



Department  
of Health



Medicines & Healthcare products  
Regulatory Agency

# Framework Agreement Between the Department of Health and the Medicines and Healthcare products Regulatory Agency

March 2016

**Title:**

Framework Agreement  
Between the Department of Health and the  
Medicines and Healthcare products Regulatory Agency

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DH employees, MHRA employees, other stakeholders seeking to understand the relationship between the Department and the Agency.

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# 1. Purpose of this document

The purpose of this document is to define the critical elements of the relationship between the Department and the Medicines and Healthcare products Regulatory Agency ('the Agency'). The document is focused on:

- How the Department and the Agency will work in partnership to serve patients, the public and the taxpayer; and
- How both the Agency and the Department discharge their accountability responsibilities effectively.

## 2. The Agency's purpose

The Agency is an Executive Agency of the Department of Health (the Department) and is a government trading fund. The main function of the Agency is to regulate medicines and medical devices, underpinned by science and research. The Agency also has an important role in bringing innovation safely to patients as rapidly as possible. The MHRA's specific functions include:

### Statutory functions

- operating 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;
- discharging statutory obligations, including those of the UK's EU competent authority, for medical devices and contributing to developing the safety and performance standards that support this work;
- ensuring compliance with statutory obligations relating to the investigation of medicines in clinical trials and assessing notifications or proposals for clinical trials from manufacturers of medical devices;
- operating and contributing to systems at both UK and EU level of post-marketing surveillance for medicines and medical devices, taking action to safeguard public health;
- ensuring compliance, in the UK, with statutory obligations relating to the manufacture, distribution, sale, labelling, advertising and promotion of medicines;
- designating and monitoring the performance of notified bodies that audit manufacturers of moderate and high-risk medical devices, and maintaining a register of all manufacturers placing medical devices on the UK market;
- devising and drawing up standards for the purity and potency of biological substances and designing appropriate test procedures;
- preparing, approving, holding and distributing standard preparations of biological substances;
- providing, or arranging for, the provision of laboratory testing facilities for the testing of biological substances, carrying out such tests, examining records of manufacture and quality control and reporting on the results;
- carrying out, or arranging for the carrying out, of research in connection with biological standards and control function;
- regulating the safety and quality of blood and blood components;
- managing the activities of the British Pharmacopoeia (BP) and work undertaken by BP staff relating to the European Pharmacopoeia;

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- discharging the functions of the UK Good Laboratory Practice Monitoring Authority (GLPMA);
- regulating consumer e cigarettes in line with the Tobacco Products Directive

## Non-statutory functions

- managing the activities of the Clinical Practice Research Datalink (CPRD) using anonymised clinical records in support of a range of public health activities;
- representing the United Kingdom at, and collaborating with, European and other international bodies, on matters concerning:
  - the regulation of medicines and medical devices;
  - development of medicines and devices regulation; and
  - in relation to the establishment of standards, for the provision of standard preparations of, and the testing of biological substances.
- Through the National Institute for Biological Standards and Control (NIBSC), the Agency is responsible for the standardisation and control of biological medicines, working both nationally and internationally.
- The Agency, together with the NHS National Institute for Health Research (NIHR) jointly funds the Clinical Practice Research Datalink (CPRD) which is run as part of the Agency operations. CPRD is the English NHS observational data and interventional research service, designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health.

## 3. Legal Framework

The Government trading fund that finances the Agency was established by the Medicines and Healthcare products Regulatory Agency Trading Fund Order 2003 (SI 2003/1076), made under the Government Trading Funds Act 1973.

The Agency performs the functions of the Secretary of State under UK legislation relating to medicines, medical devices and blood, amongst other things. From 1 April 2013, the Agency also performs the functions of the Secretary of State in relation to biological substances conferred under section 57 of the Health and Social Care Act 2012. These functions, which relate to ensuring the quality of biological medicines, were previously carried out by the Health Protection Agency through the non-statutory body, the National Institute of Biological Standards and Control (NIBSC). The NIBSC continues to deliver these functions as part of the Agency on behalf of the Secretary of State.

Further information on the legal framework within which the Agency operates is at Annex E.

## 4. Governance

The Agency is supported by a non-executive Chair, who is appointed by the Secretary of State for Health. The Chair is supported by a Unitary Board comprising the Agency's Chair, Chief Executive and Finance Director and up to nine non-executive members, who do not represent any specific customer, sectoral or stakeholder interests and are appointed by the Secretary of State. Other Directors may be invited to attend specific meetings, all or in part, as appropriate. The Department is also invited to provide an observer and the Chair may invite observers from the Devolved Administrations. The size of the board and the range of experiences sought from its non-executive members will be agreed between the Agency and the Department. The Agency Board collectively does not exercise any line management or executive functions, nor does it have a legal or constitutional role or any liability in respect of decisions of the Executive.

The Agency's Chief Executive is appointed by the Department's Permanent Secretary through fair and open competition in line with the Civil Service Commission Recruitment Principles and chairs the Corporate Executive Team (CET). The CET devolves certain areas of its business to sub-committees, each chaired by a designated director.

The Permanent Secretary nominates a Senior Departmental Sponsor (SDS) who acts as the Agency's designated, consistent point of contact within the Department. The SDS acts as the link at executive level between the Agency and the senior officials of the Department, and also with Ministers. The SDS also supports the Permanent Secretary in holding the Agency to account and providing assurance on its performance.

A Departmental sponsor team supports the SDS by undertaking the principal day-to-day liaison between the Department and the Agency.

The Secretary of State has delegated some of his statutory responsibilities to the Agency, listed in Annex E to this Agreement.

### Agency Corporate Plan

Every five years, the Chief Executive is responsible for the Agency preparing a five-year Corporate Plan which:

- sets out how the Agency will deliver the functions delegated by the Secretary of State;
- describes the Agency's longer-term aims and objectives;
- sets out a strategy for achieving them, and forms the agreed basis for detailed annual business planning.

The Department and the Agency review the Agency's Corporate Plan at least annually as part of the annual business planning cycle and if, as a result of this review, the Agency's Corporate Plan needs to be amended, these changes will be agreed with the Department.

## Agency Business Plan

Each year, as part of the Department's annual planning process, the Agency's strategy, targets and plans are summarised and reported to the Department for scrutiny and review.

Before the start of each financial year, the Chief Executive prepares, for endorsement by the Agency Board and agreement with the Department, a Business Plan which demonstrates how the Agency will deliver its objectives and the regulatory functions that the Secretary of State has instructed the Agency to carry out on his / her behalf.

The Business Plan sets out the Agency's intended activity and anticipated resource requirements for the following financial year. The business plan will include specific objectives and key performance targets and reflect Ministerial and any wider Government initiatives of relevance to the work of the Agency.

A draft business plan will be shared in sufficient time to facilitate comment from the Department prior to being submitted to the Senior Departmental Sponsor for approval. Once cleared by the Agency Board and the Department, the Agency publishes its annual business plan on its website.

Progress against the objectives, targets and metrics in the Agency's annual business plan is reviewed as part of quarterly and annual accountability meetings.

The Agency is responsible for the delivery of its objectives as agreed in its Business Plan, and the Department will limit the circumstances in which it will intervene in its activities. The following constraints do, however, apply:

The Agency should trade and raise funds in order to fulfil its objectives as set out in Section 2 (Legal Framework) and for no other purpose.

Any public money should be spent as specified.

Sufficient controls should be in place to support propriety and regularity.

## Discharge of statutory functions

The Agency ensures that it has appropriate arrangements in place for the discharge of each of the statutory functions for which it is responsible and is clear about the legislative requirements

associated with each of them, specifically any restrictions on the delegation of those functions. It ensures that it has the necessary capacity and capability to undertake those functions, and ensures that it has the power to take on a function on behalf of another person or body before it does so. The Agency also ensures that there is periodic audit<sup>1</sup> of the discharge of its statutory functions and ensures that its annual governance statement provides appropriate evidence that it is adequately discharging these functions so that the delivery of them remains effective, efficient and legally compliant.

## Cross-government clearance

In addition to internal governance, cross-government clearance is required for major new policy decisions of the type set out in Cabinet Office guidance. As the Agency is part of the Department and has policy responsibilities for certain areas, the Secretary of State is responsible for obtaining clearance and the Agency will adhere to any conditions applied through the clearance process. There will also be cases where the Secretary of State must consult Cabinet colleagues before giving the Government's view, even if collective agreement is not required. In such cases, the Agency will supply the Secretary of State with any information he or she needs in a timely fashion.

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<sup>1</sup> The Agency should include a review of this in their three-year audit cycle, but ensure that they take steps to sufficiently assure themselves on an annual basis and include details of this within their governance statements

## 5. Accountability

The Agency has a number of overarching accountabilities to assure Parliament, the Department and the public about the delivery of its objectives and its use of public funds.

### Secretary of State

The Secretary of State is accountable to Parliament for the health system (its “steward”), including the Agency. This involves:

- setting national priorities and monitoring the whole system’s performance to ensure it delivers what patients, people who use services and the wider public value most;
- setting budgets across the health system and determining the financial framework in which the Agency operates
- supporting the integrity of the system by ensuring that funding, legislation and accountability arrangements protect the best interests of patients, the public and the taxpayer;
- agreeing the Agency’s strategic objectives and high-level performance targets;
- accounting to Parliament for the Agency’s performance and the effectiveness of the health and care system overall.

If the Secretary of State considers that the Agency is underperforming or significantly failing in the exercise of its functions, he/she is able to intervene and require the Agency to take certain steps. Depending on the urgency and nature of the failing, the SDS would use the quarterly accountability meetings to assess performance and escalate to the Permanent Secretary as and when required; and steps will be taken to address the failing. If the Agency fails to comply, the Secretary of State may make arrangements for another body to help him exercise these functions on his behalf.

The Secretary of State may remove any non-executive member from the Board on the grounds of misbehaviour or failure to carry out his or her duties as a non-executive member.

The Department supports the Secretary of State in his or her role.

Medicines are a reserved subject matter as regards Scotland and Wales and, as such, the Department’s Minister accounts to Parliament on all matters concerning the regulation of human medicines in England, Scotland, and Wales. Medicines are transferred as regards Northern Ireland; but in practice, by agreement, many functions relating to the regulation of medicines are carried out by the Agency UK-wide, for example, the authorising of medicines.

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Medical devices are a reserved subject matter as regards Scotland and Wales. Medical devices are transferred as regards Northern Ireland; but in practice, by agreement, functions in relation to medical devices are carried out by the Agency UK-wide.

The regulation of blood is a reserved subject matter as regards Scotland and Wales. It is transferred as regards Northern Ireland; but in practice, by agreement, functions in relation to the regulation of blood are carried out by the Agency UK-wide.

The Agency will consult the devolved administrations on issues that relate to or affect them.

## The Principal Accounting Officer (PAO) and the Agency's Accounting Officer (AO)

The respective responsibilities of the PAO and the AO for the Agency are set out in chapter 3 of *Managing Public Money*, which is sent to the AO on appointment.

### The PAO

The Department's Permanent Secretary is the PAO and so is accountable in Parliament for the general performance of the health system in England, including the Agency. This requires him or her to gain assurance that the Agency is discharging the statutory duties it is tasked with performing and meeting the objectives set out in its Corporate and Business Plans. In this way the PAO is able to give Parliament an informed account of the Department's stewardship of the public funds it distributes and manages.

The PAO is accountable to Parliament for the issue of any grant-in-aid to the Agency.

The PAO is also responsible for advising the responsible minister:

- on an appropriate framework of objectives and targets for the Agency in the light of the department's wider strategic aims and priorities;
- on an appropriate budget for the Agency in the light of the sponsor department's overall public expenditure priorities; and
- how well the Agency is achieving its strategic objectives and whether it is delivering value for money.

The PAO is also responsible for ensuring arrangements are in place in order to:

- monitor the Agency's activities;

- address significant problems in the Agency, making such interventions as are judged necessary;
- periodically carry out an assessment of the risks both to the department and the Agency's objectives and activities;
- inform the Agency of relevant government policy in a timely manner; and
- bring concerns about the activities of the Agency to the full Agency board and, as appropriate to the departmental board requiring explanations and assurances that appropriate action has been taken.

The MHRA sponsor team in the Department is the primary contact for the Agency. They are the main source of advice to the responsible minister on the discharge of his or her responsibilities in respect of the Agency. They also support the PAO on his or her responsibilities toward the Agency.

### **Responsibilities of the Agency's Chief Executive as AO**

As MHRA is also a Trading Fund, HM Treasury (HMT) appoints the Chief Executive of the Agency as Accounting Officer (AO) of the Agency.

The chief executive as accounting officer is personally responsible for safeguarding the public funds for which he or she has charge; for ensuring propriety, regularity, value for money and feasibility in the handling of those public funds; and for the day-to-day operations and management of the Agency. In addition, he or she should ensure that the Agency as a whole is run on the basis of the standards, in terms of governance, decision-making and financial management that are set out in Box 3.1 of Managing Public Money.

### **Responsibilities for accounting to parliament**

The accountabilities include:

- signing the accounts and ensuring that proper records are kept relating to the accounts and that the accounts are properly prepared and presented in accordance with any directions issued by the Secretary of State;
- preparing and signing a Governance Statement covering corporate governance, risk management and oversight of any local responsibilities, for inclusion in the annual report and accounts;
- ensuring that effective procedures for handling complaints about the ALB are established and made widely known within the ALB;

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- acting in accordance with the terms of this document, Managing Public Money and other instructions and guidance issued from time to time by the Department, the Treasury and the Cabinet Office;
- giving evidence, normally with the PAO, when summoned before the PAC on the ALB's stewardship of public funds.

The Agency's AO may also be called to account for the Agency's performance in Parliament.

The PAO's oversight of the Agency's performance relies upon the provision of information and processes to enable both parties to review performance. The information provided to the Department by the Agency includes (not an exhaustive list):

- quarterly reports on the Agency's performance including as a minimum:
- quarterly finance report (in addition to periodic finance reports, as requested by the Department's Finance team).
- quarterly reviews of risks and issues
- quarterly performance reports on priority programmes
- policy development updates
- reports in support of Cabinet Office and Departmental spending controls
- a full set of Board papers in advance of the monthly Agency Board meetings
- a full set of papers in advance of the quarterly Audit and Risk Assurance Committee meetings.

The Chief Executive will notify the Department promptly if over or underspends are likely and that corrective action is taken; and that any significant problems whether financial or otherwise, and whether detected by internal audit or other means, are notified to the Department in a timely fashion.

The processes in place to enable The Department and the Agency to review performance include:

- The Agency's Chief Executive meets the Permanent Secretary, relevant Minister and SDS on a regular basis.
- Quarterly accountability meetings, which are chaired by the Department's SDS and secretariat is provided by the Department. They are attended by the Chief Executive of the Agency and other key Agency Directors and Departmental officials. The focus of the meeting will be on strategic issues and any issues of delivery which the SDS believes appropriate to bring to this meeting, including compliance with the framework agreement.

Each quarter The Department reviews:

- the Agency's contributions against the Department's strategic objectives and progress against the Agency's business plan;
- performance against agreed key performance indicators and appropriate performance targets
- the Agency's internal control arrangements;
- Agency's governance and risk management arrangements;
- the relationship between the Department and the Agency, and any other key issues identified in delivery of the Department's strategic objectives .
- Annual accountability meeting to review the performance and strategic development of the Agency, discuss the annual report and inform the next set of objectives. This is chaired by the relevant minister.
- Regular contact between the Department's Sponsor Team and the Agency.

## 6. Roles and responsibilities

### Chair

The Chair is responsible to the Secretary of State, and will work closely with the Senior Departmental Sponsor to ensure that the Agency's affairs are conducted with probity and that the Agency's policies and actions support it in the discharge of its functions and duties efficiently and effectively and meet the Agency's objectives.

The Chair is responsible for:

- providing leadership to the Board and the Agency itself, for enabling all Board members to make a full contribution to the Board's affairs and for ensuring that the Board acts as a team for the benefit of the Agency and its stakeholders;
- annual evaluation and appraisal of the non-executive directors; and
- providing feedback on the CE's performance to the Permanent Secretary.

The Chair will meet the Secretary of State, or relevant Minister (or their nominee) at least once a year, including at an annual accountability meeting to discuss the Agency's strategy and performance. The Senior Departmental Sponsor will ensure that there is an annual objective setting and review process in place for the Chair.

The Chair and non-executive directors are appointed by the Secretary of State. Appointments are transparent, made on merit, and managed in a way which follows the principles of the Commissioner for Public Appointments' Code of Practice for Ministerial Appointments to Public Bodies.

### The Board

The Chair is supported in his role by a unitary Board; the role of the Board is to provide strategic advice on the running of the Agency. The Chair, in chairing the Board, follows good practice as set out in the Government's Corporate Governance in Central Government Department's: Code of Good Practice, modified as appropriate for its circumstances.

The Board is collectively responsible for the following:

- agreeing the strategic aims and objectives of the Agency, consistent with its overall strategic direction and within the policy and resources framework determined by the Secretary of State;
- endorsing the Agency's recommendations to Ministers on the Agency's key financial and performance targets and the Agency's annual business plan and five-year corporate plan;
- agreeing the content of the Agency's annual report to be proposed to Ministers;
- advising on and monitoring:
  - 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 EU and international level;
  - the implementation of strategies for increasing public knowledge and understanding about the safe use of medicines and medical devices;
  - 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 that medical devices meet appropriate standards of safety, quality and performance; and
  - the steps taken by the Agency to support innovation and growth and the impact these have had.

The Board ensures that effective arrangements are in place to:

- Provide assurance and review the controls needed for effective risk management, governance and internal control.
- demonstrate sound financial management and good value for money;
- ensure that the Agency has the capability to deliver.

The Board is expected to assure itself of the effectiveness of the internal control and risk management systems.

## Chief Executive

The Chief Executive is responsible for advising the Secretary of State on issues relevant to the safety, quality and efficacy of medicines; the safety, quality of blood and blood components; issues relating to the Agency's responsibilities as a medicines licensing authority and for the Agency's contribution to EU regulatory networks for medicines and devices.

The Chief Executive is responsible for:

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- safeguarding the public funds and assets for which the Chief Executive has charge;
- ensuring propriety, regularity, value for money and feasibility in the handling of those funds;
- the day to day operation and management of the Agency
- accounting to Parliament and the public for the Agency's financial performance and the delivery of its objectives;
- ensuring that the PAO has assurance that the Agency is run on the basis of the standards (in terms of governance, decision-making and financial management) set out in *Managing Public Money*, including seeking and assuring all relevant financial approvals;
- reporting quarterly to the PAO on performance against the Agency's objectives, and discussed at the quarterly accountability meetings chaired by the Senior Departmental Sponsor.
- advising the board on the Agency's performance compared with its aims and objectives;
- ensuring that financial considerations are taken fully into account by the Board at all stages in reaching and executing its decisions, and that financial appraisal techniques are followed;

The Chief Executive should take action as set out in paragraph 3.8.6 of *Managing Public Money* if the board, or its Chairman, is contemplating a course of action involving a transaction which the Chief Executive considers would infringe the requirements of propriety or regularity or does not represent prudent or economical administration, efficiency or effectiveness, is of questionable feasibility, or is unethical.

The Chief Executive's annual appraisal is undertaken by the Permanent Secretary, taking into account feedback from the Chair on the Chief Executive's performance.

## 7. Partnership working

To support the development of the relationship, the Department and the Agency have agreed to a set of shared principles:

- Working together for patients, people who use services and the public, demonstrating our commitment, where appropriate, to the values of the NHS set out in its Constitution.
- Respect for the importance of autonomy throughout the system, and the freedom of individual organisations to exercise their functions in the way they consider most appropriate.
- Recognition that the Secretary of State is ultimately accountable to Parliament and the public for the system overall. The Agency will support the Department in the discharge of its accountability duties, and the Department will support the Agency in the same way.
- Working together openly and positively. This will include working constructively and collaboratively with other organisations within and beyond the health and social care system.

The Department and the Agency will work together, and with the Department's other ALBs and both will follow an 'open book' approach. In the case of issues with an impact on the development or implementation of policy, the Department can expect to be kept informed by the Agency. In the same way, the Department will seek to keep the Agency apprised of developments in policy and Government. There are likely to be some issues where the Department or the Agency will expect to be consulted by the other before the Department or the Agency makes either a decision or a public statement on a matter. The Department and the Agency will make clear which issues fall into this category in good time. The sponsor team will be responsible for ensuring that this works effectively.

To support the Secretary of State and the Principal Accounting Officer in their accountability functions, they may require the Agency to disclose to him or her, such information as he or she feels necessary to fulfil their duties with respect to the health system. It is therefore expected that the Department will, when required, have full access to the Agency's files and information. If necessary, the Department's Sponsor team will be responsible for prioritising these requests for information.

Policy work can be commissioned of the Agency, by the Department. Collaborative working will ensure the risks and opportunities of embedding the policy function within the Agency are openly and transparently managed.

## 8. Public and Parliamentary Accountability

The Department, its executive agencies and ALBs share responsibility for accounting to the public and to Parliament for policies, decisions and activities across the health and care sector. Accountability to Parliament will often be demonstrated through parliamentary questions, MPs' letters and appearances before parliamentary committees. Accountability to the public may be through the publication of information on the Agency's website, as well as through responses to letters from the public and responses to requests under the Freedom of Information Act.

Whilst the Agency has responsibility for some health policy areas, the Department and its ministers remain responsible to Parliament for the system overall, so will often have to take the lead in demonstrating this accountability. Where this is the case, the Agency will support the Department by, amongst other things, providing information for Ministers in a timely manner, to enable them to account to Parliament. In its turn, the Department provides leadership to the system for corporate governance, including setting standards for performance in accountability.

The Agency has its own responsibilities in accounting to the public and to Parliament and its way of handling these responsibilities will be agreed with the Department. In all matters of public and parliamentary accountability the Department and its ALBs and executive agencies will work together considerately, cooperatively and collaboratively, and any information provided by the Agency will be timely, accurate and, where appropriate, consistent with information provided by the Department. To facilitate this, the Department and the Agency have agreed a public and parliamentary accountability protocol that sets out how they will work together to secure the confidence of the public and Parliament, and to maintain the service levels that MPs and the public have come to expect.

## 9. Transparency

The Agency is an open organisation that will carry out its activities transparently. It demonstrates this by proactively publishing on its website its annual report, business plan and accounts as well as information on areas including pay, diversity of the workforce, performance, the way it manages public money and the public benefits achieved through its activities, outcomes and impacts, and any other requirements set by government. It supports those who wish to use the data by publishing the information within guidelines set by the Cabinet Office<sup>2</sup> as well as rules specific to its regulatory functions. The annual report includes a governance statement, which is reviewed by the Senior Departmental Sponsor.

To underpin the principles of good communication, ‘no surprises’ and transparency, the Agency and the Department have put in place arrangements for managing communications. Further details are provided in Annex C.

Minutes of Agency Board meetings are published on the Agency’s website. The Agency Board may hold some of its proceedings in public each year. In particular, where there is call for it, the Agency Board may hold a public Annual General Meeting and/or engagement sessions with stakeholders on specific topics.

The Agency’s unitary board members operate within the general principles of the *corporate governance guidelines* set out by HM Treasury<sup>3</sup>. They also comply with the Cabinet Office’s *Code of Conduct for Board Members of Public Bodies*<sup>4</sup> and with the rules on disclosure of financial interests contained in the provisions on the membership of the Agency’s Board.

The Civil Service Code also applies to all staff in the Agency. The Agency has also developed a code of conduct.

The Agency regularly deals with the media. In respect of complying with the Civil Service Code, it has been agreed between the Department and the Agency’s directors of communications that prior approval is not required for dealing with the media in matters of an operational, routine or technical nature.

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<sup>2</sup> The guidance is available on the Gov.uk website: <https://www.gov.uk/government/topics/government-efficiency-transparency-and-accountability>

<sup>3</sup> The corporate governance guidelines are available at <https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments>. Whilst written for central government departments, although, as it says in the guidelines, “the principles in the Code generally hold across other parts of central government, including departments’ arm’s length bodies”.

<sup>4</sup> <http://www.bl.uk/aboutus/governance/blboard/Board Code of Practice 2011.pdf>

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The Agency will take all necessary measures to ensure that:

- patient, personal and/or sensitive information within its care is well managed and protected through all stages of its use including through compliance with the Data Protection Act;
- it provides public assurance in respect of its information governance practice by completing and publishing an annual information governance assessment using an agreed assessment mechanism;
- it meets its legal obligations for records management, accountability and public information by compliance with relevant standards, including government codes of practice on confidentiality, security and records management.

The Agency's Senior Information Risk Owner and its Caldicott Guardian work together to ensure that both patient and other personal information are handled in line with best practice in government and the wider public sector.

## Sustainability

As a major public sector body, the Agency has a key role to play in driving forward the government's commitment to sustainability in the economy, society and the environment. As a trading fund, the Agency does not have to report on the *Greening Government Commitments*<sup>5</sup> but will continue to collect and record sustainable development data in order to demonstrate and adhere to that commitment. This data is published in the Agency's Annual Report and Accounts.

## Whistleblowing

The Agency, as with the Department and all its ALBs, has whistleblowing policies and procedures in place that comply with the Public Interest Disclosure Act 1998, the Civil Service Code and best practice guidance as described on NHS Employers' website<sup>6</sup>. It prohibits the use of confidentiality clauses that seek to prevent staff from speaking out on issues of public interest

## Annual Report

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<sup>5</sup> <http://sd.defra.gov.uk/documents/Greening-Government-commitments.pdf>

<sup>6</sup>

<http://www.nhsemployers.org/EmploymentPolicyAndPractice/UKEmploymentPractice/RaisingConcerns/Pages/Whistleblowing.aspx>

The Agency shall prepare an annual report which describes the Agency's performance against objectives and its use of public funds. The report shall be approved and signed by the Agency's Chief Executive as Accounting Officer, prior to its submission to Ministers and being laid before Parliament.

## 10.Audit

The Comptroller and Auditor General audits the Agency's annual accounts. The accounts will be laid before Parliament, together with its annual report. 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.

The Comptroller and Auditor General may also choose to conduct a value-for-money audit of any aspect of the Agency's work: the Agency will cooperate fully with the National Audit Office (NAO) in pursuing such audits, and give them full access to all relevant files and information.

The Agency is responsible for establishing and maintaining internal audit arrangements in accordance with the Public Sector Internal Audit Standards. The Agency's internal audit function should report to its Audit and Risk Assurance Committee, and should consider issues relating to the Agency's adherence to its business plan. The Department's Audit and Risk Committee remit includes risk management, corporate governance and assurance arrangements in all its subsidiary bodies and so the Agency's Audit and Risk Assurance Committee should work closely with the Departmental committee.

# 11. Delegations and financial management

Details of the Agency's financial arrangements, including funding allocation, in-year reporting, preparation of accounts, and the accounting officer's responsibilities in relation to financial management and the Agency's accounts, are provided in Annex B.

The Agency's delegated authorities are issued to it in writing by the Department, at least annually, including those areas where the Agency must obtain the Department's written approval before proceeding. The Agency will adhere to these delegated authorities.

The 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 2003. The trading fund was established on 1 April 2003.

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 in connection with funded operations (within the meaning of the Government trading Funds Act 1973) will be paid into the trading fund and all expenditure incurred will be paid out of the fund.

The Agency is funded from:

- national fees charged by the Agency directly to organisations for the fulfilment of statutory or other regulatory obligations; fees must be calculated in line with the principles as set out in Managing Public Money;
- EU fees charged by the EMA to organisations and then shared among those agencies, such as the Agency, undertaking particular activities on behalf of the EU network;
- other charges for non-statutory services, including sales into wider markets;
- research

In agreement with the Department, the Agency will ensure that income and expenditure related to national statutory fees is aligned; this will include the process for setting and reviewing regulatory fees.

As a Trading Fund, the Agency's financial target is set by a Treasury Direction. The current minute can be found at Annex B

## Medicines and Healthcare products Regulatory Agency

Amendments to the national 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 Agency will consult interested parties before making proposals to change the level of these statutory fees. The Agency must operate within its resources. If it fails to do so, the Comptroller and Auditor General may qualify its annual accounts and refer the matter to the Public Accounts Committee. The Agency must also operate within the delegated authorities issued by the Department.

The Agency, alongside the Commercial Director within the Department and the Commercial Models team within the Cabinet Office will review plans for income generation and the relative risks involved.

The Agency must demonstrate that it is delivering its functions and using its resources in an economic, efficient and effective manner, and must provide timely returns to the Department where these are required either by it or by other departments within central government.

The Agency, as with all public bodies and government departments, must operate within any efficiency or spending controls. These controls may affect areas of spend such as information communication technology (ICT), marketing and advertising, procurement, consultancy, the public sector estate, recruitment, major projects or strategic supplier management. The Department will ensure that the Agency is kept informed of any efficiency controls in operation.

As part of the government's approach to managing and delivering public service at a reduced cost base, the Agency, as with all other ALBs, executive agencies and the Department, will in future receive its back office support, including information technology, through a shared or standardised service approach, where it makes business sense to do so. Details of the services and the contractual arrangements between the Agency and the service provider will be set out in a contract or, where appropriate, a service level agreement (SLA).

A shared or standardised value for money approach will also apply to the use of estate. The Agency will comply with guidance on property and asset management, as set out in Annex A, and the principles set out by the Department's Estate Strategy Optimisation Board.

## 12. Risk management

The Agency ensures that it deals with the risks that it faces in an appropriate manner, according to best practice in corporate governance, and has developed a risk management strategy in accordance with the Treasury guidance *Management of Risk: Principles and Concepts*<sup>7</sup>. It has adopted and implemented policies and practices to safeguard itself against fraud and theft, in line with HM Treasury guidance<sup>8</sup>. It should also take all reasonable steps to appraise the financial standing of any firm or other body with which it intends to enter into a contract.

The MHRA does not give grants or grants in aid.

The Agency has a Risk and Audit Committee which consists of three non-executive Directors and is chaired by one of the non-executive Directors, who has significant experience of financial leadership at Board level. It is a sub-committee of the Agency Board and reports independently to the Accounting Officer and the Agency Board on the adequacy of the Agency's governance arrangements, including the risk management framework and the associated control environment, the Agency's financial and non-financial performance to the extent that it affects the Agency's exposure to risk and weakens the control environment, oversight of the financial reporting process and scrutiny of the treasury management strategy and policies. It has sight of the corporate risk register at each of its meetings. The risk register is also shared with the Department to enable the Department to assure itself on risk management. The internal and external auditors and the Departmental Sponsor Team is invited to all meetings and must be allowed to see all the papers.

The Agency and the Department have agreed a process and trigger points for the escalation of risks to the Department's Assurance Risk Committee (ARC), where those risks will have a potentially significant impact on the Agency, Department or on the wider system that requires a co-ordinated response. Risks to the wider system that arise from the Agency's operations, identified by the Agency, the Department or another body, will be flagged in the formal quarterly accountability meetings chaired by the SDS. Such risks may also be flagged by the Agency's Board and escalated to the Department's ARC for consideration. It is the responsibility of the Agency and its sponsor to keep each other informed of significant risks to, or arising from, the operations of the Agency within the wider system.

The Agency has effective and tested business continuity management (BCM) arrangements in place to be able to respond to disruption to business and to recover time-critical functions where necessary. In line with Cabinet Office guidelines, the BCM system should aim to comply with ISO 22301 Societal Security – Business Continuity Management Systems.

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<sup>7</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/220647/orange\\_book.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220647/orange_book.pdf)

<sup>8</sup> [http://webarchive.nationalarchives.gov.uk/20130129110402/http://www.hm-treasury.gov.uk/d/managing\\_the\\_risk\\_fraud\\_guide\\_for\\_managers.pdf.pdf](http://webarchive.nationalarchives.gov.uk/20130129110402/http://www.hm-treasury.gov.uk/d/managing_the_risk_fraud_guide_for_managers.pdf.pdf)



## 13. Human resources

The Agency employees are departmental civil servants and the majority of staff are employed on civil service pay and pension arrangements. Some staff of the National Institute of Biological Standards and Control (NIBSC) are currently employed on the NHS Agenda for Change terms or hybrid NIBSC terms and conditions. The Chief Executive is responsible for the structure and staffing of the Agency. The Agency will comply with any departmental or government-wide recruitment controls. The Department will ensure that the Agency is made aware of any such controls. Staff may move between the Agency and other parts of the Department and participate in the Department's job selection exercises.

In general terms, the Agency has adopted policies developed by Civil Service Employee Policy (CESP), which shall be adapted where necessary and permissible to reflect the Agency business and workforce.

The Agency must obtain the approval of the Secretary of State in respect of policies relating to remuneration, pensions, allowances or gratuities.

Whilst the Agency is responsible for the structure and staffing of their organisation, it will consult with the Department when making decisions on the creation or reduction of Senior Civil Service posts. SCS remuneration is subject to the recommendations of the Senior Salaries Review Body and Very Senior Manager remuneration is subject to the recommendations of the Senior Salaries Review Body as accepted by Government.

The Agency remuneration and terms and conditions (including pensions) of its staff must be within the general pay structure approved by the Department and HM Treasury. Senior Civil Servants may be subject to additional governance as specified by HM Treasury, Cabinet Office and the Department will ensure that the Agency is aware of any such requirements or restrictions.

Like all departments and ALBs, the Agency will be required to follow any requirements for disclosure of pay or pay-related information.

Subject to its financial delegations, the Agency is required to comply with Departmental and HM Treasury approval processes in relation to contractual redundancy payments. All novel or contentious payments require the Departmental and HM Treasury approval. Special severance payments are always considered novel or contentious.

## Equality

The Public Sector Equality Duty (PSED) requires the Agency (as a public body) to have due regard to the need to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

The provisions of the Equality Act 2010 (Specific Duties) requires the Agency to:

- Publish annually, information to demonstrate compliance with the PSED. This information must include, in particular, information relating to persons who share a relevant protected characteristic who are its employees (provided the organisation has 150 or more employees) and other persons affected by its policies and procedures.
- Prepare and publish one or more objectives it thinks it should achieve to meet the PSED<sup>9</sup>.

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<sup>9</sup> This was required by 6 April 2013, and is required every four years thereafter

## 14. Relations with the Department's other ALBs

The Agency works in partnership with the Department and its other ALBs, in the interests of patients, people who use services and the public, to maximise the health and wellbeing gain for the population, and have regard to the values set out in the NHS Constitution, where these are appropriate

The Department and its ALBs have complementary but distinct roles within the system to ensure that service users receive high quality services that deliver value for public money. Annex D sets out the Agency's key relationships with other bodies.

# 15. Review

The Department will regularly review the Agency’s performance at formal accountability meetings. In addition, the Department will undertake an in-depth review of the Agency as well as its other arms’ length bodies on at least a triennial basis.

On the basis of a thorough review, and after consultation with Treasury and Cabinet Office Ministers, the Secretary of State may formally dissolve the Agency with effect from an agreed operative date. The change in the body’s status should be announced to Parliament by means of a written statement

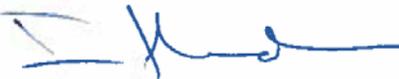
Any change to the Agency’s core functions or duties, including mergers, significant restructuring or abolition shall require the Department to put in place arrangements to ensure a smooth and orderly transition, with the protection of public health being paramount. In particular, the Department would need to ensure that, where necessary, procedures are in place in the Agency so the Department could obtain independent assurance on key transactions, financial commitments, cash flows, HR arrangements and other information needed to handle the transition effectively and to maintain the momentum of any on-going and / or transferred work.

This agreement will be reviewed every three years, or sooner upon request of either party.

Signed by: 

Date: 24 February 2016

Dr Will Cavendish, Senior Departmental Sponsor, Department of Health

Signed by: 

Date: 24<sup>th</sup> February 2016

Dr Ian Hudson, Chief Executive of the Medicines and Healthcare products Regulatory Agency

# Annex A: Wider guidance

The following general guidance documents and instructions apply to the MHRA, the Department may require the MHRA to provide additional management information on an ad hoc basis. Where this is the case, the Department will provide the MHRA with clear reasons for the request and will allow as much time as possible to comply with the request.

## General

*Appropriate adaptations of sections of Corporate Governance in Central Government Departments: Code of Good Practice and its related guidance*

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/220645/corporate\\_governance\\_good\\_practice\\_july2011.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220645/corporate_governance_good_practice_july2011.pdf)

*Managing Public Money*

<https://www.gov.uk/government/publications/managing-public-money>

*Code of Conduct for Board Members of Public Bodies*

[http://www.civilservice.gov.uk/wp-content/uploads/2011/09/code-of-conduct\\_tcm6-38901.pdf](http://www.civilservice.gov.uk/wp-content/uploads/2011/09/code-of-conduct_tcm6-38901.pdf)

*Code of Practice for Ministerial Appointments to Public Bodies*

<http://publicappointmentscommissioner.independent.gov.uk/wp-content/uploads/2012/02/Code-of-Practice-2012.pdf>

*The Parliamentary and Health Service Ombudsman's Principles of Good Administration*

<http://www.ombudsman.org.uk/improving-public-service/ombudsmansprinciples/principles-of-good-administration>

Consolidation Officer Memorandum, and relevant DCO letters

*The NHS Records Management code of practice*

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/200138/Records\\_Management\\_-\\_NHS\\_Code\\_of\\_Practice\\_Part\\_1.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200138/Records_Management_-_NHS_Code_of_Practice_Part_1.pdf)

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/200139/Records\\_Management\\_-\\_NHS\\_Code\\_of\\_Practice\\_Part\\_2\\_second\\_edition.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200139/Records_Management_-_NHS_Code_of_Practice_Part_2_second_edition.pdf)

Other relevant guidance and instructions issued by HM Treasury in respect of Whole of Government Accounts

Other relevant instructions and guidance issued by the central departments

Any statutory duties that are applicable to the MHRA

Specific instructions and guidance issued by the Department, including requests for information

Any departmental plans to ensure continuity of services

Recommendations made by the Public Accounts Committee, or by other Parliamentary authority, that have been accepted by the Government and relevant to the MHRA.

## Audit and Risk

*Public Sector Internal Audit Standards (PSIAS)*

<https://www.gov.uk/government/publications/public-sector-internal-audit-standards-good-practice-guidance>

*Management of Risk: Principles and Concepts*

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/220647/orange\\_book.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220647/orange_book.pdf)

## Finance

*Government Financial Reporting Manual (FReM)*

<https://www.gov.uk/government/publications/government-financial-reporting-manual>

Fees and Charges Guide, Chapter 6 of Managing Public Money

Departmental Banking: A Manual for Government Departments, Annex 5.7 of Managing Public Money

Relevant Dear Accounting Officer letters;

*Regularity, Propriety and Value for Money*

[http://www.esrc.ac.uk/images/Regularity\\_and\\_Propriety\\_tcm8-4769.pdf](http://www.esrc.ac.uk/images/Regularity_and_Propriety_tcm8-4769.pdf)

*Improving spending control*

<https://www.gov.uk/government/publications/improving-spending-control>

## HR

*Model Code for Staff of Executive Non-departmental Public Bodies (Cabinet Office)*

[http://www.civilservice.gov.uk/wp-content/uploads/2011/09/5\\_public\\_body\\_staffv2\\_tcm6-2484.pdf](http://www.civilservice.gov.uk/wp-content/uploads/2011/09/5_public_body_staffv2_tcm6-2484.pdf)

*DH Pay Framework (2006) for Very Senior Managers in Arms-Length (still current for Ambulance Trusts and to ALB Very Senior Managers that have not migrated into the new Pay Framework 2012)*

<https://www.gov.uk/government/publications/pay-framework-for-very-senior-managers>

*DH Pay Framework (2012)*

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/240303/Pay\\_Framework\\_25\\_April.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/240303/Pay_Framework_25_April.pdf)

## FOI

Relevant Freedom of Information Act guidance and instructions (Ministry of Justice)

## Estates and Sustainability

*Greening Government Commitments*

<https://www.gov.uk/government/publications/greening-government-commitments-targets/greening-government-commitment-targets>

Government Property Unit National Property Controls and standards for office accommodation (available from DH)

The Department of Health's Property Asset Management procedures (available from DH)

## Information Governance and Security

*The NHS Information Governance Toolkit*

<https://nww.igt.hscic.gov.uk/>

HMG IA Standard No. 6: Protecting Personal Data and Managing Information Risk (available from DH)

*HM Government's Security Policy Framework*

<https://www.gov.uk/government/publications/security-policy-framework>

*Information Security Management: NHS Code of Practice*

<https://www.gov.uk/government/publications/information-security-management-nhs-code-of-practice>

*Confidentiality: NHS Code of Practice*

<https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice>

## Transparency

*The Prime Minister's commitments on transparency*

<http://webarchive.nationalarchives.gov.uk/20130109092234/http://number10.gov.uk/news/letter-to-government-departments-on-opening-up-data/>



# Annex B-Financial and accounting responsibilities and delegated authorities

B1 The Framework Agreement sets out the governance and accountability arrangements between the Department of Health and the Agency. This annex provides additional detail on the finance and accounting arrangements which complements the Framework Agreement itself.

## Annual Expenditure Limits

B2 The Agency is a trading fund operating in accordance with the requirements of the Government Trading Funds Act 1973 and the Medicines and Healthcare products Regulatory Agency Trading Fund Order 2005.

B3 The Agency must take appropriate steps to ensure that it has put in place effective systems of financial management and internal control. The broad financial responsibilities of the Agency are set out in the Cabinet Office Corporate Governance Principles and detailed requirements are set out in Managing Public Money.

B4 The Accounting Officer has responsibility for following the principles and rules set out in HM Treasury's guidance Managing Public Money, and in particular 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 public funds for which he or she is responsible are properly and well managed and safeguarded, with independent and effective checks of cash balances in the hands of any official.
- to 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, value for money or feasibility, are taken into account, and where necessary brought to the attention of Ministers.

B5 In addition to their specific financial responsibilities, the Agency has a shared responsibility to facilitate the effective financial management of the health system, including delivery of the controls imposed upon the system by HM Treasury.

## Business Planning

B6 The Agency produces a business plan each year (see chapter 4 of the Framework Agreement). The plan will be required to be costed: supporting guidance issued by the Department will provide the format and level of financial detail required. Indicative budgets will be issued with the planning guidance, incorporating any guidance on overall efficiencies relevant to the Department and its arm's length bodies.

B7 The business plan will need to identify detailed revenue, capital and cash forecasts for activities funded by Department subsidy, and also equivalent expenditure associated with any other income sources.

## Accounts

B8 In relation to financial reporting, the Department is required by HM Treasury to report in-year financial performance and forecasts for all its arm's length bodies, by Estimate Line, and in a specified format, to a strict timetable. The Agency is required to comply with Departmental plans and schedules which enable the Department to meet HM Treasury deadlines, and the Department's overall financial planning to meet HM Treasury spending controls through the Shared Financial Planning Agreement.

B9 The Agency must prepare annual accounts for each financial year ending 31 March, and interim accounts for shorter periods if required. In relation to these accounts, the Agency must:

- ensure that accounts are prepared according to the form, content, methods and principles prescribed by HM Treasury's Accounts Direction;
- submit these accounts (both unaudited and audited) to the Department by a date to be specified by the Secretary of State; and
- submit these accounts to the Comptroller and Auditor General (C&AG) for audit as soon as reasonably practicable after the year end (or, in the case of any interim account, as soon as reasonably practicable after the end of the interim period to which that interim account relates).

B10 The Agency must publish an annual report of its activities together with its audited accounts after the end of each financial year. Information on performance against key financial targets is within the scope of the audit and should be included in the notes to the accounts. The report and accounts are to be signed by the Agency's Accounting Officer and laid before Parliament by the Agency and made available on the Agency's website, in accordance with the guidance in the Government Financial Reporting Manual (FReM). A draft of the report should be submitted to the Department in line with the published timetable.

B11 The Accounting Officer must also ensure that the Agency can participate fully in all agreement of balances exercises initiated by the Department, and in the form specified by the Department, and that it will agree income and expenditure and payables and receivables balances both with other organisations within the Department's resource accounting boundary and, for the purposes of the WGA, with other government bodies outside that boundary. In doing so, the Agency should seek to agree all outstanding balances but in any case should keep within any level of materiality set by the Department.

## Audit

B12 Section 9 of the Framework Agreement sets out the high level requirements for audit.

B13 To meet the requirements for internal audit, the Agency must:

- prepare an audit strategy, taking into account the Department's priorities, and forward the audit strategy, periodic audit plans and annual audit report, including the Agency's Head of Internal Audit's opinion on risk management, control and governance as soon as possible to the Department; and
- keep records of fraud and theft suffered by the Agency and notify the Department of any unusual or major incidents as soon as possible.

B14 The Department's group internal audit service has a right of access to all documents prepared by the Agency's internal auditor, including where the service is contracted out after which Group Internal Audit will provide the audit service – including having access to all previous audit documentation).

B15 For external audit, the C&AG audits the Agency's annual accounts and the Agency lays them before Parliament, together with his report. In the event that the Agency has set up and controls subsidiary companies, the Agency will, in the light of the provisions in the Companies Act 2006, ensure that the C&AG is appointed auditor of those company subsidiaries that it controls and/or whose accounts are consolidated within its own accounts. The Agency shall discuss with the Department the procedures for appointing the C&AG as auditor of the companies.

B16 The C&AG:

- will consult the Department and the Agency on whom – the National Audit Office or a commercial auditor – shall undertake the audit(s) on his behalf, though the final decision rests with the C&AG;

## Medicines and Healthcare products Regulatory Agency

- has a statutory right of access to relevant documents including, by virtue of section 25(8) of the Government Resources and Accounts Act 2000, those held by another party in receipt of payments or grants from the Agency;
- will share with the Department information identified during the audit process and the audit report (together with any other outputs) at the end of the audit, in particular on issues impacting on the Department's responsibilities in relation to financial systems within the Agency;
- will, where asked, provide the Department and other relevant bodies with regulatory compliance reports and other similar reports which the Department may request at the commencement of the audit and which are compatible with the independent auditor's role.

B17 The C&AG may carry out examinations into the economy, efficiency and effectiveness with which the Agency has used its resources in discharging its functions. For the purpose of these examinations the C&AG has statutory access to documents as provided for under section 8 of the National Audit Act 1983. In addition, the Agency is to provide, in conditions to grants and contracts, for the C&AG to exercise such access to documents held by grant recipients and contractors and sub-contractors as may be required for these examinations; and is to use its best endeavours to secure access for the C&AG to any other documents required by the C&AG which are held by other bodies.

## Delegated Authorities

B18 Chapter 10 of the Framework Agreement requires the Agency to abide by any relevant cross-Government efficiency controls. These controls will be communicated to the Agency.

B19 Once the business plan has been approved by the Department and subject to the Secretary of State's instructions and any other processes set out in this document, the Agency has authority to incur expenditure approved in the budget without further reference to the Department, on the following conditions:

- the Agency will comply with its delegated authorities, which cannot be altered without the prior agreement of the Department, noting that authority to approve novel, contentious or repercussive proposals cannot be delegated from HM Treasury; and
- inclusion of any planned and approved expenditure in the budget will not remove the need to seek formal departmental approval where any proposed expenditure is outside the delegated limits or is for new schemes not previously agreed.

B20 The Agency must obtain the Department's prior written approval before entering into any undertaking to incur expenditure outside its delegations in this document or not provided for in

its business plan as approved by the Department. In addition, the Department's prior written approval is required when:

- incurring expenditure for any purpose that is or might be considered novel or contentious, or which has or could have significant future cost implications;
- making any significant change in the scale of operation or funding of any initiative or particular scheme previously approved by the Department;
- making any change of policy or practice which has wider financial implications that might prove repercussive or which might significantly affect the future level of resources required; or
- carrying out policies that go against the principles, rules, guidance and advice in Managing Public Money.

B21 For major projects, the Agency will participate in the Department's common assurance and approval process.

B22 As a Trading Fund, the Agency's financial target is set by a Treasury Direction. The current version is attached below.

## HM Treasury Direction

### HM Treasury minute dated 24 February 2014

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 2013 to 31 March 2018 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 27 March 2008.

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

# Annex C - Communications

## General

C1 This annex sets out the principles that govern how the Agency and the Department of Health will work together to deliver effective and coherent communications in the spirit of common purpose. These principles apply to all parts of the Agency's activities, namely the Agency (regulator), the National Institute for Biological Standards and Control (NIBSC), the Clinical Practice Research Datalink (CPRD) and British Pharmacopoeia (BP), as they are all part of the wider Agency.

C2 To ensure that communication activities deliver real benefit for patients, the public, communities, stakeholders and the system itself, these principles will underpin all communications activities, contributing to the creation of an integrated communications approach for the health and care system as a whole.

C3 To support this, the Agency's Director of Communications will take part in the cross-system Arm's Length Bodies Directors of Communications forum that will take ownership of the cross-system communications approach. The Agency and the Department of Health will also ensure that relevant senior officials from their communications teams meet regularly, build effective working relationships and design detailed working practices.

C4 The general principles underpinning the approach to communications to be followed by the Agency and the Department will be:

mutual respect, co-operation and 'no surprises';

value for money and avoiding duplication;

a shared responsibility to promote and protect the public's health, aligning these activities where appropriate;

the most effective communication using the most appropriate voice and channels;

## Communications strategy and planning

C5 The Department will work with ALBs to develop communications strategies setting out shared, cross-system strategic objectives which reflect our common purpose. These will not be all-encompassing, or override the individual strategies of organisations. Where objectives are the shared, the organisations will work together to ensure the associated activities are coherently aligned and add value to each other.

C6 The Department will facilitate early political engagement and clearance on major communications issues that affect the Agency, to ensure clarity around the messaging and type / breadth of communications required.

## Communications expenditure

C7 The Agency is subject to the Cabinet Office Communications Spend Control.

All proposed communications expenditure over £100,000 must be approved by the Cabinet Office. Before being sent to Cabinet Office, all requests must have received sign-off from the Department's Minister and Director of Communications (DoC), on the advice of the cross system Spend Control Panel (SCP). The Department will facilitate SCP, DoC and ministerial approval and be responsible for all liaison with Cabinet Office. The Agency will provide periodic forward looks of spend likely to be above this threshold where practicable.

C8 The Agency has delegated authority to approve communications expenditure up to £100,000, except for that funded from Grant In Aid, which requires business case approval for expenditure above £20,000. As assurance, the Agency will submit quarterly logs of communications spend between £20,000 and £100,000 to the Department Director of Communications.

C9 The Agency will report annually on Communications headcount and expenditure for the audits undertaken by the Government Communications Service and others.

## Media Handling

C10 As a general rule, the Agency will lead on regulatory or safety issues, and the Department will lead on policy issues, and where there are shared issues the lead body will be identified quickly and co-operatively.

C 11 The Agency will continue to establish and maintain independent relationships with all those interested in, or affected by, its work, including the media. It will have responsibility for dealing with media enquiries received relating to its work and the way in which it exercises its functions.

C12 The Department and the Agency will keep each other informed of plans for media announcements. When it comes to the attention of the Department or the Agency that the media or any other organisation is intending to make public information related to the Agency or its work, the Agency or the Department will, where possible, bring this matter to the attention of the other.

C13 The Department and the Agency will, where possible and appropriate, bring to the attention of communications leads in each organisation issues creating media interest and expected media coverage which relates to the work of the Department or the Agency.

## Announcements

The Agency and the Department will uphold a reciprocal agreement in sharing material for demarcation and information purposes;

C14 To support the principle of partnership working described in the framework agreement and the commitment to 'no surprises', the Department and the Agency will share a schedule of relevant planned announcements weekly or fortnightly as appropriate. These should be treated "in-confidence" by the receiving parties and care taken with onward circulation.

C15 The Agency and the Department of Health will endeavour to give each other as much notice as possible to enable early discussions on all aspects of the announcement with relevant policy and communications leads from each organisation.

C16 Safety announcements to mitigate against threats to health will be discussed with the Department and shared in advance as urgently as the situation allows.

C17 The Agency and the Department of Health will also share, in confidence and principally for information, a near-final draft of any relevant report to be published, including conclusions, any executive summary and recommendations, and any press materials.

## Publications

C18 'Publications' in this section refers to documents such as annual reports, anything relating to the structure or operation of the organisation, and statutory reports such as accounts. It does not include green or white papers or any other significant statements of Government policy. In these cases the Department will commit to the principle of 'no surprises' wherever possible and endeavour to share drafts with Agency officials for comment where appropriate.

C19 There are separate arrangements for official statistics publications and these are described in the Statistics section below.

C20 To support the principle of partnership working described in the framework agreement and the commitment to 'no surprises', the Agency and the Department will share a schedule of relevant forthcoming publications weekly as appropriate.

## Medicines and Healthcare products Regulatory Agency

C21 The Agency and the Department will, except in exceptional circumstances, share publications with each other ten working days before publication for information and to allow clarification of any issues that might arise. Agency and Department of Health officials will liaise as necessary to provide briefing on the publication. The Agency and the Department will, whenever possible, send a final copy of the publication to each other's officials at least three days before publication. In exceptional circumstances, this period may be shorter and both parties will endeavour to allow as long as possible in such cases.

C22 Where the Agency and the Department cannot resolve an issue relating to the detail in a publication due for release, the organisation publishing the document will respond to the querying organisation in writing before publication explaining why the comments cannot be taken on board in the final copy of the document.

C23 When it comes to the attention of the Department of Health or the Agency that another Government Department or public body is intending to publish a report concerning the other party and its work, the Department of Health or the Agency will, wherever possible, bring this matter to the other's attention.

## Digital Communications and Channel Strategy

C24 The Department and the Agency will develop digital strategies setting out their digital communications objectives and priorities. These strategies will follow the principles set out in the cross-Government digital strategy.

C25 The Department and the Agency will use digital channels as their default channels for communications and services following the "digital first" channel strategy for health and care described in the department's digital strategy (October 2014), and the direction of travel set in the Information Strategy (May 2012), and the National Information Board framework for action (November 2014).

C26 Specialist digital content, or content targeted at professional audiences will, where it relates to the Agency's regulatory activities, be delivered through the corporate websites of the Department and the Agency on GOV.UK. The, NIBSC, CPRD and BP websites have exemptions from GOV.UK and therefore content will be delivered through these websites.

## Campaign activity

C27 Any major, public-facing campaign activity will be incorporated into the annual health communication and marketing plans developed by the Health Hub and agreed through the Efficiency and Reform Group process.

C28 The Agency will discuss this activity with DH in advance and ensure that DH has appropriate opportunities to inform the thinking and ensure a strategic fit with other campaigns across the health and care system. This will avoid unnecessary duplication and inefficient use of resource.

## Statistics

C29 Official statistics should be published in line with rules on official statistics publications, including rules on pre-announcement of publications, data sharing for briefing purposes before publication, and preparation of pre-publication access lists.

## Branding

C30 The Agency and its constituent parts (the regulator, NIBSC, CPRD and BP) engages and communicates with a wide range of stakeholders, including industry (globally), healthcare professionals and the public, and uses a range of communications and marketing approaches to support improvement and protection of public health.

C31 Requests for exemption from the use of the single Government brand for the Agency and NIBSC were approved by the Cabinet Office in October 2012. The CPRD and British Pharmacopoeia brands were agreed as out of scope for this exercise. The Agency, NIBSC, CPRD and BP will therefore continue to have distinctive brands and identities.

C32 MHRA has agreed to use the Government Identity System on GOV.UK, in publications etc. and to be GIS branded in its corporate form.

C33 Oversight of branding and identity development is managed through the Health Hub with a line of accountability back to the Brand Board.

## Annex D- Relationships with other bodies

D1 The Chair 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.

D2 To deliver its functions efficiently and effectively and to support alignment across the whole health and care system, the Agency will work closely with a number of organisations, most notably the following:

- European and international organisations
- National Institute for Health and Care Excellence (NICE) and NHS Quality Improvement Scotland (QIS)
- Health and Social Care Information Centre (HSCIC)
- Care Quality Commission (CQC)
- Public Health England (PHE)
- Health Research Authority (HRA)
- Medicines and Devices industry
- Healthcare Professionals
- Notified Bodies
- Blood establishments and hospital blood banks

### European and International organisations

D3 The Agency plays a key role in representing the UK at European and international events, providing expert scientific and technical advice and views as necessary, keeping Department of Health policy colleagues sighted in areas where policy issues are likely to emerge, and to help overall co-ordination.

D4 The organisations the Agency works with include:

- European Medicines Agency (EMA), including active participation in the EMA management board and its scientific committees, notably the Committee for Medicinal products for Human use (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC).
- European Commission, including in its capacity as licensing authority for EU-wide marketing authorisations for pharmaceuticals and its responsibilities for proposing and implementing EU legislation

- European Pharmacopoeia and other international pharmacopoeias
- Regulatory authorities in other countries
- World Health Organisation (especially relating to the establishment and distribution of International Standards for biological medicines)
- The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- European Police Office (Europol)
- European Centre for Disease control (ECDC).

## National Institute for Health and Care Excellence (NICE) and NHS Quality Improvement Scotland (QIS)

D5 The Agency and NICE and NHS Quality Improvement Scotland have complementary roles. The Agency is responsible for ensuring that medicines (and medical devices) are safe and effective and NICE and QIS are responsible for ensuring that medicines and treatments are clinically and cost effective. As such, it is important that the three organisations work closely together to ensure information about safety and effectiveness is shared as appropriate, to facilitate decision-making in a timely fashion.

## Health and Social Care Information Centre (HSCIC)

D6 The Secretary of State, on behalf of the Medicines and Healthcare products Regulatory Agency, as an Executive Agency of the Department, can direct the HSCIC to collect information. The HSCIC is a significant source of information for the secure data service (Clinical Practice Research Datalink (CPRD)) to support life sciences research that is located in the Agency. Therefore, both organisations must work in a complementary and supportive way.

## Care Quality Commission (CQC)

D7 The Agency and CQC are both regulators and need to support each other's respective regulatory roles.

## Public Health England (PHE)

D8 The PHE will carry out research activities and may seek the Agency's regulatory approval of these. The Agency and PHE will work together as appropriate to advise Ministers on topics that would benefit public health.

## Health Research Authority (HRA)

D9 The Agency will continue to support the work of the Health Research Authority.

## Medicines and devices industry

D10 Through its regulatory activities, the Agency works with manufacturers, distributors, retailers and brokers of medicines and medical devices. The Agency consults industry trade associations on new or changing policies.

## Healthcare professionals

D11 The Agency provides information to different healthcare professional specialties to assist them in the safe use of medicines and medical devices and relies on healthcare professionals to report, and encourage reporting of, suspected reactions to medicines and devices. The Agency consults healthcare professionals' representative organisations on changes to policies that affect their members.

## Notified bodies

D12 The Agency oversees and audits the performance of the UK Notified Bodies that audit medical device manufacturers.

## Blood establishments and hospital blood banks

D13 The Agency is the Competent Authority that regulates the compliance of UK Blood Establishments (including NHS Blood and Transplant) with the Blood Safety and Quality Regulations (BSQR) and which take into account the requirements of relevant European Directives. Blood establishments work with the Agency to identify and mitigate against the potential impact of any emerging threats to the safety of blood.

## Devolved administrations (DAs)

D14 As the Agency exercises its functions on behalf of the UK, it consults the DAs on, and keeps them informed of, proposed changes to legislation, policy and practice that affects them

as well as giving advance notice of (and the opportunity to observe) any investigations or inspections of manufacturers based in their country.

## Annex E- Legal Framework

E1 The Medicines and Healthcare products Regulatory Agency ('the Agency') is an executive agency of the Department of Health established on 1 April 2003.

E2 The Agency is financed by a Government trading fund established by the Medicines and Healthcare products Regulatory Agency Trading Fund Order 2003 (SI 2003/1076), made under the Government Trading Funds Act 1973.

E3 The Agency performs the functions of the Secretary of State under UK legislation relating to medicines, medical devices and blood, amongst other things.

E4 From 1 April 2013, the Agency has also performed the functions of the Secretary of State in relation to biological substances conferred under section 57 of the Health and Social Care Act 2012. These functions, which relate to ensuring the quality of biological medicines, were previously carried out by the Health Protection Agency through the non-statutory body, the National Institute of Biological Standards and Control (NIBSC). The NIBSC will continue to deliver these functions from 1 April 2013 as part of the Agency on behalf of the Secretary of State.

E5 The areas in which the Agency operates (medicines, medical devices, blood etc) are predominantly the subject of EU legislation. The Agency's role includes negotiating relevant EU legislation on behalf of the Department of Health and implementing that EU legislation in the UK. Moreover, the regulation itself of both pharmaceuticals and medical devices is discharged within an EU-wide legal and operational framework, with an increasingly important role for the European Commission as licensing authority for an increasing range of pharmaceuticals. Successfully protecting the public health interests of UK citizens means that the Agency must be an active contributor to these EU-wide regulatory structures and networks for both licensing and vigilance. Within the UK, the Agency carries out the functions of the Competent Authority under EU legislation relating to medical products, medical devices and blood regulation. The Agency also actively participates in informal networks in which regulators across the EU exchange experience and discuss implementation of EU legislation; of particular note are the Heads of Medicines Agencies and the Competent Authorities of Medical Devices. This co-operation between EU regulators is particularly important in light of the growth of pan-European regulation which binds all EU Member States.

E6 The majority of Agency's funding to discharge its regulatory activities comes from fees for services provided. The European Medicines Agency has the powers to charge fees for work undertaken by European regulatory agencies on behalf of the EU network; these fees charged by the EMA are then shared among the main agencies carrying out the work. The Agency also undertakes some work, in both its licensing and vigilance functions, that is unremunerated but necessary to protect the health of the UK public in the European system in which it operates. For example, where the Agency is not one of the lead agencies undertaking European work,

they will still need to engage with the work and with other European regulators and agencies to ensure that the health of the UK public is protected.

## Medicines

E7 Most of the UK's medicines legislation emanates from EU legislation. Key EU medicines legislation includes:

- Regulation 726/2004, as amended, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency sets out the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use;
- Directive 2001/83/EC, as amended, on the Community code relating to medicinal products for human use brings together all the provisions on the placing on the market, production, labelling, classification, distribution and advertising of medicinal products for human use;
- Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;
- Directive 2001/20/EC, as amended, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

E8 European medicines legislation aims to allow medicines to be authorised, sold and bought freely across the internal market of the EU and ensure a high level of patient safety. The legislation:

- harmonises the pre-marketing authorisation requirements for medicines;
- harmonises how clinical trials are carried out in the EU;
- harmonises good manufacturing practice and good clinical practice across the EU;
- set up the European Medicines Agency, which authorises medicines for the whole of the EU (the 'centralised procedure');
- ensures the safety of medicines once they are on the market (pharmacovigilance);
- prevents counterfeit medicines from being sold;
- sets minimum requirements for Member States to follow when they legislate on the prices of medicines (this is in the process of being revised by the EU);
- incentivises industry to research and develop medicines for children and for rare diseases.

E9 In addition to legislation, there are a range of EU-led non-legislative initiatives aimed at supporting non-binding cooperation between the Member States, including discussing implementation of relevant legislation, exchanging information and experiences and fostering voluntary collaboration. For example, the Heads of Medicines Agencies brings together the competent authorities responsible for the regulation of medicines in each Member State four times a year. There is also a voluntary network in the area of Health Technology Assessment.

E10 In the UK, the regulation of medicines is governed by:

- the Human Medicines Regulations 2012 – this replaced most of the Medicines Act 1968 and a large number of orders and regulations;
- the Medicines Act 1968;
- regulations and orders made under the Medicines Act 1968 or the European Communities Act 1972;
- EU Regulations.

E11 The Human Medicines Regulations 2012 implements Directive 2001/83/EC (amongst other things) and is the key piece of UK medicines legislation. The Agency discharges, on behalf of the Secretary of State, the functions that he exercises as the “licensing authority”, “the Ministers”, the “enforcement authority” and the “competent authority” under the Human Medicines Regulations 2012 and other UK medicines legislation<sup>10</sup>.

E12 Medicines is a reserved subject matter as regards Scotland and Wales, but transferred as regards Northern Ireland. In relation to Northern Ireland, the Human Medicines Regulations 2012 provides for a single “licensing authority” to issue licences etc, which may act by either the Secretary of State or the Northern Ireland Health Minister. In practice, by agreement, it is the Agency which performs this function for the whole UK.

E13 As regards enforcement of medicines legislation, the Agency performs the Secretary of State’s duty to enforce the Human Medicines Regulations 2012 and the “relevant EU provisions” in England, Scotland and Wales<sup>11</sup>. In Scotland and Wales, enforcement of the Medicines Act 1968 is formally the responsibility of the Scottish Ministers and the National Assembly for Wales (respectively), but both the devolved administrations have agency arrangements with the Agency, under their respective devolution legislation, under which Agency carry out this role. Enforcement in Northern Ireland is entirely a matter for the NI health minister and the Department of Health, Social Services and Public Safety (DHSSPS).

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<sup>10</sup> See regulations 6 and 8 of the Human Medicines Regulations 2012 for explanations of these terms.

<sup>11</sup> See regulation 323 of the Human Medicines Regulations 2012 For the meaning of “relevant EU provisions” see regulation 8 of the a definition of

## Medical Devices

E14 The UK's medical devices legislation emanates from EU devices legislation in the form of:

- Directive 90/385/EEC on active implantable devices;
- Directive 93/42/EEC on medical devices;
- Directive 98/79/EC on in vitro diagnostic medical devices.

E15 The aim of EU medical devices legislation is to allow medical devices to be sold and bought freely across the internal market of the EU and ensure that there is a high level of safety and performance. 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).

E16 In the UK, the EU devices legislation is implemented by the Medical Devices Regulations 2002, as amended (“the 2002 Regulations”). The 2002 Regulations are “safety regulations” within the meaning of section 11 of the Consumer Protection Act 1987. The Consumer Protection Act is the Act used for enforcement of the 2002 Regulations (see in particular sections 12 to 14, and the defence in section 39), together with Part VII of the Regulations.

E17 The Agency discharges the functions of the Secretary of State under the 2002 Regulations. This includes designating and monitoring “notified bodies” in the UK and enforcing the 2002 Regulations on the Secretary of State’s behalf.

E18 The Agency performs the functions of the Secretary of State under the 2002 Regulations on a UK wide basis. Although medical devices is a “transferred matter” as respects Northern Ireland, the Northern Ireland Health Minister agreed when the 2002 Regulations were made under s.2(2) of the European Communities Act 1972 that the Secretary of State acting through the Agency would act for the whole of the UK.

E19 The EU medical devices legislation is currently the subject of a revision exercise. The European Commission has proposed that the existing 3 Directives are replaced with 2 EU Regulations: one on medical devices and one on in vitro diagnostic medical devices. At the time of writing, the proposals are under negotiation.

## British Pharmacopoeia (BP)

## Medicines and Healthcare products Regulatory Agency

E20 The Agency discharges the functions of the British Pharmacopoeia (BP) which provides the only authoritative official standards for the quality of pharmaceutical substances and medicinal products in the UK.

E21 The Human Medicines Regulations 2012 provide for the British Pharmacopoeia Commission and the British Pharmacopoeia (BP) as the UK standard for medicinal products. The British Pharmacopoeia Commission is responsible for preparing new editions of the BP and the BP (Veterinary) and for keeping them up to date. Under regulation 318 of the Human Medicines Regulations 2012, the British Pharmacopoeia Commission is also responsible for selecting and devising British Approved Names (BANs).

## UK Good Laboratory Practice Monitoring Authority (GLPMA)

E22 Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (as amended) is implemented in the UK by the Good Laboratory Practice Regulations 1999 (“the 1999 Regulations”).

E23 The 1999 Regulations establish the Good Laboratory Practice Monitoring Authority (GLPMA) to enforce the principles of good laboratory practice. As enforcement of good laboratory practice is a matter devolved to each of Wales, Scotland and Northern Ireland, the GLPMA consists of the Secretary of State of Health, the National Assembly for Wales, the Scottish Ministers and the Department of Health and Social Services for Northern Ireland. Any one of the above acting alone or jointly may perform the GLPMA’s functions but in practice the GLPMA’s functions are carried out by the Agency.

## Human Blood and Blood Components

E24 Directive 2002/98/EC provides for the regulation of the collection, testing, processing and storage of human blood and blood products. Broadly speaking, this covers the handling of blood from its donation by individuals, up to (but not including) its use either by way of transfusion or in the manufacture of a medicine or medical device. There are various Commission Directives made under the main Directive, which set out detailed standards for various activities.

E25 The Directive is implemented in the UK by the Blood Safety and Quality Regulations 2005 (“the 2005 Regulations”). The 2005 Regulations designate the Secretary of State as the competent authority for the purposes of Directive 2002/98/EC (the blood Directive). The Agency performs those functions on behalf of the Secretary of State on a UK wide basis. Although the matter of blood safety and quality is a “transferred matters” as respects Northern Ireland, the Northern Ireland health department agreed when the 2005 Regulations were made under section 2(2) of the European Communities Act 1972 that the Secretary of State would act for the whole of the UK.

## Biological Standards and Control

E26 Section 57 of the Health and Social Care Act 2012 (HSCA) confers statutory functions in relation to biological substances on the Secretary of State. These functions relate to the standardisation and control of biological medicines including vaccines, blood products and other substances which cannot be characterised chemically and which require special testing measures to ensure their safety and efficacy. Specifically the functions are to:

- devise standards for the purity and potency of biological substances;
- prepare, approve, hold and distribute standard preparations of biological substances;
- design appropriate procedures for testing biological substances;
- provide or arrange for the provision of laboratory facilities for testing biological substances;
- carry out tests on biological substances;
- examine records kept in connection with the manufacture and quality control of biological substances;
- report on the results of tests or examinations conducted in pursuance of paragraph (e) or (f); and
- carry out or arrange for the carrying out of such research, or provide or arrange for the provision of such information or training, as it considers appropriate in connection with the functions mentioned in paragraphs (a) to (g).

E7 Up until its abolition on 1 April 2013, these functions were conferred on the Health Protection Agency. The Health Protection Agency discharged the functions acting through the National Institute of Biological Standards and Control (NIBSC) which was a 'centre' of the Health Protection Agency. The Secretary of State will also discharge these functions acting through the NIBSC which, as of 1 April 2013, has become a new 'centre' of the Agency.

E28 Biological substances are a reserved subject matter as regards Scotland and Wales, but "transferred" as regards Northern Ireland. In relation to Northern Ireland, section 57 of the HSCA confers the biological substances functions on Secretary of State and the Northern Ireland health minister acting alone or jointly. In practice, by agreement with the Northern Ireland health minister, NIBSC performs these functions on a UK wide basis.