



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

FRAMEWORK DOCUMENT

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This Framework Document has been drawn up by the Department of Health in consultation with the Medicines and Healthcare products Regulatory Agency (MHRA). It will be reviewed and updated at least once every five years.

SECTION 1

STATUS

Executive Agency

1.1 The Medicines and Healthcare products Regulatory Agency (MHRA) is a Government Trading Fund and an Executive Agency of the Department of Health (DH), established on 1 April 2003

Size of the Agency

1.2 The MHRA has around 970 staff and a total budget of around £100 million as at the beginning of 2009/2010.

Location

1.3 The Agency's head office is located in London. The Agency also retains three regional offices at York, Welwyn Garden City and Blackpool.

Legal Framework

Medicines

1.4 In the United Kingdom, control of medicines is governed by the Medicines Act 1968, relevant subordinate legislation under the Act and a body of European Union legislation¹. The legislation provides a regulatory framework in respect of the safety, quality and efficacy of medicinal products to be sold, supplied or

¹ See the "relevant Community provisions" as defined by the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (SI 1994/3144). Notably, these include Directive 2001/83/EC (which codified previous Directives relating to medicinal products for human use) and Regulation No. 2309/93 (which established the European Agency for the Evaluation of Medicinal Products and introduced community procedures for the authorisation and supervision of medicinal products).

administered to patients. The MHRA discharges, on behalf of Ministers, functions that they exercise, singly or collectively, as the “Licensing Authority”², “Health Ministers”³ or the “competent authority”⁴.

- 1.5 The legislation covers, *inter alia*, the systems by which licenses to manufacture, market, distribute, sell and supply medicines are granted by Ministers – the Licensing Authority – (or, in the case of the centralised system, the relevant Community institutions), once they are satisfied about the safety, quality and efficacy of the product. There are also controls on clinical trials, claims that may be made in advertising and other promotion of medicines, labelling of medicines (including patient information leaflets), manufacture of unlicensed products and supply of imports. The Licensing Authority is required to monitor the safety of licensed medicinal products and to take action when adverse effects are recognised. It will also instigate enforcement action when breaches of the legislation are seen to have occurred.
- 1.6 The MHRA also discharges the functions of the British Pharmacopoeia and of the Good Laboratory Practice Monitoring Authority⁵, which enforces application of the principles of good laboratory practice.
- 1.7 At the time of writing, the MHRA is in the process of consolidating and reviewing its base medicines legislation with a view to updating it and making it more coherent. This is a major project which is expected to be concluded during 2011.

² Defined in section 6 of the Medicines Act 1968; the Secretary of State for Health, the Northern Ireland Minister of Health, Social Services and Public Safety (a Northern Ireland Minister), the Secretary of State for the Environment, Food and Rural Affairs and the Minister for Agriculture and Rural Development (a Northern Ireland Minister). Where the Northern Ireland Assembly is suspended, the powers vested in the Minister may be exercised by the Department of which the Minister is in charge (see section 1(8) of and paragraph 4(1)(b) of the Schedule to the Northern Ireland Act 2000).

³ Defined in section 1(1)(a) of the Medicines Act 1968.

⁴ Referred to in the “relevant Community provisions” (see footnote above) and see regulation 2 of SI 1994/3144.

⁵ See regulation 3 of the Good Laboratory Practice Regulations 1999 (SI 1999/3106).

Medical Devices

- 1.8 The European Community Medical Devices Directives, implemented in the United Kingdom by the Medical Devices Regulations 2002 (as amended), govern the control of those healthcare products referred to in the legislation as “medical devices”. Under this legislation, medical devices placed on the market must be CE marked to confirm that they conform to the requirements of the relevant Directive governing safety, quality and performance. For the lowest-risk devices (e.g. dressings and bandages), manufacturers themselves certify that their products conform to the requirements. An independent body known as a “notified body” certifies higher-risk devices (e.g. hip implants, pacemakers, heart valves, resuscitators). The MHRA designates and monitors the notified bodies in the UK.

Competent Authority for the safety and quality of human blood and blood components

- 1.9 The Agency became the Competent Authority for Blood Safety and Quality in the UK in the UK in 2005 adding to its responsibilities and widening the range of its stakeholders to include blood establishments (e.g. the national blood transfusion services) and hospital blood banks . It regulates the safety and quality of blood and blood components in accordance with the EU Blood Quality and Safety Directives⁶ as implemented by the Blood Safety and Quality Regulations⁷

⁶ Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC

⁷ The Blood Safety and Quality Regulations 2005 No. 50 as amended

Advisory Committees

- 1.10 The Commission for Human Medicines is the main advisory body established in legislation (Section 2 of the Medicines Act 1968) to provide advice to the Licensing Authority on all matters relating to medicines. It is supported by a number of specialist advisory committees also set up under existing medicines legislation (section 4 of the Medicines Act 1968). In addition there are two further advisory committees dealing with herbal (the Herbal medicines Advisory Committee) and homoeopathic products (Advisory Board for the Registration of Homoeopathic products (ABRH)).
- 1.11 There is a similar, but non-statutory, advisory committee for medical devices (the Committee on the Safety of Devices).

SECTION 2

AIMS, KEY ACTIVITIES AND OPERATING PRINCIPLES

Aim of the Medicines and Healthcare products Regulatory Agency

The aims of the Medicines and Healthcare products Regulatory Agency are:

Protecting public health through regulation, with acceptable risk:benefit profiles for medicines , devices and blood and blood components;

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.

Key Activities

2.1 In order to achieve its aims, the Agency:

- a. Operates a system of licensing, classification, monitoring and enforcement to ensure that medicines for human use, sold or supplied in the UK, are of an acceptable standard.
- b. Discharges statutory obligations under the various UK regulations for medical devices and contributes, as necessary, to developing the safety and performance standards that support this work.
- c. Ensures compliance with statutory obligations relating to the investigation of medicines in clinical trials and assesses notifications of proposals for clinical trials from manufacturers of medical devices.

- d. Operates systems of post-marketing surveillance for:
- Reporting and monitoring of suspected adverse reactions to medicines and of suspected defective medicines and, where necessary, taking action to remove or restrict the availability of such products.
 - Reporting adverse incidents with medical devices and, based on analysis and prompt investigation of reports, taking any necessary action to safeguard public health, e.g. issue safety warnings.
- e. Promulgates good practice in the safe use of medicines and medical devices.
- f. Ensures compliance, in the UK, with statutory obligations relating to the manufacture, distribution, sale, labelling, advertising and promotion of medicines.
- g. Designates and monitors the performance of notified bodies that audit manufacturers of moderate and high-risk medical devices, and maintains a register of all other manufacturers placing medical devices on the UK market.
- h. Monitors compliance with the medical devices regulations and, where necessary, takes enforcement action.
- i. Provides advice and support on policy issues to Ministers in the Department of Health and the devolved administrations.
- j. Represents the United Kingdom in European and other international fora on matters concerning the regulation of medicines and medical devices.
- k. Manages the activities of the General Practice Research Database (GPRD) of anonymised clinical records in support of a range of public health activities.
- l. Manages the activities of the British Pharmacopoeia (BP) and work undertaken by BP staff relating to the European Pharmacopoeia.

- m. Discharges the functions of the UK Good Laboratory Practice Monitoring Authority (GLPMA).
- n. Regulates the safety and quality of blood and blood components in accordance with the European Blood Directive as transposed into UK legislation by the Blood Safety and Quality Regulations 2005.

Operating Principles

2.2 In carrying out these activities, the Agency:

- a. Operates within Department of Health objectives for protecting and improving public health;
- b. Operates as a government trading fund in accordance with the requirements of the Government Trading Funds Act 1973 and provides services efficiently and effectively within the terms of the Medicines and Healthcare products Regulatory Agency Trading Fund Order 2005 (SI 2005 No 2061);
- c. Maintains effective working relationships with the Department of Health and other government departments;
- d. Operates within the framework of legislation on Freedom of Information, Data Protection and Human Rights;
- e. Develops and implements human resources strategies to recruit, reward, develop and retain staff with the skills and expertise to deliver its objectives;
- f. Maintains appropriate management and financial accounting systems;
- g. Matches the quality of its services to the identified needs of its customers, whilst ensuring that levels of regulation are not excessive;

- h. Uses appropriate indicators and measures to assess its performance, and continually seeks to improve the quality, efficiency and effectiveness of its activities.

Stakeholders

2.3 Some of the Agency's main stakeholders are:

- Ministers in the Department of Health, in other government departments and in the devolved administrations in Scotland, Wales and Northern Ireland;
- Patients, purchasers and users of products, carers, members of the public and their representatives;
- Health and social care professionals and their representative organisations;
- The staff of the Agency;
- Manufacturers, distributors and retailers of medicines and medical devices, and their trade associations;
- Blood establishments and hospital blood banks ;
- The National Patient Safety Agency (NPSA), the National Institute for Clinical Excellence (NICE) and NHS Quality Improvement Scotland;
- Notified bodies;
- The European Commission, the European Medicines Agency (EMA), the European Pharmacopoeia and regulatory authorities in other countries.

(This list is not exhaustive)

SECTION 3

ACCOUNTABILITY

Ministerial Responsibility

- 3.1 The Secretary of State for Health has Ministerial responsibility for the Medicines and Healthcare products Regulatory Agency. The Secretary of State for Health, in consultation with Ministers in Scotland, Wales and Northern Ireland, determines the policy and financial framework within which the Agency operates, agrees high-level performance targets and approves its corporate and business plans, but is not involved in the day-to-day management of the Agency.
- 3.2 DH Ministers account to Parliament on all matters concerning regulation of human medicines in England, Scotland and Wales. Although medicines control is a transferred matter in Northern Ireland, the MHRA acts, under administrative arrangements, as the competent authority. Although responsibility for securing enforcement of the Medicines Act 1968 and related legislation in Scotland and Wales is the responsibility of the Scottish Executive and the National Assembly for Wales respectively, the MHRA acts on behalf of those administrations under agency arrangements. In Northern Ireland, responsibility for all medicines control policy rests with the Department of Health, Social Services and Public Safety, which works closely with the MHRA.
- 3.3 The MHRA is the competent authority for the whole of the UK on all matters relating to the regulation of medical devices. None of these functions, which include the enforcement of the Medical Devices Regulations, have been devolved and DH Ministers are accountable to Parliament for them. However, MHRA routinely consults the devolved administrations on device-related issues. This includes giving advance notice of (and the opportunity to observe) any investigations or inspections of manufacturers of medical devices based in Scotland, Wales or Northern Ireland.

- 3.4 The MHRA is the Competent Authority for Blood Safety and Quality in the UK. These functions have not been devolved and DH Ministers are accountable to Parliament for them. However, MHRA routinely consults the devolved administrations on blood safety and quality-related issues.

Accountability to Parliament

- 3.5 The Secretary of State is answerable to Parliament for all matters concerning the MHRA. The Secretary of State will usually ask the Chairman or Chief Executive of the Agency to write to Members of Parliaments or Assemblies in response to individual letters about matters that are delegated to the MHRA. The replies to parliamentary questions are published in the Official Report.

Chairman

- 3.6 The Chairman is directly accountable to Ministers for the performance of the Agency and its decisions. They are responsible for advising the Secretary of State on issues relevant to the safety, quality and efficacy of medicines safety, quality and performance of medical devices and safety and quality of blood and blood components. The Chairman meets with the Secretary of State, or Minister of State responsible for medicines (or their nominee), at an annual accountability meeting at least once a year, to discuss the Agency's strategy and performance.
- 3.7 The Chairman of the MHRA is responsible for providing leadership to the Agency Board (AB) and the Agency itself, for enabling all AB members to make a full contribution to the Board's affairs and for ensuring that the AB acts as a team for the benefit of the Agency and its stakeholders.

3.8 The role of the Chairman, together with the Agency Board, is to advise on and monitor the implementation of:

- Strategies to ensure that the regulatory systems for medicines and medical devices are effective and robust, given developments in science and technology, and at an international level;
- Strategies for increasing public knowledge and understanding about the safe use of medicines and medical devices.

3.9 Furthermore, the Chairman, together with the Agency Board, will advise on and monitor:

- The steps taken by the Agency to carry out its statutory responsibilities, meeting its targets and objectives, while remaining, within budget and using its available resources efficiently and effectively;
- The service provided to the manufacturers of medicines and medical devices, to health and social care professionals and to the general public;
- The steps taken by the Agency to protect the interests of the public by ensuring that medicines meet appropriate standards of safety, quality and efficacy and medical devices meet appropriate standards of safety, quality and performance.

3.10 The Chairman annually reviews the performance of the Chief Executive in carrying out their responsibilities.

Agency Board

3.11 The Agency Board (AB) of the MHRA is responsible for the monitoring of the implementation of Ministers' objectives for the strategic direction of the Agency, taking into account the perspective(s) of its stakeholders, and advising Ministers and the Agency accordingly. The AB consists of not more than 12 individuals. Non-executive members are appointed by the Secretary of State following open competition undertaken by the NHS Appointments Commission and do not represent any specific customer, sectoral or stakeholder interests. The AB normally meets once a month. The AB approves:

- the Agency's business strategy and corporate objectives;

- the Agency's five-year corporate plan and annual business plan;
- the Agency's key financial and performance targets;
- the content of the MHRA's annual report.

The AB, as a whole, does not exercise any line management or executive functions. It will not have a legal or constitutional role or any liability in respect of decisions of the Executive.

Sponsorship of the Agency

3.12 Sponsorship of the MHRA, within the Department of Health, is undertaken by the Chief Medical Officer (CMO) or by one of their deputies acting on their behalf. The CMO acts on behalf of his/her counterparts in the devolved administrations. He/she or their deputy is a key link between the MHRA and the Department and, in particular, ensures that the Department and the Agency both have a clear understanding of each other's objectives, methods of working and how these fit together.

3.13 The Chief Medical Officer/Senior Departmental Sponsor:

- Keeps the Chairman and Chief Executive informed of any central policy developments that might impact on the Agency.
- Advises Ministers on the strategic direction of the Agency in the context of wider Departmental or cross-governmental objectives.
- Agrees a framework for the strategic performance management of the Agency.
- Advises the Chairman and Chief Executive on steering the Agency's activities to ensure that they most effectively support delivery of Departmental objectives.
- Ensures that the Agency has the necessary delegations and authorities for effective delivery and continuous improvement.
- Agrees Service Level Agreements where they are required
- Reviews annually the personal performance of the Chairman in carrying out their responsibilities.

3.14 The Senior Departmental Sponsor and the Chief Executive of the Agency meet regularly through a DH Partnership Committee. The Committee meets 3 – 4 times a year at the most senior official level between DH and MHRA to ensure effective joint working.

3.15 The remit of the Committee is:

- To provide a regular exchange between DH and MHRA at the level of MHRA CEO/ Director General of Health Improvement and Protection Directorate (HIPD) / Head of Medicines and Pharmacy Industry Group (MPIG), to ensure that there is a shared understanding of strategic policy and delivery issues
- To consider specific major topics, identified in advance, that merit discussion at this senior level, and that are not being adequately addressed through other channels
- To ensure that other existing arrangements for liaison, accountability and governance are working adequately, and to oversee the sponsor role as set out in the Agency Framework Document.

Chief Executive

3.16 The Chief Executive is responsible for the day-to-day management of the MHRA. For the staffing and operation of the Agency, the Chief Executive is directly accountable to the Chairman and, for the financial management of the Agency, to the Permanent Secretary of the Department of Health.

3.17 The Chief Executive, in consultation with the Chairman and Board of the Agency and subject to his/her agreed delegated powers, determines (and may adapt) the organisational and management structure of the Agency to meet its business needs.

3.18 The Chief Executive is responsible for:

- Playing a central role in the strategic direction of the Agency, including anticipating and monitoring key trends affecting its work.
- Developing the MHRA into an organisation that is outward-looking and equipped to carry out its regulatory obligations and other business functions.
- Developing strong links between the Agency and its stakeholders, both within the UK and overseas, including manufacturers, patients' representatives and organisations in the NHS and social care.
- Representing the Agency at European or other international meetings and negotiations.
- Keeping the Department of Health informed about the Agency's work, progress and plans.

3.19 The Chief Executive is accountable for the governance of the Agency. The Chief Executive may be called to account by the Public Accounts Committee for the way the Agency carries out its work, its stewardship of resources and for its performance against targets. Ministers will decide who should represent them at Select Committee hearings. In practice, where the interest of a committee is confined to the day-to-day operations of the Agency, Ministers will normally wish to be represented or accompanied by the Chief Executive and/or Chairman.

Senior Management Team/Executive Board

3.20 The Chief Executive meets regularly with the executive directors and other senior managers of the MHRA to discuss matters relating to the day-to-day operation and efficiency of the Agency.

Accounting Officer Responsibility

- 3.21 As the Principal Accounting Officer, the Permanent Secretary of the Department of Health is responsible for ensuring that a high standard of financial management is achieved throughout the Department and that the Agency has adequate financial systems and procedures in place for promoting the efficient and economic conduct of business and to safeguard financial propriety and regularity. He/she must also satisfy him/herself that the funds voted are used for the purpose intended by Parliament. The Permanent Secretary will ensure that the Agency receives, at an appropriate standard, those support services that it has been agreed will be provided by the Department.
- 3.22 The Chief Executive is appointed by HM Treasury as Accounting Officer for the MHRA Trading Fund and as an additional Accounting Officer within the Department of Health. The Chief Executive is responsible for ensuring that the requirements of Managing Public Money are met and that proper procedures are followed for securing the regularity and propriety of public funds administered by the Agency. The Chief Executive is also responsible for observing any general guidance issued by the Treasury and Cabinet Office and for implementing recommendations of the Public Accounts Committee or other Parliamentary Select Committees, where they have been accepted by the Government. The Chief Executive will sign the Agency's accounts.
- 3.23 The Accounting Officer will be personally responsible for the propriety and regularity of the public finances for which he or she is answerable; for the keeping of proper accounts; for prudent and economical administration; for the avoidance of waste and extravagance; and for the efficient and effective use of all the available resources.
- 3.24 The Accounting Officer must:
- sign the trading and other accounts assigned to him/her, and in doing so accept personal responsibility for their proper presentation as prescribed in legislation or by the Treasury;

- ensure that proper financial procedures are followed and that accounting records are maintained in a form suited to the requirements of management as well as in the form prescribed for published accounts;
- ensure that the public funds for which he or she are responsible are properly and well managed and safeguarded, with independent and effective checks of cash balances in the hands of any official;
- ensure that assets for which he or she are responsible, such as land, buildings or other property, including stores and equipment, are controlled and safeguarded with similar care, and with checks as appropriate;
- ensure that, in the consideration of policy proposals relating to the expenditure or income for which the Accounting Officer has responsibilities, all relevant financial considerations, including any issues of propriety, regularity or value for money, are taken into account, and where necessary brought to the attention of Ministers.

3.25 The Accounting Officer should ensure that effective management systems appropriate for the achievement of the organisation's objectives, including financial monitoring and control systems have been put in place. The Accounting Officer should also ensure that managers at all levels:

- have a clear view of their objectives, and the means to assess and, wherever possible, measure outputs or performance in relation to those objectives;
- are assigned well defined responsibilities for making the best use of resources (both those consumed by their own commands and any made available to organisations or individuals outside the department), including a critical scrutiny of output and value for money;
- have the information (particularly about costs), training and access to the expert advice which they need to exercise their responsibilities effectively.

- 3.26 The Accounting Officer will ensure that arrangements for delegation promote good management and that he or she is supported by the necessary staff with an appropriate balance of skills. The latter requires careful selection and development of staff and the sufficient provision of special skills and services (scientific, economic, statistical, accountancy, consultancy, inspection and review, etc). Arrangements for internal audit should accord with the objectives, standards and practices set out in the Treasury's "Government Internal Audit Standards"⁸.
- 3.27 The Accounting Officer should ensure that the impact of the Agency's activities on others is properly identified and where appropriate taken into account. He/she will need to ensure that the participation represents good value for money overall and that lines of responsibility are clearly defined.

Engagement with External Stakeholders

- 3.28 The Chairman and/or Chief Executive are responsible for ensuring that there is pro-active engagement across the wide range of its external stakeholders including: industry organisations representing manufacturers of pharmaceuticals and medical devices; professional organisations representing health and social care professionals; and groups representing patients and users
- 3.29 The Agency is responsible for maintaining its own communications function, including a proactive press office function. The MHRA Press office will take the lead role in all communications about Agency business, and in so doing will ensure that it liaises with the Department of Health and other relevant Government press offices in relation to the timing and co-ordination of media activity.

⁸ http://www.hm-treasury.gov.uk/psr_governance_gia_guidance.htm

SECTION 4

COMPLAINTS

- 4.1 The Agency has a published process for handling both complaints about administrative issues or levels of service. The guiding principles for dealing with complaints are:
- speedy handling;
 - answering all points of concern;
 - being factually correct;
 - fair investigation;
 - effective response; and
 - confidentiality.
- 4.2 All complaints are handled initially through the line management chain but, if the complainant remains dissatisfied with the response they receive, they may request the complaint is escalated to the Central Complaints Officer. The next steps for a complaint would be to the Chief Executive and/or the Independent Complaints Adviser.
- 4.3 Anyone not satisfied with the outcome of their complaint or with the decision of the Independent Complaints Adviser, may ask for the matter to be taken up, on their behalf, by their Member of Parliament, who, if it appears that there has been maladministration, may refer it to the Parliamentary Commissioner for Administration.

SECTION 5

FINANCE

Financial Regime

- 5.1 The Medicines and Healthcare products Regulatory Agency operates as a trading fund in accordance with the requirements of the Government Trading Funds Act 1973 and the Medicines and Healthcare products Regulatory Agency Trading Fund Order 2005. The trading fund was established on 1 April 2003.
- 5.2 In accordance with Section 3 of the Government Trading Funds Act 1973 (as amended by the Government Trading Act 1990), all sums received by the Agency as payment for services provided will be paid into the trading fund and all expenditure incurred will be paid out of the fund. The Agency's target is to break even, taking one year with another, after taking account of HM Treasury's requirement to earn a real terms' return on capital employed.
- 5.3 The Agency provides financial reports, as required, to the Department.

Financial Provision

- 5.4 The Agency is funded from:
- fees charged for the fulfilment of statutory or other regulatory obligations;
 - other charges for non-statutory services, including sales into wider markets;
 - the Department of Health.

5.5 The cost of chargeable services will be set in accordance with HM Treasury’s guidance contained in “Managing Public Money”. Amendments to the fees for statutory services are the responsibility of the Secretary of State, who, with the consent of HM Treasury, will bring proposals before Parliament for approval. The MHRA will consult interested parties before making proposals to change the level of statutory fees.

Financial Delegations

5.6 The Principal Accounting Officer delegates financial authority to the Chief Executive. In accordance with the guidance set out in “Managing Public Money”, the Chief Executive has authority to accept receipts and to commit, authorise and certify expenditure and make payments deemed necessary for the smooth running of the MHRA Trading Fund, subject to the limits below:

- authorise extra-contractual payments £100,000
- authorise bad debts and claims abandoned £250,000
- make ex-gratia payments £100,000
- authorise disposal of assets, excluding gifts of official property £100,000
- write off payments £100,000
- authorise capital expenditure £1 million

The Chief Executive will notify the Department of Health should these limits be breached. The Chief Executive may give written authority for the further delegation of the powers shown above to named staff of the Medicines and Healthcare products Regulatory Agency, subject to his/her retaining overall responsibility.

Capital

5.7 Capital investment is funded from within the framework of an approved investment programme set out in the MHRA’s corporate and business plans. Individual

projects will be evaluated using the standard government investment appraisal criteria.

5.8 The business case for the Agency's information management system, Sentinel, has been approved by the Department of Health. The Agency has delegated authority outside of the above capital limit to continue to invest in the Sentinel system. Should the system be replaced, the Department would need to approve the business case for such an investment.

5.9 A register of all capital assets is maintained, which forms the basis for related depreciation charges that are included in the full economic cost to be recovered from fees and charges for the Agency's services.

5.10 The capital structure of the MHRA includes public dividend capital in respect of which the MHRA pays an annual dividend into the Consolidated Fund. As a trading fund, the MHRA may establish and maintain capital and other reserves with the agreement of the Secretary of State for Health.

Support Services

5.11 The Chief Executive is responsible for arranging the provision of all support services required by the Agency, either from the Department or externally, and must ensure that they meet relevant central and Departmental requirements. Where appropriate, the MHRA may use support services provided by the Department and will pay for the provision of any such services from the trading fund. The Agency may, subject to adequate notice, undertake some or all of these services itself or contract them out elsewhere, if that offers value for money.

5.12 The level of any services commissioned from the Department will be set out in a Service Level Agreement and charged to the MHRA at full cost. Charges will not

be increased in-year and will only be increased after a period of notice has been given, as specified in the relevant Service Level Agreement.

Accounting and Auditing Arrangements

- 5.13 The MHRA has developed an accounting system for its Trading Fund in consultation with HM Treasury and the National Audit Office. The Agency's financial and management information system produces commercial-style accruals accounts in accordance with the Treasury's "Government Financial Reporting Manual".⁹ The accounts are audited the by the National Audit Office.
- 5.14 The MHRA shall set up an independent audit committee as a committee of its Agency Board in accordance with the Cabinet Office's Guidance and the Treasury's Audit Committee Handbook¹⁰.
- 5.15 The MHRA shall arrange for periodic quality reviews of its internal audit in accordance with the Government Internal Audit Standards¹¹. The Department shall consider whether it can rely on these reviews to provide assurance on the quality of internal audit. However, the Department reserves a right of access to carry out independent reviews of internal audit in the MHRA.
- 5.16 The Department's Internal Audit Service shall also have a right of access to all documents prepared by the MHRA's internal auditor, including where the service is contracted out. The audit strategy, periodic audit plans and annual audit report, including the MHRA's Head of Internal Audit's opinion on risk management, control and governance shall be forwarded as soon as possible to the sponsoring team who shall consult the Head of Internal Audit as appropriate.

⁹ http://www.hm-treasury.gov.uk/frem_manual.htm

¹⁰ http://www.hm-treasury.gov.uk/psr_governance_gia_guidance.htm

¹¹ http://www.hm-treasury.gov.uk/audit_committee_handbook.htm

SECTION 6

PLANNING AND REPORTING OF PERFORMANCE

Corporate Plan

- 6.1 A five-year corporate plan describes the Agency's longer-term aims and objectives, sets out a strategy for achieving them, provides a framework for monitoring progress against them and forms the agreed basis for detailed planning. The Medicines and Healthcare products Regulatory Agency updates the plan annually, between the beginning of December and the end of March, for approval by the Secretary of State.
- 6.2 The corporate plan sets out the strategic direction of the Agency and provides information on the current and forthcoming year's performance, together with projections for the following four years.
- 6.3 The Department of Health will provide assistance to the MHRA in the preparation of the corporate plan, by providing information about likely policy developments and/or other changes that could impact on the Agency.

Business Plan

- 6.4 Each year, the Chief Executive prepares a business plan for the agreement of the Agency Board that sets out the Agency's intended activity and anticipated resource requirements for the financial year immediately ahead. The business plan includes specific objectives and key performance targets and also reflects Ministerial, as well as internally generated objectives, and any wider Government initiatives of relevance to the work of the Agency. Following discussion with representatives of the Agency's staff, the business plan is submitted, by 31 March, to the Secretary of State for approval. Once approved, the business plan is published on the Agency's website.

Performance Targets

- 6.5 The performance of the Agency is measured against a number of objectives, performance measures, targets and standards that will be agreed annually with the Secretary of State.
- 6.6 The Agency's strategic objectives are aligned with those of the Department of Health and address the following themes:
- **Safeguard public health** through a primary role in ensuring that the products the Agency regulates meet required standards, that they work and are acceptably safe;
 - Carry out a **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 effective **European and International** relationships;
 - Run an **organisation** with a skilled and equipped workforce that is **fit for the future**.
- 6.7 Key targets and performance indicators to be included in the Annual Business Plan will vary from year to year and will be informed by the Department of Health's guidance to Arms Length Bodies on Business Planning and targets.
- 6.8 Representatives from the MHRA, including the Chief Executive, meet with the Departmental Sponsor on a quarterly basis, usually through the Partnership Committee, to review progress against the Agency's targets and monitor its financial performance.

Annual Report and Accounts

6.9 The Chief Executive is responsible for producing and signing the Annual Report and Accounts of the Medicines and Healthcare products Regulatory Agency, prepared in accordance with the Treasury's Accounts Direction. The annual report sets out the Agency's progress against objectives, targets and performance measures and explains any remedial action taken in response to significant deviations from the business plan. The Agency's accounts are audited and certified by the Comptroller and Auditor General. The annual report and audited accounts will be laid before Parliament (and made available on the Internet) before the summer recess and placed in the libraries of both Houses of Parliament. In accordance with Section 4(6) of the Government Trading Funds Act 1973, HM Treasury may require additional data to be provided for the information of Parliament.

SECTION 7

PERSONNEL MANAGEMENT

Status of Staff

- 7.1 Staff of the Medicines and Healthcare products Regulatory Agency are civil servants in the Department of Health and are employed on civil service pay and pension arrangements. Staff have the same terms and conditions as civil servants in the Department of Health, unless delegated authority has been given to the MHRA to alter those terms and conditions (as set out in other parts of this document) and that authority has been exercised. Staff and posts in the MHRA that fall within the Senior Civil Service (SCS) are covered by SCS central arrangements and by the Department's terms and conditions and other procedures governing the Senior Civil Service, including performance-related pay. All staff of the MHRA are members of the Principal Civil Service Pension Scheme.
- 7.2 Staff may transfer between the MHRA and other parts of the Department of Health and participate in Departmental job selection exercises.

Delegated Functions

- 7.3 Authority for the personnel matters listed below (except, as indicated in paragraph 7.4, for certain issues concerning the Senior Civil Service) is delegated by the Department of Health to the Chief Executive:
- Creation, re-grading and reduction in numbers of posts.
 - Permanent, temporary, casual and fixed-period appointments; also reinstatement, re-employment and consultancies (includes direct external recruitment, recruitment through the Department of Health, the selection process, conversion of temporary to permanent appointments and probation

decisions). The Chief Executive must observe the requirements and processes of the Civil Service Commissioners for external recruitment.

- Assignments and promotions to posts within the Agency (posting of staff recruited through trawls and arrangements for loans and secondments).
- Decisions on retirements includes early retirement/severance on grounds such as inefficiency, ill health or structural change; application of appropriate retirement/severance compensation and retention of staff beyond normal retirement age within existing employment legislation.
- Department of Health will play a part in seeking opportunities for any displaced staff to work within the Department or any other of its agencies.
- Decisions on disciplinary matters (includes suspension (with or without pay), downgrading or dismissal) and grievance procedures.
- Decisions on termination of service (includes accepting resignations and cancellation of fixed-period appointments).
- Authorisation of pay and variations in pay (includes starting pay, responsibility and shift allowances, overtime pay, performance pay and bonus payments within existing central and Departmental arrangements).
- Management of the staff appraisal system (includes initiation and completion of reports, disclosure and follow-up, and arrangements for career development).
- Provision and purchase of training.
- Authorisation of annual, special and special unpaid leave.
- Variation of hours of attendance, within contracted or conditioned hours, including job-sharing and part-time working.
- Hearing of appeals against decisions taken under delegated authority.

The Chief Executive may further delegate these functions to other staff of the MHRA, provided he/she does so in writing.

- 7.4 For the Senior Civil Service decisions on all appointments in Pay Band 3 will be subject to consultation with the Permanent Secretary of the Department of Health or other person to whom the Permanent Secretary delegates that responsibility. For appointments in Pay Bands 1 & 2 where the grading of such posts needs to be evaluated using the DH Job Evaluation arrangements the Permanent Secretary of the Department of Health or other person to whom the Permanent Secretary delegates that responsibility will be consulted. DH will be responsible for ensuring that any overall Civil Service controls on cost and/or numbers of SCS staff are applied with the agency.
- 7.5 Decisions taken by the Chief Executive under these delegated responsibilities, including the use of the flexibilities inherent in the Department's pay agreements, will be fully recognised by the Department.
- 7.6 The Chief Executive, following consultation with the Chairman and the Agency Board and the recognised Trades Unions, is free to establish alternative personnel and pay policies, including arrangements designed to respond to employment market conditions, suited to the specific requirements of the Agency and its staff. The Department of Health will be consulted on any such proposals affecting staff.

Personnel Policies and Procedures

- 7.7 The Medicines and Healthcare products Regulatory Agency is an equal opportunities employer, committed to policies on valuing diversity, health and safety, and staff welfare similar to those of the Department of Health.
- 7.8 The Chief Executive is responsible for the preparation and implementation of a training and development strategy aimed at giving staff the opportunity to acquire the professional, managerial and other skills necessary to achieve the Agency's

aims and objectives, maximise job satisfaction and develop their careers within the Agency, DH or the Civil Service.

Performance Appraisal

7.9 Staff of the MHRA are subject to annual appraisal of performance, including a written assessment and a job appraisal review, comparable with the Department of Health's appraisal system and in accordance with DH procedures for the SCS.

Discipline and Inefficiency

7.10 DH policies on inefficiency and discipline will apply, unless they have been amended to meet the needs of the Agency by prior agreement with the Department.

Industrial Relations

7.12 The Chief Executive is responsible for maintaining good staff and industrial relations and will consult with staff and their Trades Union representatives on any proposal that would affect the terms and conditions of staff. The normal expectation is that all matters affecting the Agency will be resolved within the Agency's framework of consultation arrangements.

Staff Inspections and other Reviews

- 7.13 Any inspection, consultancy or review instigated by the MHRA will be paid for out of the trading fund. If the Department calls for a review or inspection, it will meet any costs.

Standards of Business Conduct

- 7.14 The staff of the Medicines and Healthcare products Regulatory Agency are required to maintain strict ethical standards in all aspects of their employment. They are required to declare any possible conflict of interest that might arise in the exercise of their responsibilities in accordance with Agency Guidelines, and abide by the Civil Service Code. They are also required to follow the code on political activities, wherever applicable.

Recruitment and Remuneration of the Chairman and Chief Executive

- 7.15 The Chairman of the Medicines and Healthcare products Regulatory Agency is a permanent part-time appointment and the Chief Executive is a fixed term appointment. The Chairman and Chief Executive are subject to the terms and conditions, including performance pay arrangements, of the Senior Civil Service. Their appointments can be terminated on grounds of poor performance.

SECTION 8

REVIEW OF THE FRAMEWORK DOCUMENT

Review

- 8.1 This document was revised in the light of recommendations from a DH review of the MHRA which was undertaken in 2008/9. The Framework Document and its operation will be reviewed at intervals of not less than three and not more than five years. In addition, the Secretary of State for Health, the Agency Board of the Medicines and Healthcare products Regulatory Agency, its Chairman or the Chief Executive may propose modifications to the Framework Document at any time, if these appear necessary in the light of experience or to take account of changed circumstances.
- 8.2 No substantial change will be made to the Framework Document without the agreement of HM Treasury. The staff of the MHRA and their Trades Union representatives will be consulted on any proposal that would affect terms and conditions of employment.

Publication

- 8.3 The Framework Document is available on the website of the Medicines and Healthcare products Regulatory Agency (www.mhra.gov.uk)

Agreed

Professor Kent Woods
Chief Executive, MHRA

Date

Agreed

Professor David Harper
Senior Department of Health Sponsor

Date