Safeguarding public health

MHRA

ANNUAL REPORT & ACCOUNTS 2009/10

Medicines and Healthcare products Regulatory Agency

HC196

Medicines and Healthcare products
Regulatory Agency

Annual Report and Accounts 2009/10

Presented to Parliament pursuant to Section 4(6) of
the Government Trading Funds Act 1973 as amended
by the Government Trading Act 1990

Ordered by the House of Commons
to be printed on 8 July 2010

HC196 London: The Stationery Office **£19.75**

ISBN: 9780102966749

Printed in the UK for The Stationery Office Limited on behalf of the Controller of Her Majesty's Stationery Office

ID 2371415 07/10

Printed on paper containing 75% recycled fibre content minimum.

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Chairman and Chief Executive's
REVIEW

It is a truism that virtually all annual reports refer to the year they review as challenging, stretching or eventful, and we are sure that the Agency's is no exception.

However, we think that for 2009-10 we are justified in reflecting on the year in these terms. The rise and global spread of pandemic influenza H1N1 has placed demands on public health organisations all over the world, so we have not been alone in facing the challenges. In the event, the severity of the disease appears to have been less than many previous pandemic strains. But nonetheless, the preparation and delivery of public health interventions appropriate to the spread and impact of the disease has been a major theme of activity for staff working on medicines, devices and blood products within the MHRA.

The spread of pandemic flu has provided further evidence – were it still needed – that public health is a global concern, and more so than ever before. This is something we have reflected on in previous reports, but this year has underscored it. Whether in the spread of infectious disease, the trade in counterfeit products, or the global sourcing of raw materials for legitimate products, the world at large is our operating environment. The UK regulatory system has a strong reputation both within Europe and beyond, and it is important that we work hard to maintain that position so that we can exercise appropriate influence in global issues.

The worldwide economic situation is affecting all of our stakeholders, and consequently us too. Patients and the public are more conscious of the costs of healthcare; the health service is feeling the impact of constrained public finances; and the industries we regulate are subject to the wider economic climate. The Agency's focus is on whether the products we regulate do what they should and in an acceptably safe way, rather than on their cost. But we must still be mindful of the wider economic situation, and ensure that our regulatory decisions do not have perverse effects on healthcare.

These challenges look set to continue into 2010-11 and beyond, and it is fitting therefore that our sixth annual lecture in January 2010 was delivered by Mr Thomas Lönngren, the Executive Director of the European Medicines Agency. He was able to draw together for the large audience of Agency stakeholders both the regulatory challenges and the international context in which we now operate. We present our approach to meeting these future challenges in our Business and Corporate Plans, and encourage you to read those documents if you would like to know more about how we intend to develop the Agency in the coming years. In this document, however, we would like to identify a few highlights from 2009-10.

Public health issues

Influenza H1N1 (swine flu) was the subject of a level 6 pandemic alert from the World Health Organization on 11 June. This annual report is not the place for an exhaustive review of the Agency's activities in this area, although we are conducting a separate review and lessons learned exercise to ensure that positive lessons and improvements are captured for the future.

In outline, we contributed to the special European procedures for the licensing of pandemic flu vaccines, providing a significant part of their scientific assessment. We established a special online portal to capture reports of adverse reactions to vaccines and antivirals, and published weekly updates on these. We were involved in providing advice and regulatory input on the diagnostic tools being used to confirm the spread of H1N1. As well as conducting our own review of what we did, we will work with colleagues internationally in the coming months to collectively consider what we can learn for the future.

Another public health issue with an international dimension was that of contaminated unfractionated heparin. Early in 2009, we received information that a number of batches of unfractionated heparin, used widely in hospitals as an anti-clotting agent for blood, was contaminated with low levels of over-sulphated chondroitin sulphate. This posed a dilemma: to withdraw the product from the market, in effect causing a product shortage and exposing patients to the risks of not being treated with heparin; or to leave the product on the market to maintain continuity of supply, but expose patients to the potential contamination risk.

We took independent advice from the Commission on Human Medicines, and concluded that the potential risks from low levels of contamination were outweighed by the more substantial risks of a supply shortage of this product. We therefore issued a cautionary note to healthcare professionals, explaining the situation and asking them to be particularly alert for any problems. Although we received one report of suspected anaphylaxis with a fatal outcome in association with a contaminated heparin batch we were subsequently informed by the Coroner that the patient had died of natural causes. Uncontaminated product is now back in the UK supply chain, but with global sourcing of the ingredients for pharmaceuticals we must ensure that we remain alert to the possibility of these problems so that we can take rapid action to protect public health, and build in reasonable safeguards to prevent such problems arising.

Another global phenomenon to which we have referred in previous years is the criminal trade in counterfeit medicines. Although we have had only one case of counterfeit medicines penetrating the legitimate UK supply chain for a couple of years, there is no scope for complacency. To this end, in November 2009 we took part in Operation Pangea II, an international internet week of action in which authorities across the world clamped down on those selling products illegally over the internet. In the UK alone, we seized counterfeit and illegal medicines valued at over £350 000, arrested three people and took down illegal websites.

An Expert Advisory Group bringing together representatives of the British Orthopaedic Association, the National Joint Registry and MHRA is currently looking at the issue of soft tissue damage in association with Metal on Metal hip implants and how this should be investigated and managed.

Outreach work

Our regulatory decisions are only as good as the public health action which they lead to – to be of value, they must be accepted, understood and acted upon by healthcare professionals and patients. Whilst we are not primarily an education body, we do nonetheless devote time and effort into ensuring that our information reaches and helps patients and those who treat them.

One of our most visible commitments to this is the network of Medical Device Liaison Officers (MDLOs). There are some 490 of these in PCTs, acute and other Trusts in England. They provide a vital link between the Agency and the frontline of the NHS, cascading our alerts and other information out to those who need it, and passing back to us feedback and comments. In November, we held our eighth national MDLO conference in Birmingham, at which 170 delegates, guests and other professionals came together to share their experiences and discuss how we can optimise our interactions with the NHS. We have also launched an online module, Devices in Practice, as a training tool for those procuring and using medical devices.

At the policy as well as the delivery end of what we do, we are striving to engage more with our stakeholders and learn from them. We have established a medical device technology forum to bring together experts on different aspects of device technology and help us to ensure that the regulation keeps pace with the science. For example, in Spring 2009 the forum looked at quicker ways of bringing new technology to market and to the benefit of patients. Other fora on different subjects are planned for the future, and we have similar initiatives for medicines issues.

We have continued to produce our regular publications for healthcare staff, including Device Bulletins, One Liners and our now well-established monthly Drug Safety Update. Campaigns are also being developed to promote some of our communications mechanisms. In particular, we have attended a number of primary care events in the past six months to try to promote to GPs our Yellow Card scheme for reporting adverse drug reactions. We have gathered useful feedback from our discussions at these events, and will use this to inform future promotional activity.

Following a review of our strategic priorities a few years ago, we are increasingly trying to involve our stakeholders at an earlier stage of policy development, to help us shape policy in a way which meets their needs. For example, over the past year we have been exploring the possibility of making certain medicines – for life-threatening or seriously debilitating conditions – available to patients earlier, and before a full licence is granted. In shaping our thoughts on that, we ran a number of discussion groups with patients, the public, healthcare professionals and with children and young people. Their insights were frequently incisive, and have played a vital part in helping us develop a proposal which ministers have approved and which we will be taking forward to implementation over the next year. We will continue to engage with them on the details of that implementation plan.

Regulating effectively

The primary aim of our regulatory activity is to protect public health. This is partly about keeping unsafe products off the market; but it is also about ensuring that an unnecessary regulatory burden does not prevent promising new products from reaching patients. It is in this latter area in particular that better regulation initiatives play their part.

In this regard, the year got off to a good start with the publication of the Better Regulation Executive's Hampton Review of the Agency (named after the expert who recommended better regulation principles against which regulators should be judged). The Review was very positive, concluding that we were compliant with the Hampton principles, and were a proportionate, transparent and risk-aware regulator.

Areas for development included the formalisation of risk-based approaches to regulation and greater awareness of the risk of gold-plating regulatory requirements, and we are considering and working on these recommendations. Overall, though, as our first review against the Hampton principles we found this a very encouraging report, and were pleased that our own initiatives to manage the regulatory framework within which we operate had been recognised.

On a rather different note, the year has seen the reappointment of many of our independent expert advisory committees. These committees are an important part of the regulatory infrastructure, and without their expert advice and input the Agency would be unable to function as effectively as it does. Appointed by and accountable to the Secretary of State, these committees are able to provide expert input on critical public health issues, and make recommendations to ministers on appropriate regulatory action. During the course of the year, Sir Gordon Duff was reappointed as Chair of the Commission on Human Medicines; and following the retirement of John Williams, Dr John Perrins was appointed as Chair of the Committee on the Safety of Devices.

Corporate issues

Over the past few years, one of the main concerns expressed by the pharmaceutical industry has been the Agency's performance in the timely processing of work, and in particular the backlogs in considering industry applications in certain areas. We have been addressing this systematically over the last several years, and this year has been no exception. We are therefore pleased to say that during the course of this year we have made considerable progress in reducing or eliminating backlogs in all areas of medicines licensing.

Looking ahead, we have a major change on the horizon as the lease on our headquarters building at Market Towers comes to an end. Over the last year we have secured new accommodation in Victoria, London, and have been making preparations for our move which we now hope to undertake late in 2010. In order to ensure we make the most efficient and cost-effective use of space, this will require us to look at new ways of using the office environment which are both challenging and full of opportunity. Naturally, we will work with our staff on delivering this new office environment.

It is the staff of the Agency who make all the achievements outlined in this report possible, and we would like to put on record our gratitude to them for all that they have done over the past year. Our staff survey results regularly show very high levels of commitment to the Agency's purpose and objectives, and this shows through in the high quality of work. With this in mind, we were delighted that the Agency successfully maintained its Investors in People accreditation following re-assessment in late 2009.

Our non-executive Directors also make a vital contribution to the life of the Agency, ensuring strong oversight and governance of our activities. During the year we bade farewell to Charles Kernahan who left the Board after six years of service, and we thank him for all that he has given to the Agency, including a long spell on the Risk and Audit Committee. We welcomed Sir John Lilleyman and Mr John Williams as non-executives, and look forward to working with them over the coming years.

We hope that this short review has provided an insight into the Agency's activities over the last 12 months, and some sense of the priorities and challenges as we move forward. We look forward to working with all of our stakeholders on continuing to deliver the best possible health outcomes for patients.

Prof Sir Alasdair Breckenridge
Chairman

Prof Kent Woods
Chief Executive Officer

Corporate GOVERNANCE

The MHRA is an executive agency of the Department of Health and operates as a government trading fund. The Agency came into existence on 1 April 2003.

The Secretary of State for Health determines the policy and financial framework within which the MHRA operates, but is not involved in the day-to-day management of the Agency. The terms under which the Agency operates are set out in its Framework Document.

MHRA has an Agency Board, a Risk and Audit Committee and an Executive Board. Together these three entities oversee the Agency's corporate governance and risk management systems to ensure that the highest standards of integrity, accountability and operational capability are maintained.

The Agency Board consists of the Agency Chairman and eight non-executive Directors. The Agency Board's role is to monitor the Agency's strategic direction and to take action as appropriate. The Chairman is directly accountable to ministers for the performance of the Agency and its decisions.

The Risk and Audit Committee consists of three non-executive Directors. It is a sub-committee of the Agency Board and reports independently to the Accounting Officer and the Agency Board on the effectiveness of the operation of the Agency's corporate governance and risk management systems. The Committee is chaired by Lisa Arnold.

The Executive Board comprises the Chief Executive, the Chief Operating Officer and the other Heads of Divisions, who take executive responsibility for the strategy, operational management and service delivery of the Agency, including risk management. As the Accounting Officer, the Chief Executive also has responsibility for the Agency's resources.

The Board Members have no significant interests to disclose which may conflict with their responsibilities.

The Remuneration Report on pages 32 to 39 of this report gives details of the remuneration paid to the members of the Agency and Executive Boards.

External auditors - the Comptroller and Auditor General is appointed as the MHRA's external auditor. The cost of the statutory audit for 2009/10 was £98k. (2008/09: £104k)

During the year the Comptroller and Auditor General undertook an audit review of the Agency's 2008/09 shadow accounts as part of the HM Treasury IFRS trigger points measuring progress on the implementation of International Financial Reporting Standards which are being fully introduced from the start of the 2009/10 Financial Year. The cost for this work was £6k.

No non-audit work was undertaken by the Comptroller and Auditor General.

Events after the reporting period - There have been no significant events between the period under review and the date of issue of this Annual Report and Accounts.

Agency Board

Professor Sir Alasdair Breckenridge

Lisa Arnold

Shelley Dolan

Michael Fox

Professor Barrington Furr

Professor Vincent Lawton

Sir John Lilleyman

Professor Angus MacKay

John Williams, CBE

Executive Board

Professor Kent Woods

Clive Bray

Peter Commins

Alison Davis

Simon Gregor

Gerald Heddell

Dr Ian Hudson

Geoff Le Fevre

Dr Susanne Ludgate

Dr June Raine

Jonathan Mogford (from March 2010)

Shaun Gallagher (to Dec 2009)

Agency Board Meeting – attendance of Non-Executive Directors

April 2009 to March 2010 inclusive

2009 – 2010	Apr	May	Jun	Jul	Aug	Sep
Sir Alastair Breckenridge					No meeting in August	
Lisa Arnold				Absent		
Shelley Dolan			Absent			Absent
Michael Fox			Absent			
Professor Barrington Furr						
Professor Vincent Lawton						
Professor Angus Mackay						
Charles Kernahan		Absent				Not in post
John Williams	Not in post	Not in post	Not in post	Not in post		
Sir John Lilleyman	Not in post	Not in post	Not in post	Not in post		Absent

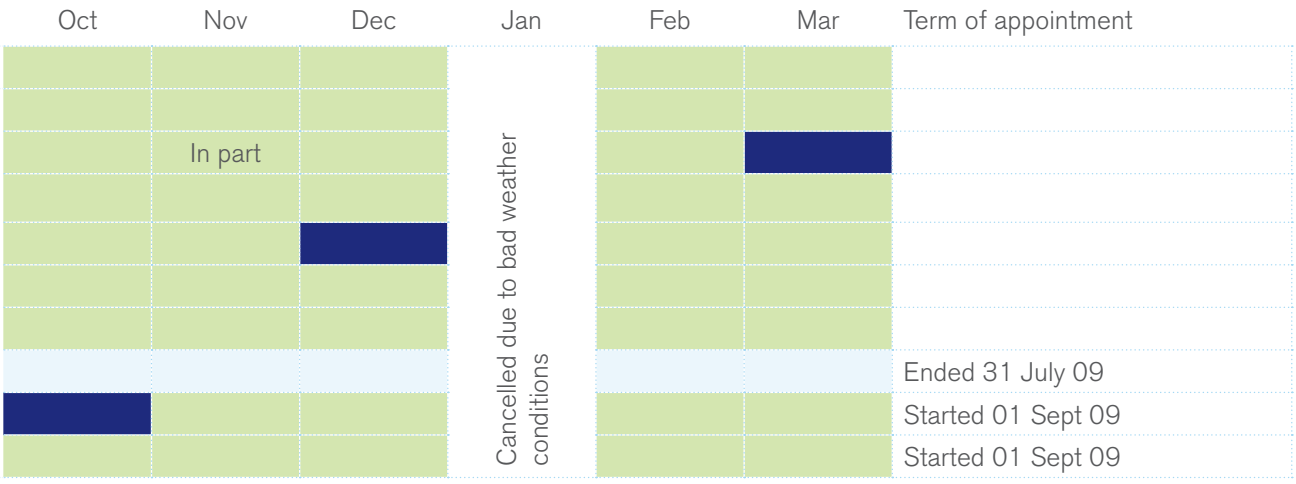
Colour key

	Attended
	Absent
	Not in post

Agency Board Awayday – attendance of Non-Executive Directors

April 2009 to March 2010 inclusive

	May	November
Sir Alastair Breckenridge		
Lisa Arnold		
Shelley Dolan		In part
Michael Fox		
Professor Barrington Furr		
Professor Vincent Lawton		
Professor Angus Mackay		
Charles Kernahan	Absent	
John Williams	Not in post	
Sir John Lilleyman	Not in post	



Risk and Audit Committee attendance

April 2009 to March 2010 inclusive

	Lisa Arnold	Michael Fox	Charles Kernahan	Vincent Lawton
10 June 2009				
21 October 2009				
13 January 2010				
24 March 2010				

Register of interests

Lisa Arnold

Personal Interest			
Name of organisation	Nature of interest	Fee earning	Whether current
Futura Medical PLC	Non Executive Director	Yes	Current
Allied Domecq Pension Funds Investment Committee	Independent Chairman	Yes	Current
Kraft Foods Pension Fund	Independent Investment Specialist	Yes	Current
Cheltenham Ladies College	Council Member	No voluntary	Current
Metal Box Pension Fund	Independent Chairman, Investment Committee	Yes	Current
John Laing Pension Trust Limited	Trustee Director	Yes	Current
Indirect interests			
Various companies including major pharmaceutical companies	Spouse's and own shares and pension portfolio independently managed by investment managers	Yes	Current

Shelley Dolan

Personal Interest			
Name of organisation	Nature of interest	Fee earning	Whether current
The Royal Marsden NHS Foundation Trust	Executive Director	Yes	Current

Michael Fox

Personal Interest			
Name of organisation	Nature of interest	Fee earning	Whether current
Barnet, Enfield and Haringey Mental Health Trust	NHS Mental Health Chairman	Yes	Current

Professor Barrington Furr

Personals Interests			
Name of organisation	Nature of interest	Fee earning	Whether current
Avesthagen	Consultancy	Yes	Not current
Astex	Consultancy	Yes	Current
AstraZeneca	Employee	Yes, salary	Current
Modern Biosciences	Consultancy	Yes	Current
Abingworth	Consultancy	Yes	Current
Pharma Profiles	Consultancy	Yes	Not Current
Sequella	Consultancy	Yes	Current
Genus	Employee	Yes, salary	Current
Palatin	Consultancy	Yes	Not current
Almirall	Consultancy	Yes	Current
MVM	Consultancy	Yes	Current
Avila	Consultancy	Yes	Current
Shroders Life Sciences	Consultancy	Yes	Current
Almac	Consultancy	Yes	Current
Enkam	Consultancy	Yes	Not Current
Intekrin Inc	Consultancy	Yes	Current
Medivir	Consultancy	Yes	Current
Trusteeships		Fee earning	Whether current
Breast Cancer Campaign	Trustee	No payment	Current
CRUK	Trustee	No payment	Not current
Non Personal Interests			
Welsh Cancer Tissue Bank	Advisory Board member	No payment	Current
CRUK Research Strategy Committee	Member	No payment	Current

Professor Vincent Lawton

Personal Interest			
Name of organisation	Nature of interest	Fee earning	Whether current
IMS	Consultancy	Yes	Current
Merck Sharpe Dohme Ltd	Shares / options	Shares / options	Current
Medco Ltd	Shares	Shares	Current
Addex Pharmaceuticals (Switzerland)	Non-Exec Director	Yes	Current

Sir John Lilleyman

Personal Interest			
Name of organisation	Nature of interest	Fee earning	Whether current
Appointing Authority for Phase 1 Ethics Committees	Director	Annual honorarium	Yes
ITP Support Association UK	Honorary President	No	Yes

Professor Angus Mackay

Personal Interest			
Name of organisation	Nature of interest	Fee earning	Whether current
NIL RETURN			
Professional/personal interests			
The Sackler Foundation	Chair of the Scientific Advisory Committee of the Sackler Institute in Glasgow	No – but a substantial research grant to Glasgow University.	Current
Indirect personal interests			
My wife and I have an investment portfolio managed by Barclays Wealth, with explicit instructions that this is managed "blind" with regard to myself and any member of my family			

John Williams

Personal Interest			
Name of organisation	Nature of interest	Fee earning	Whether current
NIL RETURN			
Professional/personal interests			
International Association of Oral and Maxillofacial Surgeons	Charity	No fees	Yes
Royal College of Surgeons of England Court of Patrons	Charity	No fees	Yes

Performance against Key Targets 2009/10

Targets		Comments
K1	Ensure all reported adverse incidents (medicines and devices) are dealt with promptly and efficiently; and promote and develop the Agency's reporting systems.	Achieved
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.	Achieved
K3	Tackle the threat from counterfeit medicines and devices.	Achieved
K4	Take steps to improve the Agency's communications with its various stakeholders, with particular emphasis on healthcare professionals.	Achieved
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.	Achieved
K6	Pursue UK objectives in EU negotiations on changes to the regulatory framework; and implement EU legislation through changes in UK law.	Achieved
K7	Invest in regulatory science by further developing links with external research groups to support regulatory decisions or assess outcome of action.	Achieved
K8	Ensure the Agency's finances are sound and stable.	Achieved
K9	Ensure further improvement in the efficiency and performance of the core medicines licensing functions, in particular in areas where backlogs remain.	Achieved
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.	Achieved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Performance Targets
2010/11

PM1 Medicines Licensing time targets	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 Type IA: • Nationals validated within 30 days • RMS validated 30 days from receipt of application and Despatch Date List (DDL) 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

PM2 Clinical trials and investigations time targets	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
PM3 Timescales for capturing and analysing adverse event reports	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.
	Publish medical device alerts (MDAs) within 55 working days of senior management agreement to issue a MDA Immediate action MDAs within 18 working days of senior management agreement
PM4 Transparency of decision-making in the Agency and accountability to the public	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 98% of UK Public Assessment Reports for medicines licensed within 60 days of final determination

Performance Targets
2010/11 cont'd

PM5 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
PM6 Finance target	Achieve an income and expenditure surplus during 2009/10, and as a minimum, exceed a 3.5% per annum return on capital employed

PM7 The recruitment, development and retention of a workforce of the necessary size, motivation and skill to undertake the objectives of the agency.	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 within the following 3 months
	Introduce an organisational leadership programme as part of the Agency's Maximising Talent Strategy by December 2011
	Develop and implement a continuous learning action plan to maximise the development opportunities identified in the Agency's recent successful IiP assessment by March 2011

Management

COMMENTARY

1 Description of the business

The MHRA is an executive agency of the Department of Health and operates as a government trading fund. The Secretary of State for Health determines the policy and financial framework within which the MHRA operates, but is not involved in the day-to-day management of the Agency.

2 Mission

The MHRA's mission is to enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.

3 Aims

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; and
- improving public health by encouraging and facilitating developments in products that will benefit people.

MHRA

4 Objectives

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; and
- run an organisation with a skilled and equipped workforce that is fit for the future.

5 Activities

The Agency's main activities are:

- assessing the safety, quality and efficacy of medicines, and authorising their sale or supply in the UK for human use;
- overseeing the UK Notified Bodies that audit medical device manufacturers;
- operating vigilance and other systems for reporting, investigating and monitoring adverse reactions to medicines, adverse incidents involving medical devices, and blood and blood products, and taking any necessary action to safeguard public health;
- operating a proactive compliance programme for medical devices;
- operating a quality surveillance system to sample and test medicines and to address quality defects, monitoring the safety and quality of imported unlicensed medicines and investigating Internet sales and potential counterfeiting of medicines;
- regulating clinical trials of medicines and medical devices;
- monitoring and ensuring compliance with statutory obligations relating to medicines and medical devices through inspection, taking enforcement action where necessary;
- promoting good practice in the safe use of medicines and medical devices;
- managing the General Practice Research Database (GPRD) and the British Pharmacopeia (BP) and contributing to the development of performance standards for medical devices;
- offering scientific, technical and regulatory advice on medicines and medical devices; and
- providing the public and professions with authoritative information to enable informed dialogue on treatment choices.

6 Legal, Regulatory and External environment.

The Agency's Corporate Plan 2009-2014 (available on the MHRA website at http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con043991.pdf) gives details of the legal, regulatory, operational and external environment, including key relationships with stakeholders.

7 Performance targets

The MHRA had ten key targets (set by the Minister) for 2009/10, for the successful achievement of its business objectives. An internal audit review of the outcome confirmed that all ten had been achieved, though certain elements of some were not amenable to quantitative assessment of their achievement.

The key targets for 2009/10 and their outcomes are detailed within this Annual Report.

The key targets for 2010/11 are detailed within this Annual Report.

8. HM Treasury accounts direction

The accounts have been prepared in accordance with accounts direction given by HM Treasury, in accordance with section 4(6)(a) of the Government Trading Funds Act 1973.

9 Financial Review

Agency Financial Position

The MHRA is required to achieve at least a 3.5% return on average capital employed over the period 1 April 2008 to 31 March 2013, as detailed in the HM Treasury minute dated 27 March 2008 attached at the end of the Annual Report and Accounts.

Income and Expenditure

The total income for the year at £112.5M was 0.3 per cent lower than last year (£112.8M).

Total costs for 2009/10 at £99.0M were 13.5% higher than the level of £87.2M in 2008/09. Staff numbers increased by 5.2% and total staff costs increased by 6.8% from £50.0M to £53.4m, whilst other operating costs increased from £37.2M to £45.6M. The depreciation charge increased by £0.8M to £6.1M.

The operating surplus for 2009/10 was £13.6M, compared to £25.6M in 2008/09. For 2010/11 there is a planned operating surplus of £10M, based on both higher revenues and higher operating costs. An average increase in fees of 1% has been put in place with effect from 1 April 2010.

Interest receivable less payable amounted to £0.1M in 2009/10, compared with £1.3M in 2008/09.

After charging a public capital dividend amount of £1.6M (2008/09 £0.9M), the net surplus in 2009/10 was £12.1M, leaving a retained surplus carried forward into 2010/11 of £46.9M.

Assets and liabilities

At 31 March 2010, the Agency had tangible fixed assets of £4M, a decrease of £1.3M in the year and intangible assets of £15.1M. Net current assets were £72.3M. After allowing for deferred revenue of £31.3M and long-term creditors and provisions of £9.7M, the total net assets were £50.4M.

10. Staff resources

The most important asset of the Agency is its staff, and during the year an average of 972 full-time equivalent staff were employed which included those on short term contracts. The MHRA has undertaken a busy recruitment programme, successfully attracting suitably qualified staff covering the complete range of specialist and corporate roles in delivering medicines and medical devices regulation. Its recruitment practices are in accordance with the Civil Service Commissioners Code and this was recently confirmed in a recruitment audit.

The Agency has maintained and developed its knowledge capability through a comprehensive career development programme built on the individual, specialist and corporate needs of staff. A key feature has been the management and leadership programme which also included an annual management and leadership conference for staff. This programme has continued to deliver excellent results demonstrating improved performance for individuals and the Agency. Continuing professional development (CPD) has been actively encouraged across all professions.

Recruitment

MHRA recruits staff on the basis of fair and open competition and selection on merit, in accordance with the recruitment code laid down by the Civil Service Commissioners. Systems are subject to internal and external checks.

97 staff were recruited during 2009-10:

	Male	Female
Executive Directors	1	-
Senior Civil Servants	-	2
Other Civil service staff	40	54
Total	41	56

25 people from ethnic minority groups and one person with a disability were recruited. 26.6 per cent of MHRA's staff are from ethnic minority groups and 1.0 per cent have a disability as defined under the Disability Discrimination Act 1995.

The permitted exceptions to the principles of fair and open competition and selection on merit were used 85 times for appointments over 12 months.

People with disabilities

In relation to employees with disabilities, MHRA complies with the equal opportunities legislation and provides special facilities where necessary.

Sickness absence

During the year, 3.7% of available working days were recorded as sickness absence.

Employee involvement

Regular contact between managers and staff is actively encouraged to involve everybody in the work of their team and the Agency. A performance management system is operated to enable managers and staff to discuss and agree objectives and measure performance on half and full year basis. There are a variety of mechanisms for achieving two way exchange of information including monthly team briefing, one to one, unit, divisional and Agency all-staff meetings. There is also regular consultation and negotiation with trade union representatives.

11. Events after the reporting period

None.

12. Directors' statement with respect to conflict of interest

All Executive and Agency Board members have confirmed that they have no significant outside interests that conflict with their management responsibilities.

13. Supplier payment performance

MHRA's policy is to pay all suppliers within 30 days of receipt of goods or services or of a correctly documented invoice (whichever is received later), or according to contract where a different payment period is agreed. MHRA observes the principles of the CBI Better Payment Practice Code.

Using the Civil Service standard measure, during 2009-10 MHRA paid 99 per cent of supplier bills within 30 days (97 per cent in 2008-09).

14. Contractual arrangements

Accenture provide an outsourced IT contract to MHRA covering information technology infrastructure support, applications development and maintenance services essential to the business of the Agency.

15. Risk management

The Agency's risk management and internal control systems are the responsibility of the Executive Board, who are assisted by the Agency Board and the Risk and Audit Committee in a monitoring role. The Executive Board are responsible for the detailed identification, monitoring and review of the Agency's corporate risks, which range from public health, operational, reputational, financial and personnel issues to the Agency's stakeholder interests with the public, service users, ministers and other organisations both inside and outside of government.

Divisional risk registers maintained at operational level record the divisional risks identified and the actions taken to mitigate those risks in similar manner as for the corporate risk register. These are dynamic working documents, which are updated regularly in order to ensure that the risk registers reflect the current position.

An internal audit is commissioned annually to review various aspects of the Agency's corporate governance and risk management systems in order to ensure continuous improvement by identifying new areas where best practice could be adopted.

16. Going concern

Based on normal business planning and control procedures, the Agency Board has reasonable expectation that the MHRA has adequate resources to continue in operational existence for the foreseeable future. For this reason the Board continues to adopt the going concern basis for preparing the financial statements.

17. Sustainable development

The Agency has continued to progress with its efforts in relation to sustainable development during the course of the year. Whilst there have been no new targets set, or significant breakthroughs made, during the year, we have been looking forward to a new start in our new accommodation next year. We are concentrating on ensuring that our forthcoming accommodation move in 2010/2011 takes sustainability issues fully into account. Our sustainable development plan can be found on our website at : http://www.mhra.gov.uk/Aboutus/Sustainabledevelopment/index.htm.

18. Pension liabilities

These are covered in notes 1.8 and 17.1 to the accounts.

19. Disclosure of relevant audit information

As far as the Chief Executive is aware, there is no relevant audit information of which the MHRA's auditors are unaware, and the Chief Executive has taken all reasonable steps he ought to have taken to make himself aware of any relevant audit information and to establish that the MHRA's auditors are aware of that information.

20. Audit services and costs

The Comptroller and Auditor General (C&AG) is head of the National Audit Office and is appointed as the auditor of the MHRA trading fund under section 4(6) of the Government Trading Funds Act 1973. The auditor's remuneration payable is £98,000 for the year ended 31 March 2010 (£104,000 for the year ended 31 March 2009). The C&AG has been appointed by MHRA under a non-statutory letter of engagement to provide an independent review of the systems and workings supporting performance indicators reported in the annual accounts. During the year, a review was undertaken of MHRA's restatement of its accounts at 31 March 2009 into an International Financial Reporting Standard (IFRS) compliant format. An audit fee of £6,000 was payable for this work.

21. Data protection

The MHRA recognises the importance of respecting the privacy of all data subjects and the need for appropriate safeguards as defined by the Data Protection Act 1998. The Agency complies with the principles of the Act. As the MHRA is an Executive Agency of the Department of Health, the required data protection notification lodged with the Information Commissioner is included within the Department's notification. This can be viewed on the website of the Office of the Information Commissioner at http://www.ico.gov.uk/.

22. Personal data security incidents

During the year, there was one incident involving loss of personal data, which was assessed by the MHRA SIRO and judged to be of Minor impact, following the Cabinet Office guidelines. In line with recommended procedure, this was reported to the Agency's Risk and Audit Committee.

23. Freedom of information

The Freedom of Information Act creates a general right of access to all types of recorded information held by public authorities. The Act sets out exemptions from that right and places a number of obligations on public authorities. The MHRA seeks to be as open and transparent as possible and is committed to the implementation of the Act. The Agency already places large volumes of information on its website, and information disclosed under the Act is routinely published or listed on the website and available via the Agency's disclosure log. 2009 saw the Agency deal with its highest ever number of requests, with the majority coming from industry and members of the public. Requests for Internal reviews increased in 2009 although the number of Information Commissioner investigations of Agency decisions declined from the previous year, indicating growing confidence in experience levels and the interpretation of the Act throughout the Agency. The MHRA also successfully implemented the Information Commissioner's new model publication scheme, producing a more comprehensive and user-friendly product which is readily available on the Agency's website.

REMUNERATION REPORT

REMUNERATION REPORT

Service Contracts

Civil service appointments are made in accordance with the Civil Service Commissioners' Recruitment Code. The Code requires appointments to be on merit on the basis of fair and open competition but also includes the circumstances when appointments may otherwise be made.

With the exception of the Chief Executive (see below), the members of the Senior Management Team (Executive Board Directors) hold appointments which are open-ended. Their appointment can be terminated with three months notice on either side. Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme. The Chief Executives' appointment can be terminated with three months notice on either side.

Further information about the work of the Civil Service Commissioners can be found at www.civilservicecommissioners.gov.uk

The Chairman and the Agency Board non-executive Directors are appointed by the Appointments Commission and are on fixed term contracts.

Salary and pension entitlements

The following sections provide details of the remuneration and pension interests of the most senior management (i.e. Executive and Agency Board members) of the Agency. Executive Board members salary and bonus awards were decided by a Pay Committee whose members are Professor Kent Woods, Lisa Arnold (non-executive director) and Harbhajan Singh Brar (DH HR Director). Professor Kent Woods', Professor Sir Alasdair Breckenridge's and non - executive Directors' salary and bonus awards are set by DH through the Department's senior salaries review processes.

REMUNERATION REPORT cont'd

Executive Board - Salaries - £000	2009/10	2008/09
Professor Kent Woods - Chief Executive[1]	**190 - 195**	215 - 220
Mr Peter Commins - Chief Operating Officer	**140 - 145**	150 - 155
Dr June Raine - Director of Vigilance & Risk Management of Medicines	**135 - 140**	145 - 150
Dr Ian Hudson - Licensing Director	**130 - 135**	140 - 145
Mr Gerald Heddell - Director of Inspection, Enforcement and Standards Division	**115 - 120**	120 - 125
Mr Clive Bray - Director of Device Technology & Safety	**105 - 110**	105 - 110
Mrs Alison Davis - Director of Information Management	**105 - 110**	105 - 110
Dr Susanne Ludgate - Clinical Director - Devices	**100 - 105**	100 - 105
Mr Simon Gregor - Director of Communications	**95 - 100**	100 - 105
Mr Geoff LeFevre - Director of Human Resources	**95 - 100**	100 - 105
Mr Shaun Gallagher - Director of Policy [2]	**80 - 85**	105 - 110
Ms Margaret Jackman - Acting Director of Policy[3]	**10 - 15**	N/A
Mr Jonathan Mogford - Director of Policy[4]	**5 - 10**	N/A

(Footnotes)

1. The Chief Executive is on secondment to the Agency from the University of Leicester commencing 1 January 2004 and ending on 31 May 2013. During 2009/10 the MHRA paid a total of £243,801 (2008/09 £270,308) to the University of Leicester to reimburse the University of Leicester for his annual salary and achievement bonus, employers national insurance and superannuation contributions.
2. Mr Shaun Gallagher resigned as Director of Policy with effect from 31st December 2009.
3. Ms Margaret Jackman was Acting Director of Policy from 1st January to 28th February 2010.
4. Mr Jonathan Mogford was appointed as Director of Policy on 1st March 2010.

Agency Board - Salaries - £000	2009/10	2008/09
Professor Sir Alasdair Breckenridge - Chairman	**105 -110**	100 - 105
Ms Lisa Arnold - non-executive Director	**10 -15**	10 - 15
Miss Shelley Dolan - non-executive Director	**5 - 10**	5 - 10
Mr Michael Fox - non-executive Director	**5 - 10**	5 - 10
Professor Barrington Furr - non-executive Director	**5 - 10**	5 - 10
Professor Vincent Lawton - non-executive Director	**5 - 10**	5 - 10
Professor Angus Mackay - non-executive Director	**5 - 10**	5 - 10
Mr Charles Kernahan - non-executive Director[5]	**0 - 5**	5 - 10
Sir John Lilleyman - non-executive Director[6]	**0 - 5**	N/A
Mr John Williams, CBE - non-executive Director[7]	**0 - 5**	N/A

Salary

'Salary' includes gross salary; performance pay or bonuses; reserved rights to London weighting or London allowances; and any other allowance to the extent that it is subject to UK taxation. No benefits in kind are paid.

This presentation is based on payments made by the Agency and thus recorded in these accounts.

5. Mr Charles Kernahan's appointment as a non-executive Director ended on 31st August 2009.
6. Sir John Lilleyman was appointed as a non-executive Director on 1st September 2009.
7. Mr John Williams was appointed as non-executive Director on 1st September 2009.

REMUNERATION REPORT cont'd

Pension Benefits

The Chairman, the Chief Executive and the Agency Board Directors have no pension entitlement arising from their service with the MHRA.

The following table provides details of the pension entitlements of Executive Board Directors:

	Accrued pension at pension age as at 31/3/10 and related lump sum	Real increase in pension and related lump sum at pension age
	£000	£000
Mr Peter Commins Chief Operating Officer	60 - 65	2.5 - 5.0
Dr June Raine Director of Vigilance & Risk Management of Medicines	35 - 40 plus lump sum of 115 - 120	0.0 – 2.5 plus lump sum of 5.0 - 7.5
Dr Ian Hudson Licensing Director	30 - 35	2.5 - 5.0
Mr Gerald Heddell Director of Inspection and Standards Division	5 -10	0.0 - 2.5
Mr Clive Bray Director of Devices Technology & Safety	40 - 45 plus lump sum of 130 - 135	0.0 - 2.5 plus lump sum of 5.0 - 7.5
Mrs Alison Davis Director of Information Management	5 - 10	0.0 - 2.5
Dr Susanne Ludgate Clinical Director - Devices	35 - 40 plus lump sum of 115 - 120	2.5 - 5.0 plus lump sum of 12.5 - 15.0
Mr Simon Gregor Director of Communications	15 - 20	2.5 - 5.0
Mr Geoff LeFevre Director of Human Resources	20 - 25 plus lump sum of 60 - 65	0.0 - 2.5 plus lump sum of 2.5 - 5.0
Mr Shaun Gallagher Director of Policy to 31.12.09	15 - 20 plus lump sum of 55 - 60	0.0 - 2.5 plus lump sum of 2.5 - 5.0
Ms Margaret Jackman Acting Director of Policy from 01.01.10 to 28.02.10	40 - 45 plus lump sum of 125 - 130	0.0 -2.5 plus lump sum of 2.5 - 5.0
Mr Jonathan Mogford Director of Policy from 01.03.10	15 - 20 plus lump sum of 55 - 60	0.0 - 2.5 plus lump sum of 0.0 - 2.5

*CETV at 31/3/10	*CETV at 31/3/09	Real increase in CETV
£000	£000	£000
1,054	928	63
856	769	45
509	440	37
186	149	34
1,045	1,002	42
93	66	20
906	811	94
175	142	21
477	444	32
267	231	14
980	960	36
306	293	6

* The figure may be different from the closing figure in last year's accounts. This is due to the CETV factors being updated to comply with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008.

The disclosures in this table are subject to audit by the Comptroller and Auditor General.

REMUNERATION REPORT cont'd

Civil Service Pensions

Pension benefits are provided through the Civil Service pension arrangements. From 30 July 2007, civil servants may be in one of four defined benefit schemes; either a 'final salary' scheme (Classic, Premium or Classic Plus); or a 'whole career' scheme (Nuvos). These statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under Classic, Premium, Classic Plus and Nuvos are increased annually in line with changes in the Retail Prices Index (RPI). Members who joined from October 2002 could opt for either the appropriate defined benefit arrangement or a good quality 'money purchase' stakeholder pension with a significant employer contribution (partnership pension account).

Employee contributions are set at the rate of 1.5% of pensionable earnings for Classic and 3.5% for Premium, Classic Plus and Nuvos. Benefits in Classic accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. For Premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike Classic, there is no automatic lump sum. Classic Plus is essentially a hybrid with benefits for service before 1 October 2002 calculated broadly as per Classic and benefits for service from October 2002 worked out as in Premium. In Nuvos a member builds up a pension based on his pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and, immediately after the scheme year end, the accrued pension is uprated in line with RPI. In all cases members may opt to give up (commute) pension for lump sum up to the limits set by the Finance Act 2004.

The Partnership pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of three providers. The employee does not have to contribute but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).

The accrued pension quoted, is the pension the member is entitled to receive when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for members of Classic, Premium and Classic Plus and 65 for members of Nuvos.

Further details about the Civil Service pension arrangements can be found at the website www.civilservice-pensions.gov.uk

Cash Equivalent Transfer Values

A Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. The figures include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their buying additional pension benefits at their own cost. CETVs are calculated in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are taken.

Real increase in CETV

This reflects the increase in CETV that is funded by the employer. It does not include the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency

23 June 2010

Medicines and Healthcare products Regulatory Agency Statement of Agency's and Chief Executive's

RESPONSIBILITIES

Under Section 4(6)(a) of the Government Trading Funds Act 1973, HM Treasury has directed the Medicines and Healthcare products Regulatory Agency (MHRA) to prepare for each financial year a statement of accounts in the form and on the basis set out in the Accounts Direction.

The accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the MHRA and of its income and expenditure, recognised gains and losses and cash flows for the financial year.

In preparing the accounts, the Accounting Officer is required to comply with the requirements of the Government Financial Reporting Manual and in particular to:

- observe the Accounts Direction issued by HM Treasury, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards as set out in the Government Financial Reporting Manual have been followed, and disclose and explain any material departures in the accounts;
- prepare the accounts on a going concern basis.

HM Treasury has appointed the Chief Executive of the MHRA as Accounting Officer of the Agency. The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which the Accounting Officer is answerable, for keeping proper records and for safeguarding the MHRA's assets, are set out in the chapter under Accounting Officers in Managing Public Money, published by HM Treasury.

Statement on

INTERNAL CONTROL

year ended 31 March 2010

Scope of responsibility

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the Medicines and Healthcare products Regulatory Agency's policies, aims and objectives, whilst safeguarding the public funds and Agency assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Managing Public Money.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and operates as a trading fund. The MHRA came into existence on 1 April 2003. I was appointed as Chief Executive and Accounting Officer on 1 January 2004. I have held both positions since then and throughout the year to 31 March 2010.

The Agency Board, the Risk and Audit Committee and the Executive Board support me in my role as Accounting Officer. The Agency's risk management system was developed on guidance from the Department of Health, HM Treasury, the National Audit Office and Internal Audit. A representative from the Department of Health attends the Agency Board and Risk and Audit Committee meetings. Internal audit services during the year to 31 March 2010, conducted in accordance with the Government Internal Auditing Standards, were provided by PricewaterhouseCoopers LLP, engaged on a three-year contract commencing 1 April 2008. The external audit is carried out by the Comptroller and Auditor General.

MHRA

The purpose of the system of internal control

The Agency's system of internal control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness. The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of the Agency's policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically. The system of internal control has been in place in the Medicines and Healthcare products Regulatory Agency for the year ended 31 March 2010 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

Capacity to handle risk

The Agency's Standard Operating Procedure on Risk Management and the associated Guide to Risk Management are both reviewed and updated as appropriate; these documents are available to staff on the MHRA Intranet. Information about corporate governance and risk management is also included in the induction pack for new staff.

A dedicated corporate risk management and business efficiency manager is responsible for the continuous improvement in the MHRA's risk management policies and procedures. The manager also provides support and advice on risk management issues where required.

The systems for corporate governance, risk management and internal control are monitored by the Agency Board, the Risk and Audit Committee and the Executive Board, and have been in existence throughout the year to 31 March 2010.

The Executive Board are responsible for the identification, monitoring and review of the Agency's corporate risks and they maintain corporate responsibility for the operation of the risk management system.

An internal audit is commissioned annually to review various aspects of the Agency's corporate governance and risk management systems in order to ensure continuous improvement by identifying new areas where best practice could be adopted. The review in 2009/10 of corporate governance and risk management by the internal audit team gave a moderate level of assurance on the adequacy and operating effectiveness of controls in place over governance and risk management. Some areas of good practice were highlighted, examples include: the HR Division's proactive implementation of recommendations raised in previous audits concerning payroll processes; the Information Processing Unit's well documented practices and the developments made to their procedures as technology progresses as well as the ability for companies to submit information electronically. The practices and good working relationship with establishments created by the Haemovigilance team in the Adverse Incident Centre were also cited as examples of good practice.

Statement on

INTERNAL CONTROL

year ended 31 March 2010

The risk and control framework

Our management of risk is embedded in planning and delivery through:

- the business planning process with risk registers,
- policies and standard operating procedures across the whole Agency.

The consideration of risk includes public health (in relation to the safety quality and efficacy of all medicines and devices), operational, financial and human resource issues, the Agency's reputation, public interests, service user interests, ministerial interests and other aspects of relationships both inside and outside of government. The identification and management of risks are integrated into the Agency's planning system.

The Agency's corporate risk register is reviewed quarterly by the Executive Board and updated as appropriate. Each corporate risk is vested in a specific Executive Board member, who owns and monitors the particular risk. The corporate risk register is also subject to regular review by the Risk and Audit Committee. In addition any risks that are considered by divisional management to be of a corporate nature are communicated to the corporate risk management and business efficiency manager either directly or through the divisional representative at the quarterly meetings of the Risk Management and Audit Liaison Group.

The cross-Agency Risk Management and Audit Liaison Group, formed to strengthen the Agency's risk management system, held four meetings during the year to 31 March 2010. It is a forum where Divisional risk and audit issues are discussed and monitored by senior representatives from all Divisions of the Agency. If appropriate, remedial action is recommended to the Executive Board.

Divisional risk registers maintained at operational level record the divisional risks identified and the actions taken to mitigate those risks in a similar manner as for the corporate risk register. These are dynamic working documents which are updated regularly in order to ensure that the risk registers reflect the opportunities and the threats that may arise during the daily course of business operations.

Divisional Heads in accordance with their duty of accountability, are required to complete an annual statement, confirming if appropriate that effective systems of internal control have been in place within their areas of responsibility, throughout the particular period under review. All such accountability statements have been received for the year to 31 March 2010.

Information assets within the Agency are handled in accordance with GSI (Government Secure Intranet) standards. Information Governance risks are reviewed regularly and escalated to the Agency's corporate risk register where appropriate. The Agency is involved in the Department of Health's Information Governance Assurance Programme (IGAP) and is working to ensure that all appropriate policies are adhered to. The Agency already has in place policies regarding the acceptable use and security of data.

Information is retained centrally on servers in a secure remote hosting facility and is backed up on a daily basis. The Agency's servers and client workstations have virus protection. User access to systems is strictly controlled in accordance with written procedures. The Agency has a disaster recovery plan, with ITSR (Information Technology Service Restoration) exercises being carried out twice yearly. Secure transfer of information to companies takes place via the MHRA Portal, this being SAFE (Signatures and Authentication For Everyone) compliant. Agency laptops have encrypted hard disks. The Agency has BS7799 accreditation.

The internal audit services are conducted in accordance with the Government Internal Auditing Standards and those of the International Auditing and Assurance Standards Board. The Internal Auditors adopt a risk based approach in their annual programme of audits of the Agency's operations. This programme is detailed in an annual internal audit plan, which is discussed by the Risk and Audit Committee and the Executive Board. During the year follow-up audits are also conducted to monitor management's compliance with the previously agreed responses to recommendations. The outcome of these internal audits is reported to the Risk and Audit Committee by the internal auditors via their progress reports at each Risk and Audit Committee meeting. The results are summarised in an internal audit annual report, together with an overall assurance opinion on the system of internal control, for the attention of the Agency's Accounting Officer.

Review of effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors and the divisional heads within the Agency who have responsibility for the development and maintenance of the internal control framework, and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the result of my review of the effectiveness of the system of internal control by the Agency Board, the Risk and Audit Committee and the Executive Board, and a plan to address weaknesses and ensure continuous improvement of the system is in place.

Agency Board

The Agency Board consists of the Agency Chairman and eight non-executive directors. The Agency Board had regular meetings during the year to 31 March 2010, to monitor the Agency's strategic direction and to take action as appropriate. The Chairman is directly accountable to ministers for the performance of the Agency and its decisions.

Risk and Audit Committee

The Risk and Audit Committee, a subcommittee of the Agency Board, is an integral part of the Agency's risk management system, and reports independently to the Accounting Officer and the Agency Board on the effectiveness of the operation of the Agency's corporate governance, risk management and internal control systems. The Committee which is chaired by an Agency Board non-executive director, held four meetings during the year to 31 March 2010. The main agenda items were the corporate risk register, the 2008/09 Annual Report and Accounts, the NAO 2009/10 Interim Audit Management letter, various Internal Audit progress reports for 2009/10, the Audit Recommendations Tracker for monitoring the implementation of audit recommendations, the Fraud Risk Review, the Office of Civil Service Commissioners audit of recruitment policies and compliance with the civil service recruitment code and the Internal Audit plan for 2009/10. These reviews in aggregate played a significant part in the Risk and Audit Committee's advice to the Accounting Officer on the effectiveness of the Agency's corporate governance, risk management and internal control systems.

Agency Board and Risk and Audit Committee members are required to declare any conflicts of interest at the start of each meeting.

Statement on

INTERNAL CONTROL

year ended 31 March 2010

Executive Board

The Executive Board, consisting of the Chief Executive and the heads of divisions, also convened regularly during the year to 31 March 2010, to undertake their executive responsibility for the strategy, operational management, corporate risk management and service delivery of the Agency. As the Accounting Officer, the Chief Executive is responsible for the financial management of the Agency and for the Agency's resources.

Quarterly reports were received by the Executive Board, setting out the Agency's key performance targets and monitoring their progress. The reports also brought to the Executive Board's attention any control issues through the early warning processes embedded within the Agency's business operations.

A register of interests is maintained for all staff including Executive Board members.

Internal Audit

The role of the internal audit service is to provide an independent and objective opinion to the Accounting Officer on risk management, governance and control, by measuring and evaluating their effectiveness in achieving the organisation's agreed objectives. Risk management, governance and control comprise the policies, procedures and operations established to ensure the achievement of objectives, the appropriate assessment of risk, the reliability of internal and external reporting and accountability processes, compliance with applicable laws and regulations, and compliance with the behavioural and ethical standards set for the organisation.

The Agency's internal audit service during the year to 31 March 2010 was provided by PricewaterhouseCoopers (PwC) under a three-year contract, which commenced on 1 April 2008. The PwC appointment was made under an Office of Government Commerce (OGC) Framework Agreement.

The PwC Engagement Director in charge of the Agency's internal audit service performed the role of Head of Internal Audit. He produced regular reports on the adequacy and effectiveness of the systems of internal control in the various operational areas under audit, including finance, and suggested ways of improvement in these reports, by detailing the findings and recommendations.

The internal audit plan for 2009/10 was designed to focus mainly on the high and medium risk areas within the Agency. Consequently the plan devoted 60% of the total resources to business processes (including a review of the Information Processing Unit), finance risk and control (including Accounts Receivable/General Ledger) and corporate governance. The remaining resources (excluding administration) were deployed on other business systems.

In total ten audit reviews were conducted. One internal audit, namely on Haemovigilance received high assurance. Five internal audits namely on Corporate Governance, Payroll and Human Resource, Information Processing Unit, Biologicals and the Follow Up Audit received moderate assurances. Two others relating Accounts Receivable/General Ledger and Business Continuity/Disaster Recovery Plan received limited assurances. The latter two audits contained between them 6 high priority weaknesses which management have agreed to address. High priority weaknesses highlighted in the Accounts Receivable/General Ledger audit referred to General Ledger posting periods left open, user settings on Oracle and segregation of duties and access controls within the payables module. All the other internal audit recommendations, with the exception of one regarded as medium priority were also accepted by management. A programme of implementation has been agreed, with anticipated completion during the current year 2010/11 commenced.

The Head of Internal Audit has in addition provided an independent opinion and an overall annual assessment of the Agency's systems of corporate governance, risk management and internal control. This report identified certain control weaknesses within the areas mentioned in the preceding paragraph, on which limited assurance opinions were given. However the internal audit annual report concluded that on balance, moderate assurance could be given on the design adequacy and effectiveness of the Agency's overall system of internal control. This is the second highest of four categories used by PwC in their assurance classification and which they have emphasised should be seen in the context of the Agency seeking scrutiny of the operational areas.

Significant internal control issues

The internal audit reports on Accounts Receivable/ General Ledger and Business Continuity/Disaster Recovery plan each contained elements of high risk areas where the controls were not adequate, as a result of which only limited assurances were given. These reports were specifically brought to my attention. They have also been discussed at the various Risk and Audit Committee meetings during the year. Management action to rectify these weaknesses has been agreed and a programme of implementation designed for completion during the current year 2010/11 commenced.

Accounting Officer's comment

I am satisfied, based on the advice given to me by the Head of Internal Audit, the Agency Board, the Risk and Audit Committee and the Executive Board, that on balance there are adequate and effective risk management, corporate governance and internal control systems to manage the achievement of the Agency's objectives.

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency

23 June 2010.

The CERTIFICATE
of the Comptroller and Auditor General to The Houses of Parliament

I certify that I have audited the financial statements of the Medicines and Healthcare products Regulatory Agency (the Agency) for the year ended 31 March 2010 under the Government Trading Funds Act 1973. These comprise the Income Statement and Statement of Changes in Taxpayers' Equity, the Statement of Financial Position, the Statement of Cash Flows and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the Agency Chief Executive and auditor

As explained more fully in the Statement of the Chief Executive's responsibilities, the Agency and Chief Executive are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Agency's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Agency; and the overall presentation of the financial statements.

In addition, I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

Opinion on Regularity

In my opinion, in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

Opinion on Financial Statements

In my opinion:

- the financial statements give a true and fair view of the state of Agency's affairs as at 31 March 2010 and of its profit , changes in taxpayers' equity and cash flows for the year then ended; and
- the financial statements have been properly prepared in accordance with the Government Trading Funds Act 1973 and HM Treasury directions issued thereunder.

Opinion on other matters

In my opinion:

- the part of the Remuneration Report to be audited has been properly prepared in accordance with HM Treasury directions made under the Government Trading Funds Act 1973; and
- the information given in the management commentary for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept; or
- the financial statements are not in agreement with the accounting records or returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Statement on Internal Control does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Amyas C E Morse

Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

29 June 2010

ACCOUNTS

INCOME STATEMENT for the year ended 31 March 2010

	Note	2009/10	2008/09
		£000	£000
Revenue			
Revenue from trading activities	3	**101,036**	101,517
Revenue from Department of Health	3	**11,504**	11,295
Total Revenue		**112,540**	112,812
Expenditure			
Staff costs	5	**(53,373)**	(49,988)
Operating costs	7	**(45,600)**	(37,174)
Total operating expenditure		**98,973**	87,162
Operating surplus		**13,567**	25,650
Finance costs:			
Interest revenue	8	**147**	1,579
Other gains	9	**4**	40
Finance costs	10	**(64)**	(256)
Surplus for the financial year		**13,654**	27,013
Dividend Payable		**(1,583)**	(932)
Retained surplus for the year		**12,071**	26,081

The notes on pages 56 to 81 form part of these accounts.

STATEMENT OF FINANCIAL POSITION

as at 31 March 2010

	NOTE	31 March 2010	
		£000	£000
Non-current assets			
Plant and equipment	11	3,963	
Intangible assets	12	15,127	
Total non-current assets			19,090
Current assets			
Trade and other receivables	13	17,398	
Cash and cash equivalents	18	79,385	
Total current assets			96,783
Total assets			115,873
Current liabilities			
Trade and other payables	14	(19,733)	
Borrowings	16	-	
Provisions	17	(3,163)	
Other liabilities	15	(1,583)	
Total current liabilities			(24,479)
Total assets less current liabilities			91,394
Non-current liabilities			
Borrowings	16	(1,328)	
Provisions	17	(8,354)	
Other liabilities	15	(31,341)	
Total current liabilities			(41,023)
Assets less liabilities			50,371
Taxpayers' equity:			
Public dividend capital			1,329
Revaluation reserve			155
Income and expenditure reserve			954
Government grant reserve			953
Retained earnings			46,980
Total Taxpayers' equity			50,371

The notes on pages 56 to 81 form part of these accounts.

Professor Kent Woods
Chief Executive and Accounting Officer
Medicines and Healthcare products Regulatory Agency
23 June 2010

31 March 2009		1 April 2008	
£000	£000	£000	£000
5,257		3,485	
17,445		18,273	
	22,702		21,758
17,424		20,842	
51,439		21,861	
	68,863		42,703
	91,565		64,461
(14,817)		(16,422)	
(400)		(1,000)	
(74)		(217)	
(932)		(322)	
	(16,223)		(17,961)
	75,342		46,500
(1,328)		(1,728)	
(3,719)		(3,709)	
(32,348)		(29,510)	
	(37,395)		(34,947)
	37,947		11,553
	1,329		1,329
	168		142
	954		954
	587		300
	34,909		8,828
	37,947		11,553

Statement of

CASH FLOWS year ended 31 March 2010

	NOTE	2009/10 £000	2008/09 £000
Cash flows from operating activities			
Operating surplus		**13,567**	25,650
Depreciation and amortisation		**5,968**	5,166
Impairments and reversals		**865**	-
Gain on foreign exchange	9	**4**	40
Transfer from government grant reserve		**500**	400
Finance costs	10	**(64)**	(256)
Dividend paid		**(1,583)**	(932)
Movement in deferred revenue		**(1,007)**	2,838
Decrease in trade and other receivables	13	**26**	3,418
Increase/(decrease) in trade and other payables		**5,167**	(1,995)
Increase/(decrease) in provisions	17	**7,724**	(133)
Net cash inflow from operating activities		**31,167**	34,196
Cash flows from investing activities			
Interest revenue	8	**147**	1,579
Purchase of plant and equipment	11	**(1,247)**	(3,220)
Purchase of intangible assets	12	**(2,121)**	(2,977)
Net cash (outflow) from investing activities		**(3,221)**	(4,618)
Net cash (outflow) before financing		**27,946**	29,578
Net increase in cash and cash equivalents	18	**27,946**	29,578
Cash and cash equivalents at the beginning of the financial year	18	**51,439**	21,861
Cash and cash equivalents at the end of the financial year	18	**79,385**	51,439

The notes on pages 56 to 81 form part of these accounts.

Statement of changes in

TAXPAYERS' EQUITY

	Public dividend capital (PDC)	Retained earnings	Revaluation reserve	Gov't grant reserve	Income & expenditure reserve	Total
	£000	£000	£000	£000	£000	£000
Balance at 31 March 2008						
As stated under UK GAAP	1,329	10,435	142	300	954	13,160
Changes in accounting policy	-	(1,607)	-	-	-	(1,607)
IFRS Restated balance at 31 March 2008	1,329	8,828	142	300	954	11,553
Changes in taxpayers' equity for 2008-09						
Surplus for the year	-	26,081	-	-	-	26,081
Receipt of government grant	-	-	-	400	-	400
Depreciation of government grant	-	-	-	(113)	-	(113)
Indexation	-	-	26	-	-	26
Balance at 31 March 2009	1,329	34,909	168	587	954	37,947
Changes in taxpayers' equity for 2009-10						
Surplus for the year	-	12,071	-	-	-	12,071
Receipt of government grant	-	-	-	500	-	500
Depreciation of government grant	-	-	-	(134)	-	(134)
Revaluation	-	-	-	-	-	-
Indexation	-	-	(13)	-	-	(13)
Balance at 31 March 2010	1,329	46,980	155	953	954	50,371

The notes on pages 56 to 81 form part of these accounts.

NOTES to the accounts

1. Accounting Policies

1.1 Compliance with government accounting requirements

The financial statements have been prepared in compliance with the Government Trading Funds Act (1973) and in accordance with the 2009/10 Government IFRS based Financial Reporting Manual (FReM) issued by HM Treasury. The accounting policies contained in the FReM apply International Financial Reporting Standards as adapted or interpreted for the public sector context. Where the FReM permits a choice of accounting policy, the accounting policy which is judged to be the most appropriate to the particular circumstances of the Medicines and Healthcare products Regulatory Agency for the purpose of giving a true and fair view has been selected.

The particular policies adopted by the Medicines and Healthcare products Regulatory Agency are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

1.2 Accounting convention

The Accounts have been prepared under the Historical Cost Convention, modified to allow for the revaluation of non-current assets (excluding IT equipment and assets under the course of construction), at their value to the business by reference to their current costs.

1.3 Non Current Assets

1.3.1. Plant & Equipment

Capitalisation

Plant & Equipment are capitalised provided they:

- individually have a cost equal to or greater than £5,000; or
- collectively have a cost of at least £5,000.

Computer and telecom equipment are stated in the Statement of Financial Position at cost less subsequent accumulated depreciation and any impairment in value. This carrying amount is broadly consistent with fair value due to the short economic life of these assets.

Laboratory Equipment, fittings, furniture and office equipment are revalued annually using Office of National Statistics Cost indices. These indices reflect the upward or downward movements in valuation of these assets and are broadly consistent with fair values.

Increases arising on revaluation are taken to the Revaluation Reserve except when it reverses a revaluation decrease for the same asset previously recognised in the Income Statement, in which case it is credited to the Income Statement to the extent of the decrease previously charged there. A revaluation decrease is charged to the Revaluation Reserve to the extent that there is a balance on the reserve for the asset and, thereafter, to the Income Statement.

1.3.2. Depreciation, amortisation and impairments

Assets under construction are not depreciated. Otherwise, depreciation and amortisation are charged on a straight line over the estimated useful life of the asset as follows:

Personal computer and faxes	3 years
Laboratory Equipment	5 -10 years
Computer servers, laptops and associated applications, Software, Office equipment, Furniture, Fixtures and Fittings	5 -10 years
Office refurbishment costs (other than at HQ)	10 years
HQ office refurbishment costs	Expected relocation date

At each Statement of Financial Position date, the Agency checks whether there is any indication that any of its tangible or intangible non-current assets have suffered an impairment loss. If there is indication of an impairment loss, the recoverable amount of the asset is estimated to determine whether there has been a loss and, if so, its amount.

If there has been an impairment loss, the asset is written down to its recoverable amount, with the loss charged to the Revaluation Reserve to the extent that there is a balance on the reserve for the asset and, thereafter, to the Income Statement. Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of the recoverable amount but capped at the amount that would have been determined had there been no initial impairment loss. The reversal of the impairment loss is credited to the Income Statement to the extent of the decrease previously charged there and thereafter to the revaluation reserve.

1.3.3. Intangible Assets

Intangible assets are capitalised when they have a cost of at least £5,000.

Items or groups of related items with a combined value in excess of £5,000 are capitalised.

Intangible assets acquired are initially recognised at fair value and amortised over a period not exceeding ten years. Following initial recognition, they are carried at cost less accumulated depreciation and any impairment in value.

Assets in the course of construction are carried at cost, less any impairment loss. Cost includes professional fees. Assets are revalued and depreciation commences the month after they are brought into use.

The useful lives of intangible assets are assessed to be either finite or indefinite. The Agency holds no assets with indefinite life. The estimated useful lives are:

RAMA XL	5 years
Computer software	5 -10 years
Sentinel architecture costs	10 years
Sentinel software	Remaining life of the Sentinel architecture

Intangibles include the following assets developed in house:

Description	Amortisation period	Carrying value (£000)
Sentinel architecture	120 months	3,092
Product licensing	96 months	3,069
Pharmacovigilance	94 months	3,033

1.4 Cash and cash equivalents

Cash consists of cash in hand and deposits with any financial institution repayable without penalty on notice of not more than 24 hours. Cash equivalents are investments that mature in 3 months or less from the date of acquisition and that are readily convertible to known amounts of cash with insignificant risk of change in value.

1.5 Losses and Special Payments

Losses and special payments are items that Parliament would not have contemplated when it passed legislation. By their nature they are items that ideally should not arise. They are therefore subject to special control procedures compared with the generality of payments. They are divided into different categories, which govern the way each individual case is handled and are charged to the relevant functional headings on a cash basis.

1.6 Revenue

Revenue from trading activities represents the invoiced amount and accrued amounts to be invoiced for licences and inspection fees. Revenue is determined by reference to the value of work carried out to the statement of financial position date. Revenue is recognised according to type of income stream. The Agency has the following income streams:

- Applications and variations: A number of processes have been assigned to determine the stage of work completed. This determines the level of revenue to recognise and to defer.
- Service fees: These are invoiced annually early in the financial year.
- Inspections: Income is recognised on completion of all the inspection processes.
- EMA (European Medicines Agency). Income from EMA work is recognised on completion of predetermined stages.
- Clinical trials: A number of processes have been assigned to determine the stage of work complete. Revenue is recognised upon completion of each process.
- Miscellaneous income: This is non statutory income recognised as and when earned.

The proportion of the fees receivable for licence applications, representing the work estimated to be outstanding to complete the processing of such applications is deferred to future periods.

Interest revenue is recognised in the income statement and represents interest earned.

1.7 Foreign currencies

The Agency's functional currency and presentational currency is sterling. Transactions denominated in a foreign currency are translated into sterling at the exchange rate ruling on the dates of the transactions. At the end of the reporting period, monetary items denominated in foreign currencies are retranslated at the spot exchange rate on 31 March. Resulting exchange gains and losses for either of these are recognised in the Income Statement in the period in which they arise.

1.8 Employee Benefits

The Agency's staff are civil servants in the Department of Health and are subject to centrally determined terms and conditions. Staff who are members of the Senior Civil Service (SCS), including members of the Executive Board, are covered by SCS central arrangements and the Department of Health's terms and conditions and other procedures governing implementation of the SCS, including the Senior Salaries Review Body's performance-related pay recommendations

Short-term employee benefits

Salaries, wages and employment-related payments are recognised in the period in which the service is received from employees. The cost of leave earned but not taken by employees at the end of the period is recognised in the financial statements. The calculated cost is based on a weighted sample covering all grades of staff. The resulting liability has been charged to the retained surplus carried forward and is shown under other current liabilities within the Statement of Financial Position. This exercise is repeated annually and subsequent movements taken to future Income Statements.

Retirement benefit costs

Past and present employees of the Agency are covered by the provisions of the Principal Civil Service Pension Schemes (PCSPS) which are defined benefit schemes

or a "money purchase" stakeholder pension scheme. The Agency recognises the expected cost of providing pensions on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS.

The PCSPS is an unfunded multi-employer defined benefit scheme, but the Agency is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out at 31 March 2007. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation (www.civilservice-pensions.gov.uk).

The employees of the Agency are civil servants to whom the conditions of the Superannuation Acts 1965 and 1972 and subsequent amendments apply. Employees are eligible to join the PCSPS.

For early retirements, other than those due to ill health, the additional pension liabilities are not funded by the scheme. The full amount of the liability for the additional costs is charged to the Income Statement at the time the Agency commits itself to the retirement, regardless of the method of payment.

1.9 Leases

Leases are classified as finance leases when substantially all the risks and rewards of ownership are transferred to the lessee. All other leases are classified as operating leases.

The Agency as lessee

Operating lease payments are recognised as an expense on a straight-line basis over the lease term. Lease incentives are recognised initially as a liability and subsequently as a reduction of rentals on a straight-line basis over the lease term.

Contingent rentals are recognised as an expense in the period in which they are incurred.

1.10 Provisions

Provisions are recognised when the Agency has a present legal or constructive obligation as a result of a past event, it is probable that the Agency will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation. The amount recognised as a provision is the best estimate of the expenditure required to settle the obligation at the end of the reporting period, taking into account the risks and uncertainties. Where a provision is measured using the cash flows estimated to settle the obligation, its carrying amount is the present value of those cash flows using HM Treasury's discount rate of 3.2 % in real terms.

Present obligations arising under onerous contracts are recognised and measured as a provision. An onerous contract is considered to exist where the Agency has a contract under which the unavoidable costs of meeting the obligations under the contract exceed the economic benefits expected to be received under it.

The provision for bad debts and credit notes is reviewed each year and reflects the level of trade debtors that it is anticipated may result in either a bad debt or a requirement to issue a credit note.

1.11 Contingent Liabilities

A contingent liability is a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Agency, or a present obligation that is not recognised because it is not probable that a payment will be required to settle the obligation or the amount of the obligation cannot be measured sufficiently reliably. A contingent liability is disclosed unless the possibility of a payment is remote.

1.12 Value Added Tax

Most of the activities of the Agency are outside the scope of VAT and, in general, output tax does not apply and input taxes on some purchases are recoverable. Irrecoverable VAT is charged to the relevant expenditure category or included in the capitalised purchase cost of non-current assets. Where output tax is charged or input VAT is recoverable, the amounts are stated net of VAT.

1.13 Government Grant Reserve

Government grants are grants from the Department of Health for the provision of services. Revenue grants are treated as deferred income initially and credited to income to match the expenditure to which they relate. Capital grants are credited to the government grant reserve and released to operating revenue over the life of the asset in a manner consistent with the depreciation and impairment charges for that asset. Assets purchased from government grants are valued, depreciated and impaired as described above for purchased assets. Gains and losses on revaluations and impairments are taken to the government grant reserve and, each year, an amount equal to the depreciation charge on the asset is released from the government grant reserve to the offset the expenditure.

1.14 Public Dividend Capital (PDC)

Public dividend capital represents taxpayers' equity in the Agency. PDC is recorded at the value received. As PDC is issued under legislation rather than under contract, it is not treated as an equity financial instrument.

1.15 Development expenditure

Development expenditure is assessed and capitalised if it meets all of the following criteria:

- An asset is created that can be identified;
- It is probable that the asset created will generate future economic benefits; and
- The development cost of the asset can be measured reliably.

Capitalised development costs are amortised over their expected economic lives. Where no internally generated intangible asset can be recognised, development expenditure is recognised as an expense in the financial year in which it is incurred.

2 Financial Duty

The MHRA's financial duty is set out in full in a HM Treasury minute dated 27 March 2008, which is reproduced at the end of the notes to the accounts.

The requirement is that the MHRA should be managed so that its revenue:

a) consists primarily of receipts in respect of goods and services provided in the course of its funded operations;

b) is sufficient, taking one year with another, to meet outgoings that are properly chargeable to revenue account and to achieve a surplus on ordinary activities before interest and dividends equivalent to 3.5% return on average capital employed;

Net asset values are shown in the Statement of Financial Position. The actual operating surplus for the year was £13.567M (2008/09 £25.650M).The Agency is required to pay dividends and interest to HM Treasury via the Department of Health each year equivalent to the 3.5% required rate of return. The dividend payable is £1.583M (2008/09 £0.932M).

The Agency plans its fee strategy so as to achieve a return averaged over the period 1 April 2008 to 31 March 2013 of at least 3.5% in the form of a surplus on ordinary activities before interest and dividends expressed as a percentage of average capital employed.

NOTES to the accounts cont'd

3 Revenue

	2009/10		2008/09	
	£000	**£000**	£000	£000
Licences and inspections income	**64,088**		66,015	
Service fee income recognised during the year	**26,576**		25,829	
Income from miscellaneous activities	**10,372**		9,673	
Trading Income		**101,036**		101,517
Income from Department of Health		**11,504**		11,295
Total Revenue		**112,540**		112,812

	2009/10		2008/09	
	£000	**£000**	£000	£000
Licences and inspections				
Applications	**30,329**		31,988	
Clinical trials	**2,661**		2,376	
EMA*	**6,871**		6,310	
Inspections	**9,443**		8,502	
Variations	**13,103**		15,129	
Others	**1,681**		1,711	
		64,088		66,015
Service fees		**26,576**		25,829
Miscellaneous income				
British Pharmacopoeia	**2,286**		2,208	
GPRD	**5,277**		4,629	
RAMA XL	**992**		1,054	
Seminar and twinning	**702**		485	
Others	**1,115**		1,297	
		10,372		9,673
Trading Income		**101,036**		101,517
Department of Health		**11,504**		11,295
Total Revenue		**112,540**		112,812

Income is stated net of trade discounts, VAT and other taxes.
*EMA income relates to assessments of medicines and drugs, scientific advice provided and inspections undertaken on behalf of the European Medicines Agency.

4. Segmental analysis

4.1 Operating segments

The Agency's income is derived solely from its regulatory function in achieving its objectives of protecting, promoting and improving public health. The Agency is therefore determined that reporting the overall financial position is more appropriate as it is this that drives the Agency's decision making.

4.2 Fees and charges

Treasury guidance on fees and charges is applied when setting fee levels for the MHRA. Fees are set following consultation with Industry, the Department of Health and HM Treasury and are intended, taking one year with another, to cover the costs of the Agency. Department of Health funding in relation to devices activities is intended to cover the costs of providing this specific service.

Principal activities are as follows:

Devices: Operating vigilance and other systems for reporting, investigating and monitoring adverse reactions to medicines, adverse incidents involving medical devices and blood products and taking any necessary action to safeguard public health

Medicines: Responsible for assessing the safety, quality and efficacy of medicines and authorising their sale or supply in the UK for human use.

	Devices		Medicines		Total	
	2009/10	2008/09	**2009/10**	2008/09	**2009/10**	2008/09
	£000	£000	**£000**	£000	**£000**	£000
Operating Income	**12,021**	11,726	**100,519**	101,086	**112,540**	112,812
Operating Expenditure	**(12,043)**	(9,750)	**(86,930)**	(77,412)	**(98,973)**	(87,162)
Operating (deficit)/surplus	**(22)**	1,976	**13,589**	23,674	**13,567**	25,650

The table above is for the purposes of providing information on fees and charges, not IFRS 8 purposes

5. Staff costs	**2009/10**			2008/09
	Total	**Permanently Employed**	**Other**	Total
	£000	**£000**	**£000**	£000
Salaries and wages	**41,687**	**40,816**	**871**	39,142
Social security costs	**3,651**	**3,651**	**-**	3,334
Pension contributions	**8,019**	**8,019**	**-**	7,643
Early retirement and redundancy	**16**	**16**	**-**	(131)
Total staff costs	**53,373**	**52,502**	**871**	49,988

6. Employee details

The average number of full-time equivalent persons employed by the Agency during the period was:

	2009/10			2008/09		
	Total	**Permanently Employed**	**Other**	Total	Permanently Employed	Other
Chairman	**1**	**-**	**1**	1	-	1
Executive Directors	**10**	**10**	**-**	11	10	1
Senior Civil Servants	**103**	**99**	**4**	94	94	-
Other Civil service staff	**858**	**769**	**89**	818	741	77
	972	**878**	**94**	924	845	79

7. Expenditure

7.1 Operating costs

	2009/10	2008/09
	£000	£000
Computing	**8,958**	9,216
Increase in provisions	**7,706**	-
Depreciation and amortisation	**6,102**	5,277
Rentals under operating leases (see 7.2 below)	**4,284**	3,709
Other accommodation costs	**3,934**	4,154
Travel and subsistence	**2,457**	2,399
Medicines testing and laboratory expenses	**2,099**	1,843
Other administration costs	**1,426**	1,554
Contracted-out administration services	**1,355**	582
Legal Services	**1,244**	1,587
Training	**1,145**	1,013
Telecommunication	**1,001**	869
Committee costs	**912**	697
Impairment of furniture and fittings	**865**	-
Contracted-out personnel and payroll services	**584**	460
Printing, stationery and distribution	**577**	671
Consultancy	**340**	1,178
Marketing	**270**	164
Pharmacovigilance database and other costs	**237**	171
Auditors remuneration - audit fee	**104**	104
Net increase in debt and credit note provision	**-**	1,534
Debt written off	**-**	(8)
Total operating costs	**45,600**	37,174

7.2 Operating leases

The operating lease rental payments represent rent payable by the Agency for its properties and equipment under non-cancellable operating lease agreements. Most of the agreements are renewable at the end of the lease period at market rate and contain no rental escalation clauses. The Agency does not have an option to purchase the leased asset at the expiry of the lease period and no arrangements have been entered into for contingent rental payments.

As lessee

	Others	Land and buildings	Others	Land and buildings
Payments recognised as an expense	**2009/10**	**2009/10**	**2008/09**	**2008/09**
	£000	**£000**	£000	£000
Minimum lease payments	**62**	**4,222**	64	3,645
Contingent rents	**-**	**-**	-	-
Sub-lease payments	**-**	**-**	-	-
	62	**4,222**	64	3,645

Total future minimum lease payments	**2009/10**	**2009/10**	**2008/09**	**2008/09**
	£000	**£000**	£000	£000
Payable:				
Not later than one year	**43**	**4,187**	32	3,647
Between one and five years	**19**	**3,561**	13	6,432
After five years	**-**	**127**	-	223
	62	**7,875**	45	10,302

Total future sublease payments expected to be received: £176k (2008/09: £276k).

7.3 Finance Leases

The Agency had no finance leases in 2009/10.

8. Interest revenue

	2009/10	2008/09
	£000	£000
Bank Accounts	147	1,579
	147	1,579

9. Other gains and losses

	2009/10	2008/09
	£000	£000
Gain on foreign exchange	4	40
	4	40

10. Finance Costs

	2009/10	2008/09
	£000	£000
Interest on loans	(64)	(256)
	(64)	(256)

11. Plant and equipment

	Computer and telecom equipment	Laboratory equipment	Fittings furniture and office equipment	Total
2009/10:	**£000**	**£000**	**£000**	**£000**
Cost or valuation				
At 1 April 2009	**5,425**	**1,278**	**4,292**	**10,995**
Additions	1,019	188	40	1,247
Disposals other than by sale	(1,250)	-	(432)	(1,682)
Indexation	-	13	(40)	27
Impairments*	-	-	(3,430)	(3,430)
At 31 March 2010	**5,194**	**1,479**	**430**	**7,103**
Depreciation				
At 1 April 2009	**2,263**	**957**	**2,518**	**5,738**
Disposals other than by sale	(1,250)	-	(432)	(1,682)
Indexation	-	10	(24)	(14)
Charged during the year	915	125	623	1,663
Impairments	-	-	(2,565)	(2,565)
Depreciation				
At 31 March 2010	**1,928**	**1,092**	**120**	**3,140**
Net book value				
At 31 March 2010	**3,266**	**387**	**310**	**3,963**
At 31 March 2009	3,162	321	1,774	5,257
Asset financing:				
Owned				
Net book value at 31 March 2010	**3,266**	**387**	**310**	**3,963**

* Write down asset values following decision to relocate the Agency's headquarters.

	Computer and telecom equipment	Laboratory equipment	Fittings furniture and office equipment	Total
2008/09:	£000	£000	£000	£000
Cost or valuation				
At 1 April 2008	2,741	1,110	4,155	8,006
Additions	2,968	157	95	3,220
Disposals other than by sale	-	-	-	-
Indexation	-	11	42	53
Revaluation	-	-	-	-
Transfers	(284)	-	-	(284)
Impairments	-	-	-	-
At 31 March 2009	5,425	1,278	4,292	10,995
Depreciation				
At 1 April 2008	1,775	840	1,906	4,521
Disposals other than by sale	-	-	-	-
Indexation	-	9	19	28
Charged during the year	488	108	593	1,189
Depreciation				
At 31 March 2009	2,263	957	2,518	5,738
Net book value				
At 31 March 2009	3,162	321	1,774	5,257
At 31 March 2008	966	270	2,249	3,485

Asset financing:				
Owned				
Net book value at 31 March 2009	3,162	321	1,774	5,257

12. Intangible assets

	Computer systems	Software licences	Assets under construction	RAMA XL	Total
2009/10:	**£000**	**£000**	**£000**	**£000**	**£000**
Cost or valuation					
At 1 April 2009	**31,038**	**1,076**	**1,095**	**1,561**	**34,770**
Additions	803	-	1,318	-	2,121
Disposals other than by sale	(2,478)	-	-	-	(2,478)
Transfers	1,095	-	(1,095)	-	-
At 31 March 2010	**30,458**	**1,076**	**1,318**	**1,561**	**34,413**
Amortisation					
At 1 April 2009	**15,664**	**458**	**-**	**1,203**	**17,325**
Disposals other than by sale	(2,478)	-	-	-	(2,478)
Charged during the year	3,904	177	-	358	4,439
Amortisation					
At 31 March 2010	**17,090**	**635**	**-**	**1,561**	**19,286**
Net book value					
At 31 March 2010	**13,368**	**441**	**1,318**	**-**	**15,127**
At 31 March 2009	15,374	618	1,095	358	17,445

Asset financing:					
Owned					
Net book value at 31 March 2010	**13,368**	**441**	**1,318**	**-**	**15,127**

	Computer systems	Software licences	Assets under construction	RAMA XL	Total
2008/09:	£000	£000	£000	£000	£000
Cost or valuation					
At 1 April 08	28,228	665	1,056	1,561	31,510
Additions	1,511	411	1,054	-	2,976
Disposals other than by sale	-	-	-	-	-
Revaluation	-	-	-	-	-
Transfers	1,299	-	(1,015)	-	284
At 31 March 2009	31,038	1,076	1,095	1,561	34,770
Amortisation					
At 1 April 08	12,093	331	-	813	13,237
Disposals other than by sale	-	-	-	-	-
Charged during the year	3,571	127	-	390	4,088
Amortisation					
At 31 March 2009	15,664	458	-	1,203	17,325
Net book value					
At 31 March 2009	15,374	618	1,095	358	17,445
At 31 March 2008	16,135	334	1,056	748	18,273

Asset financing:					
Owned					
Net book value at 31 March 2009	15,374	618	1,095	358	17,445

13. Trade and other receivables

	31 March 2010	31 March 2009	1 April 2008
	£000	£000	£000
Due from the Department of Health (see 13.1 below)	**510**	840	810
Other trade receivables	**12,121**	12,623	15,880
Other receivables	**256**	238	214
Accrued income	**2,256**	2,194	1,527
Prepayments	**2,255**	1,529	2,411
	17,398*	17,424*	20,842

*Intra government balance disclosed in note 21.

13.1 Amount Due from the Department of Health consists of:

	31 March 2010	31 March 2009	1 April 2008
	£000	£000	£000
Other trade receivables	**2**	244	21
Value Added Tax	**508**	596	789
	510	840	810

Other trade receivables are shown net of a provision for irrecoverable debts and credit notes of £10.341m (31 March 2009 £8.918m).

14. Trade and other payables

	Current			Non-current		
	31 March 2010	31 March 2009	1 April 2008	**31 March 2010**	31 March 2009	1 April 2008
	£000	£000	£000	**£000**	£000	£000
Due to the Department of Health (see 14.1 below)	**-**	131	916	**-**	-	-
Payments received on account	**11,757**	8,703	10,028	**-**	-	-
Other trade payables	**2,307**	535	1,386	**-**	-	-
Other payables	**1**	1	-	**-**	-	-
Accruals	**5,668**	5,447	4,092	**-**	-	-
	19,733*	14,817*	16,422	**-**	-	-

*Intra government balance disclosed in note 21

14.1 Amount Due to the Department of Health consists of:

	Current			Non-current		
	31 March 2010	31 March 2009	1 April 2008	**31 March 2010**	31 March 2009	1 April 2008
	£000	£000	£000	**£000**	£000	£000
Interest payment	**-**	68	148	**-**	-	-
Accruals	**-**	63	768	**-**	-	-
	-	131	916	**-**	-	-

15. Other Liabilities

	Current			Non-current		
	31 March 2010	31 March 2009	1 April 2008	**31 March 2010**	31 March 2009	1 April 2008
	£000	£000	£000	**£000**	£000	£000
Deferred revenue:						
Licence fees (applications and variations)	**-**	-	-	**28,697**	29,445	26,677
Other fees	**-**	-	-	**2,644**	2,903	2,833
Dividend Payable	**1,583**	932	322	**-**	-	-
	1,583	932	322	**31,341**	32,348	29,510

16. Borrowings

	Current			Non-current		
	31 March 2010	31 March 2009	1 April 2008	**31 March 2010**	31 March 2009	1 April 2008
	£000	£000	£000	**£000**	£000	£000
Loan from Department of Health	**-**	400	1,000	**1,328**	1,328	1,728
	-	400	1,000	**1,328**	1,328	1,728

An analysis of the maturity and interest rates of the medium-term loans is as follows:

	Total 2009/10	Less than one year	Between one to two years	Between Two and three years	Between three and five years	More than five years	Total 2008/09
	£000	£000	£000	£000	£000	£000	£000
Fixed interest rate							
4.35%	-	-	-	-	-	-	400
3.50%	-	-	-	-	-	1,328	1,328
At 31 March 2010	**1,328**	**-**	**-**	**-**	**-**	**1,328**	
At 31 March 2009	1,728	400	-	-	-	1,328	1,728

The fourth tranche of loan repayment was made during 2009/10 when £0.4m (2008/09 £1.0m) was repaid to the Department of Health.

17. Provisions and contingencies

17.1 Provisions for liabilities and charges

	Current			Non-Current		
	31 March 2010	31 March 2009	1 April 2008	**31 March 2010**	31 March 2009	1 April 2008
	£000	£000	£000	**£000**	£000	£000
Early retirement /voluntary severance	**46**	74	217	**58**	92	18
Other provisions	**3,117**	-	-	**8,296**	3,627	3,691
	3,163	74	217	**8,354**	3,719	3,709

	Early retirement/ voluntary severance	Other provisions	**Total**
	£000	£000	**£000**
At 1 April 2009	166	3,627	**3,793**
Arising during the year	-	7,706	**7,706**
Used during the year	(78)	-	**(78)**
Unwinding discount	16	80	**96**
At 31 March 2010	104	11,413	**11,517**
Expected timing of cash flows:			
Between 1 April 2010 and 31 March 2011	46	3,117	**3,163**
Between 1 April 2011 and 31 March 2013	32	8,296	**8,328**
Between 1 April 2013 and 31 March 2015	26	-	**26**
	104	11,413	**11,517**

The provision for early retirement and voluntary severance is to cover the MHRA's estimated liability for pensions in respect of early retirements. These are long term commitments dependent on the life expectancy of the pensioners.

Other provisions are in respect of the headquarters building costs. This includes a provision for dilapidations which is the cost for reinstating the structure of the building as required by the lease and an onerous contract provision which includes rent, rates, and service charges payable as well as impairment of furniture and fittings.

17.2 Contingent liabilities

The Department of Health has agreed that it will meet the costs of any liabilities arising from legal claims in respect of functions performed by the Agency and that such costs should not be met from the Agency's Trading Fund. Consequently, the Agency does not have any contingent liability in this regard.

18. Cash and cash equivalents

	31 March 2010	31 March 2009	1 April 2008
	£000	£000	£000
Balance at 1 April	**51,439**	21,861	18,119
Net change in year	**27,946**	29,578	3,742
Balance at 31 March	**79,385**	51,439	21,861
Made up of			
Cash with Office of HM Paymaster General	**68,579**	50,971	20,303
Commercial banks and cash in hand	**10,806**	468	1,558
Cash and cash equivalents	**79,385**	51,439	21,861

19. Capital commitments

	Intangible	**Tangible**	Intangible	Tangible
	31 March 2010	**31 March 2010**	31 March 2009	31 March 2009
	£000	**£000**	£000	£000
Contracted	**2,941**	**-**	732	-
	2,941	**-**	732	-

20. Related party transactions

The MHRA is a Government Trading Fund and an Executive Agency of the Department of Health. The Department of Health is regarded as a related party. During the year, the MHRA has had a significant number of material transactions with the Department and with other entities for which the Department is regarded as the parent Department, notably various NHS Trusts. In addition, the MHRA has had various material transactions with other government departments and other central government bodies. Most of these transactions have been with:

- The Department of Work and Pensions, primarily for the purchase of legal services from the DWP (£1,234,000);
- The University of Leicester for the secondment of the Agency's Chief Executive (£243,801);

The value of total transactions and balances outstanding at the end of the year are set out below. No amounts were written off during the year.

	Payments to Related Party	Receipts from Related Party	Amounts owed to Related Party	Amounts due from Related Party
	£000	£000	£000	£000
Department of Health	11,867	12,337	3	13
Various NHS Trust	168	1,984	-	352
Department of Work and Pensions	1,234	-	-	-
Other government bodies	548	1,450	-	1
Local Authorities	2,520	-	-	21
Educational Bodies	383	790	-	426
As at 31 March 2010	**16,720**	**16,561**	**3**	**813**
Department of Health	51,297	12,235	-	245
Various NHS Trust	164	1,952	12	1,169
Department of Work and Pensions	1,058	-	-	-
Other government bodies	897	674	1	222
Local Authorities	65	-	-	-
Educational Bodies	354	425	-	162
As at 31 March 2009	53,835	15,286	13	1,798

During 2009/10, none of the Board members, members of the key management staff or other related parties had undertaken any material transactions with the MHRA.

21. Intra Government balances

	Debtors: Amounts falling due within one year	Debtors: Amounts falling due after more than one year	Creditors: Amounts falling due within one year	Creditors: Amounts falling due after more than one year
	£000	£000	£000	£000
Balances With Other Central Government Bodies	535	-	613	-
Balances With Local Authorities	184	-	-	-
Balances with NHS Trusts	2,133	-	225	-
Balances with Public Corporations and Trading Funds	27	-	-	-
Subtotal	2,879	-	838	
Balances with Bodies External to Government	14,519	-	18,895	-
As at 31 March 2010	**17,398**	**-**	**19,733**	**-**
Balances With Other Central Government Bodies	842	-	410	-
Balances With Local Authorities	64	-	3	-
Balances with NHS Trusts	-	-	323	-
Balances with Public Corporations and Trading Funds	-	-	3	-
Subtotal	906	-	739	-
Balances with Bodies External to Government	16,518	-	14,078	-
As at 31 March 2009	17,424	-	14,817	-
Balances with Other Central Government Bodies	1,007	-	455	-
Balances with Local Authorities	77	-	3	-
Balances with NHS Trusts	-	-	358	-
Balances with Public Corporations and Trading Funds	-	-	3	-
Subtotal	1,084	-	819	-
Balances with Bodies External to Government	19,758	-	15,603	-
As at 31 March 2008	20,842	-	16,422	-

22. Losses and special payments

There were no other material losses or special payments during the year (2008/09:£nil) than elsewhere disclosed in the financial statements.

23. Financial Instruments

Financial risk management

International Financial Reporting Standard (IFRS) 7 requires disclosure of the role that financial instruments have had during the period in creating or changing the risks a body faces in undertaking its activities. Because of the nature of the MHRA's activities, financial instruments play a much more limited role in creating or changing risk than is typical of the listed companies to which the IFRS mainly applies, the Agency is therefore exposed to little credit, liquidity or market risk.

Liquidity risk

The MHRA's resource and capital expenditure requirements are financed by revenues generated from its activities, with the exception of a loan facility with the Department of Health of £10.0M. This requires the Agency to ensure it has sufficient reserves of cash to enable it to undertake its statutory activities.

The table below provides details of cash balances held at the end of the year and the average rate during the year. Balances held in the commercial accounts are denominated in Sterling, Euros and US dollars.

	2009/10	2008/09
	£000	£000
Paymaster	**68,579**	50,971
Commercial	**10,806**	468
	79,385	51,439

* The interest rates for both types of account are variable.

Interest rate risk

The MHRA is not exposed to significant interest rate risk. The average total of loans, which are at a fixed rate of interest, held throughout the year was £1.328M (2008/09:£1.728M). This resulted in interest payable of £0.064M (2008/09: £0.256M) out of total expenditure in excess of £98.973M (2008/09: £87.162M)

Currency risk

The level of currency risk is determined by the level of income generated by activity undertaken on behalf of the EMA. For 2009/10 this was £6.871M (Euro 7.698M) (2008/09: £6.310M; Euro 8.267M). This represents 6.8% (2008/09: 5.6%) of the total gross income for the year. The Agency is potentially exposed to significant falls in the value of this currency; however, the risk is mitigated by the regular transfer of funds to the sterling accounts of the Agency.

Credit risk

The Agency is not exposed to significant credit risk.

24. Transition to IFRS

	Public Dividend Capital (PDC)	Retained surplus	Income & Expenditure reserve	Revaluation reserve	Government grant reserve
	£000	£000	£000	£000	£000
Taxpayers' equity at 31 March 2008					
Under UK GAAP:	**1,329**	**10,435**	**954**	**142**	**300**
Adjustments for IFRS changes:					
Leases	-	-		-	-
Accrued staff leave	-	(1,607)		-	-
Adjustments for:					
Impairments recognised on transition	-	-		-	-
UK GAAP errors	-	-		-	-
Taxpayers' equity at 1 April 2008 under IFRS	**1,329**	**8,828**	**954**	**142**	**300**
Taxpayers' equity at 31 March 2009					
Under UK GAAP:	**1,329**	**37,038**	**954**	**168**	**587**
Adjustments for IFRS changes:					
Leases	-	-		-	-
Accrued staff leave	-	(2,129)		-	-
Adjustments for:					
UK GAAP errors	-	-		-	-
Taxpayers' equity at 1 April 2009 under IFRS:	**1,329**	**34,909**	**954**	**168**	**587**

	£000
Surplus for 2008/09 under UK GAAP	**26,603**
Adjustments for:	
Accrued staff leave	(522)
Surplus for 2008/09 under IFRS	**26,081**

25. Events after the reporting period

None.

HM TREASURY MINUTE dated 27 March 2008

1. Section 4(1) of the Government Trading Funds Act 1973 ("the 1973 Act") provides that a trading fund established under the Act shall be under the control and management of the responsible Minister and, in the discharge of his function in relation to the fund, it shall be his duty:

    a. to manage the funded operations so that the revenue of the fund:

        i. consists principally of receipts in respect of goods or services provided in the course of the funded operations; and

        ii. is not less than sufficient, taking one year with another, to meet outgoings which are properly chargeable to revenue account; and

    b. to achieve such further financial objectives as the Treasury may from time to time, by minute laid before the House of Commons, indicate as having been determined by the responsible Minister (with Treasury concurrence) to be desirable of achievement.

2. The Trading Fund for the Medicines and Healthcare products Regulatory Agency was established on 1 April 2003 under the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (SI 2003 No. 1076).

3. The Secretary of State for Health, being the responsible Minister for the purposes of section 4(1)(a) of the 1973 Act, has determined (with Treasury concurrence) that a further financial objective desirable of achievement by the Medicines and Healthcare products Regulatory Agency Trading Fund for the five-year period from 1 April 2008 to 31 March 2013 shall be to achieve a return, averaged over the period as a whole, of at least 3.5% in the form of a surplus on ordinary activities before interest (payable and receivable) and dividends expressed as a percentage of average capital employed. Capital employed shall consist of the capital (PDC and long-term element of loans) and Reserves.

4. This minute supersedes that dated 9 February 2004.

5. Let a copy of this Minute be laid before the House of Commons pursuant to section 4(1)(b) of the Government Trading Funds Act 1973.


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ISBN 978-0-10-296674-9

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