



“People Power: Reforming QUANGOs” – Is this Applicable to Health Agencies?

by

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1. Introduction

“The growth in the number of QUANGOs [quasi autonomous non-governmental organisations], and in the scope of their influence, raises important questions for our democracy and politics. Questions of *accountability* – now vital in the light of the damaged trust in our political system. Questions about *public spending control* - now vital in the light of the debt crisis. And questions about *sheer effectiveness* – increasingly urgent as people see their taxes going up, but the quality of their lives going down...I’m convinced that the growth of the QUANGO state is one of the main reasons so many people feel that nothing ever changes; nothing will ever get done and that government’s automatic response to any problem is to pass the buck and send people from pillar to post until they just give up in exasperated fury” (*Rt Hon. David Cameron MP, July 6th 2009, Speech to Reform*).¹

In July 2009, David Cameron made the unequivocal statement that “we do need to reduce the number of QUANGOs in this country” to increase public accountability and save taxpayers’ money. Although the Conservative Party leader made it clear that it would be far too “simplistic” to propose a “bonfire of the QUANGOs”, it is more than apparent there is a strong appetite for significant reform of these organisations and a general rolling back of unelected governmental bodies. Indeed, Mr. Cameron has already asked his Shadow Cabinet to review every QUANGO within their respective policy briefs in a process continuing “up to and beyond the general election”.

It is evident that significant policy research has already been conducted on this topic. In his speech, Mr Cameron made specific pledges to remove OFCOM’s policy-making role; abolish

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the Qualifications and Curriculum Development Agency; and reform NICE by introducing a system of “payment-by-results for drug companies”. The Government has since announced a review of public bodies in a bid to ensure money reaches frontline services and foster efficiency savings.

2. Research Objectives

Given that the Conservative Party has pledged to ring-fence the NHS budget and is committed to real terms spending increases as way of number one policy priority, it is an important question to ponder as to which health QUANGOs could and should be scrapped; reduced in scope and size; reformed and renewed; or merged. This is not least the case given the continual push for better healthcare service deliverability and efficiency; the parlous state of the public finances and associated recessionary pressures on NHS spending; and the wide-ranging number of health agencies that currently exist.

In the same Reform speech, David Cameron set out the following questions that his Shadow Cabinet will have to ask when undertaking their QUANGO review:

- *Does this organisation need to exist?*
- *If its functions are necessary, which of them should be carried out in a directly accountable way within the department?*
- *And which, if any, should be carried out independently, at arm’s length from political influence?*
- *If there really is a need for an independent QUANGO, how can we make sure it is as small as possible, operating with maximum efficiency, frugality and respect for taxpayers’ money?*¹

This research paper is designed to apply Mr. Cameron’s criteria of assessment to the key health agencies and bodies in the UK in order to glean a better understanding as to which health QUANGOs (defined as agencies, committees, advisory boards and other organisations) should be scrapped, reformed or merged. For the purposes of this research piece, and given their relative prominence and stated policy importance to the NHS, we specifically focus on the following major health agencies:

- 1) The National Institute for Health and Clinical Excellence (NICE);
- 2) The Medicines and Healthcare products Regulatory Agency (MHRA);
- 3) The Care and Quality Commission (CQC);
- 4) The Health Protection Agency (HPA);
- 5) The Joint Committee for Vaccination and Immunisation (JCVI);
- 6) The Council for Healthcare Regulatory Excellence (CHRE); and,
- 7) Monitor.

We also look at the following less well-known health agencies in order to scrutinise their *de jure* purpose relative to their *de facto* functions:

- 1) Regional Development Agencies (RDAs) and their link to healthcare;
- 2) The Appointment Commission; and,

- 3) Advisory committees (particularly those relating to infectious disease and health protection).

Furthermore, unless otherwise stated the primary focus of our research concerns health agencies that are applicable to **England** and thereby directly accountable to the **UK Department of Health** (DH). Given the devolved and increasingly fragmented structure of the NHS, it is important to note that there are other health agencies specific to Scotland, Wales and Northern Ireland that also exist. Examples include the Scottish Medicines Consortium (SMC), which is answerable to the Scottish Executive at Holyrood, and the All Wales Medicines Strategy Group (AWMSG), which reports to the Welsh Assembly. Both the SMC and AWMSG are broadly the Scottish and Welsh equivalents of NICE albeit much smaller in size and less far-reaching in scope. Other agencies such as the MHRA and HPA cover the whole of the UK.

In addition to quantitative and qualitative analysis of the roles and responsibilities of each agency, our research methods include personal communications and interviews with agency representatives and other healthcare/industry experts. A copy of the generic questionnaire used throughout the interviews is provided in **Appendix A**. For each agency of interest, we evaluate where available and possible 1) what the agency is legislatively supposed to do and what it is doing in practice; 2) the overall cost and budget; 3) the number of employees; 4) the number of employees with a communications functions; 5) the pay of the Chief Executive, the Chair and the Board; and 6) its relationship with the DH.

3. The Health Agency Landscape

The health agency landscape across the UK can best be described as diverse and far-reaching. Indeed, it is defined by a significant number of different bodies, organisations and institutions. A full and complete list of the health agencies covering England and, in some cases, the whole of the UK is provided in **Appendix B**. As can be seen, at the time of publication we were able to identify 74 agencies. Historical analysis shows that the number of agencies has grown quite significantly in recent years, which in turn raises important questions about the roles and responsibilities of the DH.

4.1. National Institute for Health and Clinical Excellence (NICE)

4.1. Roles and responsibilities

NICE is officially defined as “...the national organisation responsible for providing guidance on promoting good health and preventing and treating illness”.² The Institute is the NHS body responsible for making recommendations regarding the introduction of treatments and medical devices into the NHS. Originally founded in 1999 and then merged with the Health Development Agency (HDA) in 2005, NICE’s key functions are to appraise the clinical benefits and costs of healthcare interventions, and to develop clinical guidelines for providing advice on good healthcare practice. NICE plays a pivotal role in formulating, maintaining and disseminating a strong evidence-base for effective public health action and attempting to reduce of health inequalities.

NICE is often seen as the most sophisticated and pre-eminent national attempt to systematically review the value of different treatments. However, the environment in which NICE operates has changed considerably since its creation in 1999. This is largely the consequence of a shifting healthcare landscape; a dramatic increase in NHS spending; and continued debates surrounding the issue of value for money.³

Under the broad rubric of developing guidance on health technologies and interventions, NICE's key roles and functions include:

- 1) identifying new treatments that offer the NHS the best value for money;
- 2) enabling evidence of clinical and cost-effectiveness to inform these value judgments;
- 3) supporting and advancing healthcare innovation;
- 4) promoting the most effective care pathways for the benefit of NHS commissioners; and,
- 5) advising the government and the NHS on the effectiveness of public health interventions.

As of 2009, NICE has assumed responsibility for developing indicators for the Quality and Outcomes Framework (QoF) – a pay-for-performance contract between the government and the British Medical Association (BMA) under which points gained mean additional money for GP practices. With a committee of primary care experts, NICE develops a “menu” of national indicators backed up by evidence on cost-effectiveness. NICE is also responsible for implementing NHS Evidence. This remit includes providing drug reference information in England for the British National Formulary (BNF).

Furthermore, under the new Pharmaceutical Price Regulation Scheme (PPRS) – the mechanism for pricing branded pharmaceuticals in the UK – more flexible drug pricing arrangements now involve NICE in undertaking assessments to determine whether a proposed change in a drug's initial launch price is cost-effective and to consider the possibility of risk-sharing.

4.2. Political comment

All the main political parties are supportive of NICE and there has been no suggestion of abolishing the Institute. However, there are important policy differences regarding NICE's structure, remit and approach to appraisal.

In November 2008, the **Conservative Party** published detailed proposals on NICE outlining policies for improving the systems and processes for making decisions about NHS drug availability. The Conservatives have clearly stated their support for NICE, but highlighted six areas to improve its configuration, structure and efficiency. These areas are consistent with the Conservative commitment to focus on health outcomes rather than central targets.

A “NICE Charter” to codify the Institute's roles and responsibilities; scrapping the current system of Ministerial referral; allowing appraisals to commence at the time of drug licensing; and increasing the use of risk-sharing schemes are among the headline pledges. The policy document also makes clear the need for pharmaceutical companies to better demonstrate product clinical value by shifting the burden of proof from NICE to the manufacturer. Improved cooperation between industry and NICE is promised through the creation of a steering committee. Furthermore, a clear commitment to evaluate wider social costs and benefits is provided. The Conservative proposals make clear that there are no easy solutions to tackle the

basic health economic problem of how to best allocate finite NHS resources to satisfy all healthcare needs. However, the proposals offer a solid blueprint for focused reform moving forward.

Through the 2008 Darzi review, the **Labour** government transferred responsibility for the determination of QoF to NICE.⁴ Furthermore, under the new NHS Constitution, there is now pressure on NICE to ensure appraisals are completed within 3-6 months where drugs are referred prior to launch.

Out of the three main political parties, the **Liberal Democrats** have been the most laconic when it comes to NICE. However, the Liberal Democrats are supportive of NICE and have certainly not proposed its abolition.

4.3. Expert opinion

In some circles, NICE is seen as a highly controversial organisation not least given its primary role in determining which drugs and medications are made available on the NHS. Indeed, the Institute has been the subject of virulent criticism from the media and patient lobby groups as by a recent Panorama documentary.⁵ Notorious examples include the Alzheimer's drug Aricept, which led to a High Court ruling against NICE, and more recently the rejection of kidney cancer drugs.

Such media opprobrium and patient group hostility has led some to question the sustainability of NICE. When we asked **Professor Karl Claxton of the University of York**, who sits on one of the NICE technology appraisal committees, where he thought NICE would be in 10 years time, we were told: *“This is a really good question because 10 years ago when NICE was created, I honestly and truthfully did not think it would stand the test of time and be around 10 years later. I thought it would create so much conflict, tension and disagreement due to the nature of the tough and difficult decisions in hand and, of course, the high stakes of rejecting certain treatments. We have seen the ferocity of the media backlash and how that can affect public perceptions...I am really astonished that NICE is still alive so thinking ahead is interesting!”*⁶

Given its central role in determining market access, NICE is one of the important agencies for the pharmaceutical industry. This is applicable not just to the UK but also globally due to NICE's increasing international reach and the fact that other countries have sought to mirror the NICE model and use of health technology appraisal (HTA). Indeed, **Dr. Richard Barker, Director General of the Association of the British Pharmaceutical Industry (ABPI)**, told us: *“The three agencies that immediately come to mind from our point of view is NICE, the MHRA and CQC – and it is probably in that order of importance. NICE has an increasingly broad and impressive set of responsibilities. Its budget is growing dramatically”*.⁷

Pharmaceutical companies have locked horns with NICE and questions have been raised over the appraisal process. Key issues relate to the definition of cost-effectiveness; the inclusion of wider social costs and benefits; and the value of innovation. **Dr. Richard Barker** told us: *“The guidance NICE gives on appraised technologies is of crucial importance to the pharmaceutical industry and there has been a long-standing campaign on the side of industry to broaden the way in which this guidance is issued and the value attributed to all technologies and not just medicines. We have long been of the view that NICE needs to broaden its view on how it*

assesses different types of patient value – clinical value, economic value and social value. The recent Kennedy study into the value of innovation is something we broadly welcome because it has opened the door for new definitions of value”.^{III, 6}

Concerns have also been raised about the consistency, completeness and efficiency of NICE guidance across the NHS and the associated impact on reducing health inequalities and improving standards of care. Indeed, the Audit Commission reported in 2005 that initiation of NICE guidance is not routinely part of financial planning. The report suggested only 26% of NHS bodies were actively “horizon scanning” in order to prepare for, and absorb, future guidance.⁸ The recent splurge of NHS budget deficits is hardly helpful in this regard. This means implementation is often deferred, or sometimes completely shelved, resulting in uneven and disjointed national uptake.

There is also the issue of inaccurate and mistaken implementation. A 2007 study commissioned by NICE revealed that, out of 28 NICE appraisals, 12 were under-implemented and four over-implemented.⁹ Since many NICE decisions are based on marginal and sometimes optimistic judgments of cost-utility, over-implementation is likely to be expensive and under-implementation clinically inadequate. This was backed up by findings from the Health Select Committee Parliamentary inquiry into NICE that reported in early 2008.¹⁰

When speaking to us, **Dr. Richard Barker** raised the issue of the effectiveness of NICE guidance: *“The function of NICE that is of most interest to the ABPI is that of health technology assessment. NICE would probably argue that clinical guidelines, which are not specific to technologies but specific to diseases specific, are a more intensive part and important part of their work...the open question here is how much these guidelines are understood by doctors and how consistently they are followed across the NHS. The detail of guidelines is important and I think there needs to be some sort of effectiveness measure to assess how effective these guidelines are in terms of affecting local behaviour in the right sorts of way”.*⁶

4.4. Analysis – does NICE pass the Cameron test?

Access to life-saving treatments, and the role played by NICE in reaching these difficult decisions given the NHS budget constraint, continues to represent an important part of modern health policy. Spiraling healthcare costs, rising expectations, an ageing population and tighter budget constraints have impelled modern governments to place additional emphasis on allocating available resources efficiently and effectively.¹¹ The purchasing and pricing of pharmaceutical drugs is one such important area. Approximately 10% of the entire NHS budget – roughly £11 billion per year – is spent on drugs and medicines. Of this expenditure, close to £8 billion is spent on branded products alone.¹² It is from this premise that decisions regarding NHS drug availability are vital. HTA is increasingly employed by countries as a tool to more effectively control the diffusion and utilization of health technologies.

High profile cases and critical media coverage have sharpened public, and in turn political, interest in this issue. However, most analysts and experts agree – regardless of which side of the

^{III} In January 2009, NICE commissioned **Professor Sir Ian Kennedy** to conduct a short study into how the Institute should value innovation as part of its appraisal process. In late July 2009, the Kennedy report was published making 26 recommendations to the NICE Board.

divide they stand on – that NICE does need to exist and that the Institute plays an important role in deciding which drugs should be made available on the NHS.

There is also general consensus that NICE’s key roles and responsibilities should not, and arguably could not, be undertaken by the DH. As **Mr. Andrew Dillon, Chief Executive of NICE**, told us: *“Civil servants in the Department of Health do not have the skills to prepare the advice that NICE offers to the NHS and the wider public health community. In addition, civil servants’ proximity to ministers would make it almost impossible for them to argue successfully that their interpretation of the evidence had been unfettered; and therefore that the guidance was independent and objective. No other existing organisation has the skills, the experience or the credibility to take responsibility for producing the guidance for which NICE is currently responsible”*.¹³

This same view is supported by **Professor Karl Claxton**: *“No, the work of NICE could not be undertaken by the Department of Health or another body. The reverse applies. Some of the Department of Health’s current responsibilities and functions should go to NICE or a NICE-like body. This is particularly the case when considering the issue of pricing. NICE should be made more independent”*.⁵

Although most industry experts and representatives agree that there is need for NICE, or an equivalent body, the issue of price remains an area of contention. As **Dr. Richard Barker** told us: *“In relation to the issue of price, we would not be in favour of NICE playing an increasing role here. We think the separation of powers between NICE doing the evaluation and the Department of Health, which is good at negotiating price, should remain. We think the objectivity of NICE doing the evaluation and not getting caught up in negotiations is important. However, we need to ensure the time period between the two processes is not too long, and that there is cohesion. As for the idea of value-based pricing, I think it is a nice phrase that slips off the tongue, but what it actually means remain a big question”*.⁶

The road ahead for NICE constitutes an important policy question. When we asked **Sir Michael Rawlins, Chairman of NICE**, and **Mr. Andrew Dillon, Chief Executive**, this question we were told: *“A publicly respected, widely known national Institute, continually improving care for patients and the health of the country as a whole, by providing high quality advice on clinical and public health practice and by setting standards for the NHS”*.¹² However, others foresee a more uncertain future. **Professor Karl Claxton** told us: *“I think the future for NICE is “up for grabs”. There are clearly huge pressures commercially and politically. It is not clear NICE will survive these pressures to sustain its credibility and teeth to make the difficult decisions. I think the future of NICE is very uncertain in this regard”*.⁵

As the appraiser of cost-effectiveness of pharmaceutical drugs, there is also the important issue of the cost-effectiveness of NICE itself. Indeed, the NICE budget for 2008/09 stood at £34.6m and is set to grow given the acquisition of additional responsibilities. NICE employs over 270 people with its Chief Executive and Chair paid approximately £188,000 and £60,000, respectively. As **Dr. Richard Barker** told us: *“NICE has a very substantial budget now and proportionality has to be a question. Are we spending NICE’s budget on the issues that will give the greatest return to the NHS?” I think that is an open question, but NICE does need to demonstrate that it is value for money itself”*.⁶

On a different note, there is a compelling argument in favour of NICE acquiring responsibility for the National Screening programme. As part of its clinical guidelines programme, NICE often offers targeted screening advice, e.g. screening during antenatal care, but there is a growing danger that, if the current arrangement persists, discontinuities between the National Screening Programme and the target programme will materialise. Commenting on this proposal, **Mr. Andrew Dillon** told us: “*By subsuming the National Screening Programme into NICE, consistency in the application and use of cost-effectiveness data would be enhanced. Finally, the incorporation of National Screening would allow greater transparency in its deliberations and conclusions*”.¹²

It is clear that there is a solid and unequivocal justification for NICE’s fundamental existence. To this extent, NICE can be seen to pass the Cameron’s test and there is a solid argument for further entrenching its role moving forward. The issue is not so much should NICE exist, but rather how it *should exist* and whether changes should be made to its *modus operandi*. It is from this perspective that there are important policy questions concerning reform of NICE particularly in relation to the appraisal process and the application of existing methodologies for assessing product value. The **Conservative Party’s** proposals on NICE are the most sensible, thoughtful and considered. The issue raised by **Dr. Richard Barker** about the cost of NICE itself carries notable importance and is something that policymakers should pay increasing attention to as ongoing debates about public spending cuts continue to determine the terms of reference about future priorities.

4.5. Summary of Recommendations for NICE

- There is an **absolute need** for an institution such as NICE. The tough, and often unpalatable, reality is the unavoidable existence of a basic health economic problem – infinite healthcare needs but finite healthcare resources – and an NHS budget constraint (pretty much regardless of how much governments spend on healthcare). This therefore means that not every drug or treatment can be purchased by the NHS, which in turn requires difficult decisions as to how funds should be allocated. **NICE is here to say.**
- The issue is therefore not whether NICE should exist, but how it should exist. To this extent, we believe the Institute needs to ensure its appraisal process and methodologies are not simply about, or seen to be about, *economic evaluation* and “hard cash” but rather the *evaluation* of all relevant factors and considerations as far as is practically possible. For example, as Dr. Richard Barker states, there is a need to ensure the **value of innovation** is more robustly and comprehensively considered in the NICE appraisal process.
- It is the **Conservative Party** that is leading the debate on NICE as exemplified by its detailed policy document published in late 2008. We are supportive of the policies contained within this document.
- We concur with Mr. Dillon’s proposal that the **National Screening Programme** should be subsumed into NICE.

5. The Medicines Healthcare products Regulatory Agency (MHRA)

5.1. Roles and responsibilities

The MHRA is the regulator of medicines and medical devices and equipment used in the UK. The agency was formed from a merger of the Medicines Control Agency and the Medical Devices Agency in 2003. It operates under the Medicines Act and European legislation, and its main activities include:

- assessing the safety, quality and efficacy of medicines and authoring their sale or supply in the UK for human use;
- overseeing the UK Notified Bodies that audit medical device manufacturers;
- reporting, investigating and monitoring adverse reactions to medicines and adverse incidents involving medical devices;
- operating a compliance programme for medical devices;
- sampling and testing medicines and to address quality defects, monitoring the safety and quality of imported unlicensed medicines and investigating Internet sales and potential counterfeiting of medicines;
- regulating clinical trials of medicines and medical devices;
- monitoring and ensuring compliance with statutory obligations relating to medicines and medical devices;
- promoting good practices in the safe use of medicines and medical devices;
- managing the General Practice Research Database (GPRD) and the British Pharmacopoeia (BP) and contributing to the development of performance standards for medical devices;
- offering scientific, technical and regulatory advice on medicines and medical devices; and,
- Providing the public and professions with authoritative information to enable informed dialogue on treatment choices.¹⁴

5.2. Political comment

There are no proposals from any of the main political parties to radically reform or change the MHRA.

The DH recently published a review of the MHRA and made a series of recommendations to improve joint-working with stakeholders and other government bodies. It recommended developing additional outcome metrics to measure its contribution to enhancing and safeguarding the health of the public, and called on the MHRA to do more to reduce waste and inefficiencies and strengthen its governance.¹⁵

5.3. Expert opinion

It is clear that the work of the MHRA is of fundamental importance, particularly its licensing role, and is an essential agency within the healthcare landscape. As **Dr. Richard Barker** told us: *“In large, the MHRA performs an absolutely necessary task. The question is not whether the MHRA should exist. They are one of the best regarded national agencies in Europe and therefore very important participants in the EMEA process”*.⁶ **Mr. Michael Carroll**, an industry consultant and adviser with over 35 years of pharma experience, confirmed this view: *“[The MHRA] is widely regarded as the best agency of its kind in Europe...it is highly respected in industry and regulatory circles as a mature, intelligent and professional body which is consulted on a wide range of health care issues, most notably in the field of medicinal and medical device applications”*.¹⁶

However, there are valid issues to do with the performance of the MHRA and whether the agency could be improved in this regard. As **Dr. Richard Barker** told us: *“The questions we [APBI] worry about are not remit, but rather performance and the quality of their performance. We have had an ongoing dialogue about the handling of the national side with issues such as labelling, inspections and licensing. The MHRA has a very set of rigorous guidelines for its EMEA commitments, but in our opinion it does not have the same set of rigorous guidelines for the other things it does. This is not news to the MHRA – this is a message we have been sending for some time”*.⁶ This is an area worthy of further exploration to see if ways can be found to further enhance the work and performance of the MHRA.

Thinking further along these lines, **Dr. Richard Barker** told us: *“We are in favour of performance incentives for the MHRA, but there is a dilemma there. The activities of the MHRA are financed by industry and user fees, but the issue of reduced funding could lead to a spiral of decline. The feedback is not a favourable one to the idea of performance incentives...we would like to be in a situation where the MHRA has a guaranteed budget and is then subject to performance assessment. The likelihood of this happening is very slim and you have to be careful what you wish for. However, I do think we need to have a performance metric in place to ensure the MHRA is properly assessed and to allow a better understanding of its performance. It may be the case that the performance of the MHRA should be compared with its European peers”*.⁶

The international reach of the MHRA is particularly noteworthy. As **Mr. Michael Carroll** told us: *“The pharmaceutical industry is truly global in nature with both its R&D and manufacturing axis rapidly shifting from its traditional base in Western Europe towards Asia, Eastern Europe and Latin America. This has serious implications for the upholding of quality, safety and efficacy standards of treatments and their associated impact on the health of the UK public. The licensing and subsequent enforcement role of the MHRA is therefore absolutely critical in this regard”*.¹⁵ Indeed, the MHRA is widely seen as a paragon in the world of pharmaceutical licensing and carries considerable weight in ongoing debates pertaining to drug licensing. UK policymakers should seek to augment this international role and continue to support the MHRA to ensure its reputation as a world leader is consolidated.

5.4. Analysis – does the MHRA pass the Cameron test?

In general, the MHRA has sustained a reputation for pragmatic professionalism and clearly plays a pivotal role both nationally and internationally as the one of the pre-eminent global licensing authorities. The MHRA has credibly – and creditably – deployed a “light touch” approach to pharmaceutical and drug regulation, which has been aided by a tradition of employing people in key positions who have complementary proven experience in a sphere outside the regulatory circuit, e.g. the pharmaceutical industry and other similar sectors. This enforcement style has a key role to play in moderating and curbing excess, non-value adding and expensive regulation from bodies outside the UK, which most notably manifests in the guise of unduly burdensome European Directives. The expertise of the MHRA should therefore be preserved, sustained and indeed, where possible, built upon.

It is from this perspective that it is clear that the MHRA passes the Cameron test with flying colours. However, this does not mean that the MHRA cannot be further improved or should somehow slip off the policymaking radar.

In common with all QUANGOs, the internal efficiency and productivity of the MHRA should be scrutinised to identify areas where its significant business processes could be improved through the application of lean – and other associated – techniques. It might make sense for policymakers to further examine whether closer collaborative working, or even targeted mergers, with other agencies would deliver economies of scale and scope where the issue of quality and health protection standards enforcement are on the agenda.

One immediate opportunity for greater collaboration is between the MHRA and NICE. As **Dr. Richard Barker** told us: *“In my own personal view, I think there should be more joint scientific advice and for that dialogue to be taking place at the same time. However, I think industry is very wary about cost-effectiveness being absorbed into licensing and the work of the MHRA, and I agree with this concern. We would not want the fourth hurdle to get absorbed into the MHRA and regulatory approval. That would cause all sorts of issues”*.⁶

In the quest to rationalise the QUANGO population to yield not only cost benefits but to promote synergistic gain resulting in greater public protection, it is tempting to consider closer affiliation of those agencies which substantially share *broadly* common objectives, and which deploy similar technologies, *modus operandi*, and human resource competences.

For example, it could be argued that the MHRA shares a broadly similar agenda with the likes of the Environmental Agency and Food Standards Agency in aiming to protect the public from the dangerous consumption of, and/or exposure to, regulated and unregulated materials. In the prosecution of their respective duties, they almost certainly have a fundamentally common approach to quality and risk management strategy and execution including resource prioritisation, inspection regimes, public awareness campaigns, and legislative enforcement. It is therefore possible to postulate that the sharing of general overhead support systems and staff in areas such as information technology, human resources and finance, would be cost-efficient, and that closer affiliation and cross-collaboration would promote a more consistent inter-agency approach to the management of matters concerning public protection.

In seeking such further affiliations, whether this be simply greater inter-agency collaboration or fully fledged mergers at the other extreme, there a fine and crucial balance to be struck between

achieving economies of scale and scope on the one hand and retaining sufficient topical focus and expertise on the other. Ultimately, for any increased affiliations strategy to be worthwhile, the business case would have to demonstrate irrefutable, compelling synergistic gain alongside acceptable re-organisational costs. Furthermore, it would be critical to protect “front line core expertise” and safeguard a shift towards generalist roles with concomitant expert loss that currently makes respective individual agencies excel in what they do. This said, it would be instructive to examine the models of other countries, for example the Food and Drug Administration (FDA) of the USA, to determine whether further in-depth analysis was appropriate.

5.5. Summary of Recommendations for MHRA

- The MHRA performs an **absolutely necessary** and important task, and is a global leader in the world of drug licensing and safety assessment. The expertise of the MHRA should be preserved and where possible enhanced.
- The question is not one of remit, but **performance**. Policymakers should focus on finding ways to improve the operational efficiency of the MHRA; consolidate existing strengths; and identify opportunities moving forward.
- Our findings have accentuated the possibility for **greater cross-collaboration** between the MHRA and other agencies and government bodies. One such example is **NICE**. This is particularly important in terms of attempting to speed up the processes for ensuring drugs can be made available on the NHS. Another may be the regulation of borderline substances and hence the **Advisory Committee on Borderline Substances (ACBS)**.
- It would also be worthwhile benchmarking how other high performing nations organise their resources with a view to adopting best practices in the field.

6. The Care Quality Commission (CQC)

6.1. Roles and Responsibilities

The CQC is the new independent regulator for health and adult social care in England, established on 1st April 2009 under the Health and Social Care Act 2008. It combines the regulatory functions of the Healthcare Commission, the Commission for Social Care Inspection, and the Mental Health Act Commission.

The establishment of a single health and adult social care regulator was announced in the Chancellor of the Exchequer’s Budget Statement in 2005 as a proposal to reduce the number of public sector inspectorates.¹⁷ The Government’s consultation on the proposal states that the new regulator would “reduce the burden of regulation” and “achieve efficiency gains” by “bringing expertise together in one body”. It was also intended to improve co-operation between health and adult social care to “ensure that services across the whole care pathway are safe and fit for purpose”.¹⁸

In legislation the main objective of the CQC is “to promote the health, safety, and welfare of people who use health and social care services”. It is required to perform its functions to for the general purpose of encouraging “the improvement of health and social care services”, “the provision of health and social care services in a way that focuses on the needs and experiences of people who use those services”, and “the efficient and effective use of resources in the provision of health and social care services”.¹⁹

Further to the regulatory powers inherited from the three former regulators, the CQC has introduced a registration system for all health and adult social care service providers in England. By 2012 all service providers of “regulated activities” (as defined by the Regulated Activities Regulations) are required to register with the CQC to demonstrate that they meet common standards of safety and quality (as defined by the Registration Requirement Regulations). From 2010 the CQC will also be granted extended enforcement powers in relation to all registered service providers.²⁰

6.2. Political Comment

The **Conservative Party** and **Liberal Democrats** were both broadly supportive of the principle of a single health and social care regulator in the parliamentary debates on the Health and Social Care Bill. Perhaps given its newness, neither party has since suggested radical reforms to the organisation instead adopting a cautious “wait and see” approach in order to assess the relative merits of the CQC.

The **Conservative Party** has indicated a preference for the CQC to retain its current functions and gain additional responsibilities to provide “value-for-money audit and advice” and to work with the NHS Information Centre to determine “common standards of information” to inform patient choice.^{21, 22, 23} It is expected that further policy announcements regarding standards of information will be made leading into the next general election.

6.3. Expert opinion

The announcement of a single independent regulator with responsibility for both health and adult social care was almost universally welcomed across both sectors. Its founding legislation, the Health and Social Care Act 2008, is widely recognised as being invaluable in producing a “level playing field” across health and adult social care. As **Mr. Jamie Rentoul, Director of Regulation and Strategy at the CQC**, told us: *“Regulating health and social care under a single piece of legislation has real benefits, both for people using services and those providing them. People using services - such as the elderly - understandably want to know that all the services they use meet the same standards of safety and quality, so they can have confidence in their care wherever they are getting it. Also a single piece of legislation helps join up health and social care and ensure integration. Those providing services - whether independent sector, voluntary sector, NHS or local authority - rightly want a 'level playing field' in terms of the standards they are expected to meet. Nobody wants one sector treated more favourably than another, particularly where there is a significant variety in the types of provider offering services”*²⁴.

Closely linked to this is recognition of the CQC's role in providing objective performance assessment and promoting quality across the NHS. As **Mr. Jonathan Manuja, Policy Analyst at the CQC**, told us: *"The CQC is important to provide an impartial assessment of the NHS and ensure that high quality standards are adhered to - this is mainly done through periodic assessment. This acts as a driver to enable the patients and public to choose the best public healthcare services - therefore stimulating competition. It is also important in a surveillance capacity - and uses data to target and inspect NHS organisations that are suspected as having problems"*.

The pharmaceutical industry has a vested interest in seeing how the CQC evolves over time and how it monitors performance in the NHS. When speaking to us, **Dr. Richard Barker, Director General of the APBI**, agreed that there is an intrinsic need for the CQC, but raised the important issues of objectivity and type of performance review: *"I think you do need an agency such as CQC that is independent and objective to makes these important judgements without the political pressures. These are important judgements and a body like CQC is therefore necessary. There was a tendency with the Healthcare Commission to do a lot of self-assessment. I hope the CQC does not go down this road and instead focuses on the key imperatives for the NHS"*.

The issue of measuring and rewarding pharmaceutical innovation is particularly important to the pharmaceutical industry and, as discussed above, constitutes a central point of focus on the commentary of NICE. **Dr. Richard Barker** told us that this is also important when considering the CQC: *"There is clearly a need for the CQC. However, I think the CQC needs to ensure that it rewards and encourages best practice rather than simply punishing bad practice. I know that Baroness Young would agree with that and has said things along those lines. It needs to be about the promotion of goodness and not just the identification and punishment of badness. We think that innovation should be higher up the agenda. Innovation is actually part of the solution and is a way to increase productivity – it is not the enemy of the NHS. We therefore think it needs to be higher up the criteria of assessment. I am not sure it is quite there yet and I think that is area for consideration for the CQC"*.

6.4. Analysis – does the CQC pass the Cameron test?

Given the newness of the legislation and the CQC itself, monitoring the implementation of existing legislation and the effectiveness of the organisation for a period of 3 – 5 years to will be fundamental to building an evidence-base with which to assess whether further reforms are necessary. This can be considered a policy imperative moving forward and essential to adjudicating the CQC's worth against the Cameron criteria. The regulation of health and social care has been subject to massive reorganisation in recent years, and it can be strongly argued that the emphasis of any future reforms should be placed on refining – rather than reorganising – the newly created regulatory process.

If the CQC is intended to "reduce the regulatory burden" and "achieve efficiency gains", as suggested by the Labour government's original consultation document, it will be crucial to review the extent to which it has effectively implemented its duty to "promote the effective coordination of reviews or assessments carried out by public bodies or other persons in relation to the carrying on of regulated activities".²⁵ The effective implementation of this duty would significantly reduce the duplication of work by other public bodies, leading to potential efficiencies within the regulatory system.

The establishment of a single regulator with responsibility for both health and adult social care, and the requirement for all service providers to be registered, brings the benefit of providing service users with a single source of independent information about the quality of services being provided. As **Mr. Jamie Rentoul, Director of Regulation and Strategy at CQC**, told us: *"We help to give power back to those using services. We do this by providing information people can trust about the quality of care available. Without such a counterweight, people would be more likely to feel that they have been 'given what they get'. They would be less able to have an informed view about the provider they go to or the standards of care they receive"*²⁶.

The CQC is also required to "give power back to those using services" in other ways. In contrast to many other healthcare agencies, it is required by legislation to publish a statement of involvement describing how it proposes to "promote awareness amongst service users and carers of its function", "promote and engage in discussion with service users and carers about the provision of health and social care services and about the way in which the Commission exercises its functions", "ensure that proper regard is had to the views expressed by service users and carers" and "arrange for any of its functions to be exercised by, or with the assistance of, service users and carers".²⁷

Furthermore, the CQC intends to involve service users directly in fulfilling its function of assessing service providers. **Mr. Jamie Rentoul** told us: *"We plan to give more weight to people's views in our assessments, as well as expecting providers of care services to do the same when delivering services. This means that in future providers will have to be more responsive to the needs of users in order to be successful"*²⁸.

These activities go some way to reduce the lack of accountability that is often thought to characterise QUANGOs. There is a strong case for amending the legislation establishing other healthcare QUANGOs to introduce equivalent requirements to involve the members of the public who are affected by their activities.

The cost to the taxpayer of the CQC is likely to be significantly less than the combined costs of the Healthcare Commission, the Commission for Social Care Inspection, and the Mental Health Act Commission. Furthermore, the DH estimates that a 1% gain in health and adult social care efficiency caused by regulation would lead to efficiency gains of £1.2 billion per annum.²⁹ Any future review of the CQC budget should assess the effectiveness with which the regulator has been able to perform its functions in relation to the savings made by improved efficiency.

The **Conservative Party** proposal to introduce an additional responsibility for the CQC to provide value-for-money audits and advice remains an area of debate. The CQC is primarily a regulator of quality, and there is an argument that this function should remain distinct from economic regulation in the immediate term, which given the policy of establishing all NHS trusts as foundation trusts falls ever increasingly to Monitor.

It can therefore be concluded that the future of the CQC is very much dependent on its performance over the next 3-5 years and its ability to adequately demonstrate to policymakers and patients its effectiveness at, and in turn its justification for, performing such a expansive and important set of practical responsibilities.

6.5. Summary of Recommendations for the CQC

- The newness of the CQC means the “jury is still out” against Mr. Cameron’s criteria. However, the creation of a **single regulator** can be considered desirable and the need for an organisation such as the CQC is essential for monitoring and assessing performance across the NHS.
- Given Labour’s countless reconfigurations, there is little value in seeing the CQC restructured anytime soon. Its performance should be thoroughly assessed **over the next 3-5 years**.
- Importantly, the CQC must not simply focus on the identification and punishment of **badness**, but also the accentuation and promotion of **goodness**. This is fundamental to fostering improved efficiency and **productivity** across the NHS – particularly NHS productivity which has recently fallen.

7. Council for Healthcare Regulatory Excellence (CHRE)

7.1. Roles and responsibilities

CHRE has the responsibility to “promote the health, safety and well-being of patients and other members of the public” in relation to the performance of the functions of the nine professional regulators in the UK.^{30, 31} It has specific responsibilities, under the National Health Service Reform and Health Professions Act 2002 and the Health and Social Care Act 2008, to “promote best practice in the performance of those functions”, “formulate principles relating to good professional self-regulation, and to encourage regulatory bodies to conform to them”, and “promote co-operation between regulatory bodies”.³²

In practice, the CHRE conducts a diverse range of activities including investigating and reporting on the functions of the professional regulators, comparing the performances of the regulators and making recommendations about the way they operate, and reviewing the regulators’ decisions in relation to fitness to practise cases and referring them to the courts.³³

7.2. Political comment

The **Liberal Democrats** have pledged to “axe NHS QUANGOs”, including the CHRE, in order to “introduce proper accountability”, but exact details have been scarce.³⁴

The **Conservative Party** has made no direct or specific policy recommendations in relation to the CHRE, but has talked more broadly about the issues of clinical excellence, performance improvement and, as the cornerstone of its programme of reform for the NHS, the importance of outcomes over targets.

The **Labour** government continues to support the existence of CHRE.

7.3. Expert comment

The CHRE's legislative power to review the performance of the nine professional regulators, and to take action where their performance is found to be wanting^{IV}, provides an additional level of accountability within the regulatory system.

As an independent organisation with the responsibility to “formulate principles relating to good professional self-regulation”, the CHRE should be commissioned to conduct a comprehensive review of professional regulation and make recommendations to introduce what **Mr. Harry Cayton, Chief Executive of CHRE**, describes as “right touch regulation”: *“Right touch regulation means doing more with less. We have already started to reduce the burden of our performance reviews on the regulators by addressing ourselves more clearly to outcomes. In making a judgement on how they perform we seek more insight with less oversight, we aim to ask less but understand more. Right touch regulation will mean always asking ourselves what risk we are trying to regulate. To be proportionate and targeted in regulating that risk or to find ways other than regulation to promote good practice and safety”*.³⁵

7.4. Analysis – does CHRE pass the Cameron test?

In addition to reviewing the overall burden of regulation itself, the CHRE should also consider whether there is a case for merging any of the existing professional regulators to improve the efficiency and cost-effectiveness of the regulatory system. This is an important policy consideration not least given the current economic climate.

Given the establishment of the CQC to harmonise the regulation of health and adult social care services, it is anomalous that the nine regulators the CHRE officially scrutinises and oversees do not include the General Social Care Council (GSCC), the regulator of social care workers. The CHRE already has *de facto* responsibility for the GSCC and has been commissioned by the Secretary of State for Health to conduct a review of its governance and performance.³⁶ In the interests of harmonising the quality of professional regulation across health and social care, it would therefore seem sensible for the CHRE to assume legal oversight of the GSCC.

Similarly, the CHRE should assume responsibility for the new Office of Health Professions Adjudicator (OHPA) established under the Health and Social Care Act 2008 to adjudicate on fitness to practise cases.³⁷ Although the OHPA will adjudicate cases referred to it by professional regulators overseen by the CHRE, at present the CHRE has no powers to review its decisions or assess the extent to which it is successfully fulfilling its functions. Introducing CHRE oversight of the OHPA would ensure consistency across the professional regulatory system.

^{IV} This refers to the way the regulators handle fitness to practice cases. The CHRE reviews the decisions of fitness to practice cases, and when it identifies a judgement as being unduly lenient and not protecting the public it has the powers to refer the decision to court.

In the longer term, there is a case for transforming the CHRE into an organisation scrutinising professional regulation beyond health and social care to promote consistency and raise standards of professional regulation across the board.

As **Mr. Harry Cayton, Chief Executive of CHRE**, told us: *“A single body for quality in professional regulation would reduce the number of bodies and improve communication”*.³⁸

7.5. Summary of Recommendations for CHRE

- Although perhaps not one of the pre-eminent health agencies, our research shows that the CHRE seems to play an **important professional regulatory role**. The scope for abolition or merging would therefore seem limited.
- It would seem logical for the CHRE to assume responsibility for the professional regulation of the **GSCC** and the **new OHPA**.

8. Joint Committee on Vaccination and Immunisation (JCVI)

8.1. Roles and responsibilities

The JCVI is an independent expert advisory committee that advises the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters relating to communicable diseases that are preventable and/or potentially preventable through immunisation. “The JCVI gives advice to Ministers based on the best evidence reflecting current good practice and/or expert opinion. The process involves a robust, transparent, and systematic appraisal of all the available evidence from a wide range of sources. The committee is appointed by the Appointments Commission and is independent of the Department of Health”.³⁹

The JCVI is constituted as a Standing Advisory Committee. The Committee consists of a group who has particular specialised knowledge of vaccination and its implementation. They provide critical advice on vaccine policy to the government to allow it to optimise the protection of the public.

Until this year (2009), the JCVI was appointed to provide advice to Ministers. The NHS Constitution now confers powers to establish the right to vaccination for individuals, but only under certain conditions. These include:

- a) where the vaccine is provided by the government (i.e. not occupational or travel vaccines);
- b) where the JCVI has been asked by the Secretary for State to make a recommendation; and,
- c) where the recommendation meets established cost-effectiveness criteria

As **Professor Andrew Hall, Chair of the JCVI**, told us, this is an important change to the work of the JCVI: *“This is a relatively recent change which the committee has only limited experience with working under. However, it has changed the work of the committee and provides underpinning to the advice and recommendations that the committee provides”*.⁴⁰

8.2. Political comment

The **Labour** government has further entrenched the role of the JCVI through its measures announced as part of the new NHS Constitution.

As part of its NICE proposals, the **Conservative Party** has proposed to bring the JCVI under the NICE umbrella: *“At present, the remit of NICE does not extend to the assessment of vaccines as treatment options, or their evaluation as public health measures. This is reserved for the JCVI. While there is undoubted expertise in JCVI and its committees, it is essential for the future that vaccines and immunization programmes form part of a consistent process of evaluation and advice to Ministers and NHS commissioners. For this to be the case, the evaluation of vaccines and immunization programmes must be added to the NICE remit, with a corresponding transfer from the DoH. This will also ensure greater transparency in the evaluation of vaccines”*.⁴¹

8.3. Expert opinion

Bearing in mind the **Conservative Party’s** pledge to subsume the JCVI into NICE, we asked a range of experts what their view was on this proposal and whether the work of the JCVI could be undertaken by another body.

Professor Andrew Hall, Chair of the JCVI, told us: *“There are one or two individuals within the Department of Health who have extensive knowledge of vaccination, but the broad range of skills and knowledge represented by the JCVI is needed to formulate policy. No other body currently has such a skill base. It could be created as an alternative to JCVI. However, this would not necessarily carry the established reputation of the JCVI with it”*.³⁸

This view is supported by vaccines expert **Professor John Edmunds** of the **London School of Tropical Hygiene**: *“[Vaccines] is a very technical area. Indeed, every developed country has such an advisory group of experts, and WHO are trying to encourage middle and lower income countries to set up these groups as well. It is essential”*. When asked about the specific proposal of absorbing the JCVI into NICE, **Professor Edmunds** argued against telling us that *“...there is a need to have a UK focus, rather than just England. It is important that the schedules and vaccines are the same across the UK to ensure that children do not miss out on doses by just moving over the border. Also, NICE does not have the necessary expertise - vaccines are very technical, and their impact is difficult to predict since people not vaccinated are also affected by vaccination programmes”*.⁴² A recently published 2020health report buttressed this view arguing from a similar perspective.^v

However, this view is contended in other quarters. **Mr. Andrew Dillon, Chief Executive of NICE**, told us: *“We believe that the JCVI, currently operated as an advisory committee within the Department of Health, should transfer to NICE. We believe that we could enhance the way in which JCVI operates by making improvements to the methods and process used to source and interpret evidence and by improving the transparency, inclusiveness and contestability of its processes”*.

^v 2020health, ‘Not immune: UK vaccination policy in a changing world’, March 2009.

A Senior Source at the HPA told us: *“I think there is scope for more collaboration here and to have “joint” HPA and NICE activities whereby the two agencies work more closely with one another. I have read the arguments for the work of the JCVI to be brought under the NICE umbrella retaining its committee structure. NICE would review the cost-effectiveness and evidence base for vaccination, and if there were HPA collaboration, the HPA could play an important role in collecting and interpreting the relevant evidence before passing it on to NICE”*.⁴³

Closely allied to this view, **Professor Andrew Hall, Chair of the JCVI**, did concede that perhaps the HPA could take on the role of the JCVI: *“The other possible agency to take on the work of JCVI would be the HPA. Since the HPA provides advice on infections in general to government and has responsibility for their control, this would seem a logical step. However, much of the evidence, for example surveillance and vaccine evaluation, is generated by the HPA. It is therefore helpful to have another independent body – the JCVI – which looks at and interprets this evidence”*.³⁸

8.4. Analysis – does the JCVI pass the Cameron test?

Out of all the major health agencies considered in this research piece, it is clear that the JCVI attracts polarised views regarding its future existence. There is a strong body of opinion, most notably within the vaccine community, that the JCVI should be retained, whilst there is an equally strong school of thought propounding the case in favour of the JCVI being subsumed within NICE – or at least the HPA. One thing is for certain. Given the importance of vaccines to preventative healthcare and public health, a committee focusing on vaccines is essential whether it is in its current format or in an alternative form.

One of the greatest issues to do with the JCVI is a lack of transparency and sophistication associated with assessment methodologies and the fact that committee members are unpaid and essentially part-time. Given that vaccines are a pivotal part of public health programmes and campaigns – and are absolutely seminal to the preventative healthcare model – it is imperative that the decision-making process determining the approval, part-approval or rejection of vaccinations and immunisations is rigorous and robust. One of the clear advantages of integrating the JCVI into NICE would be the opportunity to truly “professionalise” these processes with full-time members and expert support teams in place to review all relevant clinical and economic materials and make recommendations.

It is also evident that decisions pertaining to vaccines will – just like any other part of the NHS – be increasingly subjected to the rigours of cost-effectiveness analysis and economic evaluation. Although the JCVI in its current form houses invaluable expertise, particularly on the clinical side, it is less well-equipped on the health economics and health outcomes side of evaluation. This is in contrast to NICE, which has extensive in-house expertise for undertaking cost-effectiveness evaluations.

As has been widely discussed in the published literature, it is axiomatic – or at least it should be – that vaccines are different to other curative or reactive pharmaceutical interventions and treatments.⁴⁴ This is not least the case given the need to account for indirect consequences such

as herd immunity, serotype replacement, and antibiotic resistance.^{VI} Furthermore, many of the benefits associated with vaccination accrue in future years, which raises important technical questions for assessment and evaluation. It is therefore not wise or credible to evaluate vaccines against the exact same criteria as other interventions.

We therefore recommend that the JCVI be integrated into NICE as a separate vaccines committee in addition to the existing NICE technology appraisal committees, but with some important qualifications. Indeed, the success and effectiveness of this integration would depend on a number of key factors.

- 1) The committee would need to have a UK remit and be legislated as such. NICE is only responsible for England and Wales, but to ensure a joined up approach to vaccination across the UK – not least given that vaccines are designed to counter infectious diseases – this would be important.
- 2) Given the nature of infectivity, the assessment criteria and appraisal process for vaccines would need to account for the fact that vaccines are different and cannot be properly understood in the same light as other curative or reactive pharmaceutical drugs and interventions. Indeed, accounting for indirect consequences, such as herd immunity, and the fact that benefits from vaccination often accrue way into future is important.
- 3) Existing expertise and experience within the JCVI should be transferred to this new committee.
- 4) The vaccines committee should essentially have the same roles and responsibilities of the current JCVI with appropriate adjustments to methodology and assessment as required.

Furthermore, we believe there is considerable scope for the HPA to provide support to any such vaccines committee with the assessment of relevant clinical evidence. Indeed, by involving the HPA in this process greater synergies and cross-collaboration could be achieved between NICE and the HPA. This would be complementary to both agencies, but arguably particularly the HPA given that its exposure to this type of assessment is currently limited.

8.5. Summary of Recommendations for the JCVI

- We recommend the JCVI be **integrated into NICE** as proposed by the Conservative Party. This should enhance the way in which JCVI operates and allow for improvements to its **current methods and processes**. It would also allow for opportunities to address existing issues to do with transparency and inclusiveness.
- However, for this policy of integration to be successful a number of **key factors** need to be considered. These include ensuring the committee is UK wide, assesses vaccines according to technical imperatives, and retains the expertise of the current JCVI.

^{VI} **Herd immunity** is the indirect coverage conferred to a wider population from individuals vaccinated who are immunised and therefore protected against an infectious disease. **Serotype replacement** refers to the change in serotypes and pathogens due to the efficacy of vaccination programmes. **Antibiotic resistance** in this context refers to a reduction in bacterial resistance against antibiotics as antibiotic consumption reduces due to vaccination.

9. Health Protection Agency (HPA)

9.1. Roles and responsibilities

Established in 2003, the HPA is responsible for protecting “...the public from threats to their health from infectious diseases and environmental hazards. It does this by providing advice and information to the general public, to health professionals such as doctors and nurses, and to national and local government”. The HPA’s primary role is to provide an integrated approach to protecting UK public health through the provision of support and expert advice to the NHS, local authorities, emergency services, other health agencies, the DH and Devolved Administrations.

A key function of the HPA is to identify and respond to health hazards and emergencies caused by infectious disease, hazardous chemicals, poisons or radiation. It gives advice to the public on how to stay healthy and avoid health hazards; provides data and information to government to help inform its decision making; and advises people working in healthcare. The HPA also makes sure the nation is ready for future threats to health that could happen naturally, accidentally or deliberately.

Employing close to 4,000 staff and with a budget of over £336 million of which over £130 million is recovered through external revenue streams, the HPA has recently risen up in prominence given the ongoing swine flu pandemic.

9.2. Political comment

The **Labour** government is supportive of the HPA. The recent swine flu pandemic has illustrated the extent to which the UK Department of Health is dependent on the expertise and insight of the HPA.

The **Conservative Party** has also expressed strong support for the HPA having identified it as a key health agency within the wider NHS landscape.

The **Liberal Democrats** have made little comment on the HPA, but have also inferred its support for the Agency throughout the ongoing swine flu pandemic.

9.3. Expert opinion

The HPA has arguably grown in importance on the back of bird flu and the ongoing swine flu epidemic. Many believe that these recent examples highlight the significance of the HPA. As a **Senior Source at the HPA** explained to us the benefit of the HPA as an arms-length body to the Department of Health: *“I think the advantage of the HPA is that, if the agreements are right between the Department of Health and the HPA, it can be a source of independent scientific evidence and advice, which the Department of Health can utilise, along with evidence from other sources, to make informed policy decisions. I think there is a lot to say about the independence of the HPA. However, this independence must be respected by the HPA and must not be used to raise controversy towards the government but rather used as a source of independent information to the government that the government considers as it makes the necessary health policies”*.⁴¹

Mr. Michael Carroll, an industry expert with over 35 years experience in the pharmaceutical industry, reaffirmed this view: *“Since its inception in 2003, the HPA has been effective in discharging its cardinal responsibility, namely protecting the public from adverse health factors, through the provision of sound, objective advice based upon high quality science which is regarded as world class and leading edge by much of the fellow international community in areas such as biologically based medicine quality control (NIBSC), radiation exposure (Chilton), and incident investigation (e.g. the Northwick park CT episode associated with the TN1412 IND molecule.)”*.¹⁵

Indeed, it is precisely this pre-eminent science base which enables the HPA to reduce the grant in aid burden by some £130 million per annum.

A noteworthy aspect of the HPA is its international reach and its interaction with other global agencies. As a **Senior Source at the HPA** told us: *“The HPA has quite a lot of interaction with other respective national agencies and, in particular, the European Commission, ECDC, and WHO. I believe such interaction adds value to what the UK is doing...The health security of the UK is necessarily dependent on the health of other countries around the world, and collaboration with other country agencies will strengthen our collective ability to detect risks and to ensure infectious and other disease events do not spread internationally. We have seen the value of collaboration with other countries, in particular the US, Mexico and Australia, with the current swine flu pandemic, for example”*.⁴¹

9.4. Analysis – does the HPA pass the Cameron test?

The HPA now houses under one roof what was previously a disparate set of different activities. It is our judgement that the HPA has been effective in extracting scientific synergies through more closely coupled working relationships, whilst improving its productivity and efficiency base through the appropriate exploitation of economies of both scale and scope. The HPA attracts sizeable grants from internationally based third parties, including the World Health Organisation (WHO), to undertake leading edge research in diverse areas of critical public health concern. It therefore partially offsets the level of grant needed from the DH, and has also made steady progress in the integration of the previously separate predecessor organisations with accruing benefits in productivity gain. It can therefore be argued that the HPA has sustained its reputation for excellent science, whilst delivering a value for money proposition. To this extent, the HPA clearly passes the Cameron test.

This is further supported by the HPA’s sterling work on pandemic flu planning, which was widely commended. Likewise, the Agency’s rapid preparation of the Swine flu seed vaccine – and accompanying bio-assays for quality control purposes from which commercial manufacturers were able to expedite supply to the UK – must be commended not least given the public interest and media attention surrounding this topical issue.

It is from this premise that the expertise of the HPA should be protected, supported and built upon, not only because of its status as a “public health good” but also because it represents one of the UK’s key bastions for the sustainability of scientific excellence.

One potential area for development is greater collaboration with NICE. As a **Senior Source at the HPA** told us: “*I think an area [of possible collaboration] is screening. Screening for vaccination and diagnosing cancers. I think a joint activity between NICE and the HPA would be highly synergistic*”.⁴¹

9.5. Summary of Recommendations for HPA

- The HPA has demonstrated its **value and expertise** throughout the ongoing swine flu pandemic, and is a health agency of critical importance to the UK.
- The HPA has also proven its **self-sufficiency** by attracting significant grants and revenues from international third parties, thereby reducing the grant and aid burden on central government. This in turn has allowed the agency to foster and promote cutting edge research.
- The HPA should be protected and supported, but encouraged to increase its **cross-collaboration** with other agencies such as NICE to further extend opportunities for synergistic complementation and to open up the HPA to a “new way of thinking” to further its strategic goals.
- Whilst *full merger* with other Agencies may prove difficult in practice, there may be activity areas currently sitting in other agencies which would be better placed in the HPA, resulting in greater health policy cohesion, superior execution, and cost synergies. These should be explored with full government support.

10. Monitor

10.1. Roles and responsibilities

Monitor is the Independent Regulator of NHS Foundation Trusts. Established under the Health and Social Care (Community Health and Standards) Act 2003 and the National Health Service Act 2006, its primary function is to assess whether NHS trusts meet the criteria to become foundation trusts and to authorise or reject their applications to do so. It also has extensive powers to intervene when a Foundation Trust fails to meet its terms of authorisation, including powers to “require the trust, the directors or the board of governors to do, or not to do, specified things or things of a specified description within a specified period” and “remove any or all of the directors or members of the board of governors and appoint interim directors or members of the board”.⁴⁵

10.2. Political Comment

The **Labour** government has stated that it is committed for all NHS trusts to achieve foundation trust status “at the earliest opportunity”, and the role of Monitor is central to achieving this aim.⁴⁶ The **Conservatives Party** shares this commitment, and has proposed to “develop Monitor into an economic regulator that will oversee aspects of access, competition, and price setting in the NHS”.⁴⁷ It has also pledged to give Monitor a range of new duties and functions, including:

- securing the provision of universal access to healthcare services;
- promoting competition in healthcare services, wherever practicable;
- promoting safety and quality in healthcare services;
- promoting efficiency and economy in the provision of health services;
- promoting research and development in health;
- promoting the sufficient supply of skilled healthcare professionals;
- authorising NHS Foundation Trusts;
- intervening in the event of market failure; ensuring that services for patients are maintained and that assets needed for this are protected;
- controlling market entry, including authorising the constitutions of NHS Foundation Trusts;
- applying price controls and, in particular, determining the NHS tariff;
- specifying the ‘universal service obligations’ and protected services which providers will have to deliver; stipulating licence conditions requiring that providers guarantee services to the NHS; and determining the levels of subsidy needed to maintain a ‘provider of last resort’ in the case of market failure;
- exercising concurrent competition powers, such as how competition laws are applied to the healthcare sector;
- promoting NHS Foundation Trust freedoms; and,
- adhering to best regulatory practice.

The **Liberal Democrats** have made no specific proposals in relation to Monitor despite the party’s stated policy on foundational hospitals.

10.3. Expert Opinion

When speaking to us, **Dr. Bill Moyes, Executive Chairman of Monitor**, emphasise the need for independence to allow Monitor to perform its functions: *“Independence is critical to Monitor’s success. It is essential that health ministers do not have the ability to determine, directly or indirectly, Monitor’s approach to assessment and regulation or the decisions taken on specific cases. Reconstituting Monitor as a non-Ministerial Government Department – the original intention, but not achieved in the 2003 legislation – would secure proper independence from the Department of Health by removing its role in setting Monitor’s budget and overseeing how we manage ourselves”*.⁴⁸

Dr. Richard Barker, Director General of the APBI, raised the issue of having two different regulators to assessing finance (Monitor) and quality (CQC): *“I do not think it is very sound to have purely financially orientated regulator and a separate quality orientated regulator. There is an argument in the future should all trusts reach Foundation Trust status for these two functions to be merged and for a single agency to take on this role. It is an interesting question and one worthy of further thought. Practically, we are not there yet though”*.⁶

10.4. Analysis – does Monitor pass the Cameron test?

The need for Monitor to assert its independence from the government will increase should all trusts be authorised as foundation trusts, over which the Secretary of State has no direct legal

authority. To guarantee this independence, the legislation establishing Monitor should be amended to transform Monitor from an Executive Non-Departmental Governmental Body (as it is currently defined by the Cabinet Office) into a non-Ministerial Government Department.⁴⁹ Whilst the new Monitor would remain accountable to Parliament and the Courts, it would no longer have its budget allocated by, or be answerable to, Ministers.

As more and more trusts are authorised as foundation trusts – and are therefore free from ministerial control – it is logical to “develop Monitor into an economic regulator that will oversee aspects of access, competition, and price setting in the NHS” as the **Conservatives** propose. To achieve this, it will be particularly important for Monitor to assume responsibility for the NHS tariff and incorporate the Co-operation and Competition Panel. It should perform the “value-for-money audit and advice” function initially recommended by the **Conservatives** for the CQC.

As **Dr. Bill Moyes** told us: “*To operate as a full economic regulator Monitor needs to be able to regulate price, to set the competition rules and to police them in cooperation with the competition authorities. This would reflect the responsibilities of the economic regulators in other sector, where it generally works well*”.⁵⁰

However, there is an argument that other duties and functions proposed for Monitor by the **Conservative Party** would be best performed by other organisations to prevent duplication and mission creep. For example, the responsibilities to secure provision of “universal access to health services” and to “promote safety and quality in healthcare services” would be best performed by the quality regulator the CQC, which already performs the function of “controlling market entry” through the new registration requirements. Similarly, the duty to “promote research and development in health” would be best performed by the NHS Institute for Innovation and Improvement and the duty to promote the “sufficient supply of skilled healthcare professionals” would be best performed by the General Medical Council (which is incorporating the Postgraduate Medical Education and Training Board).

In addition to its primary legislative functions, Monitor also performs a quasi-commercial development function, providing development programmes for Non-Executive Directors and on strategic financial leadership and service-line management with partner organisations including Cass Business School, Manchester Business School, and the NHS Institute for Innovation and Improvement.⁵¹ In the longer term, this function would be best performed by another organisation. However, given the independence of foundation trusts it would be inappropriate for this function to be performed by Strategic Health Authorities (SHAs). Rather, it should be performed by an independent profit-making organisation.

10.5. Summary of Recommendations for Monitor

- We are strongly supportive of the policy of **real foundation hospitals** in the NHS and therefore the **need** for an agency such as Monitor. With this in mind, there is no scope for the abolition or scrapping of this type of organisation.
- For Monitor to be successful, its **independence** is crucial. We therefore recommend current legislation be amended to transform Monitor from an Executive Non-

Departmental Governmental Body (as it is currently defined by the Cabinet Office) into a non-Ministerial Government Department. Monitor would remain accountable to Parliament and the Courts, but it would no longer have its budget allocated by Ministers.

- As more trust gains foundation status, we believe it is logical to develop Monitor into an **economic regulator** as the **Conservatives** propose. However, other functions pertaining to access and quality should be performed by the CQC.

11. Other Organisations

In addition to the above organisations, for the purposes of this research piece we briefly examine a handful of other health organisations. In particular, we focus on Regional Development Agencies (RDAs). In brief, we consider the Appointments Commission and other advisory committees.

12. Regional Development Agencies (RDAs)

An overlooked but nonetheless very important part of the wider government agency landscape is the existence of Regional Development Agencies (RDAs). RDAs are responsible for generating and developing local economic growth and are very important when considering certain aspects associated with the delivery of healthcare. Although it is not the intention of this research piece to explore individual RDAs or to discuss in detail their various functions, it is important to accentuate their significance as part of the broader health agency landscape.

12.1 Roles and responsibilities

RDAs are particularly powerful insofar as they have a significant degree of delegated autonomy and a comparatively high proportion of public finance awarded from central government to not only influence but also actually direct their regional economies. This is typically achieved through locally developed eco-environmental industrial policy as expressed in the 5 year regional business plans of individual RDAs – all of which have the declared aim of growing local GDP to prescribed levels over this period.

One area of particular relevance to the field of healthcare is the work of RDAs in the sphere of biotechnology and pharmaceuticals. This sector is regarded by all RDAs as an important, and in some cases essential, component of local GDP generation, and as such tends to feature prominently in the individual plans of most RDAs.

12.2 Political comment

The **Conservative Party** has pledged to remove from RDAs powers over housing, planning and regional spatial strategies. In relation to economic development functions, the **Conservative Party** published a Green Paper in February 2009 promising that councils will be given the option to form “enterprise partnerships”.

Rhetoric from the **Liberal Democrats** has been hostile towards RDAs.

12.3 Expert opinion

Mr. Michael Carroll, who is an independent pharmaceutical consultant with over 35 years of experience working in industry, told us that the issue of value for money has to be a question when considering the performance of RDAs: *“Given that RDAs are well-equipped, housed and resourced, their running costs must be substantial, and it would be instructive to compute whether this cost base is merited and indeed effective; this could be done by calculating the generated “economic value added” and comparing the resultant net local GDP gain from policy implementation versus the declared target in the individual RDA business plan”*.¹⁵

Mr. Carroll further told us that some of his most significant observations about RDAs concern the lack of strategic insight to facilitate a better understanding of a rapidly changing sector: *“As a general observation, in their efforts to support a complex, fast moving technical sector, RDAs are ill-equipped in sufficiency of personnel expertise to direct and influence policy and strategy in the quest to sustain the bio-pharmaceutical business...There appear to be too many generalists whose sectoral reach is so diverse as to be dilutive and minimally value adding, whilst there also appears to be a surfeit of administrative roles, for example account management posts, filled by people who know little about the industry to which they are assigned. Where an industry sector is critical to sustaining local GDP, then the local RDA should have in place a specialist unit resourced with core expertise to support it.”*¹⁵ Our research confirms this important observation and in turn raises serious questions about the degree to which RDAs are fostering x-inefficiency (high staff and operational costs with little value added), which is of absolutely no value to an increasingly beleaguered taxpayer.

Allied to this point is the important issue of strategic focus. It would seem that many RDAs continue to be seduced into supporting and favouring those sectors and organisations which are responsible for the generation of the *largest number* of jobs rather than jobs which provide the greater *value added* that are more enduring and sustainable. On this point, **Mr. Carroll** told us: *“In areas such as training assistance, there remains a definite bias towards small to medium enterprises at the expense of multi-national corporations .Whilst the former may have the potential to generate substantial gross valued added (GVA) in the future, it is the multinational corporations (MNCs) which provide the jobs and the local GVA right now. In truth, this phenomenon probably has its origins in central government led policy and in the belief that value and wealth creation are predominantly generated by small company activity. In reality, this is never an either/or situation and a balance has to be struck, which greatly depends upon the particular local economy context and where local cluster organisations are in terms of their respective business lifecycle”*.¹⁵ It would seem that RDAs are generally deficient in some competences to appreciate the above concepts, which disables them from refining local policy in the light of specific, and often esoteric, sectoral challenges. This has arguably led industry, and big pharma especially, to feel ill-supported, poorly understood and disengaged.

When speaking about the responsibility for local marketing and promotion of regional economies, **Mr. Carroll** told us: *“Responsibility is firstly unclear and secondly, probably not as effective as it could be, despite significant sums of money being deployed on promotional activity. Two points are very salient in this matter. Firstly, whilst central government via the trade desk of the former DTI apparently have the lead responsibility for promotion of R&D, it*

has no such responsibility for manufacturing! This leads to a lack of joined up action and poor stakeholder management with the loss of FDI opportunities, given that many of the RDA heads have never met the “shakers and movers” of those companies who are concerned in making investment decisions. Secondly, it is not uncommon for industry observers to see RDAs competing against one another at trade delegations, shows etc, when, in reality, for an essentially globally decision based business such as bio-pharmaceuticals, a centrally led promotional policy would be far more appropriate.”¹⁵

12.4 Analysis – do RDAs pass the Cameron test?

It would seem that there are some important policy questions concerning the role of RDAs in terms of incentivising regional pharmaceutical activity. Associated issues pertaining to “value added”, cost-effectiveness and organisational efficiency and expertise are also significant in this regard. Although there must be an appropriate degree of freedom to enable local dynamics and knowledge to shape regional activity, it is unclear whether the RDA structure is the best way to achieve this objective. It is arguable that while the RDA concept is apposite, the actual execution is markedly lacking effectiveness due to inefficiencies in organisational, structural and competency matters within many RDAs.

We therefore strongly recommend that a thorough and comprehensive independent review of RDAs in terms of their impact on the healthcare sector is undertaken. This would help to better establish the effectiveness and performance of RDAs in terms of hitting their set objectives.

12.5 Summary of Recommendations for RDAs

- Key issues relating to RDAs include “**value added**”, **cost-effectiveness** and **organisational efficiency**.
- Concerns regarding the **effectiveness** of RDAs at incentivising appropriate interests for the pharmaceutical and healthcare industries are important. This is not least the case given apparent **inefficiencies** in organisational, structural and competency matters within many RDAs. Both policy and executional cohesion between local RDAs and central government is lacking and needs to be optimised if foreign direct investment (FDI) opportunities are to be maximised in a fiercely competitive arena.
- We strongly recommend that a comprehensive **independent review** of RDAs in terms of their impact on the healthcare sector be performed.

13. The Appointments Commission

The Appointments Commission was established as a Non-Departmental Public Body by the Health Act 2006. It has powers to exercise the appointment functions of the Secretary of State and the Privy Council in relation to the appointment of chairmen and non-executive members to NHS and other health and social care bodies and health professional regulatory bodies.⁵² Given that it could be argued that these functions could be performed more effectively and efficiently

by the private sector, the Appointments Commission should be abolished with its functions subjected to competitive tendering processes.

14. Advisory Committees

A central feature of the broader health agency landscape is the number of advisory committees and bodies. Indeed, we recommend that all such committees and bodies be reviewed by the DH in order to identify where better value added can be achieved. Based on our provisional research, we believe there is sufficient scope for some of these committees and bodies to be merged with other major agencies focusing on similar areas of health and healthcare delivery. For example, it would seem logical and sensible against Mr. Cameron's criteria for the following committees to be directly subsumed within, and integrated to, the HPA:

- 1) Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI);
- 2) Advisory Committee on Dangerous Pathogens (ACPD);
- 3) Advisory Group on Hepatitis (AGH); and,
- 4) Specialist Advisory Committee on Antimicrobial Resistance (SACAR).

All of the above committees seemingly advise on matters that should fall under the remit of the HPA – at least according to the HPA's official roles and responsibilities. We therefore recommend that the above suggestions be looked at in more detail.

15. Summary of Key Findings

NICE

- Retain NICE, but ensure **appraisal process** is modified and improved to account for wider evaluation and not simply economic evaluation.
- The **Conservative Party** proposals on NICE are the most sensible in this regard.
- Subsume the **National Screening Programme** into NICE.

MHRA

- Further entrench the MHRA and build on its reputation as a **global leader** in the world of drug licensing and safety assessment.
- The real question is not remit, but the **performance** of the MHRA and finding ways to improve in this regard.
- Greater **cross-collaboration** between the MHRA and other bodies, such as NICE, should be encouraged.

CQC

- The newness of the CQC means the “jury is still out”.
- The creation of a **single regulator** is desirable and the need for a monitoring and performance assessment organisation such as the CQC is essential. There is no value in

yet another reconfiguration and thus the CQC should be assessed over a **3-5 years period** against the Cameron criteria.

- The CQC must not simply focus on **badness**, but also the promotion of **goodness**. This is fundamental to fostering improved **NHS efficiency** and **productivity**.

CHRE

- The CHRE seems to play an **important professional regulatory role**.
- It would seem logical for the CHRE to assume responsibility for the professional regulation of the **GSCC** and the **new OHPA**.

JCVI

- The JCVI should be **integrated into NICE** as a separate vaccines committee, but with important qualifications. This should enhance the way in which JCVI operates facilitating improvements in applied **methods and processes**.
- It would also allow for **opportunities** to address existing issues to do with transparency, inclusiveness and ability to properly account for cost-effectiveness.
- For this policy of integration to be successful a number of **key factors** need to be considered. These include ensuring the committee is UK wide, assesses vaccines according to technical imperatives, and retains the expertise of the current JCVI.

HPA

- The HPA is of critical importance to UK health and healthcare delivery.
- The HPA has demonstrated **self-sufficiency** by attracting significant grants and revenue streams from international third parties.
- The HPA should be protected, but encouraged to increase its **cross-collaboration** with other agencies such as NICE to facilitate opportunities for **joint working**.

Monitor

- The **independence** of Monitor is crucial to its ability to do its job.
- We are strongly supportive of the policy of **real foundation hospitals** in the NHS and therefore the **need** for an agency such as Monitor. With this in mind, there is no scope for the abolition or scrapping of this type of organisation.
- Current legislation should be amended to transform Monitor from an Executive Non-Departmental Governmental Body (as it is currently defined by the Cabinet Office) into a non-Ministerial Government Department. Monitor would remain accountable to Parliament and the Courts, but it would no longer have its budget allocated by Ministers.
- As more trust gains foundation status, it is logical to develop Monitor into an **economic regulator**. However, other functions pertaining to access and quality should be performed by the CQC.
- Key issues relating to RDAs include “**value added**”, **cost-effectiveness** and **organisational efficiency**.

RDA

- The **effectiveness** of a number of the RDAs at influencing, attracting and retaining key activities in the pharmaceutical and healthcare industries, thereby sustaining both local GVA and the UK's balance of trade, is important but questionable. This is not least the case given apparent **inefficiencies** in organisational, structural and competency matters within many RDAs.
- A comprehensive **independent review** of RDAs in terms of their impact on the healthcare sector should be performed.

Other Organisations

- The **Appointments Commission** should be **abolished** with its functions subjected to competitive tendering processes.
- It would seem logical for the following committees to be directly subsumed within, and integrated to, **the HPA: ARHAI, ACPD, AGH, and SACAR**.
- A **specific and detailed review** of all advisory committees should be undertaken to identify other potential synergies and opportunities for mergers.

16. Concluding Thoughts

A key consideration for policymakers moving forward is the relative, and often marginal, trade-off between scrapping QUANGOs – and therefore usually having to significantly restructure and reconfigure parts of the NHS with associated cost and disruption – versus a more pragmatic approach of focused reform and targeted mergers. Indeed, under the current Labour government the NHS has been subjected to enough reconfigurations and reorganisations – most of which have been vacuous, gimmicky and fruitless – to last it a lifetime and certainly a couple of parliamentary terms.

Although it is evident that QUANGOs offering no or limited value should be abolished, the reality is often more complex. David Cameron is absolutely right to demand the thorough and comprehensive review of all QUANGOs, not least given the need for a “culture of thrift” during the new “age of austerity”, but ensuring his own criteria is applied with focus, context and meaning is all-important. This is particularly pertinent when assessing the relative merits, and in turn future implications, of totally scrapping or jettisoning existing agencies. In many cases, returning functions and responsibilities to the DH would be disastrous, and in some cases, outright unworkable.

As far as the health agency landscape is concerned, there is little scope for the outright abolition of any of the major agencies such as NICE, the CQC, MHRA and HPA. However, there is considerable scope for 1) targeted reform to enhance operational efficiency and better foster opportunities for value added and value for money; 2) greater cross-collaboration and synergistic working across health agencies; and 3) the integration and merging of smaller agencies – particularly advisory committees and bodies – into major health agencies of relevance.

It is in accordance with this 3-point plan where a future Conservative government should channel its efforts and endeavours, and where the current Shadow Health Team should focus its attention. This is the best way to bring about “people power” and to ensure that any reform of QUANGOs is made applicable to the needs of patients and the NHS.

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4. **Professor Mark Schulpher – University of York**
5. **Mr. Michael Carroll – Private Industry Consultant and Adviser.**
6. **Dr. Richard Barker – Director General of the ABPI.**
7. **Professor Andrew Hall – Chair of the JCVI.**
8. **Professor John Edmunds – London School of Hygiene and Tropical Medicine.**
9. **Dr. William Moyes – Executive Chairman of Monitor.**
10. **Mr. Harry Cayton – Chief Executive of the CHRE.**
11. **Mr. Jamie Rentoul – Director of Regulation and Strategy of the CQC.**
12. **Mr. Paul Durham – Regulation Strategy Manager of the CQC.**
13. **Mr. Jonathan Manuja – Policy Analyst at the CQC.**
14. **Mr. Ross Carroll – Member of Bow Group Health Policy Committee.**
15. **Ms. Corinna Matthews – Researcher for Mark Simmonds MP.**
16. **Anonymous Senior Source at HPA.**
17. **Mr. Annesley Abercorn – Chairman of the Bow Group.**

It should be noted that the MHRA declined to participate in this research piece.

Further Information

For further information on this policy paper and the Bow Group Health Policy Committee, please contact Stuart Carroll (Chair of the Committee) on health.policy@thebowgroup.org.

Appendix A: Generic interview guide

It should be noted that variations to the standard interview guide were made as and when appropriate.

A) Justification of existence and raison d'être

- 1) Why is Agency X necessary?
- 2) Could the work of Agency X be undertaken by the Department of Health or another health agency/authority?
- 3) In your opinion, does Agency X have appropriate legislation in place to do what it is supposed to do?

B) Roles and responsibilities

- 4) What are the key roles and responsibilities of Agency X?
- 5) How do you think these responsibilities and functions have changed, and will change, over time?
- 6) In your opinion, are there any functions of Agency X that would be better undertaken within the Department of Health?
- 7) Alternatively, do think there are functions within the Department of Health that could be better undertaken by Agency X?

C) Resources and funding

- 8) In your opinion, does Agency X have the resources to do what it is supposed to do?
- 9) How does Agency X provide value for money?
- 10) How do you think the funding requirements of Agency X will change over the next 5-10 years?

D) Relationship with the Department of Health

- 11) What is your relationship with Department of Health?
- 12) How could this be improved?
- 13) How does Agency X fit in and align with government policy?
- 14) In the light of the ongoing swine flu pandemic, do you think there is scope for Agency X to play a more extensive role?

E) The Road Ahead

- 15) What are the key short, medium and long-term goals of Agency X?
- 16) Where do you see Agency X in 10 years time?

Appendix B: List of Health Agencies and Health Advisory Bodies in the UK (unless otherwise stated)

Health Agency	Acronym/ Abbreviation	Area of responsibility	Part of UK
1. Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection	ARHAI	Advises on infections and antimicrobial resistance	UK
2. Administration of Radioactive Substances Advisory Committee	ARSAC	Advises on administration of radioactive substances	UK
3. Advisory Board on the Registration of Homoeopathic Products	ABRHP	Advises on the quality and safety of homeopathic products	UK
4. Advisory Committee on Borderline Substances	ACBS	Advises on borderline substances including foodstuffs and toiletries	UK
5. Advisory Committee on Clinical Excellence Awards	ACCEA	Advises on distinction awards in NHS	England and Wales
6. Advisory Committee on Dangerous Pathogens	ACPD	Advises on hazards and risks	UK
7. Advisory Committee on the Safety of Blood, Tissues and Organs	SaBTO	Safety of blood, cells, tissues and organs for transfusion / transplantation.	UK
8. Advisory Group on Hepatitis	AGH	Prevention and control of hepatitis	UK
9. Alcohol Education and Research Council	AERC	Research body informing and influencing alcohol-related policy and practice	UK
10. Appointments Commission	-	Appoints Chairs and Non-	England and

		Executive Directors of NHS organisations	Wales
11. British Pharmacopoeia Commission	-	Provides official standards for pharmaceutical substances and medical products	UK
12. Care Quality Commission	CQC	Regulator of health and social care (performance assessment)	England
13. Commission on Human Medicines	-	Advises on matters relating to human medicinal products	UK
14. Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment	COC	Advises on the potential carcinogenicity of chemicals	UK
15. Committee on Medical Aspects of Radiation in the Environment	COMARE	Advises on the health effects of natural and man-made radiation	UK
16. Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment	COM	Advises on the potential mutagenicity of chemicals	UK
17. Committee on the Medical Effects of Air Pollution	COMEAP	Advises on the potential toxicity and effects upon health or air pollutants	UK
17. Committee on the Safety of Devices		Advises on the safety of medical devices	UK
18. Council for Healthcare Regulatory Excellence	CHRE	Overseeing 9 health professions regulators	UK
19. Expert Advisory Group on AIDS	EAGA	Advises on matters relating to HIV / AIDS	UK
20. Gene Therapy Advisory Committee	GTAC	Responsible for ethical oversight of proposals to conduct clinical trials	UK

		involving gene or stem cell therapies	
21. General Chiropractic Council	GCC	Regulates the chiropractic profession	UK
22. General Dental Council	GDC	Regulates dental professionals	UK
23. General Medical Council	GMC	Regulates doctors	UK
24. General Optical Council	GOC	Regulates optical professionals	UK
25. General Osteopathic Council	GOsC	Regulates the practice of osteopathy	UK
26. General Social Care Council	GSCC	Regulates social care workers	England
27. Genetics and Insurance Committee	GAIC	Advises on matters relating to genetic testing and insurance	UK
28. Health Professionals Council	HPC	Regulates fourteen health professions	UK
29. Health Protection Agency	HPA	Infectious disease and environmental hazards	UK
30. Herbal Medicines Advisory Committee	HMAC	Advises on the safety, quality, and efficacy of herbal medicines	UK
31. Human Fertilisation and Embryology Authority	HFEA	Licenses fertility clinics and centres carrying out IVF	UK
32. Human Genetics Commission	HGC	Advises on social, ethical and legal issues relating to developments in human genetics	UK
33. Human Tissue Authority	HTA	Licensing for storage and use of human tissue for	England, Wales and NI

		research etc.	
34. Independent Advisory Group on Sexual Health and HIV	IAG for Sexual Health and HIV	Advice on sexual health and HIV	UK
35. Independent Reconfiguration Panel	IRP	Advises on contested NHS reconfigurations and service changes	England
36. Independent Review Panel for Advertising	IRPA	Advises on pharmaceutical advertising and promotional materials	UK
37. Independent Review Panel for Classification of Borderline Products			
38. Joint Committee on Vaccination and Immunisation	JCVI	Vaccines	UK
39. Medicines and Healthcare products Regulatory Agency	MHRA	Medicinal and medical device licensing (safety and efficacy)	UK
40. Ministerial Medical Technology Strategy Group	MMTSG	Medical technology and strategy	UK
41. Monitor	-	Regulator of NHS Foundation Trusts	England and Wales
42. National Institute for Biological Standards and Control	NIBSC	Centre of the HPA responsible for assuring the quality of biological medicines	UK
43. National Blood Transfusion Committee	NBTC	Provides support and advice on blood transfusion initiatives	England and Wales
44. National Clinical Audit Advisory Group	NCAAG	Advises on matters relating to clinical audit	England

45. National Expert Panel on New and Emerging Infections	NEPNEI	Assess the threat from new and emerging infectious diseases	UK
46. National Information and Governance Board	NIGB	Promotes consistent standards for information governance across health and social care	UK
47. National Institute for Health and Clinical Excellence	NICE	National guidance and “fourth hurdle”	England and Wales
48. National Joint Registry	NJR	Collects information on knee and hip replacement operations and monitors performance of hip and knee joint implants	England and Wales
49. National Leadership Council	NLC	Oversees all matters of leadership across healthcare	UK
50. National Quality Board	NQB	Champions quality throughout the NHS	UK
51. National Patient Safety Agency	NPSA	Contributes to improved patient safety by informing, supporting and influencing the health sector	UK
52. National Treatment Agency for Substance Misuse	NTA	Improves the availability, effectiveness and capacity for treatment of drug misuse	England
53. NHS Blood and Transplant Authority	NHSBT	Optimises the supply of blood, organs, plasma and tissues	UK
54. NHS Business Services Authority	NHSBSA	Payments, management and business support.	England and Wales

55. NHS Information Centre	-	Provision of health and social information	England
56. NHS Institute for Innovation and Improvement		Develops new ways of working, new technology and world class leadership	UK
57. NHS Litigation Authority	NHSLA	Handles negligence claims and works to improve risk management	UK
58. NHS Pay Review Body	NHSPRB	Advises on pay of NHS staff	UK
59. NHS Professionals		Provides staff to NHS Trusts	England
60. NHS Purchasing and Supply Agency	NHS PASA	Purchases NHS goods and services	England
61. Nursing and Midwifery Council	NMC	Regulates nurses and midwives	UK
62. Patient Information Advisory Group	PIAG	Advises on the use of patient data	UK
63.. Pharmaceutical Society of Northern Ireland	PSNI	Regulatory and professional body for pharmacists	NI
64. Postgraduate Medical Education and Training Board	PMETB	Responsible for postgraduate medical education and training	UK
65.. Review Body Doctors and Dentists Remuneration		Makes recommendations on the doctors' and dentists' pay	UK
66.. Royal Pharmaceutical Society of Great Britain	RPSNI	Professional body for pharmacists and regulatory body for pharmacists and pharmacy technicians	England, Scotland, Northern Ireland
67. Scientific Advisory Committee on Nutrition	SACN	Advises on issues relating to nutrition	UK

68. Social Care Institute for Excellence	SCIE	Promotes good practice in social care	UK
69. Specialist Advisory Committee on Antimicrobial Resistance	SACAR	Advises on microbial resistance	UK
70. Scientific Pandemic Influenza Advisory Committee	SPI	Advises on pandemic flu	UK
71. Scientific Committee on Tobacco and Health	SCOTH	Advises on tobacco and health	UK
72. Standing Commission on Carers	SCOC	Advises on the national carers strategy	England and Wales
73. Steering Committee on Pharmacy Postgraduate Education	-	Advises on continuing education and professional development of pharmacy workforce	England
74. UK Stem Cell Initiative	UKSCI	Developing a vision for UK stem cell research	UK

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- ³⁴ Norman Lamb. Conference Speech 15th September 2008. http://www.libdems.org.uk/conference_speeches_detail.aspx?title=Bournemouth_2008%3A_Norman_Lamb_speech&pPK=c2ca30bc-95d5-4790-95b9-03dae44add20
- ³⁵ CHRE, “Assuring Patient Safety Through Regulation”!, http://www.chre.org.uk/img/pics/library/090910_Assuring_patient_safety_through_regulation.pdf.
- ³⁶ Parliament UK, <http://www.publications.parliament.uk/pa/cm200809/cmhansrd/cm090720/wmstext/90720m0002.htm>.
- ³⁷ Health and Social Care Act 2008.
- ³⁸ Personal communication, 7th September 2009.
- ³⁹ Joint Committee on Vaccination and Immunisation (JCVI), <http://www.dh.gov.uk/ab/jcvi/index.htm>, Accessed 10th October 2009.
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⁴⁵ National Health Service Act 2006.

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⁴⁶ The Operating Framework for the NHS in England 2009/10. Department of Health. 2008.

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⁴⁷ Renewal Plan for a Better NHS

⁴⁸ Personal communication, 9th September 2009.

⁴⁹ Public Bodies 2008, Cabinet Office, 2008.

http://www.civilservice.gov.uk/Assets/PublicBodies2008_tcm6-6429.pdf

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⁵² Health Act 2006. http://www.opsi.gov.uk/acts/acts2006/pdf/ukpga_20060028_en.pdf