Department of Health

Triennial Review of the Medicines and Healthcare Products Regulatory Agency

Review Report

July 2015

Title: Triennial Review of the Medicines and Healthcare Products Regulatory Agency: Review Report
Author: David Dipple, Lead Reviewer, Triennial Review Team, Assurance & Public Appointments Branch, Department of Health (17152)
Document Purpose: Corporate Report
Publication date: July 2015
Target audience: Commissioners, medical practitioners, pharmaceutical industry, health and social care organisations, regulatory bodies, academic and professional institutions, general public, patients, service users, information providers.
Contact details: Triennial Review Programme Team Department of Health Room 220, Richmond House London SW1A 2NS TR-MHRA@dh.gsi.gov.uk

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Contents

Executive Summary

The Medicines and Healthcare Products Regulatory Agency (MHRA or the Agency) is an Executive Agency of the Department of Health. It also operates as a Trading Fund, which reflects the fact that the Agency is largely self-funding, from a combination of regulatory fees and commercial revenues.

The Agency performs a key public health and safety function. It regulates medicines to ensure their quality, safety and efficacy. It regulates medical devices through monitoring safety and performance. In addition, the Agency represents the UK government in international negotiations relating to medicines and devices regulation and policy.

This is an area that is undergoing rapid technological change, with increasing use of genetics, biological medicines and new digital technologies. The distinctions between medicines and devices are becoming increasingly blurred as products are combined (such as with drug eluting stents). This poses challenges for regulators such as the MHRA. The regulatory framework needs to be flexible enough to adapt to new requirements and the Agency needs to protect public health without acting as an unnecessary barrier to innovation. Indeed, a key challenge for the Agency is to support early access to new medicines whilst retaining appropriate safeguards. Underpinning such an approach is the need for effective monitoring of the impact of medicines and medical devices once they are in use.

Further challenges arise from the increasingly international nature of the pharmaceutical and devices sector. Both the active ingredients used in medicines, and the manufactured medicines themselves, are increasingly imported. It is inefficient, and almost impossible, for national regulators to each seek to inspect all sources of medicines sold in their country. National regulators need to work together to manage these processes effectively. The MHRA is influential within its peer group and can play a lead role in driving forward change.

The Agency has already undergone a number of organisational changes in recent years, merging with the Clinical Practice Research Datalink in 2012 and with the National Institute for Biological Standards and Control in 2013. These mergers provide significant opportunities for synergies and to support the core functions of the Agency. The review found that good progress is being made in these areas.

This Triennial Review was announced through a Written Ministerial Statement on 30 October 2014. Stage One of the review considered whether the functions undertaken by the Agency are necessary and, if so, whether they could be better delivered through another organisational structure. Stage Two moved on to an assessment of the Agency's performance, efficiency and governance. The review process included gathering evidence from stakeholders, interviews and analysis of written material.

i. Main findings

Overall, the review considered that the Agency performed well in the delivery of necessary functions. The recommendations below are listed in the order in which

they appear in the report, not in any order of priority or importance. The Agency should seek to implement recommendations during 2015-16 where possible, and have an agreed plan with the Department for longer-term proposals.

As this report acknowledges, the Agency has already identified many of the issues raised in the report and is taking steps to address them. The recommendations in this report seek to support and build upon the actions already being taken. The Department, through the sponsor team and Senior Departmental Sponsor, has also addressed some of these issues in a letter of April 2015 that set out the 2015-16 priorities for the MHRA.

Stage One of the review concluded that the functions were necessary and that the current form of the Agency is most appropriate. However, there are seven recommendations covering issues around income, commercialisation and possible synergies for particular functions with other public bodies:

> **Recommendation 1:** the Agency should review its plans for income generation, and the relative risks involved, with the Commercial Director in the Department of Health and with the Commercial Models Team in the Cabinet Office.
>
> **Recommendation 2**: that the Agency should pursue the plan agreed with the Department in 2014 to align income and expenditure related to national statutory fees from 2016/17 (or from 2017-18 if necessary and agreed with the Department), whilst continuing to generate surpluses from its other activities. This should include the process for setting and reviewing regulatory fees.
>
> **Recommendation 3:** the Agency and the Department should agree a plan for efficient utilisation of the cash balance that has been built-up.
>
> **Recommendation 4**: that the functions of the Agency continue to be required.
>
> **Recommendation 5:** that the Agency continues to operate in its current form.
>
> **Recommendation 6**: that the Department is able to directly commission policy work from the Agency and that they work together to ensure that the risks and opportunities of having a policy function embedded in the Agency are openly and transparently managed.
>
> **Recommendation 7**: that the Agency, working with the Department and the Cabinet Office Commercial Models Team, undertakes a short assessment to consider whether the CPRD commercial revenues are appropriately maximised, commensurate with the MHRA's public health role, and whether improved links with other health data systems would yield further benefits.

Stage Two of the review looked at performance, efficiency and governance issues. There are a further 14 recommendations:

Recommendation 8: that the Agency engages with NICE and other interested parties to provide any useful guidance and standards to support appropriate use of apps and digital health services.

Recommendation 9: that the Agency develops succession plans for key posts and creates opportunities to build experience and knowledge for staff across the Agency.

Recommendation 10: that the Agency contributes to the wider government agenda on innovation and patient access to medicines and medical devices by working in partnership with industry, medical research bodies and other organisations across the health and care system to develop approaches for early engagement in the medicines and devices development process; aligning the various stages and involvement of other bodies in the health system as closely as possible. This should include close cooperation with the Accelerated Access Review.

Recommendation 11: that the Agency implements changes to raise awareness of the Yellow Card scheme; including simplifying reporting mechanisms and providing more detailed feedback on the subsequent actions to reporters.

Recommendation 12: that the Agency puts in place plans to both fully utilise digital processes and services itself and to best support their effective use to benefit public, patients and the health and care system.

Recommendation 13: that the Agency: (i) ensures that the IT replacement programme meets the needs of licence applicants; and, (ii) considers what more can be done under the existing system to improve transparency and tracking of applications.

Recommendation 14: that the Agency agrees a set of key performance indicators with the Department that reflect strategic objectives and are supported by appropriate performance targets.

Recommendation 15: that the Agency works with international partners to seek a common approach to the way in which any fees for the regulation of medical devices are applied.

Recommendation 16: that the Agency agrees with the Department the estimated cost savings and performance benefits to be delivered from the replacement to the current IT system.

Recommendation 17: that the Agency works with the Commercial Director in the Department of Health and the Crown Representative in the Cabinet Office to support negotiations with Accenture.

Recommendation 18: that, where it makes business sense to do so, the Agency develops proposals for a move to shared services provision that are agreed with the Department.

Recommendation 19: that the Department and the Agency look for opportunities to further develop bi-lateral communications and contacts that support a common understanding to take forward key priorities, as well as partnership working across the health and social care network.

Recommendation 20: that the Department and the Agency update the current draft Framework Agreement, reflecting issues covered in this report, and publish the agreed version as a priority.

Recommendation 21: that the Agency moves to a unitary board structure. The details, including size of the board and the range of experiences sought from non-executive members, should be agreed between the Agency and the Department.

Alongside this Triennial Review of the MHRA, the Department conducted parallel reviews of the Commission on Human Medicines and the British Pharmacopoeia Commission. These Commissions are Advisory Non-Departmental Public Bodies that are overseen by the MHRA, which provides their secretariat function. The reports of the Triennials Reviews of both Commissions were published on 26 March 2015.

ii. Next steps

The Agency, working with the sponsor team in the Department of Health, should produce a plan to take forward these recommendations over the next six months. The sponsor team should monitor progress and ensure that the Department of Health is actively engaged in decisions taken.

iii. Acknowledgements

The review team would like to thank everyone who contributed to the review process, including all those who completed the call for evidence questionnaire or agreed to be interviewed. Particular thanks go to Peter Commins, Jonathan Mogford, Daniel Markson, Louise Loughlin and Christina Martin in the MHRA.

1. Introduction and background

a. Aims of the review

1.1 It is government policy that an arm's length body (ALB) should only be set up, or remain in existence, where the model can be clearly evidenced as the most appropriate and cost-effective way of delivering the function in question.

1.2 In April 2011, the Cabinet Office announced that all Non-Departmental Public Bodies (NDPBs) still in existence following the first stage of public bodies reform would have to undergo a substantive review once in a three year cycle. Triennial Reviews (TRs) have two main stages:

- **Stage One** tests the continuing need for the body, both in terms of the functions it performs and the model and approach in which they are delivered

- **Stage Two** considers the body's governance, performance and capability as well as exploring opportunities for efficiencies.

1.3 The health and social care system reforms, set out in the Health and Social Care Act 2012 and the Care Act 2014, resulted in the devolution of functions and powers away from the Department of Health (DH) to ALBs and local health and care organisations. As steward of this evolving system, the DH is using TRs to provide assurance that the system, and the ALBs within it, is fit for purpose.

1.4 To support the Department in effectively delivering its stewardship function, the programme of TRs extends to all Executive Non-Departmental Public Bodies (ENDPBs), Advisory Non-Departmental Public Bodies (ANDPBs), Executive Agencies (EAs) and Special Health Authorities (SpHAs).

1.5 Although the Cabinet Office requirement for government departments to undertake TRs applies only to NDPBs, the DH is including its Executive Agencies and Special Health Authorities within this process, with the reviews playing a key role in supporting effective stewardship and oversight of the Department's ALBs. These TRs of Executive Agencies and Special Health Authorities are conducted in line with Cabinet Office guidance ("Guidance on Reviews of Non-Departmental Public Bodies", revised in 2014) so far as is appropriate and relevant. This guidance states that all reviews should be conducted in line with the following principles:

Challenge Reviews must be challenging. They should take a first principles approach to whether the function of a body is still needed, and if it is what the best form for delivery of that function is. Reviews should not just seek to evidence the status quo. They should be robust and rigorous and provide evidence for all recommendations. They must consider issues of efficiency, including the potential for efficiency savings, and make relevant recommendations. They should consider the performance of the body, and whether it could provide better value for money, including in terms of the body's contribution to economic growth. A description of how the review will

be structured to meet this aim should be set out clearly in the Terms of Reference, which will be agreed between the department and Cabinet Office.

Proportionality Reviews must not be overly bureaucratic and should be appropriate for the size and nature of the NDPB being reviewed. Where appropriate, reviews of similar bodies should be combined or clustered to ensure the maximum benefit in terms of streamlining the review process, identifying synergies across departments and NDPBs, and considering efficiency.

Contextual Reviews should not be undertaken in silos, but should wherever possible be integrated with other departmental policy initiatives, efficiency reviews or landscape reviews, and seek to look across departmental boundaries to cluster reviews of bodies to further enable informed discussions about potential efficiencies. Departments should consider the potential for integration when building their Triennial Review timetable and Cabinet Office will assist departments in doing this.

Pace Reviews must be completed quickly to minimise the disruption to the NDPB's business and reduce uncertainty about its future. Reviews should normally take no more than six months. Timetables, including start and completion dates, for individual reviews will be agreed with Cabinet Office at the beginning of each review.

Inclusivity Reviews must be open and inclusive. The NDPB being reviewed must be engaged and consulted at both an Executive and a Non-Executive level. Users and stakeholders must have the opportunity to comment and contribute. Parliament must be informed about the commencement and conclusions of reviews. Departmental Select Committees must be given the opportunity to input.

Transparency All reviews must be announced formally, both to Parliament and to the public. All review reports must be published once clearance has been given by the Minister for the Cabinet Office. The results of reviews must be announced to Parliament.

b. Process and methodology of the MHRA Triennial Review

i. Governance

1.6 The review was conducted by a small Department of Health team working under direction of an impartial senior review sponsor (SRS).

1.7 The review was overseen by a Project Board that was chaired by the SRS. The review was also subject to scrutiny by a Challenge Group, chaired by a DH non-executive director. The Challenge Group looked also at the Triennial Reviews of the National Institute for Health and Care Excellence (NICE), the Commission on Human Medicines (CHM) and the British Pharmacopoeia Commission (BPC) and made links between these reviews where appropriate. Details of the membership of the review team, the Project Board and the Challenge Group are set out in

Annex A. The Project Board and Challenge Group each met four times during the review process.

ii. Stakeholder engagement and call for evidence

1.8 Stakeholder engagement was a key element of the evidence gathering process. The review team sought to obtain views from a wide range of stakeholders to pick up key themes emerging from a variety of viewpoints. The full list of stakeholder respondents is provided at Annex D. Evidence was though gathered through a variety of means:

- A public call for evidence announced on the Department of Health and MHRA websites and open between 1 December 2014 and 9 January 2015. This included 21 questions seeking views on the MHRA, some of which sought a five point ranking (very poor; poor; average; good; very good).

- Stakeholder interviews (including MHRA staff, experts in the health and care system, pharmaceutical and medical device sector representatives, patients and charitable groups, and international bodies).

- Three workshops to which stakeholders were invited to attend.

- Meetings with relevant experts in the MHRA, DH, HM Treasury and Cabinet Office, to discuss the details of specific issues (e.g., financial controls, efficiency savings).

- Analysis of other published material (Annex E provides a list of the key papers used).

1.9 The Minister for Life Sciences also wrote to the Health Select Committee to inform them of the review and invite any comments.

iii. Previous reviews of the MHRA

1.10 A number of reviews, encompassing various aspects of the Agency, have taken place over recent years. The review team has considered these as part of the evidence gathering and analysis. Two particular reviews are summarised below.

1.11 *Review of the MHRA* (2009, Adrian Sieff) considered:

- How well the MHRA had met its objectives over the previous five years; and

- The capability and capacity of the MHRA to respond to future challenges.

1.12 The review's conclusions and recommendations revolved around two key issues:

- Being more joined-up: this included the way the MHRA operated internally, its relations with the Department of Health and other arm's length bodies, and

working effectively with industry and patients groups to join-up safety and delivery processes. The review recommended that MHRA senior management should develop closer working relationships with stakeholders to help the MHRA achieve its objectives.

- Driving forward: this included, developing benchmarks and other measurements of the MHRA's efficiency and effectiveness, embedding a proportionate risk-based approach to regulatory activity, and strengthening corporate leadership to ensure that capacity and capability is continually improved to meet new challenges.

1.13 A number of these issues remain relevant and are picked up in this report.

1.14 *Expert Clinical Advice – MHRA Medical Devices* (2013, Professor Terence Stephenson) considered:

- The MHRA's internal technical and clinical resources.
- Linkages with clinicians and other parts of the health and care system.
- MHRA strategy and horizon planning.

1.15 Although focussed on medical devices, the review's conclusions and recommendations picked up many of the same issues found in the Triennial Review, particularly:

- Increasing available resources and expertise.
- Improving information to clinicians and the public on safety and effectiveness, and to encourage more reporting of issues.
- Working more closely with other health and care organisations.

1.16 Again, a number of these issues are picked up in this report but this report does not seek to replicate recommendations where the MHRA is already in the process of addressing the issues.

iv. Estimated costs of the review

1.17 The review team started planning the reviews of the MHRA, the Commission on Human Medicines and the British Pharmacopoeia Commission in late-September 2014. The reports of the CHM and BPC were published on 26 March 2015 and this report was cleared for publication by [xx June 2015]. The estimated direct costs of the reviews based on six months duration, are set out in Table 1 below. There were no travel or other costs as interviews either took place in London or via telephone or video-conference. This estimate does not take account of indirect costs, such as the time contributed by MHRA staff.

Table 1: Estimated cost of the Triennial Reviews of the Medicines & Healthcare Products Regulatory Agency, the Commission on Human Medicines and the British Pharmacopoeia Commission.

	Proportion of time spent on reviews	Estimated cost
SRS	0.2	£14,500
Lead Reviewer	0.75	£33,375
Assistant Reviewer	1.0	£19,000
Volunteer	0.2	£8,900
Support (HEO)	0.2	£4,200
Support (EO)	0.2	£3,500
Total estimated cost for all three reviews		**£83,475.00**

c. Accelerated Access Review

1.18 1.18 On 20 November 2014, the Minister for Life Sciences announced the Accelerated Access Review, which will consider how our healthcare and regulatory systems can best respond and adapt to the new landscape of innovation. This review is expected to conclude before the end of 2015. It is not specifically reviewing the MHRA but will consider the pathways for the development, assessment and adoption of innovative medicines and medical technologies, and so this will include how the MHRA regulates the approval of medicines and medical devices.

1.19 The Triennial Review Team worked closely with the Accelerated Access Review Team to avoid overlap and duplication of effort between these reviews. Some of the issues raised by the MHRA Triennial Review will be considered in greater detail in this separate review and the Team shared any relevant material obtained as part of the Triennial Review process.

d. About the MHRA

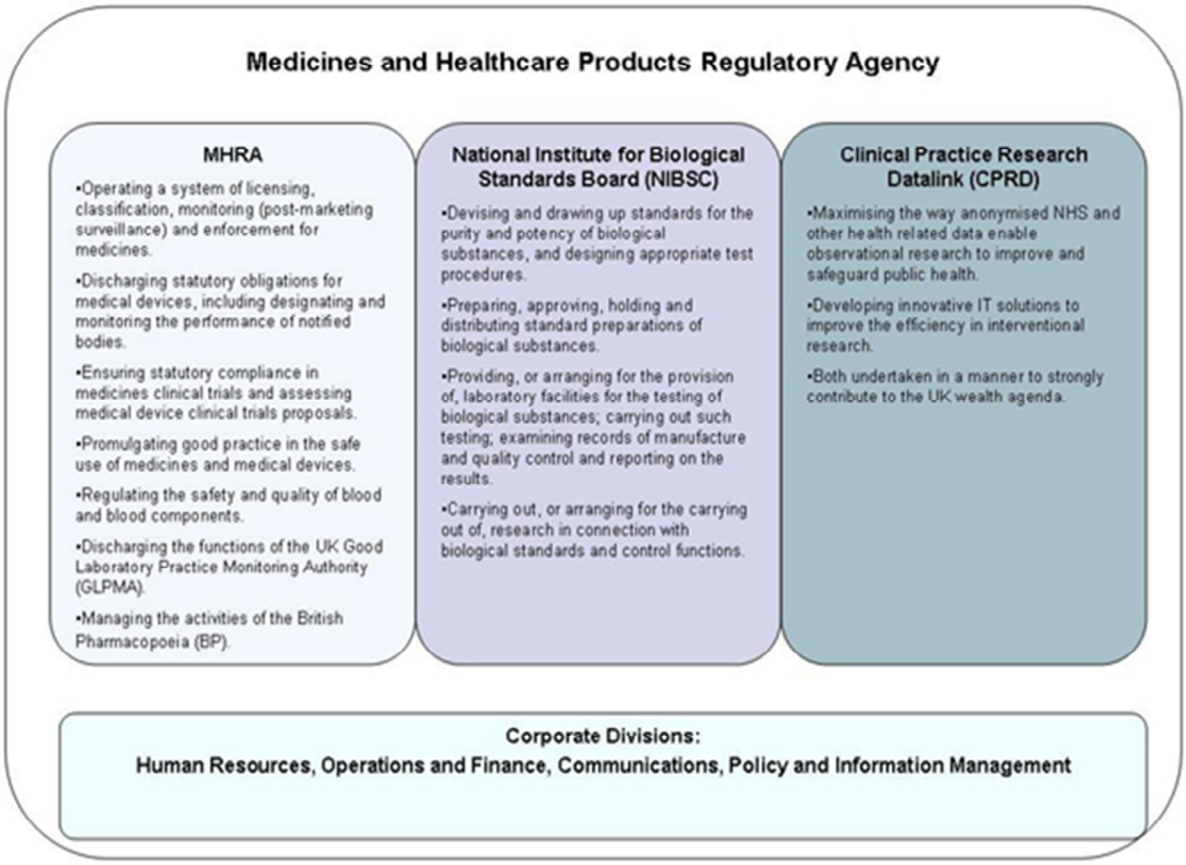
1.20 The Medicines and Healthcare Products Regulatory Agency comprises:

MHRA Regulatory: which aims to protect health and improve lives by ensuring that medicines and medical devices work and are acceptably safe; focusing on the core activities of product licensing, inspection and enforcement, and pharmacovigilance.

The Clinical Practice Research Datalink (CPRD): provides a resource for conducting observational research and improving the efficiency of interventional research, across all areas of health, medicines and devices. The CPRD merged into the Agency in 2012.

The National Institute for Biological Standards and Control (NIBSC): recognised as a world leader in assuring the quality of biological medicines through product testing, developing standards and reference materials and

carrying out applied research. The NIBSC merged into the Agency in 2013.



i. The role and remit of each of the three elements

MHRA

1.21 The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. It must make robust and fact-based judgments to ensure that the benefits justify any risks. This is achieved through:

- authorising medicines before they can be marketed, taking both their safety and effectiveness into account.
- ensuring clinical trials meet robust standards and safeguard patient's interests.
- inspecting the quality of medicines as manufactured and distributed.
- overseeing UK Notified Bodies that audit medical device manufacturers.
- encouraging everyone to report suspected problems with both medicines and devices and then investigating these reports.

- investigating, and prosecuting where necessary, cases of non-compliance, including advertising claims.

The Clinical Practice Research Datalink (CPRD)

1.22 The Clinical Practice Research Datalink (CPRD) is the English NHS observational data and interventional research service, jointly funded by the NHS National Institute for Health Research (NIHR) and the MHRA. CPRD services are 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.

1.23 CPRD provides value-added services to the General Practitioners who contribute to the database and to the researchers who want to make use of this data for research purposes.

The National Institute for Biological Standards and Control (NIBSC)

1.24 The key function of the NIBSC is the standardisation and control of biological medicines. It offers:

- Biological reference materials and customized reference materials.
- OCABR testing and contract testing.
- Research collaborations.
- Advice and training.

1.25 NIBSC is a global leader in the field of biological standardisation, responsible for developing and producing over 90% of the International Standards in use around the world to assure the quality of biological medicines. NIBSC scientists have an international reputation for excellence in research and are widely consulted on issues of biological medicine safety and efficacy.

1.26 The Institute is the UK's Official Medicines Control Laboratory (OMCL), responsible for testing of biological medicines within the framework of the European Union. It has a particularly close relationship with the World Health Organisation (WHO) and is the leading WHO International Laboratory for Standards.

1.27 Biological medicines include many of today's most widely used medicines (vaccines, blood products and biotherapeutics), together with some of the most exciting prospects for the future.

ii. Brief history of medicines and medical devices regulation and the MHRA

1.28 The formal regulation of medicines and medical devices is a relatively recent occurrence. The impact of the unforeseen and devastating side-effects of Thalidomide led to the creation of the Committee on Safety of Drugs in 1963,

which subsequently became the Committee on Safety of Medicines (CSM) under the terms of the Medicines Act 1968. In 2005 this committee became the Commission on Human Medicines (CHM).

1.29 The Medicines Control Agency was created in 1989, and merged with the Medical Devices Agency to become the MHRA in 2003.

1.30 The CPRD merged with the MHRA in April 2012. In April 2013, the MHRA further merged with NIBSC and was rebranded, with the MHRA identity being used for the parent organisation and one of the centres within the group.

1.31 The MHRA operates as an Executive Agency of the Department of Health and is also a Trading Fund under the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003. This dual classification reflects the varied nature of MHRA functions and is dealt with further in both Stage One and Stage Two of the report as it impacts on a number of the issues raised by the review.

e. Context and future challenges

1.32 The health and care system faces considerable challenges: people are living longer and an older population brings greater demands and more complex needs; expectations of what the system should deliver are growing; and the pace of innovation in the area of medicines and medical technologies is increasing. It is vital that the health and care system operates effectively and makes best use of all available resources.

1.33 There are opportunities as well as challenges. Organisations within the health and care system can play an active role in supporting innovation and growth in the UK. Ensuring that the UK is a supportive environment for medical research and development will encourage investment and encourage early access to innovative medicines for patients. New technologies and approaches also have the potential to reduce demands on the system, as well as improving the quality of patient care.

1.34 The MHRA can play a lead role. It needs to look to the future and develop robust strategies to respond to, or help to manage, future scenarios. On the regulatory side the Agency is highly regarded and is well placed to influence the regulatory framework in Europe and beyond. This could be a significant benefit to the UK by ensuring that regulation appropriately balances public safety with support for innovation across the life sciences sector.

1.35 The Agency is increasingly being encouraged to work closely with industry to support SMEs through the regulatory processes and to help bring innovative products to patients as early as possible, where appropriate and prudent.

1.36 All of this requires the Agency to work ever more closely and transparently with a wide range of other organisations. This can represent a more significant cultural shift for a regulatory body than for many others. Regulators have to maintain an appropriate distance from the organisations they regulate and one of the challenges faced by the Agency is in establishing an appropriate balance

between supporting innovation by working openly with industry in providing advice whilst retaining a clear degree of separation and independence when making regulatory decisions. Offering an open door for the provision of guidance and support needs to be distinct from the formal regulatory process and not compromise standards of assessment that underpin public safety.

1.37 Supporting innovation also requires the Agency to work closely with other organisations in the health and care system. NICE and NHS England, for example, are both key players in the process of getting innovative medicines to patients.

1.38 The Agency is already aware of these challenges and has a number of initiatives in place to build relationships across the system. This review makes several recommendations to support further change.

STAGE ONE

2. Income, expenditure and other resources

2.1 It is important to consider the functions and form of the MHRA in the context of the financial regime in which it operates, its expenditure under various functional categories, the income it generates and who pays this, and the potential for future changes.

2.2 The MHRA employs approximately 1,200 staff and in the current year is generating a net operating surplus of £20m pa against income of £150m from all three of its operational centres, with more than half of its income not being covered by the constraints of statutory fee recovery.

2.3 Shortly after the MHRA was established in 2003 it found itself in financial difficulties. A new IT system for medicines regulatory work, Sentinel (which is still operational today), encountered problems when first introduced and led to a significant backlog of licence applications, a reduction in licence fee income and a significant deficit in 2005/06. The Agency almost failed its 5 year statutory duty for the period 2003 to 2008. This led to cash-flow problems for the Agency which would have required a loan from DH but this was declined and therefore the Agency needed to establish its solvency with some urgency. Since that point the Agency has taken great care to manage its medium term financial position and has been generating a surplus, in both resource and cash terms (see Table 2 below for detailed income and expenditure data). At the same time it established a more strategic approach to managing its finances in order to provide certainty to industry and to avoid the swings in its fee levels which had existed between 2003 and 2007 (see as an example the 17% change in 2006/07 in Table 4).

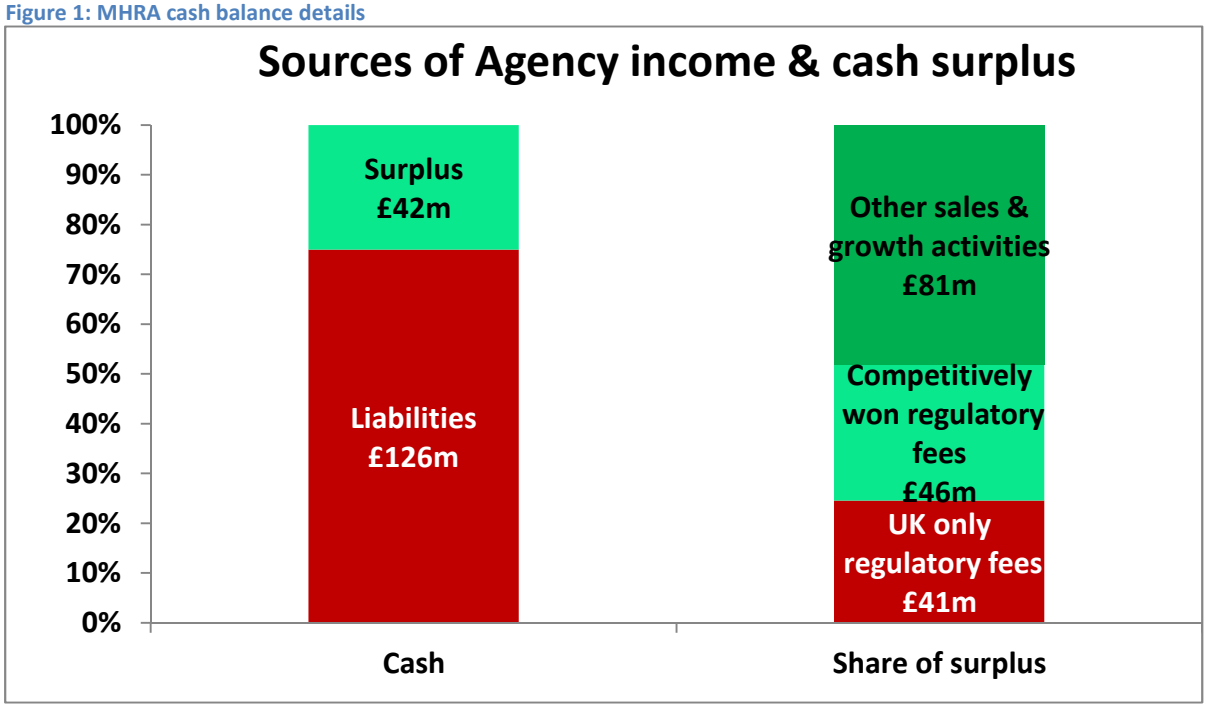
Table 2: MHRA Income and Expenditure

Income and expenditure								**(£m)**
	17-18	**16-17**	**15-16**	**14-15**	**13-14**	**12-13**	**11-12**	**10-11**
	Plans				**Outturn**			
Income								
Fee income	£112.2	£112.2	£118.3	£117.2	£113.0	£99.6	£107.0	£110.5
DH funding	£28.5	£28.5	£28.5	£28.5	£28.9	£9.2	£10.2	£10.9
Other income	£9.5	£9.5	£9.5	£9.5	£9.0	-	-	-
Total income	**£150.2**	**£150.2**	**£156.3**	**£155.2**	**£150.8**	**£108.8**	**£117.2**	**£121.4**
Expenditure								
Staff costs	£74.0	£74.0	£74.0	£75.0	£70.2	£54.7	£55.1	£55.0
Accommodation	£4.0	£4.0	£4.0	£5.5	£5.6	£6.1	£7.2	£3.5
IT	£10.0	£10.0	£10.0	£10.0	£11.4	£11.3	£10.2	£10.6
Other operating costs	£45.1	£45.1	£45.1	£45.1	£35.0	£24.6	£24.6	£21.3
Total expenditure	**£133.1**	**£133.1**	**£133.1**	**£135.6**	**£122.1**	**£96.6**	**£97.0**	**£90.5**
Operating surplus / (loss)	£17.1	£17.1	£23.2	£19.6	£28.7	£12.2	£20.2	£30.9

Income by category:								
Fees from licensing of medicines, wholesale dealers and manufacturers	£42.0	£42.0	£42.0	£42.0	£40.2	£42.9	£48.7	£56.0
Fees from inspections	£11.4	£11.4	£11.4	£11.4	£10.2	£9.6	£9.8	£10.3
National periodic fees	£26.8	£26.8	£26.8	£26.8	£31.0	£30.7	£33.0	£28.7
Fees from devices activities including DH funding	£8.1	£8.1	£8.1	£8.7	£10.8	£9.6	£10.7	£11.2
Fees from sales of the British Pharmacopoeia and associated chemical reference substances	£1.9	£1.9	£1.9	£2.9	£2.9	£2.9	£2.7	2.6
Fees from clinical trials	£3.4	£3.4	£3.4	£3.4	£3.3	£3.3	£3.3	£3.0
CPRD/GPRD	£10.1	£10.1	£10.1	£10.1	£7.9	£7.8	£5.9	£5.8
NIBSC	£40.5	£40.5	£40.5	£40.5	£35.9	-	-	-
Other income	£6.1	£6.1	£12.2	£9.5	£8.7	£2.1	£3.1	£3.8
Spend by centre:								
CPRD/GPRD	£7.8	£7.8	£7.8	£3.7	£3. 2	£5.4	£4.4	£3.7
NIBSC	£36.6	£36.6	£36.6	£35.4	£33.2	-		
Regulator	£87.5	£87.5	£87.5	£81.4	£85.8	£91.3	£92.0	£85.3

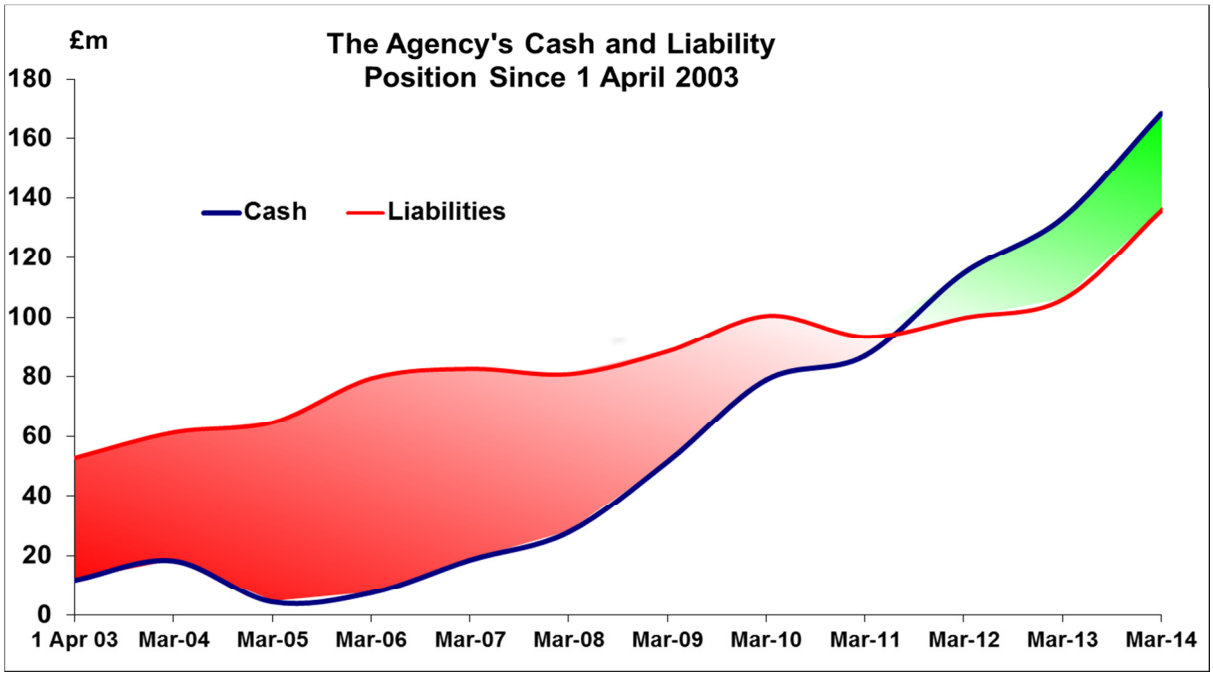
2.4 The Agency has built-up a cash balance to the point where it stood at £168m at 31 March 2014. However, most of this is covered by liabilities (see Figure 1 and Table 3 below). The increase in cash derives mainly from competitive and wider sales' activities. It has enabled the Agency to return to solvency, to invest in its IT and accommodation needs, to manage the effects of a 27% reduction in government funding for devices regulation, to implement an effective merger with NIBSC, and to jointly fund the CPRD.

Figure 1: MHRA cash balance details



2.5 Table 3 below shows the planned increase in cash over recent years, as it has moved from a position of technical insolvency to now more than covering liabilities.

Table 3: MHRA cash balance and liabilities



2.6 There are a number of factors behind this planned increase:

- In setting regulatory fees the Agency is required[1] to cover all of the costs of delivering the activity, including the relevant proportion for overheads and

[1] Managing Public Money, see Chapter 6 on Fees, Charges and Levies.

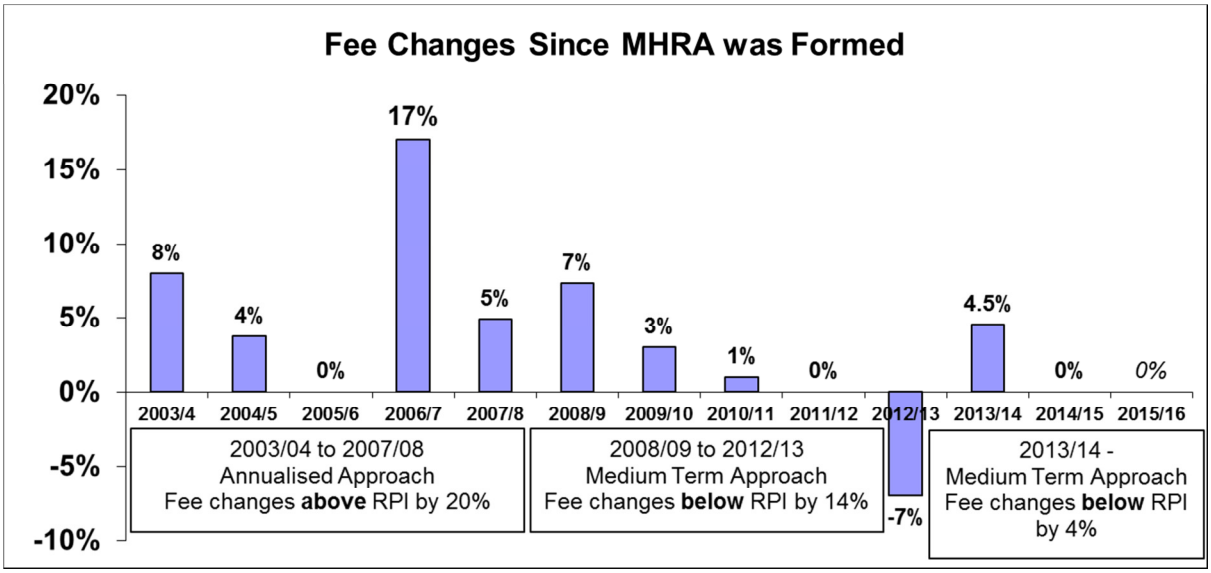
non-cash costs such as depreciation and a charge for self-insurance. Therefore, it should be expected that the Agency will build up surplus cash. In addition, statutory fees are not the primary driver of the cash position because the Agency is taking a commercial approach to all of its non-regulatory activities and the accumulation of cash is also a measure of its success in this area. It is right that the Agency is taking a medium term approach to its financial management and managing the tension between internally resourcing its development and the complexity of its diverse financial regime. The cash and fee position was last comprehensively debated with DH and ministers in 2011 which resulted in the framework which the Agency has been following since that point. The Agency's performance has been regularly endorsed through its accountability processes since turning around its financial position in 2008.

- Pharmaceutical companies often pre-pay for future licence applications, leaving the Agency with cash to offset future liabilities to carry out this work. Companies also prefer to maintain credit balances so that their work can commence without delay; speed of delivery rather than fee levels being their primary concern.

- Although the Agency has been proactive in significantly reducing the real-terms costs of medicines licences since 2010-11, through both fee cuts and the removal of fees, and plans to keep charges flat in cash terms in both 2014-15 and 2015-16 (see Table 4 below), in the short term it has set fees at a level higher than necessary to cover costs. However, in line with the Agency's medium term approach to managing its finances, there are signs that a degree of re-balancing of European licensing work is taking place and the MHRA expects its share of work to fall over the next few years. In anticipation of this reduction the Agency is currently reducing its regulatory workforce by 125 posts (14%) whilst protecting services, and cutting its accommodation costs by 33%. It agreed with DH in 2014 that it will take the earliest opportunity, the 2016/17 fees' round, to balance its income and costs on statutory regulatory activities.

- The MHRA is one of the leading such regulatory bodies in Europe, indeed the world, and has held a larger share of the European medicines licensing market than any other country. This partly reflects the ability of the MHRA to match spend on additional resources with increased income, whereas many European bodies have been constrained by central government budgetary or workforce controls.

Table 4: MHRA Medicines licence fee movements



2.7 The Agency meets approximately 85% of spend from income. In 2016 the Agency plans to introduce a fee, possibly based on a company's turnover in the UK, related to the regulation of medical devices. This will increase income to over 90% of Agency expenditure. For the Devices Division, this move will provide a secure funding stream from the beneficiaries of the regulatory activity and greatly reduce dependence of DH grant funding, which has reduced by 30% in cash-terms since 2010-11 and would be likely to come under further pressure in later Spending Reviews. Providing appropriate resource to fund growing and increasingly complex devices regulatory activity was a key recommendation of the Professor Stephenson Review.[2]

2.8 The remaining 10% of Agency funding that isn't covered by income relates to the NIBSC. The NIBSC has increased its income by 66% over the last 5 years and its place as the global leader in biological standards means it is well placed to further increase sales through global partnerships. However, this income subsidises its public health role in standardisation, control and research; which was once fully funded by government..

2.9 The CPRD meets all costs through income, which has risen by 33% over the last 3 years. The CPRD can provide access to a unique database (that other countries, such as the US, are seeking to copy in some form) that can provide researchers and pharmaceutical companies with data to support clinical trials and other studies, as well as supporting effective pharmacovigilance and medical devices monitoring. The CPRD has been working closely with the UK Trade and Investment on in-country missions aimed at opening up further markets. The Agency can continue to grow income from the CPRD and also to support innovation by improving the quality and speed of clinical trials.

2.10 The Agency has been very successful in recent years at increasing income from various sources. This is expected to become more difficult in the future, particularly on the European regulatory side, and the Agency should test its future

[2] Expert Clinical Advice – MHRA Medical Devices : Professor Terence Stephenson, 2013

plans to ensure that commercial opportunities have been fully explored and developed.

Recommendation 1: the Agency should review its plans for income generation, and the relative risks involved, with the Commercial Director in the Department of Health and with the Commercial Models Team in the Cabinet Office.

2.11 Where the Agency is charging for nationally determined regulatory licences (as with medicines marketing authorisations) it is required to set the fee at full cost recovery but cannot seek to make a profit from the process. Setting such fees requires assumptions to be made about costs and the numbers of licences expected to be sought. As such, it is not usually possible to ensure that income in any one year will match expenditure and fees can be adjusted so that, taking one year with the next, expenditure and income are in balance. The Agency has deliberately not made short term changes to fee levels for the reasons outlined above. The Trading Fund model is also designed to allow fluctuations in financial performance over a 5 year period. It was agreed with DH in 2014 that the Agency should consider making fee reductions to produce alignment from 2016/17 onwards, protecting the benefits of medium term stability referred to above and seeking to avoid swings in fee levels. This change would apply to the national statutory fees but the Agency would continue to generate a surplus from what is the majority of its other activities.

2.12 Whilst the Agency must have proper regard to the need to follow rules on setting fees and charges, it is also recognised that frequent movements in fee levels would not be sensible or welcomed by industry. Fee payers care far more about consistency and quality of service. To the extent possible, the Agency should seek to set fees to balance over a medium term and to review fees at appropriate intervals.

Recommendation 2: that the Agency should pursue the plan agreed with the Department in 2014 to align income and expenditure related to national statutory fees from 2016/17 (or from 2017-18 if necessary and agreed with the Department), whilst continuing to generate surpluses from its other activities. This should include the process for setting and reviewing regulatory fees.

2.13 In determining the appropriate level of the fees the MHRA should ensure that all reasonable costs have been included. For example, policy costs related to the execution or delivery of a service can be included, as can compliance and monitoring (but not enforcement) costs[3].

2.14 The Agency also needs to fully develop its plans to utilise the cash generated in ways consistent with Treasury rules. Stakeholders who expressed views on the MHRA's fee structure and use of its cash balance were most concerned with

[3] See Box A6.1A of Managing Public Money

obtaining a high quality service and were keen to see investment in areas that would produce benefits, in particular:

- Replacing the IT system (Sentinel) that manages the licensing process.
- Investing in increased capacity and development of the CPRD and NIBSC.

2.15 Trading Funds are able to use reserves built up from trading surpluses for capital investment purposes[4]. This flexibility is designed to give Trading Funds freedom from annual funding controls. The current cash position is as agreed with the Department in 2011 and it is timely to review the position following the merger with NIBSC and the launch of CPRD. It is intended that the CPRD joint venture between DH and the Agency should generate cash. Such a review should aim to agree a plan for efficient use of the current cash balance so that it is utilised over the next five years or so. The Agency should then aim to maintain an appropriate cash balance to meet its working needs and to provide a reasonable contingency.

Recommendation 3: the Agency and the Department should agree a plan for efficient utilisation of the cash balance that has been built-up.

2.16 Table 5 below provides details of MHRA workforce numbers, including recruitment rates in key areas of activity. The Agency is planning to reduce workforce numbers by 125 over the next three years. This is mainly on the regulatory side and reflects both efficiencies and expected reductions in workload due to fewer licence applications.

Table 5: MHRA workforce data

Number of staff at financial year end (FYE)								
	31/3/17	**31/3/16**	**31/3/15**	**31/3/14**	**31/3/13**	**31/3/12**	**31/3/11**	**31/3/10**
	Plans			**Outturn**				
No. of permanent FTE	1,132	1,240	1,162	1,113	838	867	913	878
No. of others FTE	30	30	30	101	98	44	61	94
Total FTE employed	**1,162**	**1,270**	**1,162**	**1,214**	**936**	**911**	**974**	**972**
Breakdown by category:								
CPRD (GPRD prior to 2013)	57	57	51	46	39	30	27	25
NIBSC	349	349	312	281	N/A	N/A	N/A	N/A
MHRA Regulatory	756	756	850	877	897	881	947	947
Recruitment and retention:								
Comms	2	2	1	6	8	9	0	11
CPRD	6	6	6	7	18	0	0	0
HR	2	2	3	9	12	4	3	2
Devices	4	4	4	9	9	3	2	0
Directorate	0	0	0	0	0	0	0	1
DTS	0	0	0	0	0	5	0	8

[4] See Box 7.6 of Managing Public Money

Finance	1	1	1	2	1	2	0	2
IE&S	6	6	6	11	21	6	3	24
IMD	6	6	6	11	8	13	5	23
Licensing	10	10	10	14	53	17	16	37
NIBSC	5	5	5	2	0	0	3	1
Operations	1	1	1	2	1	2	1	1
Policy	0	0	0	1	7	6	3	14
VRMM	5	6	5	18	15	12	2	32
Total	**48**	**48**	**44**	**92**	**153**	**79**	**38**	**156**

3. Functions

a. The MHRA's functions and supporting legislation

3.1 The primary functions of the MHRA relate to the regulation and monitoring of medicines and medical devices in order to ensure their quality, efficacy and safety, protecting patients and the wider public.

3.2 The Medicines Act 1968 provided the legislative basis on which the regulation of medicines was first established. The Human Medicines Regulations 2012 consolidated and modernised medicines legislation. They replace most of the Medicines Act 1968, as well as many statutory instruments, and give effect to EU Directives; in particular, Directive 2001/83/EC relating to medicinal products for human use.

3.3 All medical devices that are placed on the market in the UK have to comply with two sets of device specific legislation:

- EU laws – the Medical Devices Directives and Regulations.
- UK laws – the Medical Devices Regulations 2002 (as amended).

3.4 NIBSC activities on biological research, standards and control are covered in the Health and Social Care Act 2012.

3.5 These regulations provide the statutory basis for the key functions of the MHRA, which are set out below.

3.6 **Medicines licensing**: the MHRA operates a system of licensing (marketing authorisations for medicines, as well as manufacturer's and wholesale dealer's licences) to ensure that medicines for human use, sold or supplied in the UK, are of an acceptable standard.

3.7 When permission is sought to market medicines in the UK a marketing authorisation is needed and the applicant must provide all information from clinical trials on how well the medicine performed and any identified side effects. The applicant must also provide information on what the medicine contains, how it works, and who and what it is meant to treat. Assessments usually include obtaining the views of the Commission on Human Medicines.

3.8 **Clinical Trials approvals**: the MHRA's approval is also required for any clinical trials conducted in the UK. It ensures 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.

3.9 **Medical devices regulation**: the MHRA is responsible for ensuring that all medical devices sold in the UK are compliant with the relevant legislation. There is a vast range of medical devices available: from unmedicated bandages to MRI scanners or artificial hips. The devices market is very different to that for

medicines: it is often not possible to conduct clinical trials in the same way it is for medicines and devices are much more frequently upgraded to reflect new developments. Additionally, the risks with different types of devices can vary enormously. Medical devices are therefore classified according to the degree of inherent risk associated with them and the assessment they undergo before being awarded a CE mark[5]; not all medical devices will undergo the same level of the assessment before being awarded a CE mark.

3.10 The MHRA maintains a register of all manufacturers selling medical devices in the UK. Manufacturers are required to ensure that their devices are acceptably safe and fit for their intended purpose before they can be CE marked and placed on the market in any EU member state. Manufacturers must also ensure that any declared benefits of their devices outweigh the risks. Other than for very low risk devices, these claims must be assessed by a Notified Body before the CE mark can be used. The MHRA appoints UK Notified Bodies, of which there are currently 5 (and around 70 across the EU, appointed by the various national regulators), and is responsible for auditing them to ensure they meet the necessary standards.

3.11 **Post-marketing surveillance of medicines and medical devices**: once medicines and medical devices are being provided to the public the MHRA continues to monitor performance to safeguard public health. On the medicines side this is known as pharmacovigilance and the MHRA operates a Yellow Card scheme through which pharmaceutical companies, clinicians and patients can report incidents or concerns. For medical devices, a system of adverse incident reports operates. A further system (SABRE) operates for reporting side effects with blood or blood components.

3.12 In addition, the CPRD holds anonymised data on more than 5 million UK patients and can provide information to help monitor the impact of medicines and devices and quickly identify any emerging issues.

3.13 **Monitoring the manufacture, distribution, sale, labelling, advertising and promotion of medicines**: it is not only the specific performance of the medicine or device that requires continued monitoring. The manufacturing process, the quality of the ingredients used, changes to the way a product is stored or labelled, or changes to how it is promoted, can all have an impact on quality, safety or efficacy. The MHRA conducts risk-based inspections of manufacturing facilities, which are increasingly based in countries such as India and China. The MHRA is working with other national regulators to ensure a joined-up approach to such monitoring wherever possible.

3.14 **Biological standards and controls**: the NIBCS responsibilities are to:

- Devise and draw up standards for the purity and potency of biological substances, to design appropriate test procedures and to advise on these matters.

[5] Conformité Européenne - the CE mark is required for all new products which are subject to one or more of the European product safety Directives.

- Prepare, approve, hold and distribute standard preparations of biological substances.

- Provide, or arrange for, the provision of laboratory facilities for the testing of biological substances, to conduct such tests, to examine records of manufacture and quality control and to report on the results.

- To collaborate with the World Health Organisation, the European Pharmacopoeia Commission and other international organisations or bodies in relation to the establishment of standards for, the provision of standard preparations of, and the testing of, biological substances.

- Conduct, or to arrange for, research in connection with biological standards and control.

3.15 **Managing anonymised clinical records**: the CPRD collects primary healthcare data from participating GP services and supports a range of public health activities. It supports research, including clinical trials, and is a key element in effective oversight of medicines and medical devices in use by patients. There are some links between the CPRD and other health databases, such as the care.data programme. Over the next few years, links with other systems has the potential to reduce data collection costs and to broaden population coverage. (Paragraphs 4.19-4.25 below cover this issue in more detail.)

3.16 **British Pharmacopoeia Commission**: the Agency provides support and oversight to the British Pharmacopoeia Commission (an Advisory NDPB) and work relating to the European Pharmacopeia. This includes the annual publication of the British Pharmacopoeia. (As mentioned above, the BPC has been subject to a Triennial Review carried out alongside this one.)

3.17 **Commission on Human Medicines**: the Agency provides support and oversight to the Commission on Human Medicines (an Advisory NDPB). (As mentioned above, the CHM has been subject to a Triennial Review carried out alongside this one.)

3.18 **Discharging the functions of the UK Good Laboratory Practice Monitoring Authority**: any test facility which conducts regulatory studies must comply with good laboratory practice (GLP) regulations when carrying out safety tests on things including pharmaceuticals, veterinary medicines, cosmetics, etc. The MHRA, as the UKGLPMA, inspects such facilities and requires any necessary corrective actions.

3.19 **Medicines and medical devices policy**: developing and delivering UK government policy in this area. The MHRA represents the UK at European and other international discussions relating to the regulation of medicines and medical devices. The Agency is one of the leading medicines regulatory bodies in the world and plays a key role in the negotiation of appropriate regulatory frameworks. The Agency performs this function on behalf of the DH and has to

ensure that DH policy officials and Ministers are appropriately engaged and consulted.

b. International comparisons

3.20 The Review Team sought to make comparisons between the MHRA and equivalent bodies internationally. Data was obtained partly through the stakeholder engagement process (see Annex D for the list of international organisations consulted) and partly through analysis of publications and online data. In total, 12 countries were compared: USA, Germany, Netherlands, Sweden, Denmark, Australia, Canada, Thailand, Ireland, Scotland, Northern Ireland and Italy. In addition, various international organisations provided information and opinions.

3.21 There are three key areas that emerged from this analysis:

- **Funding regimes**: all other such organisations for which we obtained data rely more on government grant funding than does the MHRA. This enabled the Agency to take advantage of its ability to match income with spending by increasing its resources in order to take on a greater share of the European licensing market over recent years, when many other regulators were under greater budgetary constraints. Indications from other international organisations were that the MHRA funding approach is being increasingly followed. In the area of medical devices, a number of other countries (including the US, Italy and Ireland) have moved to, or plan to do so very soon, a system of charging manufacturers for the cost of regulation. The charging regimes currently vary but the planned introduction of such a charging regime by the MHRA in 2016, based on turnover in the UK, seems to be the preferred approach.

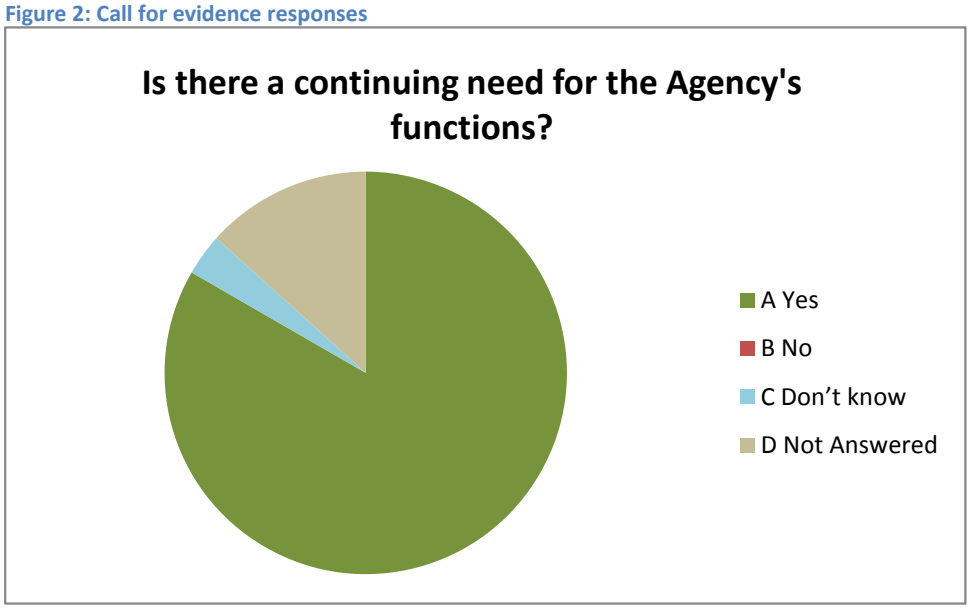
- **Range of functions**: there is a fair degree of variation in respect of the range of functions carried out by different national organisations. A tendency towards having a wider range of functions seems to be correlated with smaller countries that presumably need to consolidate functions into fewer organisations: for example, veterinary medicine (Sweden, Ireland, Northern Ireland), complementary medicines (Australia), cosmetic products (Ireland, Thailand) and blood, tissue and organ products (Ireland, Australia). None of the stakeholders consulted felt that the MHRA should take on additional functions, which are already fairly wide-ranging. They felt that while economies of scale have been achieved through the inclusion of a wider range of functions, this brings potential challenges of focus and expertise.

- **Specialisation**: some European organisations, particularly the relatively smaller ones, have decided to target their resources at particular specialist areas (such as Sweden and Belgium in oncology). The MHRA maintains a broad expertise, though it is seen as a particular specialist in certain areas, such as pharmacovogilance. Specialisation provides the potential for better use of resources across Europe but would require a high level of confidence in the quality of regulation being conducted elsewhere.

3.22 All of the comparator organisations have been set up at arm's length from direct government or ministerial control. This was strongly considered to be appropriate for the nature of the work being undertaken.

c. Are the functions of the MHRA necessary?

Figure 2: Call for evidence responses



3.23 The call for evidence responses, as shown in figure 2 above, were replicated in stakeholder interviews. There is a very clear stakeholder consensus that the functions of the Agency are necessary.

3.24 The functions of the Agency centre on public health and safety. Medicines regulation grew out of the thalidomide tragedy. Thalidomide was prescribed during the late 1950s and early 1960s to relieve morning sickness in the first few months of pregnancy but caused unpredicted serious birth defects. The pre-market assessment of the quality, safety and efficacy of medicines, alongside the post-market monitoring, is intended to reduce the risk to patients by ensuring that medicines are acceptably safe (applying appropriate risk/benefit analysis).

3.25 As has been mentioned above, most of the costs of running the Agency are met from the users of the functions, whether fees charged to the pharmaceutical industry to license medicines or from sales of products and services to users. Patients and the wider public also benefit from having a regulated system that gives confidence in the safety and efficacy of medicines.

3.26 All of the above functions that regulate or license medicines are required in legislation. The functions of the CPRD and NIBSC go beyond the formal statutory requirements and the medicines policy function is not a statutory requirement: these non-statutory functions are covered further below. However, all of the functions either directly fulfil, or indirectly support, statutory requirements under the Human Medicines Regulations 2012 and the Medical Devices Regulations 2002 (as amended). All stakeholders that commented felt that these functions remained necessary to ensure appropriate protection of the public.

3.27 Although the European Medicines Agency operates as the regional regulator it relies heavily on national regulators to perform the assessments and undertake monitoring. The MHRA is a key national regulator that currently undertakes more work at the European level than any other organisation. It would not currently be possible, and may never be, to rely on the EMA and other national regulators to perform this function. In taking a leading role in European and wider international work or discussions the MHRA helps to ensure that standards meet the concerns of UK citizens.

3.28 The work of the CPRD, which generates net income, directly supports post-market pharmacovigilance and monitoring of adverse incidents with medical devices. Relatively recent concerns over metal-on-metal joints, Poly Implant Prosthèse (breast implants) and vaginal mesh implants have highlighted the risks involved and the benefits of effective monitoring and reporting of incidents. The CPRD functions directly support the public health activities of the Agency.

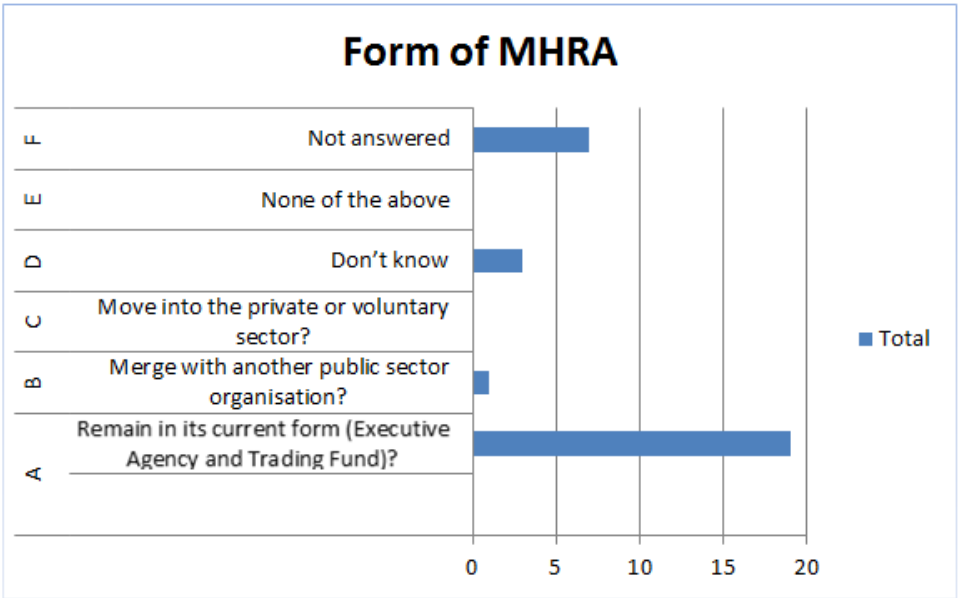
3.29 NIBSC is designated as the UK's Official Medicines Control Laboratory for biological substances. It increasingly supports MHRA core work, as medicines and devices use biological substances more and more often. NIBSC also supports a range of wider Agency functions, such as providing DNA testing for herbal medicines for use in the British Pharmacopoeia. As for the CPRD, the NIBSC functions directly support the public health activities of the Agency.

3.30 The function of developing medicines and medical devices regulatory policy and representing UK interests in Europe and elsewhere is vital for ensuring that UK interests are safeguarded. Effective performance can help ensure that regulatory requirements provide both for the safety of UK citizens and encourage innovation and growth. The Agency is best placed to carry out this function as it brings together the scientific knowledge necessary to support the effective development of policy.

Recommendation 4: that the functions of the Agency continue to be required.

4. Form

Figure 3: Call for evidence responses



4.1 The call for evidence responses, as shown in figure 3 above, were replicated in stakeholder interviews. One stakeholder suggested that a merger with the Human Tissue Authority (HTA) would better align regulatory standards between blood components (MHRA responsibility) and tissues and cells (HTA); another suggested that there are some overlaps between the functions of the MHRA and the National Institute for Health and Care Excellence (NICE), in particular in relation to efficacy assessments. These issues are dealt with below under the option of merging the MHRA with another body.

4.2 The Agency is a statutory body that operates as an Executive Agency of the Department of Health. However, the Agency is also a Trading Fund, reflecting the benefits that greater financial flexibility offers to an organisation that needs to align resources with changing demands. This dual structure is dealt with in detail in section b. below.

4.3 The Agency operates as an arm's length body of the DH and a sponsorship team provides a degree of oversight and stewardship.

a. Alternative delivery models

4.4 Triennial Reviews are required to consider whether the functions of an ALB, if still required, could be delivered more effectively through a different organisational delivery model.

4.5 In considering alternative delivery models the review team was looking for evidence that any recommended changes would deliver net benefits compared to the Agency's current form. The assessment was not simply whether the functions could be delivered by another delivery model but also about how well that model

would support the Agency's core aims and functions, including the key role of ensuring public safety in the use of medicines and medical devices. The review team consider that any changes to the form of the Agency should deliver one or more of the following benefits:

- Reduced costs.
- Improvements in the quality of service provision.
- Clearer lines of accountability.
- A greater strategic focus.

4.6 The relevant alternative options are considered below.

i. Abolish

4.7 The review has already concluded, reflecting all stakeholder responses on this issue, that the functions of the Agency continue to be required. As such, abolition of the Agency would simply require the functions to be moved elsewhere and these options are considered below.

Assessment: abolishing the MHRA is not appropriate.

ii. Move into the private or voluntary sector

4.8 A key concern for stakeholders is that the MHRA operates as a clearly independent and trusted regulator and source of advice. This not only requires a degree of separation from DH and Ministers but also from any perception that commercial pressures or other influences might impact on decisions. Pharmaceutical and medical devices industry representatives expressed concerns at any prospect of being regulated by, and providing commercially sensitive information to, a private sector body.

4.9 Operating in the voluntary sector would mitigate some of these concerns but still raises concerns about the willingness, and ability, of regulated companies and other parts of the health and care system to share information as freely as they do now. As an example, in reviewing the British Pharmacopoeia Commission the team looked at the US Pharmacopoeia (USP), which now operates as a not-for-profit organisation, and understands that the free exchange of information between the USP and the US Food and Drug Administration (the MHRA equivalent in the US) is now more limited and formalised than previously.

4.10 There are particular areas of Agency activity, such as the NIBSC and the CPRD, where greater commercialisation of activity might be possible. However, to do so outside of the public sector framework would risk significantly undermining the relationships that these parts of the Agency have with key stakeholders. The CPRD relies on patients trusting that it will hold data anonymously and operate in the interests of public health and safety. Concerns with care.data, a separate NHS patient database, in 2014 led to unprecedented

numbers of patients asking for their data to be removed from the CPRD database. The NIBSC is currently seen as the world-leading organisation for biological standards and control and can generate income from sales of biological reference materials and international or working standards for producing biological materials. However, the NIBSC relies on its reputation for scientific excellence and puts significant resource into providing advice and expertise to bodies such as the World Health Organisation and United Nations agencies. It has to strike a balance between this key international role and seeking commercial opportunities.

Assessment: moving the MHRA into the private or voluntary sector is not appropriate.

iii. Commercialise within public sector

4.11 As a Trading Fund, the Agency already operates with a commercial focus and meets the vast majority of its spend through income. As has been mentioned above, there are areas of Agency activity, particularly in the CPRD and the NIBSC, where there is potential to increase revenues quite significantly. The review considered whether the opportunities have been fully explored by the MHRA and recommendation 1 seeks to ensure that such opportunities are properly developed. Any such considerations would be dependent on a wider judgement about whether the greatest economic and social benefit is obtained from commercialising such data or from making it freely available and encouraging widespread use.

Assessment: the MHRA already operates a public sector commercial model but should test its approach with the Cabinet Office.

iv. Bring in-house

4.12 The core regulatory functions of the MHRA are ones that are entirely appropriate for an arm's length body operating with a degree of day-to-day independence from the DH and Ministers. Stakeholders were very strongly of the view that the MHRA needed to be seen to operate independently of any possible political influence that would undermine confidence in the Agency's public health and safety role.

4.13 The policy function, where the Agency represents the UK in international discussions over medicines and devices regulations and policies, is one that would normally be performed in the Department rather than by an ALB. However, retaining this function in the Agency links the policy staff with the scientific expertise that is necessary to fully understand the issues involved and to exert influence effectively in international discussions. Feedback from stakeholders, including international and other national organisations, clearly indicates that the Agency is highly regarded in this role and they felt that the function should remain with the Agency.

4.14 This issue is also addressed in section b. below as it impacts on the requirement for the relatively complex control framework within which the Agency operates.

Assessment: subject to section b. below, moving the functions of the MHRA into the Department is not appropriate.

v. Merge with another body

4.15 The MHRA has merged with both the CPRD (2012) and NIBSC (2013) in recent years. Stakeholders were very supportive of the logic of these mergers and of the way in which they have been to implemented to date, already generating synergies by bringing different parts of the Agency together to share information and expertise. Stakeholders were very largely of the view that the Agency now needed a period of consolidation to ensure that the benefits of these recent mergers are properly realised.

4.16 There are a number of other public health bodies with whom a case could be made for a merger with the MHRA but the body for which there is generally assumed to be the greatest potential benefit is the National Institute for Health and Care Excellence. Where the MHRA considers the safety quality and efficacy of medicines and devices, the NICE considers clinical and cost effectiveness. There is therefore a degree of overlap between the considerations of these bodies, although this is a relatively small proportion of their total functions. Both organisations suggest that communications and information sharing between them is sufficient to minimise any unnecessary duplication of effort.

4.17 Any merger with the NICE would risk a perceived conflict of interest between public safety and affordability decisions. This was a concern raised by a large number of stakeholders. Internationally, although Italy and Denmark have equivalent organisations that undertake functions which span those of the MHRA and the NICE, almost all countries that have these functions have placed them in different organisations.

4.18 One stakeholder response suggested that a merger with the Human Tissue Authority would better align regulatory standards between blood components (MHRA responsibility) and tissues and cells (HTA). This was not the subject of detailed analysis by the review team, which considered that these benefits ought to be deliverable regardless of any merger between the organisations and saw few wider synergies.

4.19 The review also considered whether any parts of the Agency could deliver the functions more efficiently through a merger. In considering the CPRD it is noticeable there are other health databases in other parts of the system. For example, the care.data programme is operated by the Health and Social Care Information Centre for NHS England and holds patient data from GP practices to enable the tracking of patient outcomes across health and care services. The potential for synergies between the CPRD and other systems was considered as part of the review.

4.20 The CPRD collects primary healthcare data from participating GP services. The data is anonymised and is used to conduct health research, including observational studies and clinical trials, as well as to support pharmacovigilance. The care.data programme, as an example of another health database, also uses patient data from GP practices; though this is currently at a pilot stage and will develop only over time. Care.data patient information is also normally anonymised, though there is a potential for information about an individual patient to be identifiable if the patient had a very rare disease. The longer-term aim is to use this data to improve prevention and treatment of illnesses, assess risk factors, etc.

4.21 There are already some links between the CPRD and the care.data programme. The data being evaluated through the pathfinder programme of care.data is being analysed in conjunction with CPRD. The output of this process will, in part, inform the potential uses of the data collected by care.data. CPRD will take an active role in this programme with a view to ensuring it is able to support secondary research uses of the data collected. This has the potential to reduce data collection costs and to broaden population coverage (thereby increasing its value for research purposes). These are longer-term potential benefits but for the present time care.data cannot provide the type of information held by the CPRD and which is necessary for research purposes. This is acknowledged by the HSCIC itself, which is currently concentrating on the pilot programme and plans for a national roll-out. Providing data that could be used for observational studies is thought to be at least three years away. In such a future scenario the HSCIC would collect and link data while the CPRD would provide the research capability.

4.22 There would be risks to any merger of the CPRD, whether with care.data or with any other health database. First, these data systems rely on patients being willing to have their data held and used in this way. This means that public confidence in the security of the data is vital; particularly that it is properly anonymised. That the public trusts and values the uses made of the data is also key to maintaining support. In early 2014 public concerns over these issues with regard to the information held by care.data led to a delay in implementation by six months. Even though they are separate systems and not directly linked, this issue had a negative impact on the CPRD, leading to unprecedented numbers of patients asking for their data to be removed from the CPRD database. If the CPRD had been merged into the HSCIC it is likely that the impact would have been far greater. This would adversely affect not only commercial revenues but also the key role that CPRD data plays in supporting pharmacovigilance and health research.

4.23 The second key risk is around service provision and access to the data. The Agency has a strong vested interest in ensuring that the CPRD is operating effectively. This was borne out by stakeholder responses, which overwhelmingly supported the 2012 merger and the progress that has been made since then in using CPRD data to support the core functions of the Agency.

4.24 The MHRA regulatory centre needs to have immediate access to the data held in the CPRD to support fulfilment of its public health functions and needs be

able to prioritise the work of the CPRD to ensure critical public health issues are dealt with rapidly. As an example, there is work currently going on between the regulatory centre and the CPRD on taking forward new approaches to pharmacovigilance and medical devices vigilance, to be able to rapidly assess safety signals by getting numerators/denominators. Further technological changes, such as unique device identifiers or scanning of medicines, will increase the value of close cooperation between the CPRD and the MHRA regulatory centre.

4.25 At this point, there are no other bodies or health databases that would be likely to deliver an improvement in service, and the risks of service reduction would be significant.

Assessment: merging the MHRA with another body is not appropriate. However, further consideration should be given to the potential benefits of better links between the CPRD and other health data services.

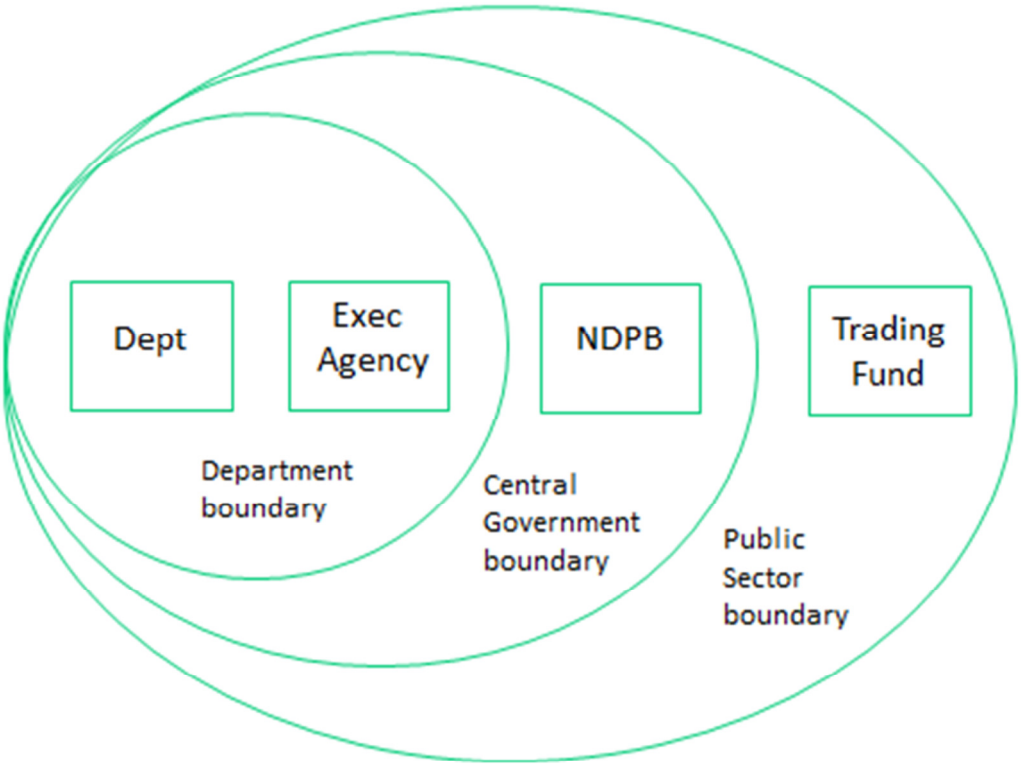
b. Continuing as an Executive Agency / Trading Fund

4.26 This review has generally found evidence and stakeholder views of an effective and well regarded organisation. Where areas of potential improvement have been picked up the Agency is already aware of many of the issues and is taking steps to address them. Where this report makes recommendations for changes they should be seen in the context of this generally positive conclusion. There is a fair degree of overlap between the various issues raised in this report and the current, relatively complex, organisational structure of the Agency, as both an Executive Agency and a Trading Fund, impacts on a number of these issues.

4.27 An Executive Agency is legally a part of the sponsoring government department and normally falls within the departmental boundary for the purposes of accounts (though it can also produce its own) and Treasury budgetary controls. As it is close to the department, an EA can undertake policy functions on behalf of Ministers (as does the MHRA in respect of international medicines/devices regulation). As a comparison, a NDPB is further removed from the department than an EA but is still a part of central government.

4.28 A Trading Fund is normally classified by the Office for National Statistics (ONS - which classifies all bodies for the purposes of the national accounts – which determines calculations of GDP, general government expenditure, public sector net debt, etc) as a public corporation (PC). The MHRA is classified as a PC in the national accounts and is treated as such for the purposes of financial controls (the MHRA is outside of the DH accounting and budgeting boundary). PCs operate much more at arm's length than bodies within the central government boundary and they do not normally perform policy functions on behalf of Ministers. Figure 4 below highlights how EAs and PCs are normally in completely different parts of the public sector.

Figure 4: Public Body Sector Classifications



4.29 The ONS sector classification guides[6] list the MHRA and four other bodies (Driver and Vehicle Standards Agency (DVSA), FCO Services, Government Procurement Service, Queen Elizabeth II Conference Centre) as both non-financial corporations and also as EAs. This classification is unusual but clearly not unique; although only the DVSA also performs a regulatory function. In a recent response to the Public Administration Select Committee:[7] the Cabinet Office explained the approach:

> *Executive agencies are business units of a department and are thus more directly accountable to ministers than either NDPBs or non-ministerial departments. However, ministers would not expect to be involved with their day-to-day operation*
>
> *Legally part of a department, they receive funding through that department and their accounts are consolidated with the departmental accounts, but they form administratively distinct units, with their own distinct identity. Staff of an executive agency remain civil servants employed by the sponsoring department. They work within a policy framework established by the minister and department. The chief executive is responsible for delivery and day-to-day operations, with a management board (usually including non-executive members) providing a challenge and support function to the chief executive. A number of executive agencies are also classified as 'trading funds'. This is a*

[6] See: http://www.ons.gov.uk/ons/guide-method/classifications/na-classifications/index.html
[7] *Who's accountable? Relationships between Government and arm's-length bodies* - House of Commons, Public Administration Select Committee, First Report of Session 2014–15

legal and financial status, separate and additional to their administrative categorisation.

4.30 Nevertheless, the Select Committee expressed some concerns at the current relationships between government departments and ALBs and recommended that the Cabinet Office simplify the types of ALBs, offering the following suggestion from the Institute for Government as a starting point:

One possible taxonomy of arm's-length bodies[8]

Functions	Form
Constitutional oversight	Constitutional bodies
Regulatory regime setters Guarantors of standards Independent watchdogs	Independent public interest bodies
Discretionary grant-giving Discretionary enforcement and inspection Stewardship of national assets	Departmental sponsored bodies
Delegated implementation of government policy	Executive agencies
Developing government policy	Core departments

4.31 The highlighted functions demonstrate where the regulatory and policy functions of the MHRA might normally be expected to appear. This report does not seek to recommend that the policy function is moved into DH, or elsewhere, as there are some clear benefits in retaining the function alongside the relevant scientific expertise. However, this function is one of the reasons that the MHRA is currently required to combine classifications that normally imply different levels of oversight and control by the sponsor department.

4.32 Stakeholder feedback on the Agency's handling of its government policy responsibilities was generally high. Work on the new Clinical Trials Regulation was highly praised and there is value in the Department being able to commission policy work from the Agency. There are, however, risks with having a policy function in an arm's length agency; particularly where the function is not simply limited to delegated implementation of government policy. Risks will relate in particular to areas where the policy relates to the fundamental fitness for purpose of the regulatory framework and approach. In this situation the Agency may need to prioritise wider government policy objectives over its own interests and objectives. It will need to develop a range of policy options, even where the impact on the Agency itself may be unwelcome.

4.33 Such risks need to be managed proportionately and it will be important for the Department, particularly the Sponsor Team and Sponsor Directors, and the Agency to work closely together to identify, agree and discuss how to manage these issues. An open, transparent and mutually supportive culture between the

[8] Suggested by the Institute for Government in 2010 and reproduced from *Who's accountable? Relationships between Government and arm's-length bodies* - House of Commons, Public Administration Select Committee, First Report of Session 2014–15

two parties is also required to manage the risks associated with the undoubted benefits of locating policy responsibilities for medicines and devices regulation in the Agency.

4.34 The policy function is not the only reason behind this dual status. The Agency is increasingly urged to support innovation in the medicines and devices sectors. This probably requires close links with the DH and other ALBs in the health and care sector and is more appropriate to an Executive Agency function than to a Trading Fund.

4.35 The differences in treatment between Trading Funds and Executive Agencies extend to a number of areas, most specifically:

- **Financial controls**: an EA is treated as a part of the sponsor department for the purposes of accounts, Supply Estimates and Treasury budgetary controls. A TF that is a public corporation operates outside of the departmental accounting and budgetary boundary so only transactions between the body and the department are recorded within them.

- **Workforce**: staff of an EA are civil servants and subject to the same controls on pay and conditions. Staff of a public corporation are not normally civil servants, though will still be subject to relevant public sector controls.

- **Oversight and accountability**: senior management of an EA are directly accountable to the sponsor department and Ministers. A Framework Agreement (which the MHRA and DH are in the process of agreeing) sets out the relationship between the EA and the department. A public corporation does not normally have a Framework Agreement and the level of accountability to, and oversight from, the sponsor department is less.

4.36 Finding an appropriate balance between these two treatments is difficult and these differences make it harder for the MHRA to focus its efforts and approach with the clarity it could otherwise achieve.

c. Conclusions and recommendations

4.37 Stage One of the Triennial Review has examined the functions and form of the MHRA. The Agency performs necessary public health and safety functions that need to continue. The Agency currently performs well and there would be risks in any change of form; which this review does not recommend. Nevertheless, the current Executive Agency/Trading Fund classification creates complexities that possibly impact on the performance of the Agency (some of these are picked up in Stage Two of the report).

Recommendation 5: that the Agency continues to operate in its current form.

Recommendation 6: that the Department is able to directly commission policy work from the Agency and that they work together to ensure that the risks and opportunities of having a policy function embedded in the Agency are openly and transparently managed.

Recommendation 7: that the Agency, working with the Department and the Cabinet Office Commercial Models Team, undertakes a short assessment to consider whether the CPRD commercial revenues are appropriately maximised, commensurate with the MHRA's public health role, and whether improved links with other health data systems would yield further benefits.

STAGE TWO

5. Performance

5.1 If the conclusion of Stage One is that the organisation should be maintained in its current form, then the review moves on to Stage Two and considers the scope for improving performance or delivering efficiencies, as well as adherence with the principles of good corporate governance.

5.2 The Agency is highly regarded as an effective regulator with professional and dedicated staff and the ability to influence international colleagues. Stakeholder responses to the call for evidence mostly rated the Agency's performance good or very good, although a fifth rated it as average (the mid-point of a five point scale). This generally positive view of the Agency was reflected in stakeholder interviews also.

5.3 There was also a wide acknowledgement of the progress that the Agency has been making to address concerns that it has either identified itself or that have been picked up in other reviews of specific activities. The sections below pick out the key issues identified by the review process where it is considered that the Agency can make changes to improve performance further but they are largely building upon actions that the Agency already has planned or are in progress.

a. Strategic planning and horizon scanning

5.4 The Agency faces a number of longer-term risks and challenges. On the regulatory side it is likely to face increasing competition from other EU regulators for the licensing income and also has to respond effectively to the changing nature of the products it regulates. Awareness of new developments with medicines and devices will better enable the Agency to anticipate the need for changes to processes or the regulatory framework and to influence international partners.

5.5 To support innovation the Agency will need to adapt the regulatory framework and engage openly on the wider issues (not simply regulatory but social, economic, legal, etc) raised by new developments. These are often not issues that the Agency can address by itself and will require open engagement across the health system and beyond.

5.6 The Agency is aware of this and has established a horizon scanning group to consider such issues. The Board and Central Executive Team have also covered this theme at meetings and away-days. It is intended that some of the recommendations in this Section and in Section 7. on governance will further support necessary longer-term planning and risk-management.

b. Supporting innovation

5.7 It can take 10-15 years and cost in the region of £1bn to bring a medicine from conception to marketing approval. For every 5,000-10,000 candidates that start

the process only one medicine gets marketing approval.[9] The process involves discovery phases, clinical trials phases and the licensing approval. The licensing part of this process normally takes less than six months and uses evidence from the clinical trials. The MHRA is often involved in working with the pharmaceutical company to help design these earlier stages of the process.

5.8 Although the core function of the Agency is to help ensure public health and safety through the effective regulation of medicines and medical devices, it is increasingly being asked to play a significant role in supporting innovation in the industry by providing pathways that will enable medicines to reach patients much faster than at present. As was mentioned earlier in this report, the Accelerated Access Review into innovative medicines and medical technology is looking at some of these issues in more detail and across the health system.

5.9 The Agency is a key player in developing such new processes but it cannot do so by itself; it needs to work with, and obtain support from, the Department, other organisations in the health and care system, and a range of other interested parties. The issues raised will often have implications that reach much further than regulation itself: there may be economic, legal, social and moral questions raised by new approaches. Innovation cannot, for example, take place without an acceptance of a degree of risk. Quite how much risk is acceptable, how the balance between risk and benefit is measured, and what can be done to mitigate risks are all issues in which the Agency plays a lead role but must engage with a wide range of other stakeholders, including patients themselves, before reaching conclusions.

5.10 The Agency can help to lead this debate but it will need support from the Department and other organisations to take it forward effectively.

i. Influencing the regulatory framework

5.11 Regulation is agreed at the European level and the Agency is well placed to influence its future development but this is not entirely within its control. The Agency has a very good record in supporting international regulatory negotiations and was particularly praised by stakeholders for its role in negotiating the Clinical Trials Regulation 2014, which will streamline the authorisations process, harmonise requirements for clinical trials across Europe, and make more data publicly available. The Agency needs to use this expertise and influence to help ensure that the regulatory framework adapts to changing medical technologies, balancing risks and benefits to protect the public and support innovation.

5.12 The MHRA was created from a merger of the Medicines Control Agency and the Medical Devices Agency in 2003. It has, however, retained separate medicines and devices divisions, a split that has been encouraged by many parts of the industry. This also reflects the different funding streams that apply to medicines and devices.

[9] Time to flourish – Inside innovation: the medicine development process. Association of the British Pharmaceutical Industry, 2012.

5.13 The regulation of medicines and medical devices is very different (see Section 3) and reflects the fact that devices have less homogeneity compared to medicines, are often not able to be tested in clinical trials and usually have a much shorter life before being updated or replaced. Medical devices do not receive a marketing approval from the MHRA but are instead granted a CE mark by a notified body (bodies that are designated – by the MHRA in the UK - to assess whether manufacturers and their medical devices meet the requirements set out in legislation). The involvement of the MHRA in relation to medical devices primarily relates to post-market monitoring and vigilance.

5.14 However, this is a fast changing environment and the separation between medicines and devices is becoming increasingly blurred. The convergence of medical devices (that more and more use digital technologies) with medicines creates increasingly complex borderline regulatory issues. The regulatory framework needs to be flexible enough to respond appropriately to these new developments. It is not likely to be sensible to regulate devices in a similar way to medicines and a sufficiently flexible risk-based approach to regulation is needed.

5.15 This is clearly demonstrated by the growth in digital technologies. Software apps have the potential to significantly reduce demands on the health system by supporting patients in monitoring themselves (e.g., heart rate, blood pressure, blood sugar) or supporting clinicians in remotely monitoring patients. Use of apps in this way is already developing but is inhibited by a lack of certainty over safety, accuracy and effectiveness.

5.16 The traditional approach to determining whether or not a product is a medical device rests upon the claims made for it by the manufacturer. There are many items that may be regarded as medical devices depending on the intended purpose for which they are provided: rubber gloves for use in the home are not classed as medical devices whereas those for use in a medical examination are.

5.17 This approach means that manufacturers may choose to forego making specific medical claims for a product in order to avoid the regulatory process. For the use of software apps particularly, this has created a degree of uncertainty for clinicians, patients or other members of the public.

5.18 A number of stakeholders commented on this issue, even though it wasn't directly raised as a question in the call for evidence, and the range of views expressed indicated just how difficult it will be to get the balance right so that appropriate regulation does not discourage developers from bringing new products to market. Whilst some stakeholders were concerned at the risk of uncertified medical devices causing injury or even death (for example if an app was used to calculate dosages and was inaccurate), others were equally concerned that over regulation of a fast-moving technology would be inappropriate and would stifle access to the potentially valuable benefits.

5.19 The Agency is well aware of these issues and published guidance on medical device software in 2014.[10] Such guidance sets out how the Medical Device Directive applies to apps or other software. Other organisations are also already working on these issues: under the umbrella of the National Information Board, NICE and Public Health England are undertaking development work on future accreditation of apps. The Agency should engage with other interested parties (such as NICE, medical bodies, industry and patients representatives) to consider other approaches that could develop agreed standards and guidance, which itself would encourage best use to be made of apps.

Recommendation 8: that the Agency engages with NICE and other interested parties to provide any useful guidance and standards to support appropriate use of apps and digital health services.

ii. Organisational structure and expertise within the MHRA

5.20 The technological changes also impact upon the organisational structure and knowledge requirements of the Agency. It is necessary for the medicines and devices sides of the Agency to work ever more closely with each other; not only because a single product might be part medicine and part device but because the skills needed to assess these products will also overlap. The devices side requires expert clinical support just as the medicines side needs to understand how the devices used to deliver medicines will work.

5.21 The increasing use of digital technologies within devices raises the need for the Agency to develop a comparatively new area of expertise. This will be a challenge, particularly given pay restraints, and the Agency will need to operate flexibly to seek the necessary support and develop skills of existing staff.

5.22 Some of these issues were raised in Professor Stephenson's report, which encouraged closer collaboration between the medicines and devices sides of the Agency. Short secondments between the two areas should be strongly encouraged for staff at all levels. In addition, the Agency should consider the opportunities to develop knowledge and expertise of staff (as well perhaps as encouraging recruitment by demonstrating that the Agency is a place within which to develop marketable skills) by establishing a range of secondment opportunities (possibly to pharmaceutical companies or other industry bodies, to other regulators or other parts of the health and care system).

5.23 The Agency's reliance on the knowledge and expertise of its board, executive team and other key staff means it is vital that succession planning arrangements are in place and kept up-to-date. Some staff in the Agency are experts in their field and replacing them will never be easy but the Agency must mitigate the risks by, for example, building the knowledge of other staff in the area.

[10] https://www.gov.uk/government/publications/medical-devices-software-applications-apps/medical-device-stand-alone-software-including-apps

Recommendation 9: that the Agency develops succession plans for key posts and creates opportunities to build experience and knowledge for staff across the Agency.

iii. Encouraging early access to medicines

5.24 The Agency already has a number of initiatives in place that support early access to innovative medicines by patients.

5.25 The Early Access to Medicines Scheme (EAMS) was announced in December 2011, was the subject of a public consultation in late 2012, and was launched in April 2014. The purpose is to support access in the UK to unlicensed or off-label medicines for patients with life threatening or seriously debilitating conditions and where there are currently no adequate treatment options. (An unlicensed medicine has no marketing approval for use; an off-label medicine has a marketing approval but is being used outside of the terms of that approval – perhaps for treating a different condition or for the treatment of a child when the approval only related to adult use.)

5.26 The scheme has three key stages. The first stage involves designation as a 'Promising Innovative Medicine' (PIM). The designation is based on early clinical data, such as from the early phases of clinical trials and may occur several years before licensing and indicates that the product is a candidate for the EAMS. Products that may apply for a designation include new biological or chemical entities but also new uses of approved medicines. The criteria are that the medicine is targeting life threatening, or seriously debilitating conditions which are either:

- Conditions for which there is no treatment; or
- Conditions for which the available treatments are unsatisfactory.

5.27 The granting of the PIM designation may well support the pharmaceutical company in securing investment. This is likely to be particularly valuable to smaller companies.

5.28 The second stage involves the MHRA issuing a scientific opinion on risk that will support clinicians and patients in making a decision on using the medicine. Where there is compelling evidence to support a positive risk/benefit balance and added clinical value the MHRA expects to give an opinion on the basis of phase II studies instead of the normal phase III. This will potentially give patients access to the next generation of medicines before they are licensed and clinicians will have greater confidence in the safety and efficacy of prescribing such medicines.

5.29 The medicine is made available free of charge by the company until the marketing authorisation is granted, after which it would be expected to be subject to a standard NICE technology appraisal. Under EAMS, NICE is involved at an earlier stage in the process to advise on the health economics which inform

commissioning and uptake decisions. Provision of the product at no cost to the NHS will remove any financial barrier which might have inhibited patient access.

5.30 This leads to the third stage, in which a co-ordinated NICE technology appraisal and NHS England commissioning process will apply. Once licensed, medicines which have been developed through EAMS will be appraised by NICE for routine use on the basis of the evidence collected in the earlier stages of the Scheme. They will typically be commissioned by NHS England through its specialised commissioning arrangements, delivering a single national approach to commissioning. NHS England has a legal duty to fund technologies positively appraised by NICE within three months of publication.

5.31 This scheme is in its early stages and the MHRA recently approved the first medicine under the scheme: Pembrolizumab is a treatment for advanced melanoma that was approved in March 2015.

5.32 There is a pilot project in place at the European level, run by the European Medicines Agency, that similarly seeks to bring new medicines to patients earlier. It looks at the process from drug development to licensing and monitoring as a continuum and is aiming to develop a process that moves seamlessly through these stages.

5.33 In March 2013 the MHRA also established an Innovation Office that aims to support small and medium enterprises, universities, or others, who have developed a novel medicine or medical device. The Innovation Office manages referrals to four regulators (Human Tissue Authority, Human Fertilisation and Embryology Authority, Health Research Authority and the MHRA itself) and helps facilitate their understanding of the regulatory considerations applicable to their innovation.

5.34 These developments were welcomed and supported by stakeholders but there were also some suggestions that the Agency could take a more proactive approach to engagement with the pharmaceutical companies, universities, research charities, or other bodies or individuals, that have developed or are developing innovative products. Such early engagement can provide invaluable support during the development and research phases to help ensure the necessary information is available to support the regulatory requirements. Nevertheless, the Agency remains a regulator and would need to avoid becoming too closely integrated with supporting any company or new product.

5.35 Some stakeholders also raised concerns at the apparent lack of continuity in the process of moving through the MHRA regulatory process, to NICE appraisal, to NHS England or Clinical Commissioning Groups agreeing to fund new medicines. This is an issue that will be considered as part of the Accelerated Access Review into innovative medicines and medical technology.

Recommendation 10: that the Agency contributes to the wider government agenda on innovation and patient access to medicines and medical devices by working in partnership with industry, medical research bodies and other organisations across the health and care system to develop approaches for early engagement in the medicines and devices development process; aligning the various stages and involvement of other bodies in the health system as closely as possible. This should include close cooperation with the Accelerated Access Review.

5.36 There is also much that can be done within the existing regulatory framework. During the recent Ebola epidemic the Agency played a central role in bringing vaccines to patients quickly.

Case Study: Tackling Ebola

The Agency played a key role in supporting the Department of Health, and the wider health and care system, in responding to the Ebola epidemic.

- The Clinical Trials Unit in the Agency provided an expedited review and approval of four UK trials for Ebola therapeutics: two vaccines and two antiviral therapies. In the case of one of the vaccines the manufacturer specifically asked the Agency to review and approve the trial because of their positive track record rather than going to another European country.
- MHRA also provided the World Health Organisation with quality rapporteur support for the guidance advice to two of the three vaccines.
- Through the National Institute for Biological Standards and Control, the Agency is also involved in a European taskforce coordinated by the European Medicines Agency in order to provide rapid scientific advice to companies developing Ebola vaccines and in evaluation of scientific data currently available for other therapeutic options.
- The Agency provided senior (Director) support to DH to organise and broker the start-up phase of the Ebola vaccines work.

This support and expertise was highly valued and helped to ensure that the UK remained at the forefront of international work to deploy safe and effective Ebola vaccines in the affected countries.

c. Adapting to an increasingly global system

5.37 The supply of raw materials, the manufacture, supply and distribution of medicines is the result of an increasingly complex global market. Many medicines are now manufactured in countries such and India and China.

5.38 This international environment is a challenge for national regulators. In 2012, the US Congress passed the FDA Safety and Innovation Act, which among other things, requires the FDA to inspect foreign facilities that make drugs sold in the

U.S. as frequently as it does domestic plants. Last year, the Indian government approved adding seven new FDA drug investigators, to bring the total up to 19 U.S. staff members working in India. This approach seems likely to be unsustainable, certainly for most national regulators. Few could realistically monitor and inspect the quality, manufacture, storage and distribution of all medicines imported into their country. Regulators must cooperate to share the responsibilities, to share information, and to rely on each other's decisions.

5.39 The Agency has already entered into bilateral joint inspection agreements with several other countries and is a member of the International Coalition of Medicines Regulatory Authorities (ICMRA). ICMRA was only established in 2014 but it has over 20 members and aims to encourage regulatory convergence, cooperation and work-sharing. The success of this initiative, or something similar, will be key to improving consistency of approach (which would be greatly welcomed by industry) and to making most effective use of the available resources of national regulators.

d. Pharmacovigilance and monitoring adverse incidents

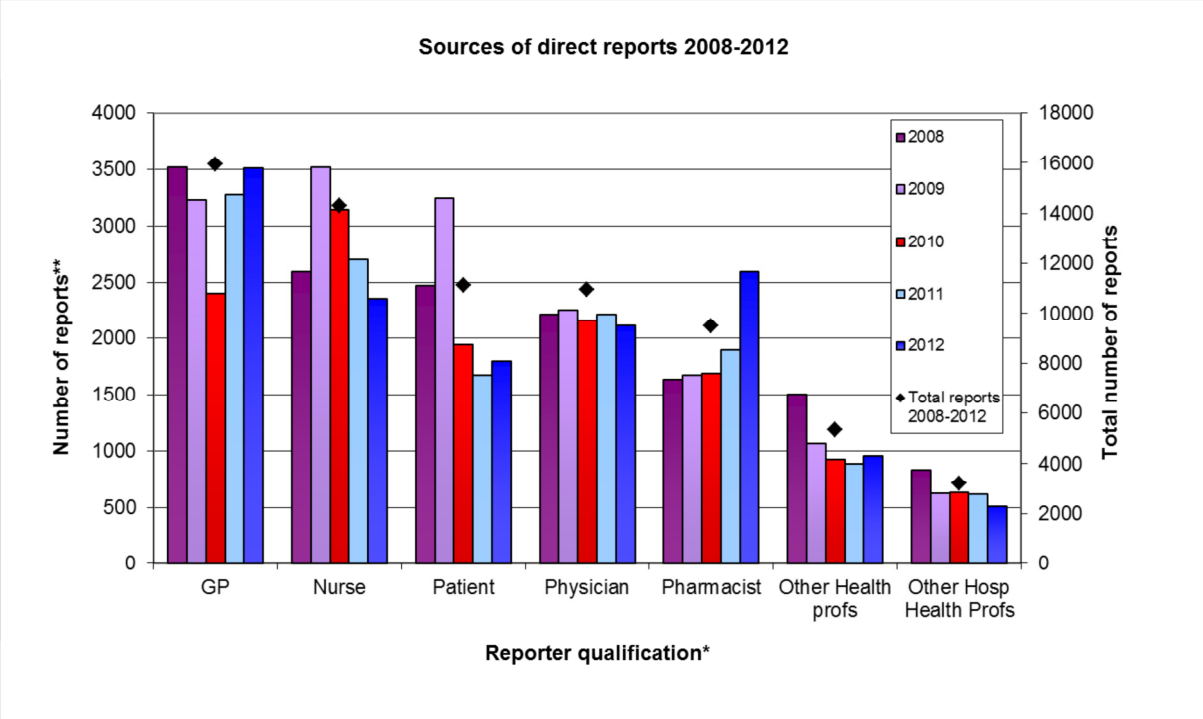
5.40 The Agency has an excellent reputation for pharmacovigilance and is regarded as a leading expert among national regulators.

5.41 The merger between the MHRA and the CPRD in 2012 further strengthened the Agency's position and it has been actively building links to make effective use of the data held by the CPRD to support monitoring of medicines and devices.

5.42 An effective programme to monitor the impact of the use of medicines and devices on patients is also vital for supporting innovation, as such monitoring is even more essential to support managed risks when medicines are being released for use at an earlier stage in the development process. It is easier to live with greater uncertainty if you know that effective monitoring is in place.

5.43 For the reporting of side effects with medicines or adverse incidents with medical devices the Agency runs a 'Yellow Card' scheme. This was first established 50 years ago. It can be used by healthcare professions or members of the public; Figure 5 below shows sources of reports over a five year period (this excludes pharmaceutical companies or manufacturers themselves, who often have a legal obligation to report side effects or adverse incidents and account for around half of total reports).

Figure 5: Reports under the Yellow Card scheme[11]



5.44 Although the review wasn't able to check this assertion, a number of stakeholders suggested that awareness of the Yellow Card scheme is not what is should be, even among many healthcare professionals. This was also a view reached by Professor Stephenson in his report[12]. As a result, levels of reporting were thought to be lower than could be achieved. This may be related to the public profile of the Agency itself (covered further in Section e. below).

5.45 Various options for addressing this were put forward by stakeholders: from making use of the reporting mechanisms a part of the performance assessment of GPs to the Agency sending out newsletters to healthcare professionals. Using the Royal Colleges and other professional organisations to raise awareness of their members should deliver benefits without requiring too much resource input.

5.46 Another way to encourage higher levels of reporting would be to make the process easier. The system allows for online reporting but it requires quite a lot of detail from the reporter. It is also likely to be much easier if the Agency could develop a digital app for reporting via smartphones or tablets. This would be more achievable if the minimum amount of information required was limited to key facts, such as: the event, the medicine or device, and the reporters contact details.

5.47 Several stakeholders also suggested that feedback to reporters was inadequate. They receive an acknowledgement but detailed information on what happens as a consequence of the report is not usually provided. Such feedback is likely to encourage further reporting by demonstrating that action is taken as a result.

[11] Trends in UK spontaneous Adverse Drug Reaction (ADR) reporting between 2008 – 2012 - MHRA
[12] Expert Clinical Advice – MHRA Medical Devices : Professor Terence Stephenson, 2013

Recommendation 11: that the Agency implements changes to raise awareness of the Yellow Card scheme; including simplifying reporting mechanisms and providing more detailed feedback on the subsequent actions to reporters.

Recommendation 12: that the Agency puts in place plans to both fully utilise digital processes and services itself and to best support their effective use to benefit public, patients and the health and care system.

5.48 The rapid pace of technological change extends to the processes through which medicines and medical devices can be monitored once out in the market. On the devices side, the introduction of Unique Device Identifiers will greatly support the collection of data on the performance of medical devices, particularly implants such as pacemakers, once in operation. Such post-market surveillance opportunities will support the CPRD in monitoring the performance of devices over their life-span and to quickly identify adverse events associated with a particular device. These were issues picked up in the Professor Stephenson report and the Agency is working with the Department, NHS England and the Health and Social Care Information Centre to encourage NHS Trusts to implement systems for UDI recording, and to adapt national data recording and transfer systems so that information can be centrally collated and analysed.

e. Communications and engagement

5.49 As might be expected, this is an area where almost all stakeholders felt able to express a view. Most rated the Agency as good or very good but over a quarter rated the Agency as average or below (one gave a rating of poor). There was though, a wide acknowledgement that the Agency has been taking significant steps to develop its communications across all stakeholder groups.

5.50 Communication and engagement cuts across many of the other issues addressed in this report and recommendation 10 in Section b. above already covers the issue of partnership working and engagement with stakeholders to support the agenda on innovation and patient access to medicines.

i. Profile of the MHRA

5.51 The Agency does not have the high public profile of organisations such as NICE. As a primarily regulatory organisation there is often little reason for the Agency to be in the media spotlight. However, there are activities undertaken by the Agency for which greater public awareness would be beneficial, or events that arise where the Agency could play a leading role in setting out the facts and providing reassurance.

5.52 The report has already mentioned the apparent impact of a relatively low awareness of the Agency by some healthcare professionals, as well as the wider public, on reporting under the Yellow Card Scheme. The Agency undertakes a

number of activities where there would be clear benefits from a wider public understanding and that ought to be of media interest. As an example, the Agency has been proactive in taking action to tackle the supply of fake or counterfeit medicines, closing down illegal production facilities or websites. It has been a lead player in Operation Pangea since 2006, an internationally coordinated operation, led by Interpol, that raids offices across the world. In the 2014 operation over 10,000 fake online pharmacies were closed and nearly ten million doses of fake drugs were seized. The Agency does already encourage media coverage of this event, often taking journalists along on raids but it might be possible to raise the profile further. Although a unscientific assessment, a Google search on 'Operation Pangea' brought back only one media website mirror.co.uk) from the top ten returns, with the rest being Interpol and various health bodies.

5.53 Greater public awareness of this activity would not simply raise the profile of the Agency it would aid better understanding of the risks posed by unregulated online websites selling medicines, and from fake or counterfeit medicines generally.

5.54 The Agency also occasionally needs to respond to public and media interest and concerns regarding a particular product. This has occurred in relation to several medical devices over recent years: metal-on-metal joints; Poly Implant Prostheses (PIP, breast implants) and vaginal mesh implants being key examples. A number of stakeholders felt that the Agency has been too slow to react to such events in the past, though there was a fairly wide recognition that this has been improving; for example, the Agency's reaction in relation to vaginal mesh implants was felt to be better than it was for metal-on-metal joints.

5.55 The argument for early and proactive engagement by the Agency in such cases is that it is an impartial source of expertise that is best placed to provide the public with the evidence and to counter any unfounded assumptions or fears.

5.56 Nevertheless, the Agency should only do this in close cooperation with the department (where the Chief Medical Officer will often take the lead on explaining issues to the media) and with any other interested parties (for example, with PIP implants one common question was about who would pay for having the implants removed or replaced).

ii. Engagement with industry and others

5.57 Stakeholder responses were largely positive about engagement with the Agency and there are a number of examples of the Agency having established bilateral meetings with industry bodies over recent years. The one area of concern on the licensing side that was raised a number of times relates to the IT system, Sentinel. Licence applications can be submitted online but the system lacks transparency from the viewpoint of applicants, who cannot automatically track progress of their applications and contact the assessor directly online. This should be addressed as part of the IT replacement programme (see Section 6.) but in the interim the Agency should assess what more could be done with the existing facilities to improve the service to applicants.

Recommendation 13: that the Agency: (i) ensures that the IT replacement programme meets the needs of licence applicants; and, (ii) considers what more can be done under the existing system to improve transparency and tracking of applications.

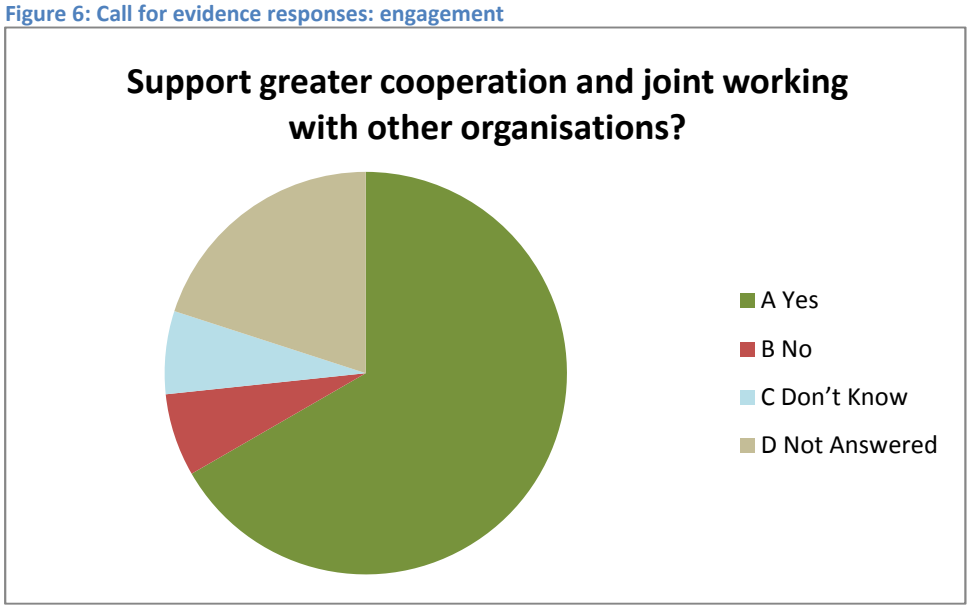
5.58 A number of stakeholders also wanted to see the Agency take a more proactive role in providing information and guidance to industry. This related to things such as the sharing Agency expertise or providing examples of best practice elsewhere. This view that the Agency could be more proactive in engaging industry was more commonly held when looking beyond the core regulatory function; as one stakeholder said: "the Agency performs well in the reactive elements like enforcement and legislative implementation but is less strong in areas where it could be proactive, like emerging technologies". This was addressed in Section b. above and will be considered within the separate Accelerated Access review.

iii. Engagement with other parts of the health and care system

5.59 The issues that the Agency deals with are increasingly linked to interests and activity in other parts of the health and care system. A key challenge for the Agency is to build those relationships and partnerships that will not only help it to meet its regulatory objectives but will also support innovation or simply help ensure that current processes are joined-up and coherent. This isn't necessarily about building complex fora; for example, NHS England requested that the NHS delay introducing a new treatment for Hepatitis C (Sofosbuvir or Sovaldi), which is estimated to cost around £50,000 per patient treated and with approximately 150,00-200,000 people infected in the UK, due to the huge potential costs. The regulatory approval process for this treatment, followed by NICE assessment, means that the possibility and increasing likelihood, of this drug coming forward was known for some years. To what extent the Agency, NICE and NHS England communicated with each other to plan a smooth transition is unclear. Some engagement is understood to have taken place but not necessarily at the right level, with the right people or with the necessary focus on the implications.

5.60 Stakeholder responses to the call for evidence were strongly in support of greater engagement by the Agency (see Figure 6 below). The review found many examples where the Agency was already doing just this, but there is more that can and should be done; some of which has been covered above. Stakeholder concerns were often about organisations across the public health sector not sharing information, applying different standards or approaches, or not taking the steps necessary for a smooth transition through the process of regulation, approval, and use within the NHS.

Figure 6: Call for evidence responses: engagement



5.61 The relationship between the Agency and NICE is only one example but raised several issues during the review. The Committee of Public Accounts raised concerns in a 2013 report[13] about information from clinical trials being provided by industry to the Agency but not being routinely shared with NICE or with doctors and researchers. While there are potentially commercial confidentiality issues with some data this was not thought to present a serious obstacle to greater sharing and transparency.

5.62 A further example was identified as part of the related Triennial Review into the Commission on Human Medicines. It found that NICE guidance on appropriate uses of medicines did not always reflect the views of the CHM. This could have a potentially serious impact on patient safety and undermine confidence in guidance issued.

5.63 Communications between the Agency and NICE have been improving since these issues arose and the two organisations signed a Partnership Agreement, to be reviewed annually, last year. The Agency should consider publicising the agreement and ensure that the principles are understood and put into practice throughout the organisation.

5.64 The draft Framework Agreement between the Agency and the Department will include an annex covering relationships with other bodies. The Department and Agency should agree text that clearly sets out the expectations on the Agency in this respect. This links to recommendation 20 in Section 7.

iv. Communications with patients and patient groups

5.65 Many of the issues raised earlier in this report require the Agency to engage effectively with patients and the wider public. Decisions regarding the risk/benefit balance, particularly in relation to new and innovative medicines, need public

[13] Access to clinical trial information and the stockpiling of Tamiflu - Thirty-fifth report of session 2013-14, House of Commons Committee of Public Accounts, December 2013.

involvement. Safety concerns about medicines or devices need the Agency to communicate quickly and openly with the public in general and with the affected patients and patient representative groups in particular.

5.66 As part of the stakeholder engagement process the review was able to speak to a number of patient representatives and there was a clear view that the Agency has taken steps to significantly improve the level of public engagement. Patients and patient groups have been invited to participate in workshops and discussions, sometimes alongside other stakeholders, to inform Agency projects on specific issues, and are then kept informed of developments. Examples have included the review of paediatric Yellow Card guidelines and the review of auto-adrenaline injectors.

5.67 The Agency has also established a patient consultative forum, which consists of a network of approximately 50 individuals and patient groups and aims to hold four topic specific meetings per year. Patients and patient representatives can also be involved in strategic work within the agency. For example, there are four places allocated to patients and patient representatives on the National Strategic Platform on the Reclassification of Medicines, which allows them to work alongside healthcare professionals to steer the engagement process to inform the reclassification of medicines from prescription only to being available through a pharmacist.

f. Performance measurement

5.68 Key Performance Indicators should reflect and support the strategic priorities of an organisation. They help organisations understand how well they are performing in relation to their strategic goals and objectives. Below this, an organisation might use a number of further targets or measures. There are a wide variety of types of performance indicators but some core examples are:

- **cost**: the money spent to acquire the resources;
- **input**: the resources (staff, materials and premises) employed to provide the service;
- **output**: the service provided, for example, in terms of tasks completed;
- **outcome**: the impact and value of the service delivery.

5.69 The Agency uses performance targets and provides an assessment of delivery against them in the annual report and accounts. The targets for 2014-15 are provided in Table 6 below. The Agency reassesses targets each year and there are some differences to the targets set out in the 2012-13 annual report and accounts.

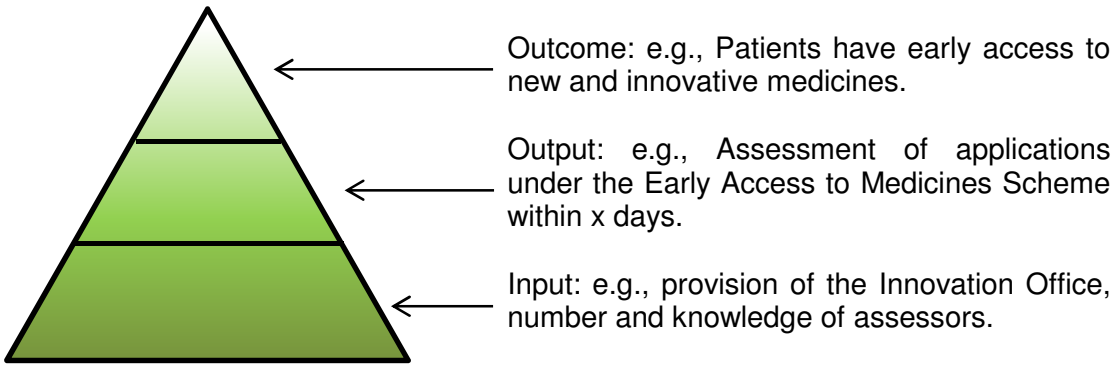
Table 6: MHRA Performance targets

MHRA 2014-15 Performance Targets		
PM1	Medicines licensing – validation of applications	a) For Type IB/II variations, 97% of scientific validation process completed within 14 days of case creation.
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.
		c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt. PM2 Medicines licensing – assessment of applications.
PM2	Medicines licensing – assessment of applications	a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days.
		b) The assessment of applications for new Marketing Authorisations in European (MR, DC & Centralised) procedures: 97% assessed within the designated time.
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: 97% assessed within the designated time. PM3 Assessment of clinical trials and investigations.
PM3	Assessment of clinical trials and investigations	a) The assessment of applications for clinical trials of medicines in the UK: 98% in 30 days (all trial phases) and an average time of 14 days (Phase I trials).
		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less.
PM4	Capturing and analysing adverse event reports –making reports available, issuing alerts and acting on signals	a) Maximum timescales between receipt of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 95% within 2 working days and 100% within 3 working days.
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days.
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours
		d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days.
		e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within 5 working days

PM5	Publication of UK assessment reports for new Marketing Authorisations	Publish 98% of UK assessment reports for new Marketing Authorisations within 60 net calendar days of grant of new Authorisations.
PM6	Standards and control	a) Biologics standards supply - 93% of all materials supplied within 6 working days.
		b) Batch release activity – 99% of all requested OCABR and non-EU testing completed within agreed timelines: 8 days for Plasma Pools 10 days for Parenterals 15 days for Haemostasis 60 days for vaccines
PM7	CPRD activity	a) To enable 280 research studies in 2014/15.
		b) To double (8% to 16%) the population cover of primary care data within the CPRD system by the end of the financial year.
PM8	Answering Freedom of Information requests, letters and Parliamentary Questions	a) In working towards achieving 100% compliance, ensure that at least 92% of requests under the Freedom of Information Act are replied to within 20 working days.
		b) Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.
		c) Return Ministerial correspondence (POs) drafts to the Department of Health within 4 working days of receipt in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.
PM9	Finance – income and expenditure position	Achieve an income and expenditure surplus during 2014-15, and as a minimum, exceed a 3.5% per annum return on capital employed.

5.70 These performance indicators are largely related to process or output. They are predominantly measured as a particular number, or percentage, of actions within a particular timescale. Such targets are helpful but do not provide a full picture of the Agency's performance and the value of the activities measured.

5.71 A range of different measures would provide a broader picture of performance. In particular, a number of outcome measures should reflect the Agency's core strategic objectives. Such measures might not be entirely within the control of the Agency but its actions should be able to influence and support the desired outcome. An example might be something like:



5.72 There might be a number of input and output measures to support each outcome. For the Agency this might include:

- Time related targets (e.g., time taken to process applications, average time from receiving a report under the Yellow Card scheme to providing a follow-up response)
- Average costs (e.g., per application processed, per case dealt with by the Innovation Office)
- Measures of quality (e.g., numbers of complaints, customer survey scores)

5.73 The Agency should also seek to benchmark performance against comparator organisations. This might include other regulators, similar organisations in other countries, or simply high-performing organisations in other sectors. It is also important that the performance targets/indicators are transparent and continue to be published within the Agency's annual report and accounts.

Recommendation 14: that the Agency agrees a set of key performance indicators with the Department that reflect strategic objectives and are supported by appropriate performance targets.

6. Efficiency

6.1 Detail of the Agency's overall spend profile has been covered in Section 2. The Agency currently generates a surplus of around £20m on income of around £155m per annum.

6.2 As well as sorting out its cash position over recent years, the Agency has also been reducing costs in a number of areas. This section sets out what has been achieved so far, what is currently planned and where further efficiencies might be delivered. Table 7 below provides a summary of savings delivered and planned.

Table 7: MHRA Efficiency Savings Summary

(£'000)	Plans				Outturn			
	17-18	16-17	15-16	14-15	13-14	12-13	11-12	10-11
Pay savings								
Medical Devices Division staffing reduced by 21 posts over 3 years.	1000	1000	1000	1000	1000	600	600	
Reduction by 50 posts in 2011-12 reflecting decline in renumerated licensing activity	2000	2000	2000	2000	2000	2000	2000	
Planned reduction of 125 posts starting 2014/15	6000	6000	2000	1000				
Accommodation savings								
Annual saving for BIS when the Agency took over part of 151 Buckingham Palace Road								6000
Saving from moving from three floors to two from 1st April 2015.	4000	3500	3000					
Annual saving from moving out of York office to smaller premises in July 2013.	36	36	36	36	36			
Sale of Blackpool office in March 2014.					236			
Annual savings on Blackpool office running costs	20	20	20	20	20			
Left premises in Welwyn Garden City in May 2014. Lease expires in 2021 but took up break clause. Savings for next 5 years.	40	40	40	40	40			
IT savings								
Reduction in computing operating budget for Accenture ad-hoc consulting.	750	750	750	750				
Post Infrastructure Operate - estimated saving on software and hardware purchases of 22% (loss of Accenture mark-up) from 2016-17 onwards.	225	225						
Laboratory savings								
Annual reduction in profit share. Reduced from £170k to £35k	135	135	135	135				
Procurement savings								
Annual savings relating to various projects	1000	1000	1000	1000	1000			

a. Charging for medical devices regulation

6.3 The Agency already covers 85% of costs through fees. It plans to introduce charges to meet the costs of regulating medical devices, which would take fee recovery to 90% of costs. The exact timing of this move remains uncertain and the proposal is the subject of discussion with industry representatives, HM Treasury and other stakeholders. The most likely approach is to apply a charge based on turnover on all medical devices sold in the UK.

6.4 This move would align the costs of the regulatory activity with the supply of the regulated devices and is consistent with the principle that the beneficiary meets the costs. A number of other countries (e.g., USA, Ireland, Italy) have introduced, or are planning to introduce, similar charges. The charging framework likely to be applied by the MHRA seems to be the most common approach but a lack of international consistency is a concern for the industry (this was an issue raised by interested parties during stakeholder engagement) and a combination of the direct costs of these charges, plus the additional administrative burden imposed, could potentially make the UK less attractive to industry if not carefully managed. An agreed and standardised approach across Europe, and beyond, to any such charging regime would be more effective and the Agency should seek to push this at the European level.

> **Recommendation 15**: that the Agency works with international partners to seek a common approach to the way in which any fees for the regulation of medical devices are applied.

6.5 Despite this potential concern, the proposed change would reduce the need for public funding of a regulatory activity and would link income to the increasing workload on the devices side. This would give the Agency greater funding certainty to provide the range of experience and expertise that is needed on the medical devices side.

b. Workforce

6.6 The Agency employs around 1,200 staff, with around 900 working on the regulatory side. The link between workload and funding that is provided by the fee regime has allowed the Agency to grow quite significantly at a time when some other European regulators were constrained by budget cuts. This reflected the large share of European regulatory work undertaken by the Agency. This is now expected to reduce gradually and the Agency has plans to reduce staff levels accordingly.

6.7 A reduction in public funding provided on the devices side, of 27% over three years to 2013-14, was managed through merging various devices divisions together to maximise efficiencies and reducing staff levels by 21 posts. This saved around £1m per annum by 2013-14. There was an additional reduction of 50 posts on the regulatory side in 2011-12 that reflected a decline in remunerated licensing activity. This saved a further £2m per annum.

6.8 Further falls in licensing activity are expected and the Agency plans to reduce the regulatory side by a further 125 posts over three years from 2014-15. This will save an additional £6m per annum by 2016-17.

6.9 The Agency has demonstrated flexibility in responding to changing demands. It also needs to ensure that it has staff with the right skills and experience and this was addressed in Section 5 above. This is particularly challenging where new technologies, such as digital and software, are being utilised with medicines and medical devices.

c. Technology infrastructure and digital processes

6.10 There are two main areas through which the Agency engages with relatively large numbers of stakeholders:

- Licensing of medicines: where pharmaceutical companies submit or update applications or seek information on progress.
- Monitoring safety of medicines and devices: the reporting of adverse drug reactions, usually through the Yellow Card Scheme, or adverse incident with medical devices.

6.11 Table 8 below provides details of the number and type of Agency transactions being recorded online by the Government Digital Service.

Table 8: MHRA Online Transactions

MHRA Online Transactions Data[14]	
Transactional service	**Transactions per year**
Adverse Drug Reactions (including Yellow Card scheme) reporting	57,962
Advisory Committee on Borderline Substances: certificate request form	120
Counterfeit medicines reporting	104
Defective Medicines Reporting Centre	1,800
Devices Adverse incident reporting	14,255
IRIS: payments for medicines licences	5,603
Medicines offences reporting	3,254
MHRA licences: cancellations	1,446
MHRA licences: change of ownership	603
MHRA licences: information update	7,790
MHRA licences: initial applications	1,573
MHRA licences: labels and leaflets	1,517
MHRA licences: product safety updates	1,364
MHRA licences: renewals	1,512
MHRA licences: variations	22,736
Serious Adverse Blood Reactions & Events (SABRE) reporting	1,316
Total number of transactions	**122,955**

[14] As recorded by the Government Digital Service: https://www.gov.uk/performance/transactions-explorer/department/dh/by-agency/ascending#transactions-table

6.12 The Agency has an IT system, known as Sentinel, that supports these digital processes. The system was criticised by a number of stakeholders for lacking any facility to monitor progress of licence applications or the actions being taken as a result of adverse reports on medicines or devices. The Agency is in the process of planning for the replacement of this system. This replacement will be phased and is expected to be completed over the next five years. (The replacement of the IT system, and the need to ensure it meets the needs of end users, is also addressed in Section 5 above (paragraph 5.57 and recommendation 13).)

6.13 The process for planning and implementing the replacement is being agreed with the Government Digital Service and complies with their requirements. The expectation is that the replacement will use cloud-based systems and will be designed around the needs of end-users; and tested with them before being implemented.

6.14 The current IT system is managed by Accenture under a contract costing around £8m per annum (see Section e. below). This contract ends in 2020. The Agency has been negotiating with Accenture to reduce the cost of the service and to ensure a smooth phased transition to the new services. Savings of around £750,000 per annum are expected from 2014-15. The replacement is not expected to be serviced by one large supplier but rather through a series of smaller contracts, supported by increased capacity and capability within the Agency.

6.15 The Agency expects cost savings, as well as performance improvements, from this replacement system but has not yet estimated the expected benefits. This should be undertaken and agreed with the Department at the earliest opportunity. In addition, the Agency should work with the Commercial Director in the Department and the Crown Representative covering Accenture within Cabinet Office to further support contract negotiations with Accenture.

Recommendation 16: that the Agency agrees with the Department the estimated cost savings and performance benefits to be delivered from the replacement to the current IT system.

Recommendation 17: that the Agency works with the Commercial Director in the Department of Health and the Crown Representative in the Cabinet Office to support negotiations with Accenture.

6.16 The Agency also uses the IT system to provide a function for the Danish regulatory agency, for which a fee is charged. Once the system is replaced the Agency believes there may be scope to extend this service to other countries also. This will be considered as part of the development process and such a service function may be outsourced to an external provider.

6.17 Finally, the IT system also supports online reporting of problems associated with medicines or medical devices. This includes side effects, poor quality or

counterfeit or fake medicines. This is available from the Agency's pages on gov.uk and is a very clear process that clinicians and members of the public can all use.

6.18 The Agency could go further by providing other digital processes for reporting incidents. The report into MHRA access to clinical advice and engagement with the clinical community in relation to medical devices by Professor Terence Stephenson[15] recommended a 'one-click' reporting system using an MHRA app to use with smartphones, tablets and PCs. Professor Stephenson's report noted the need to reduce the mandatory questions to a minimum (the event, the device (or medicine) and the reporters contact details), which would further encourage higher levels of reporting. The same issues as were picked up by Professor Stephenson in relation to devices apply equally to reports of adverse incidents with medicines. The Agency accepted the recommendation in the Stephenson report and therefore no further recommendations are made here.

d. Property

6.19 The Agency's headquarters is in central London (151 Buckingham Palace Road). This accommodation is sub-let from the Department for Business, Innovation and Skills (BIS) and this supports the public sector getting best value out of its leased estate and was agreed through the Government Property Unit. The lease runs through to April 2021. The Agency is in the early stages of producing options for accommodations once the lease expires.

6.20 During the course of the review the Agency moved from three to two floors. The vacated floor is being leased by another public body. This will reduce Agency costs by £3-4m per annum from 2015-16.

6.21 Most Agency staff desk share at a ratio of 70% desks to staff in post. Following the move to two floor occupancy the space per person in the headquarters will be down to 6.3sq metres.

6.22 The Agency has generated other accommodation savings over the last year or so: £200,000 per annum from taking up a break clause from offices in Welwyn Garden City; £36,000 per annum from moving to smaller offices in York; and £236,000 from the sale of the lease of a property in Blackpool.

6.23 The NIBSC has a large property in South Mimms. This has specialist laboratory facilities and it would not be cost-effective to leave this site and replicate the facilities elsewhere. Although the site could potentially accommodate other parts of the Agency the public transport links are limited and make access very difficult by anything other than car.

e. Contract management

6.24 Table 9 below provides details of the Agency's largest commercial contracts.

[15] Expert Clinical Advice – MHRA Medical Devices, 2013, Professor Terence Stephenson

Table 9: Largest MHRA contracts

Description	Start-End Date	Average Annual Value	Current Supplier
ICT - Specialist Applications - Sentinel	2002-2020	£8,000,000	Accenture
CPRD requirement - Trial Vis	2012-n/k	£4,630,000	Dataline
Property - BPR sub lease - Rent	2013-2016	£3,804,571	Department for Business, Innovation & Skills (BIS)
Property - BPR sub lease - Service Charge	2013-2016	£3,155,936	Department for Business, Innovation & Skills (BIS)
ICT - Infrastructure Operations BPR	2002-2015	£3,000,000	Accenture
Scientific - Physico Chemical Analytical Services	2002-2021	£2,997,537	LGC Limited
Printing of the British Pharmacopoeia	2012-2017	£1,000,000	TSO
ICT - Specialist IT Service Tower	2014-2016	£875,000	Redrock Consulting Ltd
NIBSC Estates - BSD Roof Voids	2014-2015	£770,175	Commercial Services UK Ltd
Travel Management Services	2012-2016	£749,487	Hogg Robinson
Contingent Labour – Admin and Clerical	2013-2016	£448,000	Brookstreet

6.25 The largest contracts relate to IT and property and have been covered in Sections c. and d. above. It is noticeable that these larger infrastructure contracts have been awarded for long periods and therefore run a risk of the Agency being tied into services that are no longer suitable or provide poor value for money. This is an issue that is being addressed by procurement staff and the Information Management Division in relation to the IT replacement programme. These longer contracts are all over 10 years old and the table shows that recent ones have been agreed for between 2-5 years in length.

6.26 The publishing and laboratory contracts were also considered as part of the BPC Triennial Review. The printing contract with TSO runs to 2016-17 (it will complete with the publication of the British Pharmacopoeia 2017 in August 2016) and getting best value out of the new contract will require the Agency to generate competitive interest in the contract. In addition, the alternative option of producing the digital publication element in-house needs to be carefully assessed. The BPC report covers these issues and the Agency will need to work with the BPC to implement them effectively.

6.27 The laboratory contract provides services for both the MHRA and the BPC. This contract includes a profit-sharing clause and the increasing amount of work, in particular the production and sale of monograph samples from the British Pharmacopoeia, has meant that the contractor has benefitted unexpectedly. This

has been renegotiated and savings of £135,000 per annum are expected from 2014-15 for the remainder of the contract.

f. Procurement

6.28 The Agency is not a large purchaser of common goods and services. It uses the Crown Commercial Service for certain purchases. In total, procurement savings of £1m per annum are expected to be delivered from 2013-14 onwards. In the year 2013-14, the first year for the Agency's new Procurement Department, the agency ran 57 Invitations to Tender (ITTs) of various categories. In 2014-15 this rose to 96 ITTs.

g. Shared services

6.29 During evaluation of ISSC1 in 2014, the business case for the Department and its ALBs to collectively move to ISSC1 was considered not viable. The Department wrote to ALBs informing them of this, reminding them that they could consider joining ISSC1 independently and also restating the expectation that all organisations needed to plan to deliver year on year efficiencies in their back office functions, so they should continue to explore all options available.

6.30 The Department is currently reviewing its options with respect to ISSC2, looking at the delivery of its own functions. At present, the scope of the project only includes the Department itself and not its arms-length bodies. However, where it identifies possible opportunities to align requirements or assess functionality in conjunction with ALBs these will explored.

6.31 The Agency is supportive of sharing services where this reduces costs and where the quality of service provision is appropriate. Poor levels of service would undermine the Agency's reputation, and therefore its future income streams also.

6.32 Also the Agency's main income streams from the licensing of medicines require applicants to pay on application rather than on invoice. This has the advantage of removing the risk of a customer failing to pay and gives the Agency a working capital advantage that it should retain. However, this means that the Agency, as a government trading fund, has a non-standard operating model for its income. The National Audit Office, in a report on the Next Generation Shared Services strategy[16], recommends that implementing standard operating models is necessary for the Government's shared services programme to realise the expected benefits.

6.33 The other issue impacting on the Agency's ability to move to a shared service is that its existing Oracle Enterprise Resource Planning (ERP) platform is out of support from the end of 2015 so the Agency needs to move swiftly to ensure that its income streams can continue to be collected without relying on an out of support system.

[16] http://www.nao.org.uk/wp-content/uploads/2014/03/Update-on-the-next-generation-shared-services-strategy.pdf

6.34 In order to address these issues the Agency is proposing to move to a cloud-based 'Software as a Service' (SaaS) solution, at a lower cost than a full implementation of a replacement ERP platform. It is currently developing its proposals for a SaaS facility with the Department. It is planned that this will be a shared provision, depending on its uptake by other organisations.

Recommendation 18: that, where it makes business sense to do so, the Agency develops proposals for a move to shared services provision that are agreed with the Department.

7. Governance

a. Principles of good corporate governance in ALBs

7.1 Every arm's length body needs clear arrangements for overseeing its strategic direction, performance monitoring and review. The variety of organisations means that one solution will not fit all and departments, in discussion with the arm's length body, are able to decide on the precise structure of governance arrangements as long as the key principles are met. Such arrangements are then normally outlined in the Framework Agreement.

7.2 A recent report by the House of Commons, Public Administration Select Committee[17] noted the increase in Cabinet Office's interest in public bodies, and the exercise of oversight and control by sponsor departments. The Committee emphasised the need for "*a clear understanding of statuses, roles and relationships*"[18].

7.3 The increasing challenges faced by the MHRA – from competition for licensing fees from other European regulators, the need to adapt to rapidly changing technologies, working across the health system to support innovation – require a clear and robust internal governance framework. The board and senior management will need to develop effective strategies, and the Department will need to engage with the Agency to provide support, as well as to offer challenge and ensure accountability arrangements are in place.

7.4 Cabinet Office guidance states that Triennial Reviews must assess the controls, processes and safeguards in place against the principles and supporting provisions set out in the Code of Good Corporate Governance. The Cabinet Office publishes a range of guidance on governance issues for public bodies[19].

7.5 The full assessment for each principle is detailed in tabular form in Annex F. It is based on a self-assessment by the Agency but also reflects analysis of the review team. Non-compliance is acceptable where this is justified by the particular circumstances and where appropriate alternative arrangements are in place.

7.6 Overall the Agency is fully compliant with all of the principles other than in relation to the role of the board. The sections below highlight particular issues in relation to the various principles and make a number of recommendations.

b. Accountability

7.7 The Agency complies with the principles.

---

[17] *Who's accountable? Relationships between Government and arm's-length bodies* - House of Commons, Public Administration Select Committee, First Report of Session 2014–15

[18] Ibid.

[19] www.gov.uk/government/publications/public-bodies-information-and-guidance

7.8 It complies with all statutory accountability requirements but the regulatory framework around which medicines licence fees are set is complicated (particularly the split between national and European licences) and Section 2 of this report, covering financial issues, makes a number of recommendations aimed at ensuring that regulatory fees are more transparently aligned to the principles and policies.

7.9 In its recent report on the accountability of public bodies[20], the Public Administration Select Committee stated that 'However complicated the arrangements may have to be, there is no excuse for lack of a clear understanding of statuses, roles and relationships'. The lines of accountability for an organisation such as the MHRA – operating as an Executive Agency with a policy function, as a regulator and as a Trading Fund – will inevitably be complicated but this makes it all the more important that they are clearly set out and agreed.

7.10 The principle applies[21] that the Secretary of State is responsible for the policy framework in which an Executive Agency operates. As such, agency Chief Executives have direct accountability to Ministers. However, it is also common for the Chief Executive to be accountable for performance to the Permanent Secretary of the Department (the review team looked at a number of Executive Agency accountability arrangements and found this to apply quite commonly, Public Health England and the National Offender Management Service being two examples). Further, the Chief Executive is formally appointed as the Accounting Officer for the agency. This appointment is normally made by the Permanent Secretary but for a Trading Fund the Treasury makes the appointment. As an Accounting Officer the Chief Executive is accountable for the use of public funds and financial management in the agency, and will have responsibilities direct to Parliament, to Ministers and to the Principal Accounting Officer (the Permanent Secretary).

7.11 The direct line of accountability between an agency Chief Executive and Ministers does not prevent the Chief Executive from being accountable to the Permanent Secretary for performance and financial management. Chief Executives should have a right of access to the Minister but face-to-face meetings are not necessarily expected more than one a year.

7.12 The Secretary of State appoints the Agency Chair and all other non-executive board members. The relevant departmental minister holds an annual accountability meeting with the Chair to review the performance and strategic development of the Agency. The Minister also approves a five-year corporate plan that sets out the Agency's longer-term aims and objectives.

7.13 The Permanent Secretary has appointed a Senior Departmental Sponsor (SDS, at Director General level) to provide regular senior level contact between the Department and the Agency. In this role the SDS supports the Permanent

[20] Who's accountable? Relationships between Government and arm's-length bodies - House of Commons Public Administration Select Committee - First Report of Session 2014–15
[21] Executive Agencies: A Guide for Departments – Cabinet Office

Secretary in holding the Agency to account and providing assurance on performance. The SDS has quarterly accountability meetings with the Chief Executive and is responsible for agreeing an annual business plan with the Agency.

7.14 The SDS uses the quarterly accountability meetings to assess performance and can escalate any concerns to the Permanent Secretary if necessary. Were the Agency to fail to comply with any requirement to address performance issues the Secretary of State would be able to make arrangements for another body to exercise the functions on his behalf.

7.15 The various senior roles and responsibilities are set out in a draft Framework Agreement between the Agency and the Department. This document needs to be finalised as soon as possible to provide absolute clarity on relationships and accountabilities.

c. Role of sponsor department

7.16 The Agency complies with the principles.

7.17 As mentioned above, there is a Senior Departmental Sponsor who meets the Chief Executive on a regular basis. There is also a sponsor team within the Department that has regular contact with the Agency. A departmental sponsor normally attends Agency board meeting as an observer.

7.18 The Agency is foremost a successful regulatory body. However, it also has a policy role and the demands placed upon it by the Department are growing. Not least, the Department is increasingly looking to the Agency to take a leading role in supporting innovation and patient access to new medicines. The Agency is well placed to provide this support (as has been discussed in Section 5) but this will be best achieved where there is close communication with the Department. As well as the Agency responding to the priorities of the Department, the role of the sponsor team is pivotal in ensuring that the Department understands what it is possible for the Agency to achieve and the competing priorities that need to be balanced.

7.19 The sponsor team moved within the Department during 2014 and the current team also have responsibility for NICE. At SDS level responsibility extends to the innovation and growth agenda. This suggests that the Department should be well placed to support the Agency in making the necessary links across other parts of the health and care system and in developing a long-term strategic approach. The relationship between the Department and the Agency could be further strengthened by developing ties at various levels. For example, consideration might be given to short-term secondments or job swaps.

Recommendation 19: that the Department and the Agency look for opportunities to further develop bi-lateral communications and contacts that support a common understanding to take forward key priorities, as well as partnership working across the health and social care network.

7.20 A Framework Agreement between the Department and the Agency is currently in draft. This sets out clear accountability arrangements and the roles and responsibilities of senior parties in both organisations. The current draft should be amended to reflect agreed recommendations in this report and should then be finalised as a priority.

Recommendation 20: that the Department and the Agency update the current draft Framework Agreement, reflecting issues covered in this report, and publish the agreed version as a priority.

d. Role of the Board, Chair and Non-Executive Board Members

7.21 The Agency is mostly compliant with these principles.

7.22 The Chair is a non-executive member. He is appointed by, and responsible to, the Secretary of State. He can provide advice directly to the Secretary of State and meets with the responsible DH Minister at least once a year.

7.23 The Agency Board is made up entirely of non-executive members. There can be up to 12 members, including the Chair, although there are currently eight. The Chief Executive, Chief Operating Officer, Director of Policy and Director of Communications attend board meetings as observers. However, other Agency executives, or other staff, may also be invited to attend board meetings, as appropriate to the agenda.

7.24 The board met ten times during 2013-14. The responsibilities of the board are clearly set out (for example, in the annual report and accounts, and in the draft Framework Agreement) and centre upon agreeing the strategic aims and objectives of the Agency.

7.25 In addition to the board, the Agency has a Corporate Executive Team (CET) which is chaired by the Chief Executive and is made up of Directors from across the Agency, along with a representative from the Department of Health Legal Services. It has 12 members. It is the CET that is the decision-making body within the Agency, with the board providing advice, oversight and challenge.

7.26 The current board structure is unusual and does not reflect guidance from HM Treasury and Cabinet Office regarding governance of public bodies. Although the current structure works reasonably well, a board that consisted of a mix of executive and non-executive board members ought to bring a balance that would leave the board better placed to provide scrutiny, oversight and challenge. Although most stakeholders had no views on the governance structure of the Agency, those who did offer opinions were generally supportive of the need to maximise the value of the non-executives. Some stakeholders suggested that the board saw things too late in the process, making it difficult to influence or challenge decisions.

7.27 The increasing demands being faced by the Agency create both challenges and opportunities. Meeting these effectively requires a board that is dynamic and

forward-looking. The board needs to be well placed to take a broad and long-term view, setting the strategy for the Agency going forward. This includes the need to drive engagement with other organisations across the health and care system, and beyond; ensuring that the expertise within the agency is fully utilised to address challenges.

7.28 The board would be better placed to do this under a unitary structure that ensured the non-executives were at the heart of the process; including continuing to chair the board.

7.29 As mentioned earlier in the report, there are several other public bodies that are both Executive Agencies and Trading Funds. These bodies operate with a unitary board structure, for example:

- Driver and Vehicle Standards Agency – a 'directing board' meets monthly and is made up of the Chief Executive, the five directors from the agency and three non-executive directors.

- FCO Services – the board meets bi-monthly and is chaired by a non-executive director. It has a minimum of a further two non-executive directors (one acting as Chair of the Audit Committee), the Chief Executive and all executive directors. According to the 2013-14 annual report and accounts the board has 14 members in total.

7.30 The specialist scientific nature of the Agency's work is reflected in the knowledge and expertise brought by board members. This does possibly impact on the diversity of the board as it limits the field from which non-executives can be found. There are currently two women and six men on the board. It would not be possible, or necessary, for the board to directly reflect the full range of expertise and stakeholder interests through board membership. The board should instead contain non-executive members who bring a range of knowledge and experiences. Most specifically, non-executives should bring a wider perspective and the ability to provide effective strategic challenge and support. A board with a range of diverse skills and experiences is more likely to offer innovative ideas and solutions. It should not be necessary for all non-executive board members to come from a medical scientific background; commercial or other skills are equally valuable and the Agency will particularly want non-executives who are able to contribute to the development of robust strategic plans within a fast-moving environment.

7.31 A departmental sponsor attends board meetings as an observer. The Agency and the Department should consider whether it would be beneficial to have a departmental representative on the board as a member. This could inform discussion and strengthen relations with the Department.

Recommendation 21: that the Agency moves to a unitary board structure. The details, including size of the board and the range of experiences sought from non-executive members, should be agreed between the Agency and the Department.

e. Effective Financial Management

7.32 The Agency complies with the principles.

f. Communications

7.33 The Agency complies with the principles.

7.34 Minutes of board meetings are published, though some material is considered inappropriate for publication (for example, that which is commercially sensitive) and is redacted from the minutes. The Agency does not currently hold open board meetings but is considering the possibilities. The nature of board discussions might mean that only a part of a meeting could be open, or that the agenda for that particular meeting would have to deal only with issues that could be made public.

7.35 The Agency publishes all Government Procurement Card payments over £500, but for general supplier payments has adopted a threshold of £25,000. It feels that this is more transparent than providing a large volume of data on smaller transactions.

g. Conduct and behaviour

7.36 The Agency complies with the principles.

h. Summary of proposed governance changes

7.37 The governance processes for the Agency need to reflect and support its objectives and responsibilities. The recommendations above are intended to help deliver this outcome. The Agency requires clear accountability arrangements, open and transparent communications with the Department and a board structure that supports strategic development.

7.38 The arrangements are not always simple, which reflects the complexity of the functions and accountabilities that necessarily apply. Much of the detail will remain to be set out in the Framework agreement between the Agency and the Department.

7.39 These recommendations would see the Agency led by a unitary board that is established to set the strategic direction for the Agency and to develop its role as a key player not just in the area of medicines regulation but also in leading engagement with other parties across the health and care system. The board should be chaired, as it is now, by a non-executive who has direct access to Ministers when necessary. The Chief Executive should also have access to, and be accountable to, Ministers when necessary but in practice this accountability for performance and financial management should normally operate through the Permanent Secretary. This needs to be underpinned by effective engagement and cooperation between the Agency and the Department. This requires more

than engagement between senior management in the Agency and the Senior Departmental Sponsor. Both parties should seek to build more links to support a mutual understanding of what can be achieved and ensure that there is appropriate involvement in decision-making processes. This is particularly necessary where the Agency is taking forward medicines policy on behalf of the Department.

8. Annexes

Annex A – Membership of the Review Team, Project Board and Challenge Group

a. Review Team

Senior Review Sponsor	Flora Goldhill	Director, Children, Families & Communities
Lead Reviewer	David Dipple	
Assistant Reviewer	Jamie Grant	
Volunteer Reviewer	Wayne Sumner	Ebola Response Team and Organisational Design Lead

b. Project Board

Chair	Flora Goldhill	Senior Review Sponsor (Director, Children, Families & Communities)
Member	Peter Commins	MHRA, Chief Operating Officer
Member	Jonathan Mogford	MHRA, Director of Policy
Member	Claire Armstrong	DH Sponsor Team
Member	David Dipple	Lead Reviewer
Secretariat	Jamie Grant	Assistant Reviewer

c. Challenge Group

Chair	Catherine Bell	DH, Non-Executive Director
Member	Flora Goldhill	Senior Review Sponsor (Director, Children, Families & Communities)
Member	Jon Rouse	Director General
Member	John Jeans	No. 10 Advisor on Life Sciences
Member	Anita Donley	Clinical Vice President, Royal College of Physicians
Member	Oli Blackaby	Cabinet Office, Crown Commercial Lead
Member	Dr Nisha de Silva	Cabinet Office
Secretariat	David Dipple	Lead Reviewer

Annex B – Terms of Reference

Stage One

Stage one of the review will verify the functions of the MHRA, assess how the functions contribute to the core business of the health and care system, and consider whether they are still needed.

Within this context, the review will consider:

i. Whether delivery of the functions continues to contribute to wider government policy and constitutes a justifiable use of public money;

ii. Whether there is a demand for the function or activity from users;

iii. The cost and effects of not delivering the function;

iv. How the EU legal requirements for health (drug and product) licensing link to the core legal requirements for a licensing function; and whether/where MHRA goes beyond that core legal requirement.

Where it is concluded that a function is still needed, Stage One will go on to examine how this function might best be delivered. The review will first examine whether the function would be better delivered by any of the following delivery models:

i. To be delivered by the private sector, the voluntary and community sector, under contract by the private or community sector, or as a mutual, Community Interest Company, or social enterprise;

ii. Merged with another body, either another area of central government or another public body;

iii. Remain as an Executive Agency/Trading Fund.

Stage Two

If the outcome of Stage one is that the MRHA should retain its current status, Stage Two will go on to review its control, governance and efficiency. The review will adopt a ‘comply or explain’ approach to examine whether the MHRA is operating within the recognised principles of good corporate governance in relation to its accountability arrangements, roles and responsibilities, financial management, communications, and behavioural conduct. The review will also consider whether there is adequate capability within the organisation.

Effectiveness and Efficiency (Stages One and Two)

Stage One will need to consider how the current delivery model contributes to the effectiveness and efficiency of the MHRA, and whether this might be improved through another delivery model.

Stage Two will also consider the structure, capability, efficiency and effectiveness of the organisation as part of the assessment of how well the MHRA operates under its current control and governance arrangements. Within this context, the review will consider the following key lines of enquiry:

i. Whether the MHRA makes the best use of public money and maximises commercial revenues (where appropriate and possible);

ii. Whether internal processes are sufficiently lean;

iii. Whether there is any scope for and/or benefit to the sharing of non-core functions, including finance, legal, HR, and communications;

iv. The assets held and how effectively they are used;

v. Whether the process for considering approvals applications for medicines and healthcare products is efficient, making use of, for example, digital processes where possible;

vi. How well the MHRA has assimilated the various elements with which it has merged over recent years (e.g., The National Institute for Biological Standards and Control) ;

vii. The MHRA's capacity and capability to respond effectively to changing demands or a changing regulatory environment, including:

    a. Depth and resilience of the MHRA Senior Leadership Team;
    b. Capability of MHRA to work collaboratively with partners in the health and social care system;
    c. MHRA's ability to fulfil its role in the light of rapid changes taking place in technology, affecting medicines, devices and diagnostics;
    d. MHRA's capabilities and record in negotiating and influencing in the EU on behalf of the UK government;
    e. Commercial and market understanding of the organisations they regulate and the instruments they use.

viii. The balance between risk and benefit in the decision-making process.

Annex C – Written Ministerial Statement announcing review

DEPARTMENT OF HEALTH

Triennial Reviews of Non- Departmental Public Bodies

Thursday 30 October 2014

The Parliamentary Under Secretary of State, Department of Health (George Freeman): I am today announcing the start of the triennial reviews of the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare Products Regulatory Agency (MHRA), the British Pharmacopoeia Commission (BPC), the Commission on Human Medicines (CHM), the Administration of Radioactive Substances Advisory Committee (ARSAC) and the Independent Reconfiguration Panel (IRP).

All Government Departments are required to review their non-Departmental public bodies (NDPBs) at least once every three years. Due to the wide ranging reforms made by the Health and Social Care Act 2012, the Department was exempt from the first round of reviews in 2011-14. In order to ensure that the Department is an effective system steward and can be assured of all the bodies it is responsible for, we have extended the programme of reviews over the next three years to all of its arm's length bodies and executive agencies.

The reviews of the aforementioned bodies have been selected to commence during the first year of the programme (2014-15). The reviews will be conducted in two stages. The first stage will examine the continuing need for the function and whether the organisation's form, including operating at arm's length from government, remains appropriate. If the outcome of this stage is that delivery should continue, the second stage of the review will assess whether the bodies are operating efficiently and in line with the recognised principles of good corporate governance.

Annex D – Stakeholder engagement

The review team published an online call for evidence that was made available on the Department of Health pages on Gov.Uk and was publicised on the MHRA website also. In addition, the team emailed a wide range of stakeholders to inform them of this process and encourage wider dissemination.

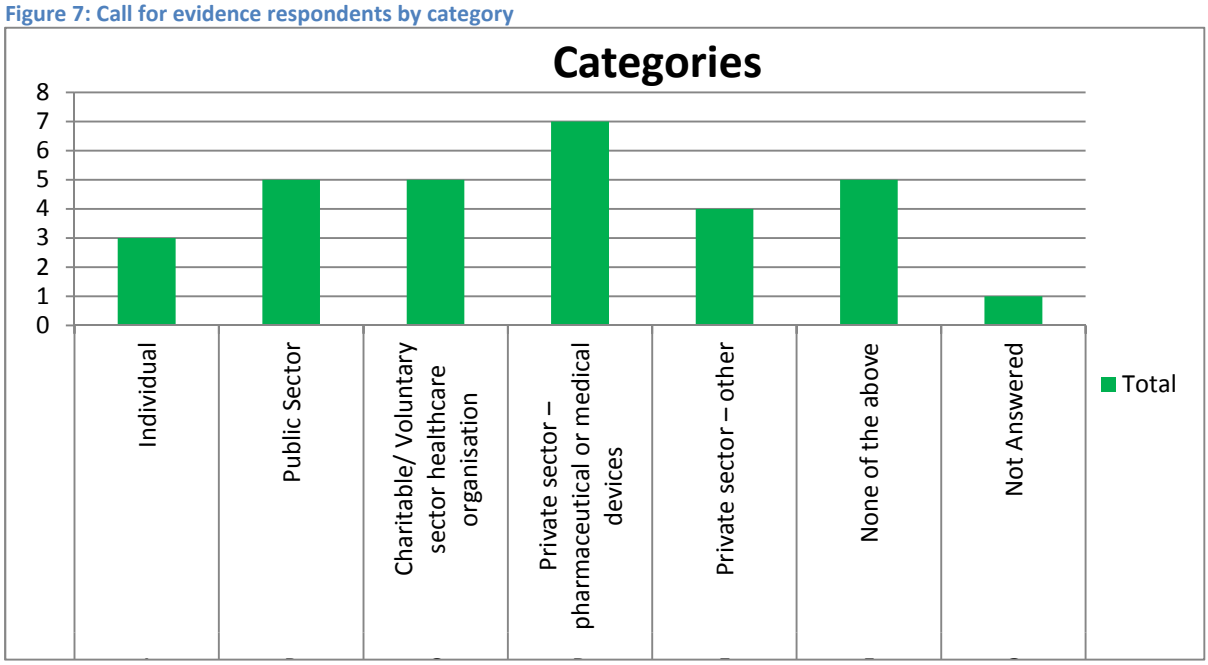
The call for evidence opened on 1 December 2014 and ran until 9 January 2015. The respondents are listed below.

Call for Evidence Respondents

1 NHS Blood and Transplant
2 Association of the British Pharmaceutical Industry
3 Quotient Clinical Ltd
4 Royal Pharmaceutical Society
5 The Proprietary Association of Great Britain
6 Mobile Data Association
7 Digital Health & Care Alliance
8 Royal College of Pathologists
9 Royal Academy of Engineering
10 Breast Cancer Campaign
11 Medical Research Council
12 Cancer Research UK
13 Human Tissue Authority
14 Neonatal and Paediatric Pharmacists Group
15 NHS Pharmaceutical Quality Assurance
16 Academy of Medical Sciences
17 Teva UK
18 BioIndustry Association
19 East Sussex Healthcare NHS Trust
20 ORION Clinical Services
21 University of Liverpool & Alder Hey Children's Hospital
22 British Specialist Nutrition Association Ltd
23 SEPT
24 British Association of Pharmaceutical Wholesalers
25 British Dental Industry Association
26 Dr Reddy's Laboratories (UK) Ltd
27 British Generic Manufacturers Association
28 Association of the British Healthcare Industries
29 Royal College of Anaesthetists
30 NHS National Services Scotland

Figure 7 below provides a breakdown of respondents self-classification of the various sectors represented.

Figure 7: Call for evidence respondents by category



Nearly half of the respondents to the call for evidence indicated that they were representing views of a wider membership. The review team took this into account but did not attempt to formally weight responses in any way.

The review team also offered three sessions where interested stakeholders could book places. These were held on 11 December 2014, 5 January 2015 and 7 January 2015. The attendees were:

Attendees at workshops

1. Proprietary Association of Great Britain
2. Roche
3. Prostate Cancer UK
4. The BioIndustry Association
5. Gloria Nneoma Onwuneme
6. Proprietary Association of Great Britain
7. Eisai
8. Association of British Healthcare Industries
9. Association of the British Pharmaceutical Industry

In addition, the review team conducted interviews with a range of stakeholders as set out below:

Interviews Conducted

Department of Health

1. DH Minister for Life Sciences
2. DH Permanent Secretary
3. Director General for Innovation, Growth & Technology
4. Director General for Public Health
5. Chief Medical Officer
6. Chief Pharmaceutical Officer for England
8. DH Sponsor Team
9. DH Appointments Team

MHRA

10. Chair – Professor Sir Michael Rawlins
11. Chief Executive – Dr Ian Hudson
12. Non-Executive Director – Vincent Lawton
13. Non-Executive Director – Deborah Oakley
14. Director of the National Institute for Biological Standards and Control – Stephen Inglis
15. Chief Information Officer – John Quinn
16. Devices Director – John Wilkinson
17. Licensing Director – Dr Siu Ping Lam
18. Communications Director – Rachel Bosworth
19. Chief Operating Officer – Peter Commins
20. Director of Policy – Jonathan Mogford
21. Director of Vigilance and Risk Management of Medicines – Dr June Rain
22. Non-Executive Director – Professor Sir Alex Markham
23. Non-Executive Director – Gerald Heddell

Other public and private sector

24. Office of Life Sciences – Advisor
25. Office of Life Sciences – Director
26. NHS England – National Medical Director
27. NICE – CEO
28. Association of British Healthcare Industries
29. The BioIndustry Association
30. Association of Medical Research Charities
31. NHS Blood and Transplant
32. Healthcare Improvement Scotland / Scottish Intercollegiate Guidelines Network
33. Cure Parkinsons

International organisations

34. UKREP – First Secretary, Health & Pharmaceuticals
35. European Medicines Agency

36. Health Products Regulatory Authority (Ireland)
37. Paul Ehrlich Institut (Germany)
38. The Medicines Evaluation Board (Netherlands)
39. US Food and Drug Administration

Annex E – Other sources of evidence

The review team referred to a range of published documents as part of the evidence gathering process, the key documents are listed below:

Published sources of information and evidence	
1.	*MHRA Annual Report and Accounts 2013-14* (https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2013-to-2014)
2.	*MHRA Corporate Plan 2013-18* (https://www.gov.uk/government/publications/mhra-corporate-plan-2013-to-2018)
3.	MHRA board papers and minutes
4.	MHRA draft Framework Agreement
5.	*Medicines and Medical Devices Regulation: What you need to know* – MHRA (http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf)
6.	*Managing Public Money* – HM Treasury (https://www.gov.uk/government/publications/managing-public-money)
7.	*Who's accountable? Relationships between Government and arm's-length bodies* - House of Commons, Public Administration Select Committee, First Report of Session 2014–15 (http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/110/110.pdf)
8.	*Corporate governance in central government departments* – HM Treasury & Cabinet Office (https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments)
9.	Executive Agencies: A Guide for Departments (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/80076/exec_agencies_guidance_oct06_0.pdf)
10.	*Review of the MHRA* - Adrian Sieff, 2009
11.	*Expert Clinical Advice – MHRA Medical Devices* – Professor Terence Stephenson, 2013
12.	Digital Agenda for Europe (mHealth in Europe: Preparing the ground) – consultation results – European Commission (https://ec.europa.eu/digital-agenda/en/news/mhealth-europe-preparing-ground-consultation-results-published-today)
13.	US Food and Drug Administration - Expedited Drug Approval Programs, Draft Guidance on Programs: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf
14.	US Food and Drug Administration - Patient involvement guidance: FDA web pages for patients (http://www.fda.gov/ForPatients/default.htm) and Patients on Advisory Committees (http://www.fda.gov/ForPatients/About/ucm412709.htm).
15.	A summary of the evidence on the benefits and risks of vaginal mesh implants – MHRA (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf)

16.	Medical device stand-alone software including apps – MHRA guidance, October 2014 (https://www.gov.uk/government/publications/medical-devices-software-applications-apps/medical-device-stand-alone-software-including-apps)
17.	Borderlines with medical devices – MHRA guidance, February 2014 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284505/Borderlines_with_medical_devices.pdf)
18.	An Informed Dialogue Supporting Safe Innovation In Medical Technology – Christopher Hodges and Sonia Macleod, European Civil Justice Systems, 2014.
19.	Trends in UK spontaneous Adverse Drug Reaction (ADR) reporting between 2008 – 2012 – MHRA (http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con408250.pdf)
20.	Access to clinical trial information and the stockpiling of Tamiflu, Thirty-fifth report of session 2013-14, House of Commons Committee of Public Accounts, December 2013.

Annex F – Compliance with principles of good corporate governance

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Accountability			
Statutory Accountability		**Compliant (Yes/No)**	**Review Findings**
Principle	***The public body complies with all applicable statutes and regulations, and other relevant statements of best practice.***		
Supporting Provisions	The public body must comply with all statutory and administrative requirements on the use of public funds. This includes the principles and policies set out in the HMT publication "Managing Public Money" and Cabinet Office/HM Treasury spending controls.	Yes	Where the Agency sets fees it does so in compliance with the rules. However, it should be noted that the Agency's licensing work is increasingly funded through the EU wide process, where fees are explicitly not cost based and are uniform across the community. This constraint is regularly explained to HMT as part of each fee setting round; nationally determined fees tend to subsidise the wider Agency role in Europe, particularly those areas of work which are unremunerated.
	The public body must operate within the limits of its statutory authority and in accordance with any delegated authorities agreed with the sponsoring department.	Yes	
	The public body should operate in line with the statutory requirements and spirit of the Freedom of Information Act 2000. It should have a comprehensive Publication Scheme. It should proactively release information that is of legitimate public interest where this is consistent with the provisions of the Act.	Yes	
	The public body must be compliant with Data Protection legislation.	Yes	
	The public body should be subject to the Public Records Acts 1958 and 1967.	Yes	

Accountability for public money		**Compliant (Yes/No)**	**Detail**
Principle	***The Accounting Officer of the public body is personally responsible and accountable to Parliament for the use of public money by the body and for the stewardship of assets***		
Supporting Provisions	There should be a formally designated Accounting Officer for the public body. This is usually the most senior official (normally the Chief Executive).	Yes	
	The role, responsibilities and accountability of the Accounting Officer should be clearly defined and understood. The Accounting Officer should have received appropriate training and induction. The public body should be compliant with the requirements set out in "Managing Public Money", relevant Dear Accounting Officer letters and other directions. In particular, the Accounting Officer of the NDPB has a responsibility to provide evidence-based assurances required by the Principal Accounting Officer (PAO). The PAO requires these to satisfy him or herself that the Accounting Office responsibilities are being appropriately discharged. This includes, without reservation, appropriate access of the PAO's internal audit service into the NDPB.	Yes	
	The public body should establish appropriate arrangements to ensure that public funds: • are properly safeguarded; • are used economically, efficiently and effectively; • are used in accordance with the statutory or other authorities that govern their use; • deliver value for money for the Exchequer as a whole.	Yes	

	The public body's annual accounts should be laid before Parliament. The Comptroller and Auditor General should be the external auditor for the body.	Yes	

Ministerial Accountability		**Compliant (Yes/No)**	**Detail**
Principle	***The Minister is ultimately accountable to Parliament and the public for the overall performance of the public body.***		
Supporting Provisions	The Minister and sponsoring department should exercise appropriate scrutiny and oversight of the public body.	Yes	
	Appointments to the board should be made in line with any statutory requirements and, where appropriate, with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The Minister will normally appoint the Chair and all non-executive board members of the public body and be able to remove individuals whose performance or conduct is unsatisfactory.	Yes	
	The Minister should be consulted on the appointment of the Chief Executive and will normally approve the terms and conditions of employment.	Yes	
	The Minister should meet the Chair and/or Chief Executive on a regular basis.	Yes	
	A range of appropriate controls and safeguards should be in place to ensure that the Minister is consulted on key issues and can be properly held to account. These will normally include: • a requirement for the public body to consult the Minister on the corporate and/or operational business plan; • a requirement for the exercise of particular functions to be subject to guidance or approval from the Minister;	Yes	The Minister agrees a five-year corporate plan and holds an annual accountability meeting. The Agency and the Department agreed that the annual business plan will be signed off at official level.

	• a general or specific power of Ministerial direction over the public body; • a requirement for the Minister to be consulted by the public body on key financial decisions. This should include proposals by the public body to: (i) acquire or dispose of land, property or other assets; (ii) form subsidiary companies or bodies corporate; and (iii) borrow money; • a power to require the production of information from the public body which is needed to answer satisfactorily for the body's affairs.		
	There should be a requirement to inform Parliament of the activities of the public body through publication of an annual report.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Roles and responsibilities			
Role of the Sponsor Department		**Compliant (Yes/No)**	**Detail**
Principle	***The departmental board ensures that there are robust governance arrangements with the board of each arm's length body. These arrangements set out the terms of their relationship and explain how they will be put in place to promote high performance and safeguard propriety and regularity.*** ***There is a sponsor team within the department that provides appropriate oversight and scrutiny of, and support and assistance to, the public body.***		
Supporting Provisions	The departmental board's regular agenda should include scrutiny of the performance of the public body. The departmental board should establish appropriate systems and processes to ensure that there are effective arrangements in place for governance, risk management and internal control in the public body.	Yes	
	There should be a Framework Document in place which sets out clearly the aims, objectives and functions of the public body and the respective roles and responsibilities of the Minister, the sponsoring department and the public body. This should follow relevant Cabinet Office and HM Treasury guidance. The Framework Document should be published. It should be accessible and understood by the sponsoring department, all board members and by the senior management team in the public body. It should be regularly reviewed and updated.	Yes	A revised framework agreement is still to be signed off. There is an existing framework document still in place in the meantime.
	There should be a dedicated sponsor team within the parent department. The role of the sponsor team should be clearly defined.	Yes	

	There should be regular and ongoing dialogue between the sponsoring department and the public body. Senior officials from the sponsoring department may as appropriate attend board and/or committee meetings. There might also be regular meetings between relevant professionals in the sponsoring department and the public body.	Yes	

Role of the Board		**Compliant (Yes/No)**	**Detail**
Principle	***The public body is led by an effective board which has collective responsibility for the overall performance and success of the body. The board provides strategic leadership, direction, support and guidance.*** ***The board – and its committees – have an appropriate balance of skills, experience, independence and knowledge.*** ***There is a clear division of roles and responsibilities between non-executive and executives. No one individual has unchallenged decision-making powers.***		
Supporting Provisions	The board of the public body should: • meet regularly; • retain effective control over the body; • effectively monitor the senior management team.	Yes	
	The size of the board should be appropriate.	Yes	
	Board members should be drawn from a wide range of diverse backgrounds.	Yes	Board diversity may require further consideration. The specialist nature of the Agency's activities may impact on flexibility. At present there is no obvious patient representation.
	The board should establish a framework of strategic control (or scheme of delegated or reserved powers). This should specify which matters are specifically reserved for the collective decision of the board. This framework must be understood by all board members and by the senior management team. It should be regularly reviewed and refreshed.	Yes	
	The Board should establish formal procedural and financial regulations to govern the conduct of its business.	Yes	
	The Board should establish appropriate arrangements to ensure that it has access to all such	Yes	

	relevant information, advice and resources as is necessary to enable it to carry out its role effectively.		
	The Board should make a senior executive responsible for ensuring that Board procedures are followed and that all applicable statutes and regulations and other relevant statements of best practice are complied with.	Yes	
	The Board should make a senior executive responsible for ensuring that appropriate advice is given to it on all financial matters.	Yes	
	The Board should establish a remuneration committee to make recommendations on the remuneration of top executives. Information on senior salaries should be published. The board should ensure that the body's rules for recruitment and management of staff provide for appointment and advancement on merit.	Yes	
	The Chief Executive should be accountable to the Board for the ultimate performance of the public body and for the implementation of the Board's policies. He or she should be responsible for the day-to-day management of the public body and should have line responsibility for all aspects of executive management.	Under active consideration	There has always been an element of dual reporting to the Chair and, as Accounting Officer, to the Permanent Secretary, but the exact nature of the accountability arrangements is currently under active consideration with the Department of Health.
	There should be an annual evaluation of the performance of the board and its committees – and of the Chair and individual board members.	Partly	There are annual appraisals of the Chair and the individual NEDs. With the recent appointment of a new Chair the Agency will put in place a mechanism for evaluation of the board as a whole, in addition to the already established appraisals of the Chair and NEDs.

Role of the Chair		**Compliant (Yes/No)**	**Detail**
Principle	***The Chair is responsible for leadership of the board and for ensuring its overall effectiveness.***		
Supporting Provisions	The board should be led by a non-executive Chair.	Yes	
	There should be a formal, rigorous and transparent process for the appointment of the Chair. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments. The Chair should have a clearly defined role in the appointment of non-executive board members.	Yes	
	The duties, role and responsibilities, terms of office and remuneration of the Chair should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The responsibilities of the Chair will normally include: • representing the public body in discussions with Ministers; • advising the sponsoring Department and Ministers about board appointments and the performance of individual non-executive board members; • ensuring that non-executive board members have a proper knowledge and understanding of their corporate role and responsibilities. The Chair should ensure that new members undergo a proper induction process and is normally responsible for undertaking an annual assessment of non-executive board members' performance; • ensuring that the board, in reaching decisions, takes proper account of guidance provided by the sponsoring department or Ministers; • ensuring that the board carries out its business efficiently and effectively;	Yes	

	• representing the views of the board to the general public; • developing an effective working relationship with the Chief Executive and other senior staff.		
	The roles of Chair and Chief Executive should be held by different individuals.	Yes	

Role of Non-Executive Board Members		Met (Yes/No)	Detail
Principle	***As part of their role, non-executive board members provide independent and constructive challenge.***		
Supporting Provisions	There should be a majority of non-executive members on the board.	Yes	
	There should be a formal, rigorous and transparent process for the appointment of non-executive members of the board. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The duties, role and responsibilities, terms of office and remuneration of non-executive board members should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The corporate responsibilities of non-executive board members (including the Chair) will normally include: • establishing the strategic direction of the public body (within a policy and resources framework agreed with Ministers); • overseeing the development and implementation of strategies, plans and priorities; • overseeing the development and review of key performance targets, including financial targets; • ensuring that the public body complies with all statutory and administrative requirements on the use of public funds; • ensuring that the board operates within the limits of its statutory authority and any delegated authority agreed with the sponsoring department; • ensuring that high standards of corporate governance are observed at all times. This should	Yes	

	include ensuring that the public body operates in an open, accountable and responsive way; • representing the board at meetings and events as required.		
	All non-executive Board members must be properly independent of management.	Yes	
	All non-executive board members must allocate sufficient time to the board to discharge their responsibilities effectively. Details of board attendance should be published (with an accompanying narrative as appropriate).	Yes	
	There should be a proper induction process for new board members. This should be led by the Chair. There should be regular reviews by the Chair of individual members' training and development needs.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Effective Financial Management			
Effective Financial Management		**Compliant (Yes/No)**	**Detail**
Principle	***The public body has taken appropriate steps to ensure that effective systems of financial management and internal control are in place.***		
Supporting Provisions	The body must publish on a timely basis an objective, balanced and understandable annual report. The report must comply with HM Treasury guidance.	Yes	
	The public body must have taken steps to ensure that effective systems of risk management are established as part of the systems of internal control.	Yes	
	The public body must have taken steps to ensure that an effective internal audit function is established as part of the systems of internal control. This should operate to Government Internal Audit Standards and in accordance with Cabinet Office guidance.	Yes	
	There must be appropriate financial delegations in place. These should be understood by the sponsoring department, by board members, by the senior management team and by relevant staff across the public body. Effective systems should be in place to ensure compliance with these delegations. These should be regularly reviewed.	Yes	
	There must be effective anti-fraud and anti-corruption measures in place.	Yes	
	There must be clear rules in place governing the claiming of expenses. These should be published. Effective systems should be in place to ensure	Yes	

	compliance with these rules. The public body should proactively publish information on expenses claimed by board members and senior staff.		
	The annual report should include a statement on the effectiveness of the body's systems of internal control.	Yes	
	The board should establish an audit (or audit and risk) committee with responsibility for the independent review of the systems of internal control and of the external audit process.	Yes	
	The body should have taken steps to ensure that an objective and professional relationship is maintained with the external auditors.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Communications			
Communications		**Compliant (Yes/No)**	**Detail**
Principle	***The Public Body is open, transparent, accountable and responsive.***		
Supporting Provisions	The public body should have identified its key stakeholders. It should establish clear and effective channels of communication with these stakeholders.	Yes	
	The public body should make an explicit commitment to openness in all its activities. It should engage and consult with the public on issues of real public interest or concern. This might be via new media. It should publish details of senior staff and boards members together with appropriate contact details.	Yes	
	The public body should consider holding open board meetings or an annual open meeting.	Yes	
	The public body should proactively publish agendas and minutes of board meetings.	Yes	These have elements redacted where necessary.
	The public body should proactively publish performance data.	Yes	
	In accordance with transparency best practice, public bodies should consider publishing their spend data over £500. By regularly publishing such data and by opening their books for public scrutiny, public bodies can demonstrate their commitment to openness and transparency and to making themselves more accountable to the public.	Yes	The Agency publishes all GPC payments over £500, but for general supplier payments has adopted a threshold of £25,000. It feels that this is more transparent than a low value level because the former tends to create an overwhelming volume of data and make any appreciation of the key information very difficult for the public or interested parties.

	The public body should establish effective correspondence handling and complaint procedures. These should make it simple for members of the public to contact the public body and to make complaints. Complaints should be taken seriously. Where appropriate, complaints should be subject to investigation by the Parliamentary Ombudsman. The public body should monitor and report on its performance in handling correspondence.	Yes	
	The public body must comply with the Government's conventions on publicity and advertising. These conventions must be understood by board members, senior managers and all staff in press, communication and marketing teams.	Yes	
	Appropriate rules and restrictions must be in place limiting the use of marketing and PR consultants.	Yes	
	The public body should put robust and effective systems in place to ensure that the public body is not, and is not perceived to be, engaging in political lobbying. This includes restrictions on board members and staff attending political conferences in a professional capacity.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Conduct and behaviour			
Conduct and behaviour		**Compliant (Yes/No)**	**Detail**
Principle	***The board and staff of the public body work to the highest personal and professional standards. They promote the values of the public body and of good governance through their conduct and behaviour.***		
Supporting Provisions	A Code of Conduct must be in place setting out the standards of personal and professional behaviour expected of all board members. This should follow the Cabinet Office Code. All members should be aware of the Code. The Code should form part of the terms and conditions of appointment.	Yes	
	The public body has adopted a Code of Conduct for staff. This is based on the Cabinet Office model Code. All staff should be aware of the provisions of the Code. The Code should form part of the terms and conditions of employment.	Yes	
	There are clear rules and procedures in place for managing conflicts of interest. There is a publicly available Register of Interests for board members and senior staff. This is regularly updated.	Yes	
	There are clear rules and guidelines in place on political activity for board members and staff. There are effective systems in place to ensure compliance with any restrictions.	Yes	
	There are rules in place for board members and senior staff on the acceptance of appointments or employment after resignation or retirement. These are effectively enforced.	Yes	

	Board members and senior staff should show leadership by conducting themselves in accordance with the highest standards of personal and professional behaviour and in line with the principles set out in respective Codes of Conduct.	Yes	