances in this aspect of child healthcare.

Herbal medicines

Our strategy to improve communications to the public about the safe use of effectively regulated products will continue this year. One of our specific priorities in herbals this year is to implement the European Directive on Traditional Herbal Medicines in accordance with better regulation principles.

We are attaching a very high priority to containing regulatory impact and recognising the scale of the practical and cultural challenge for the hitherto largely unregulated sector in coming within regulation. Our plan includes continuing to progress the strategy for bringing herbal medicine into effective regulation, and managing regulatory impact will be at the core of that.

Blood Safety and Quality

Our role as Competent Authority for Blood Safety and Quality will be maintained through continued inspections of all Blood Establishments, and the review of annual Compliance Reports from all Blood Banks leading to inspection on a risk basis.

This area is supported by 3 key targets (K1, K2 and K3), and 5 high-level targets (H1, H2, H3, H4, & H5).

5. Communicating effectively

Effective communication is an increasingly important part of our work. This includes communicating clearly with healthcare professionals and patients when advice or decisions are needed on a safety issue concerning products we regulate; but also covers broader aims to increase the transparency and openness of all the work that we do.

Communications

The Agency has been committed to enhancing communication with its stakeholders in recent years, and this is reflected in the growing investment of time and resource in communications activity. The key targets for 2009-10 refer to a number of areas where the scope of the Agency's communications will be expanded.

A key theme will be to solicit and visibly respond to feedback from

stakeholders. A new patient and public engagement action plan will ensure that views of this key group of stakeholders are actively sought and are more readily able to inform and influence the Agency's position. Alongside this, we will increase the resources available on our central telephone enquiry line to help all callers to contact the Agency more quickly and easily.

As well as listening to stakeholder views, we need to ensure that important regulatory information reaches those who need to know it in a timely, accurate and useful manner. We will expand our website to include dedicated sections to meet the needs of specific audiences including, for example, distinct groups of healthcare professionals. Our media relations activity will continue to grow both in the range of Agency work which it promotes, and the diversity of the audiences which it reaches. The creation of a new team with marketing expertise will also help us to make use of marketing tools to reinforce key public health and other messages.

For our staff, we will continue to enhance our internal communications activities. Building on a successful team briefing mechanism, we will seek opportunities to be more transparent about how we act upon staff feedback; and we will evaluate our progress with this and other internal matters in a detailed staff survey.

Patient information

We will continue to promote the patient information leaflet (PIL) as the public face of medicines and a crucial tool in ensuring their safe use. In a patient-centred NHS it is vital patients know how to access quality, regulated, medicines information and we will continue to liaise with the Department of Health to include PILs in *Information for Choice* initiatives.

To promote best practice we continue to publish a user tested "PIL of the month" with 20 PILs on the Agency website demonstrating best practice in provision of high quality information. PIL of the Month will also feature in *Drug Safety Update* bulletins.

We will focus resource on a number of strands of work to support patient awareness and improved quality of the information provided with all medicines. Specifically we will commence a publicity campaign to all stakeholders on new PILs. We will continue to work with pharmaceutical companies on further improving the quality and consistency of PILs, while shortening assessment times. Part of this work will be informed by the development of new guidance on best practice in information design. In order to ensure wider access of PILs we will continue to develop proposals for electronic access to them.

Transparency and accountability

We continue to look for further ways to make information available on the work we do and the evidence behind our decisions. We will continue to publish assessment reports and lay summaries on all new medicines, and will also publish information underpinning safety decisions, and develop a process for published lay summaries of risk management plans. From April 2009, we will introduce publication of minutes of the Agency Board and Executive Board.

Ministerial/Parliamentary business

We will continue to provide an excellent service to Ministers by securing the quality, delivery and effectiveness of MHRA's policy responsibilities across Government and by the good management and quality assurance of all MHRA Parliamentary and Ministerial business.

This area is supported by 2 key targets (K4, & K5),
and 3 high-level targets (H6, H7 & H8).

6. Shaping a balanced regulatory framework

This section covers all the work we do to influence how regulation is designed, and to make sure that the regulatory framework meets Better Regulation principles, thus supporting research and innovation. Much, though not all, of this work takes place through our contribution to European and International activity.

Negotiating and implementing EU legislation:

This year will see the implementation of new regulations for the variation of medicines marketing authorisations, initially through mutual recognition and centralised procedures. Agency experts are already leading the development of the necessary revised guidance which, together with the new legal framework are expected to deliver significant reductions in the administrative burden borne by companies in maintaining and updating their licences.

Following the publication in December 2008 of European legislative proposals on pharmaceuticals, this year will see intensive activity at EU level as these proposals are negotiated by national governments and the European Parliament. The MHRA represents the UK Government in these negotiations and has already been influential in the development of the proposals. The key changes involve;

- a strengthening of drug safety monitoring arrangements, with greater clarity on the roles of companies and regulatory authorities, alongside simplification of the current multiple reporting arrangements and greater coordination across Europe;
- proposals for enhancing the availability of high quality information to help health professionals and patients in making informed choices about medicines;
- proposals to tackle the threat of counterfeit medicines, which will complement our own proposed changes to legislation at national level to make the supply chain for medicines more secure against counterfeit infiltration.

In medical devices, we will complete the UK implementation of improvements already agreed at EU level (both the revision of the Medical Devices Directives, and the broader changes flowing from the Regulation on Accreditation and Market Surveillance), which come fully into force in early 2010. At the same time, we will be working with stakeholders and European partners to influence the development of possible further change to the regulatory framework. We will be pressing for specific improvements – in particular a much stronger oversight of Notified Bodies, and a full review and updating of the In Vitro Diagnostics Directive – but also an approach meeting the principles of better regulation.

Research and innovation in medicines will continue to receive a high level of expert support through both National and European Scientific Advice procedures and also through active participation in European and International scientific working parties. This will expand this year to include the 'advanced therapies' of gene and cell therapy and of tissue engineering, where we will take steps to ensure that regulation supports and enables the development of new treatments in this field, including stem cell technology.

Regulatory science/research studies

Investing in regulatory science and developing links with the academic and research communities is one of our new targets for this year and supports one of the key Corporate Plan priorities. This will include a programme for commissioning research studies to support and measure the impact of regulatory actions, which will help us to monitor the public health outcomes of the regulatory actions we take.

Building on our engagement with clinicians, researchers, industry and other stakeholders, we intend to increase the number of new Technology Forum meetings, covering both pharmaceuticals and medical devices. Forum meetings bring together experts and interested parties to consider specific issues of science and technology in healthcare which may need regulation to adapt to support the development of beneficial and safe new healthcare treatments.

Earlier access to medicines

We have established a working group with industry, NHS, Government and patient representation to follow up on the recommendation in Sir David Cooksey's report to enable patients to be treated with new medicines at an earlier stage than current licensing arrangements allow. The working group aims to develop a specific UK scheme to offer earlier access to medicines that are still in development, subject to controls covering issues such as patient information and consent, and requirements for gathering additional information on benefits and risks during such use that can supplement data from clinical trials. The working group's programme will include an extensive stakeholder engagement programme, in particular to assess public views on the benefit and risk trade-offs involved in choosing treatment with medicines that are not yet fully licensed.

Unlicensed medicines

When a healthcare professional prescribes an unlicensed medicine to meet the special needs of an individual patient, responsibility for protecting the patient is shared between the individual practitioner, the healthcare organisation and the MHRA as medicines regulator. We will continue our project to review and update the role of medicines regulation within this framework against the principles of better regulation to reflect wider developments in the prescribing and management of unlicensed medicines.

Better Regulation

The principles of better regulation – that regulation should be proportionate, accountable, consistent, transparent, and targeted to risk relative to benefit – are central to all our work both in designing and operating the regulatory framework. Unnecessarily burdensome regulation not only damages the commercial interests of industry, it also hampers the development of new healthcare treatments that could benefit patients, and additionally divert scarce regulatory resources from activities that could better protect health.

The Agency's progress in this area was recognised in a positive report from the review of compliance with the Hampton principles of better regulation; and in the success of the Better Regulation of Medicines Initiative (BROMI) in winning the Better Regulation category at the 2008 National Business Awards. We will keep pushing BROMI forward to its fullest potential. We are working to increase the usage of the Code of Practice on Pack Design to gather the evidence needed to support full implementation of the third party approval system for pack design. We are also looking to further simplify the BROMI variations scheme, which was fully implemented as a mainstream procedure in 2008, in readiness for the implementation of the new EU Variations Regulation. We will continue to make good progress in the area of Pharmacovigilance and are exploring proposals to simplify literature reporting, Periodic Safety Update Reports and the requirements around Detailed Description of Pharmacovigilance Systems. We will publish our Fourth BROMI report, to inform stakeholders of the progress BROMI has made and its contribution to the Government's Better Regulation Agenda.

We will also continue to roll out our risk-based inspections programme, and will take forward the project launched in 2008 to review and consolidate the 1968 Medicines Act and all the regulations made under it. This will be a major exercise to simplify the legislation that governs the regulation of

medicines, and will involve substantial engagement and consultation with stakeholders.

We recognise that Better Regulation applies to the NHS as much as the industry, and aim to minimise the burdens we place on healthcare facilities and staff, and avoid any unnecessary overlap with other regulators.

International Co-operation

Trends in the global industries we regulate, and greater need for regulatory authorities across the world to work together, make it increasingly important for the MHRA to develop stronger international links beyond Europe. Alongside partnership with established regulators in countries such as the USA, Canada, Australia, New Zealand and Japan, we are strengthening our relationships with China and India, as major source countries for active ingredients and products used in the UK. Priorities will include cooperation on counterfeits, on inspections and on quality standards for active pharmaceutical ingredients.

This area is supported by 2 key targets (K6 & K7),

and 3 high-level targets (H9 H10 & H11).

7. Running a successful organisation

Finance

One of the main objectives for 2009/2010 is to ensure that the Agency's finances are sound and stable through sound budget setting. There is more on the Agency's proposals for its budget in section 10.

Licensing performance improvement

Unprecedented increases in the volumes and complexity of medicines licensing work require constant attention to our business and information

processes and our organisational structure. Opportunities to extend a targeted approach to assessments will be taken wherever possible and consistent with maintaining quality standards. Significant additional numbers of assessors require training in regulatory science, procedures and information handling as well as the opportunities to develop professionally. We aim to maintain standards of quality and timescales, and to deliver improvement in those areas – particularly national work – where performance has yet to meet our assessment time targets.

Staff development

The agency recognises and encourages the contribution made by diverse teams and individuals. This year we will further enhance career development within the Agency by developing a talent management initiative to actively support the needs of staff as identified through the personal development plan process. Activities to promote the Investor in People standard will be introduced leading to the reassessment in December 2009 of the Agency's IiP accreditation. The evolution of our Management and Leadership programme will continue to establish a leadership and coaching culture across the Agency. We also remain committed to supporting continuing professional development programmes for the large range of specialist groups in the agency.

We will continue to support managers through enhancing our business partnering approach and to reviewing HR policies in line with changes to the organisation and employment legislation. We will continue to monitor the external employment environment to ensure that the Agency is well placed to be able to recruit and retain good quality staff. We will fully utilise the provisions within the HR policies to adequately reward and recognise staff.

The Agency will be relocating to new accommodation by the end of 2011. This is an opportunity to develop its environment and working practices in support of its strategic goals, particularly in relation to working in high performing teams. In order to do this, we will develop a high level vision for the principles underpinning the design of the new accommodation and continue the process of cultural change which will help to deliver the new ways of working

Encouraging electronic working

In 2009-10, the Agency will continue to provide stable IT systems and build on the investment which has been made in its major IT system, *Sentinel*.

The Agency will meet its targets for Information Processing and work collaboratively with other Divisions to improve the quality of data held within *Sentinel* by cleansing of historical data and ensuring quality assurance in the data handling, to avoid new errors being introduced into the system.

General Practice Research Database (GPRD)

GPRD will continue to promote its broader portfolio of services which it can offer, with the GPRD database itself being one component, but increasing focus on research services. In particular, there will be continued growth of the new ExEtrac service.

Maintaining a lead in the European environment

We will continue to take a leading role in the EU, in the development and licensing of new medicines by remaining in the upper quartile of Member States acting as rapporteur, scientific advice coordinator or reference Member State. To do this we will need to further increase our investment in the recruitment, training and professional development of staff to ensure we have the resources and skills to do an excellent job every time.

This objective is supported by 3 key targets (K8, K9 & K10),

and 3 high-level targets (H12, H13 & H14).

8. Key and High-level Targets for 2009/2010

Performance against the targets set out below will be monitored throughout the year. Following independent audit, the Agency's achievement against the Key Targets (K1 to K10) will be published in the Annual Report for 2009/10. A summary of the targets, in the Balanced Scorecard format, is at Annex A.

Safeguarding public health

	Main text	Measures/ Indicators
K1	Ensure all reported adverse incidents (medicines and devices) are dealt with promptly and efficiently; and promote and develop the Agency's reporting systems.	Maximum timescales between receipt of reports and making them available for evaluation and analysis: • For fatal and serious device adverse incidents: 100% within 3 working days. • For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours. • For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days. • For medication error notifications; identification and transmission to National Patient Safety Agency within 7 days. Promotion and development: • Delivery of on-going communications plan for the Yellow Card Scheme. • Ensure 98% of ADR reports from industry are submitted in electronic form by end of 2009/10. • Work with Connecting for Health on the introduction of direct to database ADR reporting from General Practice IT systems.

	Main text	Measures/ Indicators
K2	Issue, through an effective process, central alerting system messages for medicines, medical device alerts (MDA) and other safety warnings, supported by relevant media activity where appropriate, which identify clear and appropriate action which recipients can achieve within realistic timescales	• Monitor effectiveness of alerts and take steps to improve where appropriate. • Publish medical device alerts within 60 working days of senior management agreement to issue a MDA. • Immediate action MDAs within 20 working days of senior management agreement. • Issue central alerting system message in a timescale proportionate to the risk.
K3	Tackle the threat from counterfeit medicines and devices.	• Assess 90% of reports of suspected counterfeits within 24 hours, and 100% within 72 hours. • Implement the actions set out in the Agency's Anti-Counterfeit Strategy. • Implement an Internet Awareness campaign. • Identification of potential changes to legislation or practice by March 2010. • Continue to work closely with Trading Standards Departments and Her Majesty's Revenue and Customs Intelligence Unit to identify and control counterfeit devices through: undertaking customs awareness sessions during the year; and actively participating in the RAMS project to protect UK borders against counterfeit goods.

	Main text	Measures/ Indicators
H1	Assess applications for clinical trials for medicines and investigations for medical devices within timescales, to ensure that only those meeting the necessary requirements are given approval to proceed. Take steps to monitor and assure quality of decision making.	Timescales for clinical trial authorisations for medicines; • at least 98% in 30 calendar days. • with an average of 14 calendar days or less for Phase I (healthy volunteer) trials. Timescales for clinical investigation notifications for medical devices: • maximum of 60 days • with an overall average of 54 days or less Quality of decisions • Complete a review of the audit system for medicines Clinical Trial Authorisation decisions and implement. • Report (quarterly) the concordance of Clinical Trial medicines assessor recommendations with the advice given by the CT Expert Advisory Group and CHM, investigating all instances of non-concordance. • Annual audit by CSD of 5-10% of randomly chosen clinical investigations to assess concordance of decision making recommendations with regard to lessons for the future.

	Main text	Measures/ Indicators
H2	Carry out medicines licensing assessments within timescales, ensuring that applications for and variations to licences are thoroughly and promptly assessed before determination.	Assessment timescale targets: • National new licence/ registration applications for chemical, biological, homeopathic & traditional herbal medicines: - 80% in 100 days - 98% in 150 days • EU new licence applications for chemical & biological medicines: - MRP: 99% in 50 days - DCP RMS: 99% in 70 days - CP: 99% in 80 days - DCP CMS: 99% in 100 days • Variations for all products: Type IA notifications: - 98% validated in 14 days Type IB: - 80% in 20 days - 98% in 30 days Type II: - 80% in 60 days - 98% in 90 days Type II reduced: - 98% in 30 days Type II extended: - 98% in 120 days Quality of decisions • Complete a review of the audit system for medicines Marketing Authorisation decisions and implement. Report (quarterly) the concordance of Marketing Authorisation assessor recommendations with the advice given by the Expert Advisory Groups and CHM, investigating all instances of non-concordance.

	Main text	Measures/ Indicators
H3	Strengthen and streamline procedures for the processing of reclassification applications to support wider access to medicines.	• Work with stakeholders to develop new procedure. • Implement new procedure by end of March 2010.
H4	Deliver renewed MHRA strategy to improve availability of medicines authorised for children in new EU legislative environment	• Strategy agreed consultation if appropriate and publication by end Dec 2009. • Implementation of any new measures identified in the strategy or agree a plan by end 2009-10.
H5	Pursue Agency strategy for delivering effective regulation of herbal medicines	• Extend communications with herbals-using public, about THR scheme and safe use of herbal medicines, via media articles and briefings and website initiatives and establishing links with patient groups. • Subject to clarification by DH on proposals and timetable relating to the regulation of the herbal medicine profession, publish updated proposals for reform of s12(1) of Medicines Act.

Communicating effectively with all Stakeholders

	Main text	Measures/ Indicators
K4	Take steps to improve the Agency's communications with its various stakeholders, with particular emphasis on healthcare professionals.	• Implement specific, targeted sections on the website for the pharmaceutical industry and patients, and to develop targeted pages for healthcare professional specialists. • Identify and develop content for 5 new subject areas on the website by March 2010. • Develop and implement three marketing strategies a year which support the Agencies business objectives. • Produce Drug Safety Update on a monthly basis and take steps to promote uptake. • Produce 6 editions of “One-Liners”. • Ensure that the agency continues to be highly ranked in the major Internet search engines; and ensure at least 10 additional links are in place between the MHRA website and other priority sites.
K5	Roll out a two-year action plan to develop the involvement of patients and the public with a view to improving the quality of decision-making within the Agency and the level of understanding of its work, and with reference to both product-specific decisions and wider policies.	• Publish the two-year action plan. • Implement the first year of the patient and public engagement action plan

	Main text	Measures/ Indicators
H6	Support patient awareness and understanding of medicines through high quality and accessible patient leaflets.	• Develop and roll out publicity campaign to stakeholders on new patient information leaflets (PILs). • Develop a programme for engagement with pharmaceutical companies on improving the quality of patient information leaflets. • Develop electronic access to PILs. • Develop and publish new guidance on best practice in information design.
H7	Continue to improve the transparency of decision-making in the Agency and accountability to the public by publishing information about the Agency's work, publishing information and evidence underpinning Agency decisions.	• Publish 98% of UK Public Assessment Reports for medicines licensed within 60 days of final determination. • Provide summaries of the evidence supporting major safety decisions within one month of final regulatory decision. • Develop process for published summaries of risk management plans for new medicines by end 2009/10 • In working towards achieving 100% compliance, ensure that at least 90% of requests under the Freedom of Information Act are replied to within 20 working days. • Publish performance figures for patient information and advertising case work.
H8	Ensure excellent service to Ministers by securing the quality and effectiveness of MHRA's policy responsibilities across Government and by the management and quality assurance of MHRA Parliamentary and Ministerial business.	• Meet DH deadlines for responses to Parliamentary Questions in at least 80% of the cases, with less than 10% rewrite rate. • Meet Ministerial correspondence deadlines in at least 80% of cases with less than 10% rewrite rate.

Shaping a Balanced Regulatory Framework

[this covers the Agency's objectives on supporting research & innovation, influencing the EU/ international environment, and better regulation]

	Main text	Measures/ Indicators
K6	Pursue UK objectives in EU negotiations on changes to the regulatory framework; and implement EU legislation through changes in UK law.	Pursue and achieve UK objectives in EU negotiations on: • Proposed Recast of Medical Devices framework. • Proposals to strengthen pharmacogivilance provisions • Proposals on information to patients. • Proposals to tackle counterfeit medicines. Take steps at national level to implement: • The new Variation Regulation for medicines. • Amendments to the Medical Devices Regulations, to reflect changes in the accreditation and Market surveillance Regulation by consulting stakeholders and completing by Jan 2010.
K7	Invest in regulatory science by further developing links with external research groups to support regulatory decisions or assess outcome of action.	• Establish a programme of work with external academic groups, with a view to defining and commissioning research studies, to support regulatory decisions or assess outcome of action. • Develop and deliver a training course on methods for carrying out post-authorisation safety studies. • Hold four meetings of the New Technologies Forum (two on medicines, two on devices).

	Main text	Measures/ Indicators
H9	Develop proposals for an earlier access scheme in the UK for new medicines.	• Work with stakeholder interests, including widespread consultation and engagement with patient and public groups to develop proposals by March 2010.
H10	Take actions to progress the Government's Better Regulation agenda, to ensure that the regulation of medicines and devices is proportionate and risk-based.	• Pursue MHRA actions set out in Department of Health Simplification Plan, and work with industry to monitor delivery of administrative burdens savings up to 2010. • Continue the Better Regulation of Medicines Initiative (BROMI), encouraging uptake of arrangements already introduced, and working to identify further changes. • Deliver specific milestones for 2009 in the ongoing project to consolidate medicines legislation • Determine project plan for the review of medicines legislation by end of 2009/10. • Identify those Macrory powers appropriate for implementation by the Agency by 2010. • Take forward the Agency risk-based inspection strategy, initiating the implementation phase of the project.
H11	Review the existing arrangements for supply and use of unlicensed medicines in the UK supplied under national arrangements set up under Article 5.1 of Directive 2001/83/EC, consulting on options for change.	• Launch by Dec 2009 consultation on specific proposals arising from review of unlicensed medicines (following preliminary consultation anticipated for spring 2009).

Running a Successful Organisation

	Main Text	Measures/ Indicators
K8	Ensure the Agency's finances are sound and stable	• Achieve an income and expenditure surplus during 2009/10, and as a minimum, exceed a 3.5% per annum return on capital employed.
K9	Ensure further improvement in the efficiency and performance of the core medicines licensing functions, in particular in areas where backlogs remain	Over the year as a whole, the numbers of applications determined (completed) to exceed the predicted numbers received by at least 10% in each of the following areas of activity: • New Marketing Authorisations granted in National, Decentralised or Mutual Recognition procedures. • Major (Type II, non-safety) variations to Marketing Authorisations. • New Parallel Import Licences. • Variations and label/leaflet changes to Parallel Import Licences.
K10	Ensure that the Agency trains and develops its staff to meet current and future needs for skills and expertise throughout the Agency's area of work. Training plan published and appropriate courses delivered.	• Achieve evaluation scores of at least 75% for all courses, to demonstrate they are successful and meeting the Agency's needs. • Ensure that at least 80% of staff who complete 3 month evaluation information are able to put their learning in to practice when they have the opportunity to do so. • Talent management proposals developed and published by November 2009. • Investors in people standard achieved in re-assessment, December 2009.

	Main Text	Measures/ Indicators
H12	Maintain the Agency's position as one of the leading authorities in the EU, by undertaking significant amounts of work in EU procedure for medicines licensing	Remain in the upper quartile of EU Member States for: • Rapporteur/Co-rapporteur appointments in the Centralised Procedure. • Co-ordinator appointments for CHMP scientific advice. • Reference Member State appointments in new mutual recognition/decentralised procedures.
H13	Develop GPRD ExEtrac, to offer enhanced opportunities for research, in particular to support risk management plans for new medicines	• At least two clients in operation during the year.
H14	Work to ensure that data held on the Agency's IT system for medicines are accurate and up to date, in order to ensure the right information is available for regulatory decision-making.	• Prepare a plan and implement a project to enhance Sentinel data quality. • Plan and implement a regular system of audit and other quality assurance measures to maintain Sentinel data quality.

Targets 2009/10 (Annex A)

Safeguarding Public Health

K1 – ADR/adverse incident reports

K2 – Issuing alerts and warnings

K3 – Tackling counterfeits

H1 – Clinical trial / investigation applications

H2 – Medicines licensing time targets

H3 – Streamlining medicine reclassifications

H4 – Paediatric medicines strategy

H5 – Herbal medicines strategy

Communicating effectively

K4 – Develop communications / website

K5 – Patient and public engagement

H6 – Improving patient leaflets

H7 – Transparency / FOI

H8 – Ministerial / Parliamentary

Shaping a Balanced Regulatory Framework

K6 – Negotiating and implementing EU legislation

K7 – Regulatory science/research studies

H9 – Early access project

H10 – Better regulation

H11 – Review of Unlicensed Medicines

Running a Successful Organisation

K8 – Finance

K9 – Efficiency improvement in licensing

K10 – Staff development

H12 – EU licensing business

H13 – GPRD / ExEtrac

H14 – Sentinel data accuracy

9. Business Volumes

MEDICINES	08/09	09/10
Licensing Activities		
New Active Substances (including orphan drugs)	15	115
Complex Abridged:		
National	35	45
Mutual Recognition (CMS)	50	40
Decentralised (CMS & RMS)	330	420
Standard Abridged MA Applications:		
National (UK only)	105	110
Mutual Recognition (CMS)	95	110
Decentralised (CMS & RMS)	645	770
Simple Abridged MA Applications:		
National (UK only)	55	95
Variations to UK Product Licenses:		
Minor (Type IB) Non-safety Variations	3,300	4,350
Major (Type II) Non-safety Variations	3,800	3,950
Type IA Notifications & Certificates	14,000	14,500
Inspection		
Good Manufacturing Practice Inspections	560	409
Good Distribution Practice Inspections	375	639
Good Laboratory Practice Inspections	70	56
GCP Laboratory Inspections	17	15
GMP QC laboratories	10	23
Good Clinical Practice Inspections	116	112

	08/09	09/10
Pharmacovigilance Inspections	92	100
Manufacturers' and Wholesale Dealers' Licences:		
Applications	200	200
Variations	790	900
Export Certificates	6,000	6,000
Unlicensed Import Notifications	60,000	60,000
Borderline Cases:		
Complaints/Referrals	500	700
Advice Requests	500	500
Defect Reports	600	700
Enforcement		
Referrals		
Enforcement Referrals	550	1400
Criminal Investigations	280	300
Intelligence referrals	200	250
Case referral centre	800	900
Counterfeit Case Referrals	90	100
Internet Case Referrals	250	300
Case Disposal:		
Referrals for Prosecutions (DWP/CPS)	50	60
Intelligence		
Test Purchases	70	90
Licensing checks	370	450
Communication data checks	100	110
Dissemination to other agencies	80	100
Dissemination to other overseas agencies	70	90
Operations		
Enforcement visits	200	250
Vigilance and Risk Management Activities		
Adverse Drug Reaction Reports	25,500	26,000
Drug Safety Enquiries	6,000	6,000

	08/09	09/10
Signals Investigated	1500	1,500
Compliance Issues	25	25
Risk Management Plan assessments	120	295
	08/09	09/10
Risk assessments and risk :benefit reviews	100	100
Periodic Safety Updates – Marketing Authorisations affected (not including renewal)	2,500	4,000
Safety Variations	3,000	3,500
Assessment of Labels and Leaflets	3,000	1,700
Reclassification	20	20
Advertising: Complaints Received	150	180
Advertising: Number of products vetted	50	55
Renewals Received (European and National)	800	1,000
MEDICAL DEVICES		
Adverse Incident Reports	9,000	9,100
Medical Device Alerts	75	85
Audits of Notified Bodies	12	13
Clinical Investigation Notifications	55	55
Registrations	850	850
Advice Requests for Borderline/Interpretations	1,100	1,200
Proactive Compliance Cases	200	170
Reactive Compliance Cases	200	200
BLOOD and its components		
(started in November 2005)		
Inspections – blood establishments	9	12
Inspections – hospital blood banks	70	70
Compliance Reports	390	388
Serious Adverse Events and Reactions	1,200	1,700
Number of Registered Users	350	300

10. Budgets for 2009/10

The MHRA's business plan again reflects the Agency's over-riding priorities of improving its performance whilst ensuring that its key public health responsibilities are delivered. The key issues around the MHRA's 2009/10 draft budget are the continued needs to take a medium-term perspective and to maintain its cash strength in order to address the key strategic issues of:

- The possible accommodation move in 2011, given its attendant uncertainties; and,
- Continued IT investment, to ensure improving services to the Agency's customers.

The draft budget proposes a surplus in 2009/10, the second year in the second 5-year cycle for the MHRA's legal duty to earn a 3.5% average rate of return on its assets. The HM Treasury Minute for the period from 2008/09 was received and in outline the estimated impact on dividends to be earned and paid over is that the Agency needs to earn c£6m during the 5 year period. The Agency will, if necessary, adjust the resources dedicated to fee earning activities during the year in order to ensure that the performance improvement targets are met.

£millions Budget	**2008/2009**	**DRAFT Budget 2009/2010**
Operating income		
Trading income	86.8	96.0
Income from Department of Health	11.1	11.4
Total Operating income	**97.9**	**107.4**
Operating expenditure		
Pay	53.1	56.4
Non pay	39.8	41.0
Total Operating expenditure	**92.9**	**97.4**
Operating surplus	5.0	10.0
Capital spend	3.8	7.0


MHRA