Department of Health

An Audit of the impact of the Department of Health's Regulations upon business

Final Report

September 2013

Contents

Executive summary

1. The purpose of this Audit report is to provide a thorough overview of all the regulations for which DH has responsibility that are thought to have an impact to business. The Audit describes why we have the regulations, provides an assessment of their estimated costs and, where possible, benefits to business and to wider society. The Audit has been conducted with a view to identifying regulations that should be removed or consolidated to reduce the regulatory burden the Department places on business and Civil Society Organisations (hereafter "business") as well as reducing the number and scope of our regulations.

2. The scope of the Audit covered all regulations believed to have a potential cost to business. In a Cabinet Office trawl for the Red Tape Challenge (RTC) around 1,200 regulations had been identified as the responsibility of the Department of Health, a significant subset of which was put forward for review under the RTC. Many of the regulations attributed to the Department of Health (DH) clearly only impact on the public sector or are in fact owned by Other Government Departments. These were excluded from the scope of the Audit which has focussed on just over 650 individual regulations (Statutory Instruments for the most part).

3. There are differences between the set of regulations considered in this Audit and the set examined in the Red Tape Challenge phases one (Medicines) and two (Healthy Living and Social Care) which together cover 774 regulations. This is because this Audit did not include some regulations revoked shortly after RTC phase one (214 MHRA regulations) and because we included 91 additional regulations identified by policy teams outside of these RTC processes. The derivation of the set of regulations included in scope of the Audit is set out in the annex on the Research approach (Annex C).

4. The total regulatory burden of DH's regulations is estimated at £124.3 million. This estimate is made through strict application of the Equivalent Annual Net Cost to Business (EANCB) methodology in line with the One-in One-out/ One-in Two-out rules. The numbers presented are estimates and could be subject to change with the availability of new or additional data. More information on the reliability of the constituent estimates is given in Annex A along with a reliability rating. Our methodology is set out in Annex C.

5. A small number of regulations account for the majority of the estimated cost to business. Key areas are the NHS injury cost recovery scheme where the cost to business is a direct transfer to the NHS (£56.5 million), the Care Quality Commission (regulator for health and social care quality, at least £22.3 million) and tobacco control (£16 million). The benefits to wider society have been calculated for a limited proportion of regulations with net benefit estimated to be over £3 billion.

6. This Audit has identified significant scope for regulatory reform. While the scope to reduce DH's regulatory burden by removing regulations with impact on business is found to be relatively limited, we are making progress towards reducing our deficit. One such regulation has been identified for removal. Subject to review by the Regulatory Policy Committee (RPC), removal would be expected to count as an OUT under One-in Two-out and would, therefore, reduce the DH deficit position. Furthermore, we have identified a substantial swathe of regulations that could be consolidated or simplified to reduce the stock and

volume of DH regulations in line with good regulation principles. Detail is provided in the results section.

7. The Audit has not examined in detail whether the DH's regulatory aims could be achieved through alternative mechanisms or improved implementation of existing regulation. An example of the former is The Responsibility Deal in Public Health. An example of the latter is the Focus on Enforcement for Adult Residential Care in which the Care Quality Commission (CQC) have been involved. Some areas for further investigation were flagged during challenge meetings with BIS and Cabinet Office. These are listed below (para 25) and will be investigated further.

Background

8. The Coalition Government places great importance on reducing regulatory burdens. This is exemplified in its One-in One-out (OIOO) policy where any new burden (an “IN”) must be matched by removal of an existing burden (an ”OUT”). More recently this has developed into a One-in Two-out (OITO) policy to further stretch Departments to reduce burdens to Business. To date, the DH has not removed regulatory burdens sufficiently to meet the OIOO/OITO rules when it has introduced new regulations and the DH has a deficit (see Annex E for the DH’s closing position on Statement of New Regulation Five).

9. This Audit of DH’s stock of regulations was commissoined to aid the DH and its Arms Length Bodies (ALBs) in scrutinising our regulations in order to understand better where our regulatory burden lies and to identify areas where the cost benefit case for retaining regulations may not be strong.

10. The DH Strategy Group were commissioned to undertake the Audit between December 2012 and May 2013. This commission was part of the OIOO/OITO deficit reduction plan that PS(PH) committed to the Reducing Regulation Committee to undertake in November 2012.

11. The first phase of the Audit (Dec 2012-Feb 2013) mapped out DH’s stock of regulations to narrow the focus to the regulations that directly impact upon Business. Just over 650 relevant regulations were identified as falling within the scope of the Audit across six broad policy areas and their potential impact on business was assessed in broad terms. Less than 100 lines of regulation were considered likely to impact significantly upon Business in this first phase.

12. The second phase (March – May 2013) has focussed on estimating the costs and where possible the benefits of each of the regulations thought to have an impact to Business, as well as identifying regulations which may be removed, simplified or consolidated.

13. Annex A provides a detailed commentary on the DH’s stock of regulations considered as being within scope of this Audit. It sets out the rationale for regulation in each policy theme, costs to business estimated on the basis of the OIOO/OITO Equivalent Annual Net Cost to Business (EANCB) and evidence on the cost-benefit case for retained regulations. It also identifies regulations which are considered to be candidates for removal, retention or modification.

14. The Audit has had good engagement within and without the DH. We have engaged across the DH with both policy and analytical colleagues and across government with Cabinet Office, BIS and Defra, a leading department on reducing regulation. The format of the report draws upon Defra’s 2011 publication – *The Costs and Benefits of Defra’s Regulatory Stock.*

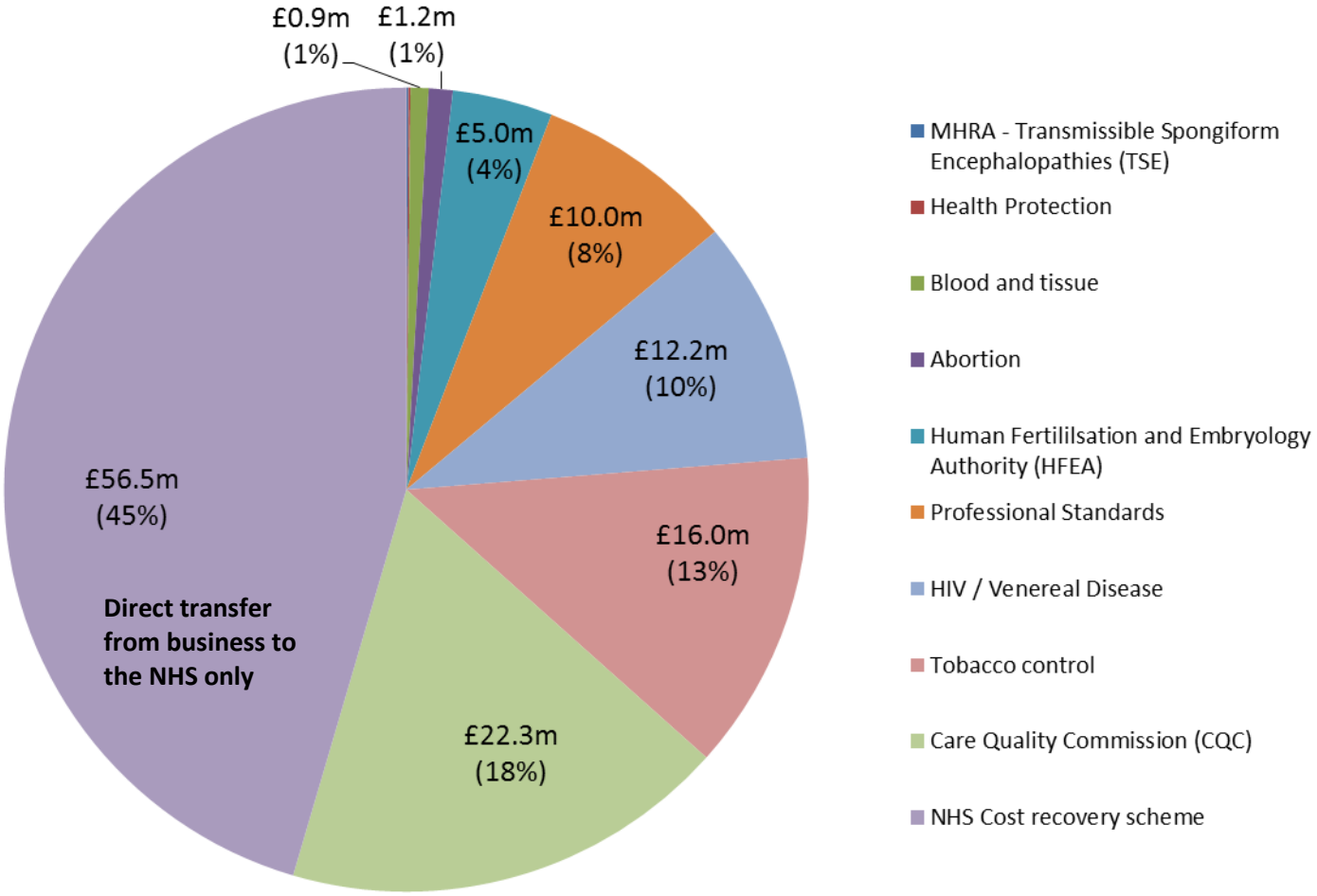
DH Regulatory landscape

15. The total estimated Equivalent Annual Net Cost to Business of DH's regulations is £124.3 million. This is shown in table one by policy area. It is a first estimate of the cost to business of DH's regulations. It is not complete and the total as well as constituent estimates should be treated as subject to change if and when more data becomes available. More information on the reliability of the constituent estimates is given in Annex A along with a reliability rating. Our methodology is set out in Annex C. In particular areas the estimates of costs are only partial, e.g. the costs of regulation associated with CQC. In others, the estimates are zero because they are considered to be measures that are out of scope of the OIOO/OITO rules (see Annex C). In most cases this is because there was no impact to Business, the measures are EU or International with no gold plating or they are contractual obligations. Regulations pertaining to fees and charges have also been excluded from the calculations as per OIOO/OITO guidance.
16. Because of time constraints and data availability, net benefits to society are not monetised for most policy areas. Across those areas where there are monetised estimates available, the total net benefit to society is approximately £3 billion.
17. Businesses are defined as organisations in the private or civil society sectors. As such public sector organisations including NHS providers are not in scope of this Audit. Further, as per BIS conventions, primary medical and dental care services are also treated as out of scope of OIOO/OITO and hence out of scope of this Audit.

Table One: Costs and Benefits by Policy Area

	Policy area	Estimated EANCB £million	net benefit to society £million	Note
Care quality	CQC	22.3	Un-monetised	EANCB is in the range £11.6m to £30.5m. This covers admin costs only. Covers staff time spent on new registrations, inspection and submission of notifications.
	Mental Health	0.0	Un-monetised	net impact may be positive benefit
	Social Care Other	0.0	Un-monetised	No impact to business
	Social Care (Isles of Scilly)	0.0	Un-monetised	No impact to business
MHRA	Transmissible Spongiform Encephalopathies (TSE)	0.1	Un-monetised	No impact to business
	MHRA (not TSE)	0.0	Un-monetised	Mostly contractual, EU or fees based
MPI	General Pharmaceutical services	0.0	Un-monetised	Mostly contractual, EU or fees based
	Charges and benefits	0.0	Un-monetised	Mostly contractual, EU or fees based
	Dental	0.0	Un-monetised	Mostly contractual, EU or fees based
	Ophthalmic Services	0.0	Un-monetised	Mostly contractual, EU or fees based
NHS	Cost recovery	56.5	54.0	Transfer from business to the NHS, covers cost of treating some injured insured patients
	NHS Litigation	0.0	Un-monetised	No impact to business
Public health	Abortion	1.2	Un-monetised	
	Blood and tissue	0.9	-4.3	
	Food composition, labelling, and food safety;	0.0	Un-monetised	No impact to business
	Healthy Start and Welfare Food	0.0	Un-monetised	net impact may be positive benefit
	Health Protection	0.1	0.1	
	Health Protection - Port Health and Travel	0.0	Un-monetised	
	Health Protection – Vaccinations	0.0	Un-monetised	No impact to business
	HFEA	5.0	-2.5	
	HIV / VD	12.2	Un-monetised	Considered to be a significant negative net benefit to society of this regulation
	National Child Measurement Programme (NCMP)	0.0	Un-monetised	No impact to business
	Radiation	0.0	Un-monetised	EU
	Surrogacy	0.0	Un-monetised	No impact to business
	Tobacco control	16.0	3,300.0	£11.9m of the £16m estimated EANCB yet to be incurred
	Public Health - Other	0.0	Un-monetised	No impact to business or EU
Professional Standards	Professional Standards	10.0	Un-monetised	
	TOTAL	124.3	3,347.3	

Figure 1 – Estimated EANCB by policy area for all DH regulations with impact to Business under OIOO/OITO rules, £million and percentage of total cost to business



Tobacco - Of which 11.9 million yet to be incurred, see section 5.13

Cost recovery - EANCB is entirely made up of a direct transfer from business to the NHS which is the aim of the policy, see section 4.1

Audit Results

18. The Audit has identified 51 regulations with an impact to business that could in theory score an OUT. For most of these, the OUT score would be relatively small. In most cases the ratio of wider benefits to costs is high. Monetised examples include tobacco control regulations, where the net benefit of regulations is estimated at £3.3 billion, over 200 times the estimated EANCB of £16 million. In other cases benefits have not been monetised, for example regulation of human fertilisation and embryology or abortion but there are strong arguments to maintain the regulatory regime.

19. The Audit has identified one regulation where the cost to business is estimated to be great and no positive wider benefit of its retention is perceived. This regulation, which bans the sale of HIV home testing kits, is a strong candidate for revocation. We plan to revoke formally this regulation.

20. The Audit has identified two regulations related to CQC where there is a burden to business and there may be scope for improvement. The regulations are being reviewed and consulted on following the Francis report and an internal DH review. Opportunities to reduce the burden on business will be sought, where possible.

21. The Audit has identified 44 regulations which have been revoked and 292 which have potential to be revoked pending legal advice. This includes 206 regulations in Professional Standards that are under review by the Law Commission. See tables two and three below and Annex F for more information.

22. The Audit has identified 38 regulations which could be consolidated. Of these, 4 could be consolidated in theory but only one regulation would be removed out of every two and significant legal input would be required. In some areas policy teams have consulted legal experts but have been advised that consolidation is inappropriate. An example is HFEA where consolidation would require consultation with Wales and Northern Ireland and combining incompatible parliamentary procedures which should be avoided.

23. The Audit has identified 17 regulations which are in fact deregulatory. Details of these are given in Annex H.

24. The Audit has identified 263 regulations where there is a case for retention, listed in table three below as no change. Of these, 48 have an impact to business and 215 have no impact to business. The strength of the case for retention is set out in the descriptions in Annex A.

25. Following discussions at DG led challenge meetings with Cabinet Office, BIS and policy teams, some potential to improve regulations listed as no change was identified in the areas listed below. The Department is investigating whether there is potential to change the way they are implemented to reduce burden to business.

    - Mental Health: House of Lords Inquiry scrutiny on the Mental Capacity Act
    - Food Claims application process, led by EU
    - Radiation IRMER review, led by EU
    - Potential to improve implementation of sunbeds regulation
    - Potential to improve Healthy Start and Welfare Foods schemes
    - Review of the Human Fertilisation and Embryology Authority (HFEA) and Human Tissue Authority (HTA)

Table two Regulations in or out of scope of OIOO/OITO, not apportioned (professional standards) or legal advice sought

	Number of regulations	Regulations considered out of scope of OIOO	Regulations with impact to business - in scope of OIOO	Unknown - either not apportioned or legal advice sought
Care quality	63	50	13	0
MHRA	62	60	2	0
MPI	89	89	0	0
NHS	97	93	4	0
Public health	119	86	32	1
Professional Standards	207	0	0	207
Total	637	378	51	208

Table three Regulations by Status

	Number of regulations	Have already been revoked/ repealed	Potential to revoke pending legal advice	consolidated or potential to consolidate	No change
Care quality	63	7	5	2	49
MHRA	62	1	11	0	50
MPI	89	14	14	27	34
NHS	97	10	51	0	36
Public health	119	11	5	9	94
Professional Standards	207	1	206	0	0
Total	637	44	292	38	263

Full tables by policy area are given in Annex F

14 of the regulations audited were found not to belong to DH. 9 are DWP regulations (vaccine damage payments – not mentioned elsewhere in document, 3 belong to DfE – mentioned in social care other and 2 to HMRC – mentioned in the tobacco control section of this report).

Further details are given in the relevant sections.

Annex A - Detailed commentary on the Department of Health's stock of regulations

This section provides a detailed commentary on the DH's stock of regulations, setting out the rationale for regulation in each policy theme, costs to business estimated on the basis of the OIOO/OITO Equivalent Annual Net Cost to Business (EANCB) and evidence on the cost-benefit case for retained regulations. It also identifies regulations which can be removed or modified. The regulations have been divided into the following policy areas (in alphabetical order):

- Care Quality;
- Medicines and Healthcare Products Regulatory Agency (MHRA);
- Medicines, Pharmacy, Dental and Eye Care Services;
- NHS;
- Public Health; and
- Professional Standards.

1. Care Quality

This section is further divided into the following areas:

- The Care Quality Commission (CQC);
- Mental Health;
- Social Care (Isles of Scilly); and
- Social Care other.

1.1 Care Quality Commission (CQC)

Why we regulate

- Everyday thousands of public and private organisations provide health and adult social care services. Where these services pose sufficient risk to service users they become regulated activities, which under the Health and Social Care Act 2008 requires providers of these services, including NHS and independent providers, to register with CQC and meet a set of registration requirements of safety and quality.

- Currently, only providers who have made a legal declaration that they meet the required standards of quality and safety are allowed to provide care. All acute, community, mental health, ambulance, dental, primary medical care and adult social care providers of regulated activities are required to be registered with CQC.

- Once services are registered, CQC is responsible for monitoring and inspecting them against agreed quality and safety standards. It responds to concerns and takes enforcement action where services are failing people.

- The requirement to register with CQC is proportionate to risk and based on the activity being carried out rather than the setting. This provides the same assurance of essential levels of safety and quality wherever people access services. The DH identified the list of regulated activities by considering the risk of harm to the person using the service, and what contribution regulation by CQC could make to the mitigation of those risks.

- A two month consultation started in mid-June (2013) on changes to the registration requirements contained in regulations to reduce and simplify their number, and make the remainder more pertinent. These are likely to include: the fundamental standards described by Robert Francis; a few organisational standards (including the fit and proper persons test); and the new duty of candour. As a result the regulatory activity of CQC should be improved and more focused. This chapter considers the current position and establishes the baseline against which future changes can be assessed.

What we regulate

- The organisations that provide health and social care activities in England, to assure standards of quality and safety are met.

Other policy instruments

- CQC Guidance about Compliance
- CQC's Regulatory Model

List of CQC Regulations		
SI	**Title**	**Origin**
The Health and Social Care Act 2008		
2010/781	Health and Social Care Act 2008 (Regulated Activities) Regulations 2010,	Dom
2009/3112	Care Quality Commission (Registration) Regulations 2009	Dom
2009/410	Care Quality Commission (Additional Functions) Regulations 2009 (revoked by 2011/1551)	Dom
2011/1551	Care Quality Commission (Additional Functions) Regulations 2011	Dom
2010/49	Care Quality Commission (Registration) Amendment Regulations 2010 (revoked by 2012/921)	Dom
2012/921	Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (regulated activities) (amendment) Regulations 2012	Dom
2012/1513	The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012	Dom
2010/496	Care Quality Commission (Specified Organisations etc) Order 2010,	Dom
2010/2484	Health and Social Care Act 2008 (Primary Dental Services, Private Ambulance Services and Primary Medical Services) (Regulated Activities) (Transitory and Transitional Provisions) Order 2010,	Dom
2011/2948	The Health and Social Care Act 2008 (Primary Dental Services, Private Ambulance Services and Primary Medical Services) (Regulated Activities) (Transitory and Transitional Provisions) (Amendment) Order 2011	Dom
2011/2711	The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2011	Dom
2010/807	The Health and Social Care Act 2008 (Commencement No.16, Transitory and Transitional Provisions) Order 2010	Dom
2010/1881	The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010	Dom
2010/813	Health and Social Care Act 2008 (Consequential Amendments No 2) Order 2010,	Dom
2008/2250	Health and Social Care Act 2008 (Consequential Amendments and Transitory Provisions) Order 2008,	Dom

2009/3049	Health and Social Care Act 2008 (NHS Blood and Transplant Periodic Review) Regulations 2009,	Dom
2008/2252	Care Quality Commission (Membership) Regulations 2008	Dom
2011/2547	The Care Quality Commission (Membership) (Amendment) Regulations 2011	Dom
2012/1186	The Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012	Dom
2012/1640	The Care Quality Commission (Healthwatch England Committee) Regulations 2012	Dom
Care Standards Act 2000		
2003/2323	Care Standards Act 2000 (Domiciliary Care Agencies and Nurses Agencies) (Amendment) (England) Regulations 2003, SI 2003/2323	Dom

OIOO/OITO Status

- Twenty-one of the regulations in the Care Quality policy area (in full or in part) directly relate to the role of the Care Quality Commission and have been scrutinised for this Audit. Of these:

- Two regulations impose a burden on business (2009/3112 and 2010/781)
  - These regulations define the regulated activities that require provider registration and set the standards and requirements providers must comply with.
  - The enforcement of these regulations is carried out by CQC. It is not dictated in the regulations themselves. For example the information CQC use to assess compliance and the frequency and content of inspections is subject to CQC policy and their regulatory model. CQC's regulatory model affects the actual impact of the regulations on provider organisations. CQC are currently developing a new and improved approach to enforcing the regulatory framework; the new approach may reduce the costs to businesses overall.
  - The costs and benefits to business of these regulations are discussed below.
  - There may be scope to improve these regulations. The regulations are being reviewed. Opportunities to reduce the burden on business where possible will be sought. For example, there may be scope to streamline some of the requirements on providers.

- The remaining regulations relate to legal process, commencement and transitional arrangements or are amending regulations. Of these:

  - Two regulations are amendments to the above-mentioned regulations and reduce the burden on businesses by changing some of the requirements and regulated activities (2012/1513 and 2012/921). They are deregulatory regulations and an OUT was counted last year for this.

- One further regulation also reduces the burden on business by imposing a duty on CQC to limit the burden of inspection (2010/496). It is also considered deregulatory.

- Two regulations have already been revoked (2009/410 and 2010/49).

- The remaining fourteen regulations do not impact business. Of these:

  - Five regulations could potentially be revoked because they are potentially spent or no longer operative. 2003/2323 and 2009/3049 relate to repealed legislations. 2010/807, 2010/2484, and its amendment 2011/2948 set out transitory arrangements for registration of providers, who are all now registered with CQC.

  - Three regulations are consequential amendments that update definitions and terminology following changes elsewhere (2010/813, 2008/2250 and 2010/1881).

  - Three regulations relate to CQC board membership (2008/2252 and amendments 2011/2547 and 2012/1186).

  - One regulation relates to Healthwatch committee membership (2012/1640).

  - One regulation relates to high security hospitals (public bodies) only (2011/1551).

  - One regulation is an amendment to transition arrangements which have now lapsed but this SI cannot be revoked for legal reasons (2011/2711).

- Of the above, five are amendments to other SIs in the list and so could be consolidated with their parent regulation.

<u>Costs and benefits to business</u>

- As mentioned above, only two of the twenty-one regulations impose a cost on business (2010/781 and 2009/3112).

- The impact of these regulations on business includes:

  - administrative costs (e.g. time spent facilitating inspection);

  - policy costs (e.g. making changes to comply with cleanliness requirements); and

  - reputational benefits (i.e. being regulated gives businesses the opportunity to demonstrate that they are providing a high quality and safe service and they can use this as a selling point).

- It has been possible to estimate administrative costs to business <u>only</u>.

- The best estimate for the administrative costs to business arising from regulation is given in the statistics table below. Businesses affected by these regulations are most of CQC registered adult social care and independent health care providers. The administrative costs cover staff time spent on: new provider registrations, facilitating inspection and submitting statutory notifications.

- Cost estimates are based on CQC activity data and DH assumptions. It has not been possible yet to speak to affected business directly. DH and CQC are seeking to do this in the future.

- It has not yet been possible to quantify the potential policy costs of regulation.

- CQC registered businesses have been required to comply with various quality and safety standards for decades. This makes it difficult to understand how businesses would behave in the absence of quality and safety standards. This lack of a counterfactual makes it difficult to assess the impact of regulation and what it is that businesses are having to do differently because of regulation. For example, requirements in relation to staffing may mean a provider ensures their staff are trained appropriately. This may involve providing resources for training. However, it is unclear whether the provider would have done this anyway. If they would have, this cost is not attributable to CQC regulation.

- In addition, the current requirements are quite broad to allow providers to take a flexible approach in how they meet the standard. As a result provider interpretation and response to the requirements will vary. Further, some providers will intentionally go above and beyond the intended interpretation of the requirements. For example, current requirements in relation to staffing may mean providers ensure their staff are trained appropriately. One provider may provide mandatory essential training while another provides extensive training and pay higher wages to attract staff with significant experience. It is difficult to ascertain which costs are necessary due to regulation and which arise out of provider choice.

- DH and CQC are committed to looking at these impacts further alongside the corresponding benefits to wider society of better quality and safer services. A project to take this forward is currently being considered.

- It has not been possible to quantify the benefits to business of regulation.

- Requiring business to comply with CQC regulation gives them a clear independent signal of quality that they can use to advertise their services. This is a benefit to business. It is not possible to quantify how this has affected revenue or any other aspect of a provider's business. In time, as well as an overall compliance assessment, CQC will also rate the quality and safety of services. As a result, this benefit of a quality signal will increase.

<u>Summary</u>

Out of twenty-one regulations:

- Two regulations could be revised as they impose a burden on business (2010/781 and 2009/3112).
    - These regulations should be retained as they are necessary to mitigate the risks to health. However, there may be scope to improve these regulations. The regulations are being reviewed and consulted on following the Francis report and an internal DH review. Opportunities to reduce the burden on business where possible will be sought.

- Two regulations have been already been revoked (2009/410 and 2010/49)

- Five regulations have the potential to be revoked as they are potentially spent or non-longer operative (2003/2323, 2010/807, 2009/3049, 2010/2484, and its amendment 2011/2948). This will be investigated further.

- Twelve regulations should be retained. Three regulations reduce the burden on business, (2012/1513, 2012/921 and 2010/496). The rest have no impact on business.

- The above is subject to change following further DH scrutiny and discussion with CQC and lawyers as part of the Quality of Care/Mental Health Red Tape Challenge and CQC focussed star chamber (July 2013).
- Five are believed to have an impact to business under OIOO/OITO rules. These are: 2009/3112, 2010/496, 2010/781, 2012/1513 and 2012/921. However, three of these reduce the burden on businesses and may be considered deregulatory (2012/1513, 2012/921 and 2010/496).

Statistics: Care Quality Commission	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	Policy costs = Un-monetised Administrative costs = £22.3 million
Estimated equivalent annual benefits to business	Regulation provides signal of quality = Un-monetised
Estimated equivalent annual net cost to business (EANCB)	(Administrative costs only) £22.3 million
Impact To Society	
Estimated annual cost to other parties/wider society	Un-monetised
Estimated annual benefits to other parties/wider society	Better quality and safer services = Un-monetised
Net estimated annual cost to other parties/wider society	Un-monetised
Notes: The estimated equivalent annual cost to business is in the range £11.6m to £30.5m. The above is the best estimate of **administrative costs to business only**. This estimate is based on CQC information and DH assumptions. At this stage it has not been possible to survey CQC registered businesses. Work will continue to improve this estimate. The policy costs of regulation, e.g. making changes to meet standards, have not been quantified. The benefit to business of regulation providing an independent signal of quality that they can utilise has also not been quantified. Work will continue to try to quantify these aspects of business impacts.	
Reliability rating: 3/5 (for admin costs estimate)	

1.2 Mental Health and Mental Capacity

Why we regulate

- Annually over 50,000 decisions are made under the Mental Health Act to detain people with mental disorder against their will in hospital, to treat them compulsorily using invasive

techniques and to discharge them into the community with continuing compulsory treatment, where if they do not comply they will be re-detained in hospital.

- People are detained against their will and treated compulsorily when their mental illness is so severe that they need to be detained in hospital for treatment and if they were not detained they would be a danger to themselves or others. Decisions under the Mental Health Act must be made with the aim of maximising the safety and wellbeing of the patient and to protect others from harm.

- Additionally the Mental Capacity Act 2005 introduced a new regime of deprivation of liberty safeguards. This provides important safeguards for people who lack mental capacity and are deprived of their liberty, in hospitals and care homes, "in their best interests" but who are not detained under the Mental Health Act.

- Detention and deprivation of liberty by the state and compulsory treatment when detained are key human and civil rights issues. These regulations are important to ensure that every individual's rights are protected and upheld.

- In addition, they ensure that both the professionals and the processes are in place so that detention and deprivation of liberty happen correctly to protect both patient and public safety.

What we regulate

- The professionals and processes that ensure that detention, deprivation of liberty and compulsory treatment are handled correctly to maintain individuals' rights and best interests and protect public safety.

Other policy instruments

- Mental Health Act 1983 Code of Practice;
- Mental Capacity Act 2005 Code of Practice;
- Part 3 of the Mental Health Act 1983 which deals with criminal detentions for offenders with mental disorder.

List of Mental Health Regulations		
SI	**Title**	**Origin**
The Mental Capacity Act (2005)		
2006/3474	Mental Capacity Act 2005 (Appropriate Body) (England) (Amendment) Regulations 2006	Dom
2006/2810	Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006	Dom
2006/2883	Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (Expansion of Role) Regulations 2006	Dom
2006/1832	Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (General) Regulations 2006	Dom

2007/679	Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007	Dom
2007/1899	Mental Capacity Act 2005 (Transfer of Proceedings) Order 2007	Dom
2007/1898	Mental Capacity Act 2005 (Transitional and Consequential Provisions) Order 2007	Dom
2009/827	The Mental Capacity (Deprivation of Liberty: Monitoring and Reporting; and Assessments -Amendment) Regulations 2009	Dom
2008/1315	Mental Capacity (Deprivation of Liberty: Appointment of Relevant Person's Representative) Regulations 2008	Dom
2008/1858	Mental Capacity (Deprivation of Liberty: Standard Authorisations, Assessments and Ordinary Residence) Regulations 2008	Dom
2009/2376	Mental Health and Mental Capacity (Advocacy) Amendment (England) Regulations 2009	Dom
2008/2368	Mental Capacity (Deprivation of Liberty: Appointment of Relevant Person's Representative) (Amendment) Regulations 2008	Dom
Mental Health Act 1983		
2008/3166	Mental Health Act 1983 (Independent Mental Health Advocates) (England) Regulations 2008	Dom
1995/2630	Mental Health Act Commission (Amendment) Regulations 1995	Dom
2008/1206	Mental Health (Approved Mental Health Professionals) (Approval) (England) Regulations 2008	Dom
2008/1205	Mental Health (Conflicts of Interest) (England) Regulations 2008	Dom
2008/2560	Mental Health (Hospital, Guardianship and Treatment) (England) (Amendment) Regulations 2008	Dom
2008/1184	Mental Health (Hospital, Guardianship and Treatment) (England) Regulations 2008	Dom
2008/1204	Mental Health (Mutual Recognition) Regulations 2008	Dom
2008/1207	Mental Health (Nurses) (England) Order 2008	Dom
Mental Health Act 2007		
2008/2828	Mental Health Act 2007 (Consequential Amendments) Order 2008	Dom
Part of Community Care Act 2003		
2003/2276	Delayed Discharges (Mental Health Care) (England) Order 2003	Dom
1992/3182	Residential Accommodation (Determination of District Health Authority) Regulations 1992	Dom
1993/582	Residential Accommodation (Determination of District Health Authority) Regulations 1993	Dom

OIOO/OITO Status

- Twenty-four of the regulations, under four separate Acts, in the Care Quality policy area (in full or in part) directly relate to mental health and have been scrutinised for this Audit.

The Mental Capacity Act (2005).

- Of the twelve regulations under the Mental Capacity Act (2005), nine are expected to have a net benefit to business under OIOO/OITO rules. These are 2008/1858, 2006/3474, 2006/2883, 2006/1832, 2007/1899, 2007/1898 and 2009/827, 2009/2376 and 2008/2368. These regulations created a new market funded by government for civil society organisations to be paid to deliver advocacy services as a Relevant Person's Representative. They also clarified the law which reduces providers' risk of litigation as depriving a person of their liberty incorrectly or unnecessarily is a very serious matter, and businesses such as private hospitals doing so are open to challenge in the Courts and are required to payment of damages for breaches of people's human rights. The legislation and the regulations protect businesses by clarifying what is and what is not lawful, and what is the correct process for legal detentions. The estimated impact to business of these regulations is set out in the table below.

- This leaves three which are not believed to have an impact to business under OIOO/OITO rules because any costs can be recouped (2008/1315), the regulation relates to the timing of commencement for other regulations (2006/2810), or is clarification of terms only (2007/679).

- The House of Lords (HoL) announced in May 2013 that it was setting up a HoL scrutiny of the Mental Capacity Act, to ascertain whether the government knows whether the aims of the legislation have been achieved and what the evidence is for its successes and limitations.

The Mental Health Act (1983)

- Of the eight regulations under the Mental Health Act (1983), none are believed to have an impact on business.

- Seven are expected to have a zero net cost on business. These are: 2008/3166, 2008/1206, 2008/1205, 2008/2560, 2008/1184, 2008/1204 and 2008/1207.

- One (1995/2630) relates to the membership of the management committee of the then Mental Health Act Commission.

The Mental Health Act (2007)

- There is one regulation under this act (2008/2828) which is a consequential amendment with no expected impact on business.

Part of the Community Care Act 2003

- Of the three regulations relevant to mental health under the Community Care Act (2003) none are believed to have an impact on business. These are: 2003/2276, 1992/3182 and 1993/582.

- All of the above regulations are important for safeguarding people in vulnerable circumstances. In addition they are expected to provide a potential net benefit to business. Therefore the case for retaining them is strong.

Statistics: Mental Health	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£0.6 million
Estimated equivalent annual benefits to business	£4.0 million
Estimated equivalent annual net cost to business (EANCB)	Potential benefit, EANCB = 0 million
Impact To Society	
Estimated annual cost to other parties/wider society	Un-monetised
Estimated annual benefits to other parties/wider society	Un-monetised
Net estimated annual cost to other parties/wider society	Un-monetised
Notes: The estimated impacts are for the nine regulations under the Mental Capacity Act (2005) that are expected to have an impact to business as explained above.	
Reliability rating: 3/5	

Summary

Out of the twenty-four mental health regulations:

- Nine may have an impact on business; this is expected to be a net benefit.

- Fifteen regulations are not expected to have any impact on business.

- The case for retaining these regulations is strong as they provide for the safeguarding of people in vulnerable circumstances and do not adversely impact business.

- There may be opportunities to reduce bureaucracy associated with some of these regulations following consideration of comments made in the Quality of Care/Mental Health Red Tape Challenge.

- Further, the House of Lords announced in May 2013 that it was setting up a House of Lords scrutiny of the Mental Capacity Act, to ascertain whether the government knows whether the aims of the legislation have been achieved and what the evidence is for its successes and limitations.

1.3 Social Care (Isles of Scilly)

- Ten regulations which extend other regulations to the Isles of Scilly have been included in this audit. Because they only marginally extend the scope of other legislation to extend the jurisdiction to a small additional population, we have considered that they have no significant additional cost to business in their own right and that any cost to business will be captured in the parent legislation. We understand there to be legal reasons why these need their own SIs.

List of Social Care (Isles of Scilly) Regulations		
SI	**Title**	**Origin**
2005/1096	Carers (Equal Opportunities) Act 2004 (Isles of Scilly) Order 2005	Dom
2004/567	Health and Social Care (Community Health and Standards) Act 2003 (Isles of Scilly) Order 2004	Dom
2003/49	Health and Social Care Act 2001 (Isles of Scilly) Order 2003	Dom
2004/1425	Health and Social Care Act 2001 (Isles of Scilly) Order 2004	Dom
1996/693	Isles of Scilly (Carers) Order 1996	Dom
1993/570	Isles of Scilly (Community Care) Order 1993	Dom
2004/1412	Isles of Scilly (Functions) (Review and Scrutiny of Health Services) Order 2004	Dom
2001/448	Isles of Scilly (Health) Order 2001	Dom
2003/761	Health and Social Care Act 2001 (Isles of Scilly) (No 2) Order 2003, SI 2003/761	Dom
1985/149	Isles of Scilly (Mental Health) Order 1985	Dom

<u>OIOO/OITO Status</u>

- Ten of the regulations in the Social Care policy area as it relates to the Isles of Scilly have been scrutinised for this Audit. Of these, one is due to be repealed as part of the implementation of The Health and Social Care Act 2012. None of these regulations are believed to have an impact to business under the OIOO/OITO rules.

- These regulations apply primary legislation to Isles of Scilly. Therefore, the case to retain the remainder of the regulations is strong.

<u>Summary Status</u>

- Of the ten regulations, there is a case to retain nine. One, SI 2004/1425 is due to be repealed as part of the implementation of The Health and Social Care Act 2012.

1.4 Social Care other

- The following four regulations are due to be repealed as part of the implementation of The Health and Social Care Act 2012. They are not thought to impose a cost to business.

    - SI 2005/499 Health and Social Care Information Centre (Establishment and Constitution) Order 2005 – Revoked by para 190 of Part 2 of Schedule 2 to S.I. 2013/235
    - SI 2008/519 Health and Social Care Information Centre (Transfer of Staff, Property and Liabilities) Order 2008 – Revoked by para 197 of Part 2 of Schedule 2 to S.I. 2013/235
    - SI 2005/500 Health and Social Care Information Centre Regulations 2005 – Revoked by para 191 of Part 2 of Schedule 2 to S.I. 2013/235
    - SI 2001/441Carers (Services) and Direct Payments (Amendment) (England) Regulations 2001

- The following four regulations have no cost to business but are still relevant and therefore cannot be revoked.

    - SI 1988/1843 Transfer of Functions (Health and Social Security) Order 1988 (makes provision consequent on the establishment of the Department of Health and the Department of Social Security and entrusting to the Secretaries of States for those Departments of functions formerly carried out by the Secretary of State for Social Services.)
    - SI 2009/649 Health and Social Care (Financial Assistance) Regulations 2009 (makes provision for financial assistance to “qualifying bodies” engaged in the provision of health and social care services, or the provision of connected services to persons providing health and social care. These regulations define the conditions which must be met to be a “qualifying body”.)
    - SI 2010/750 Health and Social Care Act 2008 (Consequential Amendments) Order 2010, (makes changes to the Water Industry Act for terminology for registered providers who should not be disconnected for non-payment)
    - SI 2010/2224 Health and Social Care Act 2008 (Consequential Amendments No 3) Order 2010 (makes changes to the Water Industry Act for terminology for registered providers who should not be disconnected for non-payment)

<u>Summary</u>

- Eight miscellaneous social care related regulations have been audited. None are thought to have an impact to business. Four are due to be repealed. Four are still relevant and cannot be revoked.

- For information, the following three regulations fall under the responsibility of the Department of Education though they have been listed in the DH led RTC:

    - SI 2005/640, National Care Standards Commission (Commission for Social Care Inspection) (Fees and Frequency of Inspections) (Adoption Agencies) (Amendment) Regulations 2005
    - SI 2010/2130 Care Standards Act 2000 (Registration) (England) Regulations 2010
    - SI 2010/2571 Care Leavers (England) Regulations 2010

2. Medicines and Healthcare products Regulatory Agency (MHRA)

- The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health. It is responsible for regulating all medicines and medical devices in the UK, ensuring they work and are acceptably safe.

- MHRA regulates in the following areas:
  - Blood;
  - Clinical Trials;
  - Devices;
  - Fees;
  - Good Laboratory Practice;
  - Herbals;
  - Homeopathics;
  - Pharmaceuticals; and
  - Transmissible Spongiform Encephalopathies (TSEs).

  Without regulating in these areas, a number of undesirable things may happen. For example:

  - Patients and practitioners would lack belief in the quality, safety and efficacy of pharmaceuticals and medical devices. Evidence for this comes from public attitudes to the unregulated and occasionally harmful “quack medicines” that were sold in the late nineteenth and early twentieth century.

  - Suppliers would also lack incentives for genuine innovation in pharmaceuticals and devices because buyers would not be prepared to pay the prices necessary to cover the costs of innovation. This unwillingness to pay higher prices for high-quality innovative products would stem from buyers’ distrust of suppliers claims about the quality, efficacy and safety of medicines and devices.

  - There would also be insufficient provision of information on product quality, safety and efficacy. Once produced, the information can benefit everyone and can be provided to everyone at the same cost as if it were provided to only a few people. Private sector suppliers are therefore under-incentivised to provide this information because competitors, patients and academia would be free to use the information without paying for it.

  - There would be high risks of very severe safety failures because any product, regardless of its safety and quality, would be allowed onto the market. Although medicines regulation existed at the time of the Thalidomide scandal in the 1960s, it clearly was not strong enough to prevent the tragic effects on unborn babies. Public confidence in the ability of the Government to keep vulnerable individuals safe was clearly undermined.

- Regulation in these areas enables the following:

  - MHRA and its European counterparts solve the problematic lack of reliable product information by requiring medicines and devices developers to conduct robust trials to test

safety and efficacy of their products and to monitor the safety and effectiveness of products once they are on the market.

- Regulators also provide independent assessments of product safety, efficacy and quality and issue or deny market access for those products on the basis of the balance between risk and benefit.

- Product quality and supply chain integrity are also regulated and inspected to ensure high standards and prevent the infiltration of counterfeit products.

- By ensuring that there is reliable product information, regulators enable patients and practitioners to make informed and reassured treatment choices.

- Regulatory licenses encourage innovation in the healthcare market. The licenses issued by MHRA and our European partners convey credible information on safety, efficacy and quality. Buyers can tell whether or not a product is safe and efficacious by checking for the existence of a licence. This in turn rewards licensed producers by being able to sell and charge remunerative prices for genuinely innovative products.

- Ultimately, medicines regulators also encourage confidence in the medicines and devices markets. By prohibiting the most dangerous products, regulators reduce the likeliness of severe safety failures, and strengthen patients' trust in medicines and devices, and provide protection for vulnerable people.

- We have listed other policy instruments where they have been identified. MHRA have committed to providing a full list of non-regulatory policy documents as part of their review of the guidance and content of their regulations for Cabinet Office Ministers, by April 2014.

2.1 Blood

Why we regulate

- To set standards for the quality and safety of the collection, testing, processing, storage and distribution of human blood and blood components.

- The aim of the regulations is to minimise risks such as a person being given blood contaminated with a virus, such as hepatitis C, or receiving blood from a blood group that is unsuitable for them.

What we regulate

- Blood establishments and hospital blood banks.

- The 2006 Amendment Regulations introduced requirements for a quality system in blood establishments and hospital blood banks. They also extend traceability and record-keeping requirements to "facilities" which may receive blood and blood components (care homes, independent clinics, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research institutes).

Other policy instruments

- Guidance – review forthcoming,
- Directive 2002/98/EC – setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components,
- Directive 2004/33/EC – regarding certain technical requirements for blood and blood component,
- Directive 2005/61/EC – regarding traceability requirements and notification of serious adverse reactions and events,
- Directive 2005/62/EC – regarding Community standards and specifications relating to a quality system for blood establishments.

List of MHRA Blood Regulations		
SI	**Title**	**Origin**
2005/50	The Blood Safety and Quality Regulations 2005	EU
2005/2898	The Blood Safety and Quality (Amendment) (No. 2) Regulations 2005	Dom
2005/1098	The Blood Safety and Quality (Amendment) Regulations 2005	EU
2006/2013	The Blood Safety and Quality (Amendment) Regulations 2006	EU
2007/604	The Blood Safety and Quality (Amendment) Regulations 2007	EU
2009/3307	The Blood Safety and Quality (Modification) Regulations 2009	EU
2010/554	The Blood Safety and Quality (Fees Amendment) Regulations 2010	EU
2008/525	The Blood Safety and Quality (Fees Amendment) Regulations 2008	EU
2008/941	The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008	EU

OIOO/OITO Status

- Nine regulations in the MHRA Blood policy area have been scrutinised for this Audit. Of these, eight are EU related and have been confirmed as not being gold plated. These are therefore considered out of scope of OIOO/OITO.

- The remaining regulation (SI 2005/2898) is also considered to be out of scope of OIOO/OITO as it relates to fees. We consider fees regulations to be out of scope because the MHRA (according to HMT 'Guide to the Establishment and operation of trading funds') charges fees to recoup costs resulting from the provision of goods and services in the course of operation and not for reasons of market regulation. Fees are set to reflect the cost of service and to account for the trading fund's 'further financial objective' (average rate of return on capital employed of 3.5%).

Summary

- Of the nine regulations:
  - Eight are EU and are not in scope of OIOO/OITO;
  - The remaining regulation relates to fees and is not in scope of OIOO/OITO.

2.2 Clinical Trials

Why we regulate

Medicines

- Medicinal products need to have a marketing authorisation granted before they can be sold or supplied to patients. Before this authorisation is granted, information about the product is assessed to ensure that it is safe and effective and also that the quality of the product is sufficient.

- Trials follow a set of rules, known as a protocol, to ensure they are well designed and as safe as possible, that they measure the right things in the right way, and that results are meaningful.

- Many clinical trials are designed to show whether new medicines work as expected and are undertaken to allow data on the safety and efficacy of new products to be collected. These results are sent to the MHRA who then decide whether to allow the company making the medicine to market it for a particular use.

- These trials can be conducted using healthy volunteers or patients, depending on the type of product and its stage of development. Information on the non-clinical safety will have been obtained before the clinical trial programme commences.

Devices

- Studies involving non-CE (Conformité Européen) marked medical devices carried out in the UK may be regulated as clinical investigations under the Medical Devices Regulations 2002 and require approval from the UK Competent Authority.

- A manufacturer may carry out a clinical investigation as part of the process of obtaining a CE marking for a medical device, i.e. to demonstrate that the device complies with the essential requirements. Where a medical device is made available for the purposes of a clinical investigation, the manufacturer or his authorised representative must comply with the notification provisions and the clinical investigation must be carried out in accordance with the relevant Directive.

What we regulate

- Before a clinical trial of a new medicine can begin, all of the following need to be in place:

- The science the research is based on must be reviewed by experts;
- The researchers must secure funding;
- An organisation, such as a hospital or research institute, must agree to provide a home base for the trial;
- The MHRA needs to review and approve trials of a medicine and issue a clinical trial authorisation (CTA); and
- A recognised ethics committee must review the trial and allow it to proceed.

- The MHRA inspects sites where trials take place to make sure they are conducted in line with good clinical practice (an international quality standard). The regulations provide a statutory basis for:
  - Standardisation of procedures for ethical and competent authority consideration and authorisation;
  - GCP standards for commencing and conducting clinical trials;
  - Good Manufacturing Practice (GMP) standards for medicines used in clinical trials; and
  - Inspections against internationally accepted principles and standards of GCP and GMP, supported by enforcement powers.

<u>Other policy instruments</u>

- Guidance – review forthcoming.

Medicines

- Requirements for the conduct of clinical trials in the EU are provided for in "Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" ("the Clinical Trials Directive").

- Clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive. If the clinical trials are conducted outside the EU, but submitted in an application for marketing authorisation in the EU, they have to follow the principles which are equivalent to the provisions of the Clinical Trials Directive.

Devices

- Directive 2007/47/EC: Amending Council Directive 90/385/EEC on active implantable medical devices.

- Council Directive 93/42/EEC for medical devices.

- Directive 98/8/EC on the placing biocidal products on the market.

- In Vitro Diagnostic Medical Device Directive 98/79/EC.

List of MHRA Clinical Trials Regulations		
SI	**Title**	**Origin**
2004/1031	The Medicines for Human Use (Clinical Trials) Regulations 2004	EU
2006/1928	The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006	EU
2006/2984	The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006	EU

OIOO/OITO Status

- Three regulations in the MHRA Clinical Trials area have been scrutinised for this Audit. All three transpose EU regulations and are therefore out of scope of OIOO/OITO.

Summary

- Three regulations in the MHRA Clinical Trials area are all EU related so are out of scope of OIOO/OITO.

2.3 Devices

Why we regulate

- The Regulations transpose the EC Medical Devices Directives into UK law. They place obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose before they receive a CE mark (Conformité Européen) and are placed on the market in any EC member state.

What we regulate

- The main difference between how medicines and medical devices are regulated lies in how a product gets onto the market. All medicines are directly approved by the MHRA which issues a 'marketing authorisation', or license. Manufacturers and distributors are also licensed directly by MHRA.

- Medical devices are approved by private sector organisations called 'Notified bodies'. Designation of notified bodies under the medical devices directives is by the Secretary of State acting through the MHRA. Each notified body will be designated to offer the services set out in one or more of the relevant annexes of the directives. To be designated, the applicant must be capable of taking responsibility for all procedures required of a notified body in any particular annex.

- Notified bodies seeking designation to carry out assessments under the regulations will themselves be subject to assessment audits against the requirements. These audits may be conducted either by the Competent Authority or by its appointed agent.

- Manufacturers need to demonstrate that their devices are safe and fit for their intended purpose before they are CE marked, and Notified Body approval is needed before the CE

mark can be put on the device (though the manufacture of low risk devices is simply registered with the MHRA. The MHRA audits the performance of Notified Bodies). However:

- when a product is on the market and in use, there are more similarities than differences in the ways medicines and devices are regulated;
- there are similar systems for receiving reports of problems with products and similar ways of issuing warnings if problems are confirmed after investigation;
- there are also similar systems for inspection of manufacture to ensure that companies are complying with regulations, and similar ways of enforcing the law if that proves necessary.

Registration

- The regulations require manufacturers and authorised representatives based in the UK who are placing class I or custom-made devices to register details of themselves and the medical devices they are placing on the market with the MHRA.

Clinical trials

- Studies involving non-CE marked medical devices carried out in the UK may be regulated as clinical investigations under the Medical Devices Regulations 2002 and require approval from the UK Competent Authority.

RAMS

- In February 2007 the European Commission adopted the Regulation and accreditation proposal (RAMS) package which forms part of its movement of goods package. The main objective of the proposal is to enhance EU competitiveness by strengthening the systems that support harmonisation legislation both before products (which includes medical devices) are placed on the market and afterwards in order to create a level playing field. RAMS gives the MHRA a legal obligation to publish a market surveillance strategy and to review this every four years.

In Vitro Diagnostics (IVD)

- Broadly, a device is an IVD when the manufacturer has intended its use for the in vitro diagnostic examination of specimens derived from the human body. Under the Medical Device Regulations 2002 it requires manufacturers or their authorised representatives or others placing in vitro diagnostic medical devices on the Community market to provide certain information to a Competent Authority in a Member State where they have a registered place of business.

Other policy Instruments

- Guidance – review forthcoming.

List of MHRA Devices Regulations		
SI	**Title**	**Origin**
1978/1138	Medicines (Intra-Uterine Contraceptive Devices) (Appointed Day) Order 1978	Dom
1980/1467	Medicines (Intra-Uterine Contraceptive Devices) (Termination of Transitional Exemptions) Order 1980	Dom
1994/3119	Medical Devices (Consequential Amendments--Medicines) Regulations 1994	EU
2002/618	Medical Devices Regulations 2002	EU
2003/1697	Medical Devices (Amendment) Regulations 2003[1]	EU
2005/2909	Medical Devices (Amendment) Regulations 2005	EU
2007/400	Medical Devices (Amendment) Regulations 2007	EU
2008/2936	Medical Devices (Amendment) Regulations 2008	EU
2012/1426	Medical Devices (Amendment) Regulations 2012	EU
1995/449	Medical Devices (Consultation Requirements) (Fees) Regulations 1995	Dom
2008/530	Medical Devices (Fees Amendments) Regulations 2008	Dom
2009/383	Medical Devices (Fees Amendments) Regulations 2009	Dom
2010/557	Medical Devices (Fees Amendment) Regulations 2010	Dom

OIOO/OITO Status

- Thirteen regulations in the MHRA Devices policy area have been scrutinised for this Audit. Of these, we have been advised that six are expected to be revoked once the new Devices regulation (currently in the final stages of negotiation in Brussels) comes into force. These are SI 1994/3119, SI 2002/618, SI 2003/1697, SI 2007/400, SI 2008/2936, and SI 2012/1426.

- SI 2005/2909 is not due to be revoked, but is EU and therefore out of scope of OIOO/OITO.

- Two regulations (SI 1978/1138, SI 1980/1467) are spent.

- The remaining four regulations (SI 1995/449, SI 2008/530, SI 2009/383, SI 2010/557) relate to fees. We consider fees regulations to be out of scope because the MHRA (according to HMT 'Guide to the Establishment and operation of trading funds') charges fees to recoup costs resulting from the provision of goods and services in the course of operation and not for reasons of market regulation. Fees are set to reflect the cost of service and to account for the trading fund's 'further financial objective' (average rate of return on capital employed of 3.5%).

Summary

- Of the thirteen regulations:
  - Six are expected to be revoked once the new Devices regulation comes into force;
  - One is EU and out of scope of OIOO/OITO;
  - Two are spent;
  - Four relate to fees and are therefore out of scope of OIOO/OITO.

2.4 Fees

Why we regulate

- The MHRA operates as a trading fund in accordance with the requirements of the Government Trading Funds Act 1973 and the Medicines and Healthcare products Regulatory Agency Trading Fund Order 2003. The trading fund was established on 1 April 2003.

- In accordance with Section 3 of the Government Trading Funds Act 1973 (as amended by the Government Trading Act 1990), all sums received by the Agency as payment for services provided will be paid into the trading fund and all expenditure incurred will be paid out of the fund. The Agency's target is to break even, taking one year with another, after taking account of HM Treasury's requirement to earn a real terms' return on capital employed.

- The Agency is funded from:
  - national fees charged by the MHRA directly to organisations for the fulfilment of statutory or other regulatory obligations;
  - EU fees charged by the EMA to organisations and then shared among those agencies, such as the MHRA, undertaking particular activities on behalf of the EU network;
  - other charges for non-statutory services, including sales into wider markets;
  - research;
  - Service Level Agreements with the Department of Health covering the regulation of medical devices and specific functions delivered by NIBSC.

- The MHRA must operate within its resources. If it fails to do so, the Comptroller and Auditor General may qualify its annual accounts and refer the matter to the Public Accounts Committee. The MHRA must also operate within the delegated authorities issued by the Department of Health.

- The majority of the funding provided to the MHRA to discharge its regulatory activities comes from fees for services provided. The European Medicines Agency has the powers to charge fees for work undertaken by European regulatory agencies on behalf of the EU

network; these fees charged by the EMA are then shared among the main agencies carrying out the work.

What we regulate

- Fees for:

Medicines

- Appeals to the Review Panel (formerly Persons Appointed);
- Clinical Trial Applications;
- Drug/Device combination products;
- Export certificates;
- Good Clinical Practice Scheme;
- Herbals – Traditional herbal medicinal products;
- Homoeopathic National Rules Scheme;
- Inspection fees;
- License Applications;
- Manufacturers licenses;
- Periodic fees;
- Renewals, reclassifications and assessment of labels and leaflets;
- Registration of Active Pharmaceutical ingredient manufacturers, importers and distributors;
- Registration of Brokers;
- Safety and quality vetting of unlicensed imported medicines;
- Scientific advice meetings;
- Variations – license variations; and
- Wholesale Dealers

Blood

- Blood banks and other blood establishments

Devices

- Medical devices regulation is mostly funded by the Department of Health against an agreed set of outcome measures, although certain regulatory activities, such as Class I device registrations, clinical trial applications etc are funded through fees paid by industry and Notified Bodies.

List of MHRA Fees Regulations		
SI	**Title**	**Origin**
1989/684	The Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989	Dom
1995/871	The Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Amendment Order 1995	Dom
2001/795	The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2001	Dom
2002/542	The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2002	Dom
2003/2321	The Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003	Dom
2007/803	The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007	Dom
2012/504	The Medicines (Products for Human Use) (Fees) Regulations 2012	Dom
2012/2546	The Medicines (Products for Human Use) (Fees) (Amendments) Regulations 2012	Dom
1998/574	Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1998	Dom
2013/532	The Medicines (Products for Human Use) (Fees) Regulations 2013	Dom
2009/372	The Blood Safety and Quality (Fees Amendments) Regulations2009	Dom
2003/1076	The Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003, SI 2003/1076 (principal SI to establish trading fund)	Dom
2005/2061	The Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2005 (trading fund amendment)	Dom

Other policy instruments

- Guidance – review forthcoming.

OIOO/OITO Status

- Thirteen regulations in the MHRA Fees area have been scrutinised for this Audit. Of these, it is believed that one was revoked (SI 2009/372) when SI 2010/554 came into force (in the Blood Section). Legal services are confirming this.

- The remaining 12 regulations relate to fees. We consider fees regulations to be out of scope because the MHRA (according to HMT 'Guide to the Establishment and operation of trading funds') charges fees to recoup costs resulting from the provision of goods and services in the course of operation and not for reasons of market regulation. Fees are set to reflect the cost of service and to account for the trading fund's 'further financial objective' (average rate of return on capital employed of 3.5%).

Summary

- Of the 13 regulations:
    - It is likely that one has already been revoked (legal to confirm);
    - All thirteen are out of scope of OIOO/OITO as they relate to fees.

2.5 Good Laboratory Practice

Why we regulate

- Compliance with the principles of Good Laboratory Practice (GLP) is a legal requirement for test facilities that undertake health and environmental safety studies, and some other testing, that will be submitted to regulatory authorities for the purposes of risk assessment.

What we regulate

- The GLP Regulations apply to any test facility which conducts, or intends to conduct, a regulatory study. A regulatory study is a study for which the regulatory authority to whom the data will be submitted, requires that study to be conducted in compliance with the principles of GLP.

- GLP is concerned with the organisational processes and the conditions under which certain laboratory studies are planned, performed, monitored, recorded, archived and reported. Adherence by test facilities to the principles of GLP ensures the proper planning of studies and the provision of adequate means to carry them out. It facilitates the proper conduct of studies, promotes their full and accurate reporting, and provides a means whereby the validity and integrity of the studies can be verified. The application of GLP to regulatory studies assures the quality of the data generated and allows its use by Government regulatory authorities in hazard and risk assessment in particular of new substances.

- The UK GLP Monitoring Authority (GLPMA) has responsibility for monitoring test facilities for compliance with the principles of GLP. The work of the GLPMA is carried out by a unit within the Inspection and Enforcement Division of the MHRA.

- The range of test facilities monitored by the GLPMA include those involved in the health and environmental safety testing of human and veterinary pharmaceuticals, agrochemicals, cosmetics, food and feed additives and industrial chemicals. The test items are frequently synthetic chemicals but may be of natural or biological origin, and in some circumstances may be living organisms.

Other policy instruments

- Guidance – review forthcoming.

List of MHRA Good Laboratory Practice Regulations		
SI	**Title**	**Origin**
1999/3106	The Good Laboratory Practice Regulations 1999, SI 1999/3106	EU
2004/994	The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004, SI 2004/994	EU

OIOO/OITO Status

- Two regulations in the MHRA Good Laboratory Practice area have been scrutinised for this Audit. Both are EU related so are out of scope of OIOO/OITO.

Summary

- Both regulations in this area are EU related and are therefore out of scope of OIOO/OITO.

2.6 Herbals

Why we regulate

- Regulatory action was required due to the increasing use of herbal medicines, an increase in reports of adverse reactions and a growing understanding regarding possible side-effects and interactions between herbal and other medicines. There were also concerns over the safety and quality of some unlicensed products, availability of accurate and sufficient patient information and fitness to practice of some practitioners.

- The new European Traditional Herbal Medicinal Products Directive (THMPD) 2004/24/EC came into effect on 30 April 2011 and is the main regulatory approval process for herbal medicines in the European Union (EU).

- The Directive establishes a regulatory approval process for herbal medicines in the European Union (EU). It requires each EU Member State to set up a traditional herbal registration scheme (Traditional Herbal Medicines Registration Scheme (THMRS)) for manufactured traditional herbal medicines that are suitable for use without medical supervision. The scheme helps protect public health by requiring specific standards of safety and quality for traditional herbal medicines.

What we regulate

- The regulations cover traditional use, the activities of wholesale dealers, importers, quality aspects, product information, advertising, and pharmacovigilance.

- The THMPD requires that herbal products comply with strict quality standards such as are required for other medicines holding marketing authorisations. They must be manufactured under Good Manufacturing Process procedures, and pharmacovigilance (safety monitoring) requirements apply. Adequate patient information must be provided along with declarations on the label and in advertisements that medicinal claims and indications are based on traditional usage.

- The Traditional Herbal Medicines Registration Scheme (THMRS) deals with manufactured traditional herbal medicines that can be used without medical supervision. It provides an assurance that the user is receiving product of satisfactory quality together with reliable information regarding its use. Manufactured herbal medicines placed on the UK market are required to have either a Traditional Herbal Registration (THR) or a Marketing Authorisation (MA). This applies whether the product is marketed to consumers, herbal practitioners, retailers, or wholesalers. To get a marketing authorisation a product needs to meet standards of safety, quality and efficacy (or effectiveness).

- Current legislation in this area is contained in a number of individual statutory instruments that implement European legislation.

- MHRA has also made a number of Orders which prohibits or restrict – with some exemptions – the sale, supply or importation of certain products or medicinal products containing certain substances. In broad terms, the purpose of the Orders is to ban or restrict the use of certain potent and toxic substances from being used in unlicensed medicinal products. The Agency additionally maintains a table providing a consolidated list of herbal ingredients which are subject to various restrictions.

<u>Other policy instruments</u>

- Guidance – review forthcoming.

<u>OIOO/OITO Status</u>

- Six regulations have been scrutinised for this Audit. Of these, five are prohibition orders. We believe that these regulations are unlikely to impose direct costs on business (SI 2001/1841, SI 2002/3170, SI 1977/670, SI 1997/856, SI 2008/548). The rationale for this is as follows:

    - the ‘cost on business’ from a prohibition is the loss of (expected) profit made with the banned substance;
    - These ‘costs’ are likely to have been transitional as sellers, suppliers and manufacturers are expected to substitute away from the prohibited substances and shift to other substances to compensate the loss; no recurring costs have been identified;
    - Four prohibition orders were enacted more than 10 years ago (the average appraisal period) and it is reasonable to expect that any transitional costs will have faded out by now.

- If these prohibition orders were to be revoked there would be no direct impacts on business because of the permissive nature of the regulatory change. A direct impact to business has not been identified. Therefore, these prohibition orders are not believed to have an impact on business under the OIOO/OITO rule.

- The case to retain the remaining regulation is strong as it is expected that there is very little impact on business.

List of MHRA Herbals Regulations		
SI	**Title**	**Origin**
2001/1841	The Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001 SI 1841	Dom
19971 1/1830	The Prescription Only Medicines (Human Use) Order 19971 1SI 1830	Dom
2002/3170	The Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 SI 3170	Dom
1977/670	The Medicines (Bal Jivan Chamcho Prohibition) (No 2) Order 1977, SI 1977/670	Dom
1997/856	The Medicines (Bal Jivan Chamcho Prohibition) (No 2) Amendment Order 1997, SI 1997/856	Dom
2008/548	Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008, SI 2008/548	Dom

Summary

- Of the six regulations:
  - Five are prohibition orders and are unlikely to impose direct costs on business;
  - The case to retain the remaining regulation is strong.

2.7 Homeopathics

Why we regulate

- To harmonize the market of homeopathic products, the European Council, by Directive 92/73/EEC directed member states to implement certain changes in their national legislation (Directive 92/73/EEC was replaced by Directive 2001/83/EC on the Community code relating to medicinal products for human use).

- Member states are required to ensure that homeopathic products (for oral or external use) can be registered without proof of therapeutic efficacy, provided that there is a sufficient degree of dilution to guarantee the safety of the product; in particular, the product may not contain either more than one part per 10,000 of the mother tincture or more than 1/100th of the smallest dose used in mainstream medicine, with regard to active principles whose presence in a medicinal product results in the obligation to submit a doctor's prescription.

- Labels of homeopathic products registered without proof of efficacy must include the words "homeopathic medicinal product without approved therapeutic indications" as well as a

warning advising the user to consult a doctor if the symptoms persist during the use of the medicinal product.

What we regulate

- Product Licences of Right (PLRs) were issued to all medicinal products on the market at the time that the Medicines Act 1968 was implemented (in 1971). Homeopathic products covered by PLRs may have indications (the descriptions of diseases or conditions for which the medicine is intended to be used). The Simplified Registration Scheme was introduced in 1992 and does not allow indications. The National Rules Scheme was therefore introduced to regularise these inconsistencies and allows homeopathic products to be indicated for the relief or treatment of mild, self-limiting conditions. Companies are encouraged to register new products in this scheme and to re-register their existing PLR products.

The Simplified Scheme

- In 1992 Directive 92/73/EC introduced a Simplified Scheme for homeopathic products (Special Simplified Registration Procedure (Article 7 of Directive 92/73/EEC - Now Article 14 of Directive 2001/83/EC on medicinal products for human use). It is regarded as simplified because although the safety and quality of products has to be demonstrated, products are not permitted to make medical claims. In order to qualify for registration under the special simplified registration procedure the products must comply with the following criteria:

    1) They are sufficiently dilute to guarantee their safety;
    2) They are for oral or external administration - this includes all methods of administration with the exception of injections; and
    3) They do not bear a specific therapeutic indication.

The National Rules Scheme

- This Scheme was introduced on 1 September 2006, following a public consultation. The purpose of the Scheme is to enable homeopathic medicinal products to be registered with indications for the relief or treatment of minor symptoms and conditions (those that can ordinarily be relieved or treated without the supervision or intervention of a doctor). Applications under the National Rules Scheme must be supported by a dossier of data on quality, safety and efficacy, together with appropriate product labelling and product literature.

Other policy instruments

- Guidance – review forthcoming.

List of MHRA Homeopathics Regulations		
SI	**Title**	**Origin**
2001/83	Special Simplified Registration Procedure (Article 7 of Directive 92/73/EEC - Now Article 14 of Directive 2001/83/EC on medicinal products for human use implemented in the Human Medicines Regulations 2012.	EU

OIOO/OITO Status

- One regulation in the MHRA Homeopathics area has been scrutinised for this Audit. It is EU related and is therefore out of scope of OIOO/OITO.

Summary

- The one regulation in the Homeopathics area is EU related and therefore out of scope of OIOO/OITO.

2.8 Pharmaceuticals

Why we regulate

- MHRA regulates a range of activities relating to pharmaceuticals with the ultimate aim of safeguarding and improving public health. This objective would not be achieved in the absence of regulation and the following paragraphs detail the rationale for why government intervention in the market for pharmaceuticals is necessary.

Licensing

- Licensing of pharmaceuticals is intended to protect and safeguard public health by providing potential buyers with credible, independent information on the safety, efficacy and quality of medicines.

- Without this information, buyers would be unsure whether the efficacy, safety and quality claims made by the supplier are genuine. Licensing fills a “credibility gap”, and in-so-doing helps buyers to charge prices that cover the high costs of pharmaceutical innovation.

- By denying licenses to dangerous products, regulators reduce the likeliness of severe safety failures, thereby strengthening patients’ trust in medicines and providing protection for patients.

Import of medicines

- Regulation on the import of medicine is intended to ensure that products coming into the UK fulfil the relevant quality, safety and efficacy criteria. This provides buyers, patients and medical practitioners with a level of reassurance that allows them to buy, prescribe, and use medicines with confidence.

Classification

- MHRA requires that all medicines are classified as either a ‘Prescription Only Medicine (POM)’, a ‘Pharmacy Only (P)’ or ‘General Sales List’ medicine, indicating the relative potency. Moreover, the Agency restricts the sale and supply of POM and P medicine to patients who have been prescribed the remedy by a physician or have sought guidance from a pharmacist.

Inspection and enforcement

- Regulation on inspection and enforcement activities are intended to check and encourage compliance with the regulatory framework.

- MHRA is committed to regulating in a proportionate way and therefore conducts inspections, focusing on high-risk entities. Moreover, the threat of financial penalties and other forms of sanctions encourages regulated parties to comply with regulation before punitive action is taken by the regulator.

Labels, patient information leaflets and packaging for medicines

- Regulation on labelling, packaging and patient information is intended to provide standardised, correct and easily understandable information about a pharmaceutical product.

- In the absence of regulation, producers may not give sufficient prominence to medical indication and product safety information or confuse the consumer with too much poorly focussed information. This could lead to patients being misinformed about the risks of the product, leading to potentially harmful treatment choices.

- MHRA ensures that suppliers provide correct and comprehensive information about medical indications, product risks and side effects in an easily accessible and understandable form, allowing patients to make well-informed choices.

Advertising

- Regulation on advertising of pharmaceutical products is intended to ensure that patients receive accurate information.

- In the absence of regulation of pharmaceutical advertisement, patients and medical practitioners may easily be misled by the advertising claims of suppliers. Suppliers know more about their products' inherent qualities than patients and practitioners and may take advantage of their customer's ignorance by making misleading claims about their products. Buyers are not usually able to verify objectively these claims and hence may be encouraged to consume unsuitable or potentially harmful medicines.

- By regulating advertising, MHRA ensures that producers can only provide accurate and balanced information about their products, allowing patients and medical practitioners to make informed choices.

Advisory bodies

- Regulation of advisory bodies is intended to ensure that Ministers receive high-quality, unbiased expert advice on technical matters relating to medicines and devices. Appointment to these bodies follows merit-based, transparent procedures and MHRA also generally requires appointees to declare any conflicts of interest.

Pharmacovigilance

- Regulation on pharmacovigilance ensures the gathering of safety and effectiveness data on a pharmaceutical product after it has been licensed and is on the market.

- Pharmacovigilance regulation adds to publicly available safety and efficacy knowledge already gathered for licensing, and ensures that the best and most up-to-date information is available for patients and medical practitioners to use when deciding which medicines to take or prescribe. In extreme circumstances, where pharmacovigilance reveals new concerns about safety, products can be removed from the market, thereby safeguarding public health and confidence in medicines.

Sale and supply

- Regulation on classification and sale and supply of pharmaceuticals is intended to avoid public harm by limiting the supply of highly potent remedies. This protects patients from misinformed decisions and helps to maintain public confidence in the safety of medicines.

What we regulate:

Licensing, import and export of medicines

- Medicines meet the standards of safety, quality and efficacy necessary to be granted a Marketing Authorisation – via any available regulatory route – before they can be prescribed or sold.

- Unlicensed imports for the special needs of individual patients meet regulatory requirements.

- Medicines for export are covered by the correct certificate.

Classification

- Each medicine is correctly assigned to one of three legal categories - prescription only (POM), pharmacy (P) or general sale list (GSL). These classifications determine how medicines can be supplied to the public.

Enforcement

- Effective and timely enforcement action is taken against breaches of the regulations

Inspection

- Inspections of the following are conducted on time and in line with regulations:
  - Good Clinical Practice (GCP)
  - Good Pharmacovigilance Practice (GPvP)
  - Good Distribution Practice (GDP)
  - Good Laboratory Practice (GLP)
  - Good Manufacturing Practice (GMP)

Labels, patient information leaflets and packaging for medicines

- Patient information, such as is contained in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SPC) is complete, accurate and up to date, and labelling and packaging of medicines are in compliance with the regulations.

Advertising

- Advertising is legal, honest and accurate.

Advisory Bodies

- Medicines advisory bodies, which provide advice to Ministers on aspects of medicines regulation, are properly constituted, and have the information they require to provide quality advice.

Pharmacovigilance

- All medicines are monitored throughout their marketed life via the process of pharmacovigilance.

Sale and Supply

- Medicines are sold and supplied in line with their legal status under the regulations i.e. POM and P medicines can only be sold or supplied at registered pharmacy premises by or under the supervision of a pharmacist. POMs are subject to the additional requirement that they are sold or supplied in accordance with an appropriate practitioner's prescription. General Sale List medicines can be sold from a wider range of premises such as supermarkets provided those premises can be secured from the public and the medicines are pre-packed.

<u>Other policy instruments</u>

- Guidance – review forthcoming.

List of MHRA Pharmaceuticals Regulations		
SI	**Title**	**Origin**
2012/1916	Human Medicines Regulations 2012	Majority EU minority Dom
2010/2785	Medicines for Human Use (Prescribing by EEA Practitioners) (Amendment) (No 2) Regulations 2010	Dom
2010/1673	Medicines for Human Use (Prescribing by EEA Practitioners) (Amendment) Regulations 2010	Dom
1997/1830	Prescription Only Medicines (Human Use) Order 1997	Dom
2005/1094	Medicines (Advisory Bodies) Regulations 2005	Dom
2005/2754	Medicines (Advisory Bodies) (No 2) Regulations 2005	Dom
2005/2750	The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations	EU
2009/1164	Medicines for Human Use (Miscellaneous Amendments) Regulations 2009	Dom
1977/2131	Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977	Dom
1979/382	Medicines (Chloroform Prohibition) Order 1979	Dom
1980/263	Medicines (Chloroform Prohibition) Amendment Order 1980	Dom
1992/2684	Medicines (Prohibition of Non-medicinal Antimicrobial Substances) (Amendment) Order 1992	Dom
1996/3269	Medicines (Phenacetin Prohibition) (Revocation) Order 1996, [1] We are reviewing if a prohibition revocation needs to be retained to have effect.	Dom
1997/1727	Medicines (Stilbenes and Thyrostatic Substances Prohibition) (Revocation) Order 1997	Dom

OIOO/OITO Status

- Fourteen regulations in the MHRA Pharmaceuticals area have been scrutinised for this Audit. Of these, four are prohibition orders which are unlikely to impose direct costs on business (SI 1977/2131, SI 1979/382, SI 1980/263, SI 1992/2684). The rationale for this is as follows:
  - the 'cost on business' from a prohibition is the loss of (expected) profit made with the banned substance;
  - These 'costs' are likely to have been transitional as sellers, suppliers and manufacturers are expected to substitute away from the prohibited substances and shift to other substances to compensate the loss; no recurring costs have been identified;
  - They were enacted more than 10 years ago (the average appraisal period) and it is reasonable to expect that any transitional costs will have faded out by now.

- If these prohibition orders were to be revoked there would be no direct impacts on business because of the permissive nature of the regulatory change. A direct impact to business has not been identified. Therefore, these prohibition orders are not believed to have an impact on business under the OIOO/OITO rule.

- Two regulations (SI 1996/3269) and (1997/1727) are revocation orders which are used to revoke other regulations. They are deregulatory.

- We have been advised that two regulations can be revoked in the future if legally necessary (SI 2010/2785, SI 2010/1673), and one (SI 2009/1164) will be revoked along with other UK Clinical Trials legislation when the new EU clinical trials Regulation comes into force circa 2016.

- The case to retain the remaining five regulations for cross-referencing is strong, and for the reasons set out in the text at the beginning of the MHRA section. All of these are expected to have very little impact to business.

Summary

- Of fourteen regulations:

  - Four are prohibition orders which are unlikely to impose direct costs on business;

  - Two regulations are revocation orders;

  - We have been advised that three can be revoked once more legal resources become available;

  - The case to retain the remaining five is strong.

2.9 Transmissible Spongiform Encephalopathies (TSEs)

Why we regulate

- Transmissible Spongiform Encephalopathies (TSEs) are a family of diseases occurring in man and animals and are characterised by a degeneration of brain tissue giving a sponge-like appearance leading to death. They include diseases such as Creutzfeldt Jakob Disease (CJD) and Kuru in humans.

- Regulations have been introduced to apply the European Commission's guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products administered to humans.

What we regulate

- The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 (SI 2003/1680) came into force on the 30 July 2003. From this date manufacturers, importers and exporters of unlicensed medicinal products for human use are required to comply with the provisions of the Regulations.

- MHRA also regulates acceptable practices for importers in assessing compliance of prospective imports of exempt imported products as defined in Statutory Instrument 1999/4, The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1999 (SI 1999/4) with UK TSE Regulations

Other policy instruments

- 1999/82/EC (requiring all **licensed** medicines to comply with the European Commission's "Notes for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" and future updates).

List of MHRA Spongiform Encephalopathies Regulations		
SI	**Title**	**Origin**
2003/1680	The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003, SI 2003/1680	Domestic

OIOO/OITO Status

- TSE regulations have been assessed as being within scope of OIOO/OITO, the estimated impacts to business are set out in the table below.

Statistics: Transmissible Spongiform Encephalopathies (TSEs)	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	Circa. £0.1 million
Estimated equivalent annual benefits to business	Un-monetised
Estimated equivalent annual net cost to business (EANCB)	Circa. £0.1 million
Impact To Society	
Estimated annual cost to other parties/wider society	Un-monetised
Estimated annual benefits to other parties/wider society	Un-monetised
Net estimated annual cost to other parties/wider society	Un-monetised
Notes: N/A	
Reliability rating: 1/5	

Summary

- There is a case for retaining this regulation to apply the European Commission's guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products administered to humans.

3. Medicines, Pharmacy, Dental and Ophthalmic Services

- This section is further divided into the following areas:
  - Charges and benefits;
  - Dental;
  - General Pharmaceutical Services, Local Pharmaceutical Services, Controlled Drugs, Responsible Pharmacist and non-medical prescribing regulations; and
  - Ophthalmic Services.

- Several sets of regulations provide for the statutory pharmaceutical pricing scheme, which ensure that some price controls exist on the sales of branded medicines to the health service in instances where a pharmaceutical company is not a member of the voluntary Pharmaceutical Price Regulation Scheme (PPRS), thereby safeguarding the financial position of the NHS. Regulations are also in place which set out the manner in which companies formally sign up to, or withdraw from, the voluntary scheme.

- Regulations regarding the statutory scheme, the PPRS and the National Institute for Health and Clinical Excellence (NICE) have not been included in full in this section for the following reasons:

  - Commenting on the Impact Assessment in 2012 which accompanied the amendment to the price adjustment in the statutory scheme, the RPC accepted that the statutory scheme was out of scope of OIOO because it is a contractual obligation. The statutory scheme is akin to procurement; in the absence of this scheme (and the PPRS), the Government would need to negotiate with pharmaceutical companies on the prices of individual drugs to secure socially optimal outcomes and efficient use of public funding, as the temporary monopoly status afforded by drug patents means there is no downward pressure on prices from external market forces.

  - The issue of OIOO and NICE was considered during the passage of the Health and Social Care Bill. It was confirmed that any new regulatory burdens imposed by NICE would impact on the public sector only.

- The eight NICE related regulations are listed here for information. All of these are due to be revoked as part of the implementation of The Health and Social Care Act 2012.

List of NICE related regulations		
SI	**Title**	**Origin**
1999/2218	National Institute for Clinical Excellence (Amendment) Regulations 1999	Dom
1999/2219	National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 1999	Dom
1999/220	National Institute for Clinical Excellence (Establishment and Constitution) Order 1999	Dom
1999/260	National Institute for Clinical Excellence Regulations 1999	Dom
2002/1759	National Institute for Clinical Excellence (Amendment) Regulations 2002	Dom
2002/1760	National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 2002	Dom
2005/498	National Institute for Clinical Excellence (Amendment) Regulations 2005	Dom
2005/497	National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 2005	Dom

- The seven regulations regarding the statutory pharmaceutical scheme and the PPRS are listed below. One regulation has been repealed (SI 2010/2798) and three regulations (SIs 2007/1320, 2008/3258 and 2012/2791) are expected to be consolidated and revised in 2013 through the proposed revision of the statutory scheme.

List of PPRS Regulations		
SI	**Title**	**Origin**
2000/870	Health Service Medicines (Price Control Appeals) Amendment Regulations 2000	Dom
2000/124	Health Service Medicines (Price Control Appeals) Regulations 2000	Dom
2007/1320	Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007	Dom
2008/3258	Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008	Dom
2012/2791	Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2012	Dom
1999/2229	Health Service Medicines (Consent to Voluntary Scheme) Regulations 1999	Dom
2010/2798	Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2010	Dom

3.1 Charges and benefits

Why we regulate

- The prescription charging arrangements raise £450 million in revenue each year via the community pharmacy sector. Prescription charges revenue is also raised by dispensing from hospital Trusts and Foundation Trusts, although this revenue remains with the Trust. The regulations describe the prescription charging arrangements, and also provide for exemption arrangements which are in effect benefits in kind.

- The NHS Low Income Scheme is a means tested assessment which provides full help (i.e. free) NHS prescriptions, NHS dental treatment, wigs and fabric supports, sight tests, access to optical vouchers and assistance with the cost of travel to a health services appointment on referral by a primary care practitioner (e.g. a doctor, dentist or optician).

- The scheme may also provide partial help to the applicant for NHS dental treatment, wigs and fabric supports, sight tests, access to optical vouchers and assistance with the cost of travel to a health services appointment on referral by a primary care practitioner. This means they will pay a contribution towards the cost based on their means.

What we regulate

- The regulations set the level of the single prescription charge and the 3 and 12 month prescription prepayment certificate. These prices are reviewed regularly, typically on an annual basis.

- Regulations provide a range of exemptions from prescription charges based on age, income and medical condition. They also describe the means tested assessment for the NHS Low Income Scheme, which are broadly the same as Income Support.

Other policy instruments

- National Health Service Act 2006.
- The Pharmaceutical and Local Pharmaceutical Services (Prescriptions, Payments and Listings) Directions 2013.

- The set directions relate to the functions carried out by the NHS BSA in relation to prescriptions charges and exemption arrangements set out in the “Charges” and “Travel Expenses” regulations.

List of Charges and Benefits Regulations		
SI	**Title**	**Origin**
2013/475	The National Health Service (Charges For Drugs And Appliances), (Dental Charges) And (Travel And Remission Of Charges) (Amendment) Regulations 2013	Dom
2000/620	National Health Service (Charges for Drugs and Appliances) Regulations 2000	Dom
2001/2887	National Health Service (Charges for Drugs and Appliances) (Electronic Communications) Order 2001	Dom
2002/2352	National Health Service (Charges for Drugs and Appliances) Amendment (No 3) Regulations 2002	Dom
2003/1084	National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003	Dom
2003/2382	National Health Service (Travel and Remission of Charges) Regulations 2003	Dom
2004/663	National Health Service (Charges for Drugs and Appliances) and (Travel and Remission of Charges) Amendment Regulations 2004	Dom
2005/578	National Health Service (Charges for Drugs and Appliances) and (Travel and Remission of Charges) Amendment Regulations 2005	Dom
2006/675	National Health Service (Charges for Drugs and Appliances) and (Travel Expenses and Remission of Charges) Amendment Regulations 2006	Dom
2008/1697	National Health Service (Charges for Drugs and Appliances) and (Travel Expenses and Remission of Charges) Amendment (No2) Regulations 2008	Dom
2008/571	National Health Service (Charges for Drugs and Appliances) and (Travel Expenses and Remission of Charges) Amendment Regulations 2008	Dom
2009/1166	National Health Service (Charges) (Amendments Relating to Pandemic Influenza) Regulations 2009	Dom
2009/29	National Health Service (Charges for Drugs and Appliances) Amendment Regulations 2009	Dom
2010/1727	National Health Service (Charges for Drugs and Appliances) and (Travel Expenses and Remission of Charges) Amendment Regulations 2010	Dom

<u>One-in One-out Status</u>

- Fourteen regulations in the Medicines, Pharmacy, Dental and Eye Care services policy area relating to charges and benefits have been scrutinised for this Audit. Of these, none are believed to have an impact to business under One-in One-out rules. These 14 regulations relate to fees and charges and are also contractual obligations placed on business.

- The prescription charge is a fee levied at the point of dispensing of a drug or appliance. The charge is paid by the patient for each item dispensed in the community. The charge is collected by the dispenser, such as a pharmacist, dispensing appliance contractor or a dispensing doctor. Charges are also collected by hospitals' outpatients and accident and

emergency departments. The value of the charge is set out in the Charges regulations and is reviewed annually.

- The Pharmaceutical and Local Pharmaceutical Services regulations include the contractual requirements (terms of service) for pharmacists, dispensing appliance contractors and dispensing doctors. These require the contractor's staff to ask the patient to make a declaration of entitlement and indicate the category for the exemption before providing a drug or appliance. If the patient does not have to pay a prescription charge, they must be asked to provide evidence to substantiate their claim. Where evidence is not provided the form must be endorsed to that effect. Equally, where a charge is due, confirmation must be given that the charge was paid. This is known as the point of dispensing check (POD) and they were introduced in April 1999.

Summary

Out of 14 regulations:

- For nine of the regulations, the Department hopes to produce a consolidated set of Regulations over the next couple of years, but the timing has yet to be agreed. These are: 2002/2352, 2004/663, 2005/578, 2006/675, 2008/1697, 2008/571, 2009/29, 2009/1166, 2010/1727.

- There is a case for retaining the remaining five regulations in order to maintain operation of fees and charges. S.I. 2013/475 includes a regulation implementing this year's dental uplifts as part of the Parliamentary handling strategy for the NHS reforms implementation.

3.2 Dental

Why we regulate

- The DH regulates in order to ensure a stable framework for the provision of NHS dental services.

- Regulations exist in order to allow for the variation of NHS dental contracts, for example in line with the current pilot scheme which is designing elements of the new dental contract promised in the Coalition Agreement.

- Regulations are also enacted in order to give effect to General Dental Council decisions regarding the disciplinary process needed to maintain professional and ethical standards within dentistry.

What we regulate

- The DH is responsible for creating the legal framework which surrounds NHS dental contracts. We are also responsible for ensuring the legal status of NHS dental charges, remuneration of dentists who provide NHS services and for enabling the dental profession's disciplinary procedures.

- Over the last two years, 29.7 million patients have accessed NHS primary dental care, provided by some 21,000 dentists. The care received by these patients, the safeguards around that care and the remuneration system for the dentists providing that care, along with the charges paid by patients, are all delivered within a legislative framework made up of primary and secondary legislation.

Other policy instruments

- Capitation and Quality Scheme 2 Statement of Financial Entitlements;
- General Dental Services Statement of Financial Entitlements;
- The National Health Service (Dental Services) (Capitation and Quality Scheme 2 Agreements) Directions 2013;
- Personal Dental Services Statement of Financial Entitlements.

List of Dental Regulations		
SI	**Title**	**Origin**
2009/1358	Dentists Act 1984 (Medical Authorities) Order 2009	Dom
2005/3435	General Dental Services and Personal Dental Services Transitional Provisions Order 2005	Dom
2006/562	General Dental Services, Personal Dental Services and Abolition of the Dental Practice Board Transitional and Consequential Provisions Order 2006	Dom
2006/913	National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations	Dom
2005/3361	National Health Service (General Dental Services Contracts) Regulations 2005	Dom
2006/185	Functions of Primary Care Trusts (Dental Public Health) (England) Regulations 2006	Dom
2006/596	Functions of Primary Care Trusts and Strategic Health Authorities and the NHS Business Services Authority (Primary Dental Services) (England) Regulations 2006	Dom

One-in One-out Status

- Seven regulations in the Medicines, Pharmacy, Dental and Eye Care services policy area relating to dental service have been scrutinised for this Audit.

- Of these none are believed to have an impact to business under One-in One-out rules. Two have been revoked (SI 2006/596 and SI 2006/185).

- One allowed King's College London to establish a dental school and issue dental degrees, which does not impose a burden to business (SI 2009/1358).

- Two are transitional provisions: SI 2005/3435 is designed to facilitate the transition between the previous dental contract and the current one, which took place in 2006. SI 2006/562, in addition to the contract transition, deals with the transfer of functions to the NHS Business Services Authority (BSA). These regulations cannot be revoked as they are still relevant to the NHS reforms.

- The remainder are contractual and are therefore out of scope of OIOO/OITO.

Summary

Out of seven regulations:

- Two have been revoked

- Two are transitional but cannot be revoked as they are still relevant to the NHS reforms.

- There is a case to retain the three with no impact to business where they ensure a stable framework for the provision of NHS dental services.

3.3 General Pharmaceutical Services, Local Pharmaceutical Services, Controlled Drugs, Responsible Pharmacist and non-medical prescribing

Why we regulate

General Pharmaceutical Services and Local Pharmaceutical Services

- Under the NHS Act 2006, regulations to enable patients to access state-funded NHS pharmaceutical services are mandatory. Their primary function is to create and manage NHS pharmaceutical services. Without these regulations, there would be no powers to enable such provision by pharmacies, dispensing appliance contractors or doctors.

- The regulations set out the overarching legal framework under which NHS pharmaceutical services are commissioned and paid for by the NHS and the terms and conditions with which the various NHS pharmaceutical providers must comply. Any significant regulatory burdens arising from new contractual obligations are factored into contractual negotiations and considered within the overall annual funding settlement.

- Further legislative instruments (for example, Secretary of State directions and determinations) support implementation of the regulations.

Non-medical prescribing

- In order to protect public safety and health, medicines legislation governs the control of medicines for human use, including the sale or supply of medicines.

- This includes specifying the regulated health professionals able to prescribe prescription-only medicines (POMs) so that only those who are qualified and competent to undertake this activity do so.

- Paradoxically, these regulations are deregulatory in effect (2006/913, 2003/699). Successive Governments have expanded the number of health care professions able to

train then act as prescribers, in order to expand and improve patient care, increase choice and make better use of senior and experienced health professionals' skills, without compromising patient safety.

Controlled Drugs

- The Health Act 2006, as part of the response to the Shipman Inquiry, provides the overarching legislative framework for the safe management and use of controlled drugs in the community.

- The Controlled Drugs (Supervision of Management and Use) Regulations 2013, which are discretionary, provide the necessary detail to implement the policy. Successive Governments have decided that they are essential to deliver the policy goals and ensure proportionate systems are in place, which safeguard the public and public health.

Responsible Pharmacist

- Under the Medicines Act 1968, each registered community pharmacy must have a pharmacist in charge of the pharmacy. This applies across the UK. Previously, the Act did not define "personal control" nor how the pharmacist is to comply with this requirement. However, it was commonly interpreted that the pharmacist had to be physically present in the pharmacy to enable the sale or supply or all medicines to continue, including those designated as general sale list medicines (which can be sold from a variety of retail outlets, not just pharmacies). The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 and section 72 of the Medicines Act from which they are derived are therefore required to introduce the concept of a "Responsible Pharmacist" (RP) and outline RP's duties including when the RP may be absent from the premises during the pharmacy's business hours.

<u>What we regulate</u>

General Pharmaceutical Services and Local Pharmaceutical Services

- The regulations require the NHS to ensure the adequate provision of NHS pharmaceutical services in England. These include access to proper and sufficient drugs and appliances (such as incontinence aids, wigs, trusses etc.) and such other services as may be prescribed.

- The regulations set out the principal services to be provided (such as traditional dispensing) and stipulate both the contractual terms and conditions under which these are provided and the various quality and governance standards that contractors and their staff must meet.

- To be a contractor requires NHS England's approval to be on a relevant list. The regulations therefore set out how NHS England determines applications to be listed. These are primarily judged against the relevant local assessment of pharmaceutical needs. These assessments are now developed and updated by Local Authority Health and Wellbeing Boards in accordance with the regulations.

- The regulations also set out various mechanisms to deal with poor or underperforming NHS contractors, including removal from the NHS list. Local pharmaceutical services are an alternative contracting mechanism available to NHS England and which enable contractors

to provide a range of services (e.g. education and training) that are broader than traditional NHS pharmacy services.

- The first 15 Regulations in the table below have now been replaced by a single set of regulations from April 2013 governing contractual requirements for general and local pharmaceutical services.

Non-medical prescribing

- The Human Medicines Regulations 2012 govern the circumstances in which medicinal products may be sold, supplied or administered. The regulations specify that a person may not sell or supply a prescription-only medicine (POM) except in accordance with a prescription given by an appropriate practitioner. Appropriate practitioners include specified health professionals who have undertaken additional post-registration training and are qualified and registered (with the relevant professional regulatory body) as prescribers. The two Regulations concerning non-medical prescribing from 2003 and 2006 in the table below (2006/913, 2003/699) expand the range of health professionals who can prescribe POMs on the NHS.

Controlled Drugs

- The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (2013 Regulations) contain measures which underpin the safe management and use of controlled drugs in England and Scotland. The 2013 Regulations designate certain organisations that are required to appoint a Controlled Drugs Accountable Officers including setting out their role, duties and functions.

- The 2013 Regulations provide the basis for establishing local intelligence networks for the purpose of sharing information and intelligence locally in confidence, and without breach of the Data Protection Act, about individuals who are engaged in activities that involve the management and use of controlled drugs, and include the powers to carry out inspections where justified.

Responsible Pharmacist

- The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 place a statutory duty on a “responsible pharmacist” to secure the safe and effective running of the pharmacy where this concerns the retail sale or supply (e.g. on prescription) of all medicines. They set out detailed requirements in respect of procedures, records and the absence of the Responsible Pharmacist. The provisions apply to all registered pharmacies in the UK, providing services for the NHS or privately

<u>Other policy instruments</u>

- NHS Act 2006
- Medicines Act 1968
- Health Act 2006
- Prescription Only Medicines (Human Use) Order 1997 as amended

List of General Pharmaceutical Services, Local Pharmaceutical Services, Controlled Drugs, Responsible Pharmacist and non-medical prescribing regulations.		
SI	**Title**	**Origin**
1996/703	The National Health Service Committee and Tribunal (Amendment) Regulations 1996	Dom
2005/641	The National Health Service (Pharmaceutical Services) Regulations 2005	Dom
2005/1015	The National Health Service (Pharmaceutical Services)(Amendment) Regulations 2005	Dom
2005/1501	The National Health Service (Pharmaceutical Services)(Amendment No 2) Regulations 2005	Dom
2006/3373	The National Health Service (Pharmaceutical Services)(Amendment) Regulations 2006	Dom
2007/674	The National Health Service (Pharmaceutical Services)(Remuneration for Persons provide Pharmaceutical Services)(Amendment) Regulations 2007	Dom
2008/683	The National Health Service (Pharmaceutical Services)(Amendment) Regulations 2008	Dom
2009/599	The National Health Service (Pharmaceutical Services and Local Pharmaceutical Services)(Amendment) Regulations 2009	Dom
2009/2205	National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations 2009	Dom
2010/914	The National Health Service (Pharmaceutical Services and Local Pharmaceutical Services)(Amendment) Regulations 2010	Dom
2012/1909	The National Health Service (Pharmaceutical Services)(Amendment) Regulations 2005	Dom
2002/888	The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002	Dom
2002/2016	The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services)(No 2) Regulations 2002	Dom
2002/2861	The National Health Service (Local Pharmaceutical Services etc) Regulations 2002	Dom
2006/552	The National Health Service (Local Pharmaceutical Services etc) Regulations 2006	Dom
2003/699	The National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc.)(England) 2003	Dom
2004/629	The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004	Dom
2004/3215	The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Amendment) Regulations 2004	Dom

2006/913	The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations 2006	Dom
2009/2230	The National Health Service (Prescribing and Charging Arrangements Relating to Pandemic Influenza) Regulations 2009	Dom
2010/2389	The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Amendment) Regulations 2010	Dom
2008/2789	The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008	Dom
2006/3148	The Controlled Drugs (Supervision of Management and Use) Regulations 2006	Dom

<u>One in One Out Status</u>

- Twenty-three regulations in the Medicines, Pharmacy, Dental and Eye Care services policy area relating to non-medical prescribing, controlled drugs, responsible pharmacist and pharmaceutical and local pharmaceutical services have been scrutinised for this Audit.
- None of these regulations is believed to be within scope of OIOO (with two exceptions discussed below). Whilst they may have an impact on business, they are primarily contractual in nature, enabling state funded NHS services to be set up and managed.
- The first fifteen regulations listed in the table (SIs 1996/703, 2005/641, 2005/1015, 2005/1501, 2006/3373, 2007/674, 2008/683, 2009/599, 2009/2205, 2010/914, 2012/1909, 2002/888, 2002/2016, 2002/2861 and 2006/552) were recently consolidated into one SI: 2013/349 – The National Health Service (General Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013.
- The penultimate Regulation - The Medicines (Pharmacy) (Responsible Pharmacist) Regulations 2008 – SI 2008/2789 - is to be scrutinised later this year by a Programme Board set up to review various aspects of medicines and professional regulation and make recommendations for change. DH will ensure any proposals to amend this legislation follow better regulation principles and requirements.
- The last regulation (2006/3148) has recently been replaced by SI 2013/373, the Controlled Drugs (Supervision of Management and Use) Regulations 2013. Whilst in scope of OIOO, there was a zero net cost to business and therefore these were exempt from OIOO consideration. The RRC signed the 2013 Regulations off.

<u>Summary</u>

Out of 23 regulations:

- Fifteen have already been consolidated into one regulation.
- There is a case to retain the remaining eight regulations. These are chiefly either outside the scope of OIOO because they underpin important policy objectives (e.g. creating and managing NHS services) or do not impose a cost to business under OIOO rules. The final

two Regulations are in scope for OIOO. The first is to be reviewed later this year, the second have already been signed off by the RRC.

3.4 Ophthalmic Services

Why we regulate

- The General Ophthalmic Services Contracts Regulations 2008 provide the legal framework for contracts with providers of NHS sight tests and allow for: contracts to be awarded and managed; payments made to contractors; and give the NHS powers to terminate contracts where there are concerns about a practice which could lead to financial loss to the NHS or risks to patients.

- The Primary Ophthalmic Services Regulations 2008 set out the grounds of eligibility for an NHS sight test and for applications for a sight test to be made to NHS contractors.

- The Optical Charges Regulations 2013 set out who is eligible for financial help with the cost of optical appliances (spectacles and contact lenses); they provide for financial help to be given by way of a voucher system, and also set out the level of financial help available and the circumstances in which that help is available; and sets out duties of suppliers who redeem optical appliance vouchers.

- Without these regulations there would be no NHS sight testing service and no help available to people with the cost of optical appliances.

- Orders issued by the General Optical Council relate to professional practice in delivering services and apply to registered optometrists and dispensing opticians whether practising privately or through NHS arrangements. These set out the duties of professionals and provide protection to the public.

- These Orders also provide for patient choice through setting out patient rights to a specification to allow purchase of contact lenses from more than one supplier; extend scope of professional practice by allowing registered opticians to manage certain cases rather than being required to refer to a medical practitioner; and further extend scope of professional practice for suitably qualified registered opticians by allowing for prescribing of appropriate medicinal products.

What we regulate

- NHS contractors for the provision of NHS sight tests;

- Patient entitlement to NHS sight tests and NHS optical vouchers; and

- Suppliers who redeem NHS optical vouchers and professional conduct by registered optometrists and dispensing opticians.

- The General Optical Council regulate professional practice, whether carried out privately or under NHS arrangements, in order to protect the public by promoting high standards of education, performance and conduct amongst their registrants.

Other policy instruments

- General Ophthalmic Services Contracts (Payment) Directions,
- General Ophthalmic Services Contracts (Continuing Education and Training) Payments Directions,
- NHS Redemption of Optical Vouchers Determination,
- NHS (Charges for Optical Appliances) Directions,
- Optical Vouchers (Cessation of Payments) Directions,
- Determination on payments to persons suspended from the ophthalmic performers list.

List of Ophthalmology Regulations		
SI	**Title**	**Origin**
1997/2488	National Health Service (Optical Charges and Payments) Amendment Regulations	Dom
1997/818	National Health Service (Optical Charges and Payments) Regulations	Dom
1998/499	National Health Service (Optical Charges and Payments) Amendment Regulations	Dom
1999/2562	National Health Service (Optical Charges and Payments) and (General Ophthalmic Services) (Amendment) Regulations	Dom
1999/609	National Health Service (Optical Charges and Payments) Amendment Regulations	Dom
2000/3029	National Health Service (Optical Charges and Payments) Amendment (No 2) Regulations	Dom
2000/594	National Health Service (Optical Charges and Payments) Amendment Regulations	Dom
2001/749	National Health Service (Optical Charges and Payments) Amendment Regulations	Dom
2002/35	National Health Service (Optical Charges and Payments) Amendment (England) Regulations	Dom
2002/547	National Health Service (Optical Charges and Payments) Amendment (No 2) Regulations	Dom
2008/1657	National Health Service (Optical Charges and Payments) Amendment (No 2) Regulations	Dom
2008/2449	Primary Ophthalmic Services and National Health Service (Optical Charges and Payments) Amendment Regulations	Dom
2008/553	National Health Service (Optical Charges and Payments) Amendment Regulations	Dom
2009/409	National Health Service (Amendments Relating to Optical Charges and Payments) Regulations	Dom

2009/2205	National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations	Dom
1988/1305	General Optical Council (Contact Lens (Qualifications etc) Rules) Order of Council 1988,	Dom
1989/375	General Optical Council (Contact Lens (Qualifications etc) (Amendment) Rules) Order of Council 1989,	Dom
1989/791	General Optical Council Contact Lens (Specification) Rules Order of Council 1989,	Dom
1999/3267	General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999,	Dom
2005/1476	General Optical Council (Injury or Disease of the Eye and Contact Lens (Qualifications)) (Amendment) Rules Order of Council 2005,	Dom
2008/1940	General Optical Council (Therapeutics and Contact Lens Specialties) Rules Order of Council 2008,	Dom
1989/1230	Sight Testing (Examination and Prescription) (No 2) Regulations	Dom
1996/705	National Health Service (General Ophthalmic Services) Amendment Regulations	Dom
1996/2320	National Health Service (General Ophthalmic Services) Amendment (No 2) Regulations	Dom
2008/1185	General Ophthalmic Services Contracts Regulations	Dom
2008/1186	Primary Ophthalmic Services Regulations	Dom
2008/1209	Primary Ophthalmic Services Transitional Provisions Regulations	Dom
2008/1700	Primary Ophthalmic Services Amendment, Transitional and Consequential Provisions Regulations	Dom
2010/634	National Health Service (Miscellaneous Amendments Relating to Ophthalmic Services)	Dom

<u>One-in One-out Status</u>

Twenty-nine regulations in the Medicines, Pharmacy, Dental and Eye Care services policy area relating to Ophthalmology services have been scrutinised for this Audit. Of these:

- Two have been revoked – 2009/409 and 2009/2205.
- Nine have been revoked in relation to England by SI 2013/461. These are SIs 1997/818, 1999/609, 1998/499, 1997/2488, 2008/553, 2000/3029, 2000/594, 2001/749, 2002/35.
- Two are spent in England but also apply to Wales. We are looking to repeal these for England only and are waiting for legal advice on this – SIs 1996/2320 and 1996/705.
- Three are spent and we will look to repeal where appropriate in a future consolidation exercise of ophthalmic legislation – SIs 2002/547, 2008/1209 and 2008/1700.

- Of the remaining 13, none are believed to have an impact to business under One-in One-out rules because they are contractual.

Summary

Of the twenty-nine regulations:

- Nine have been revoked;
- Five are spent; and,
- There is a case to retain the existing thirteen because they are contractual.

4. NHS

- This section is further divided into the following areas:
  - Cost recovery; and
  - NHS Litigation.

- Information on additional NHS related regulations that are not believed to have an impact to business is given in Annex F. Legal advice on these regulations is being sought as there may be potential to revoke a proportion of them.

4.1 Cost recovery

Why we regulate

- The fundamental principle behind the NHS Injury Cost Recovery scheme is that those responsible for causing injury should meet the costs of their actions in full, including the costs of NHS hospital treatment. Not to do so effectively means the costs of those actions are being subsidised by the taxpayer. NHS costs are only recovered where personal injury (PI) compensation is paid. Recovered funds are paid direct to the treating trust for reinvestment in patient services.

What we regulate

- The regulations supporting the scheme oblige the compensator/insurance sector to comply with the requirements of the legislation.

- They also provide for the tariff of charges, the rights to seek a review of charges and to the making of an appeal against such charges.

- Hospitals have been able to recover the cost of treating road traffic accident (RTA) victims for more than 70 years. These provisions were streamlined and modernised through the provisions of the Road Traffic (NHS Charges) Act 1999.

- The scheme was also expanded in 2007 to include *all* personal injury (PI) claims (public, employer) – including those where the accident has occurred abroad but where the patient has subsequently been treated in a UK hospital.

Other policy instruments

- An uplift to the tariff of charges is made on 1st April each year. A Statutory Instrument provides for that change. The methodology for this was agreed as part of the consultation process with the industry. The uplift uses the Hospital & Community Health Services (HCHS) inflation index. This simply maintains the 'real terms' value of any recoveries.

List of NHS Cost Recovery regulations		
SI	**Title**	**Origin**
1995/866	National Health Service (Injury Benefits) Regulations 1995,	Dom
1999/785	Road Traffic (NHS Charges) Regulations 1999	Dom
1999/786	Road Traffic (NHS Charges) (Reviews and Appeals) Regulations 1999,	Dom
Primary	Road Traffic (NHS Charges) Act 1999	Dom
2002/237	Road Traffic (NHS Charges) Amendment Regulations 2002	Dom
2002/2995	Road Traffic (NHS Charges) Amendment (No2) Regulations 2002	Dom
Primary	Part 3 of the Health and Social Care (Community Health and Standards) Act 2003	Dom
2004/560	Road Traffic Act (NHS Charges) Amendment Regulations 2004	Dom
2005/475	Road Traffic Act (NHS Charges) Amendment Regulations 2005	Dom
2006/3388	The Personal Injuries (NHS Charges) (General) and Road Traffic (NHS Charges) (Amendment) Regulations 2006	Dom
2006/3398	The Personal Injuries (NHS Charges) (Reviews and Appeals) and Road Traffic (NHS Charges) (Reviews and Appeals) (Amendment) Regulations 2006	Dom
2006/401	Road Traffic Act (NHS Charges) Amendment Regulations 2006	Dom
2007/115	The Personal Injuries (NHS Charges) (Amounts) Regulations 2007	Dom
2007/1613	The Personal Injuries (NHS Charges) (Reviews and Appeals) Amendment Regulations 2007	Dom
2007/917	The Health and Social Care (Community Health and Standards) Act 2003 Consequential Provisions (Recovery of NHS charges) Order 2007	Dom
2008/252	The Personal Injuries (NHS Charges) (Amounts) Regulations 2008	Dom
2009/316	The Personal Injuries (NHS Charges) (Amounts) Regulations 2009	Dom
2009/834	The Personal Injuries (NHS Charges) Amendment (No2) Regulations 2009	Dom
2010/189	The Personal Injuries (NHS Charges) (Amounts) Regulations 2010	Dom
2011/520	The Personal Injuries (NHS Charges) (Amounts) Regulations 2011	Dom

OIOO/OITO Status

- Twenty regulations in the NHS Cost Recovery policy area have been scrutinised for this Audit.

- Of these, eight are no longer operative or in force and can be considered as ‘zombie regulations’. Legal advice has suggested that it would not be appropriate to formally revoke them and that the Department could be criticised for spending legal time on their revocation. These are Part 3 of the Health and Social Care (Community Health and Standards) Act 2003 and then SIs: 1999/785, 1999/786, 2002/237, 2002/2995, 2004/560, 2005/475 and 2008/252.

- Of the remainder, eight have no impact to business because they represent only marginal changes to the rules that govern how the scheme operates. These are 1995/866, 2006/401, 2007/1613, 2007/917, 2009/316, 2009/834, 2010/189, 2011/520.

- This leaves four regulations with a combined impact to business via slightly increased cost of motor and employer insurance for private business. This impact is estimated in the statistics below. It is entirely made up of a direct transfer from business to the NHS which is the aim of the policy. In this respect it is quite different from the cost to business calculated for other policy areas. Administrative burden to business from this policy is marginal as the cost recovery process uses an existing mechanism owned by DWP (see detail in box below).

- This cost to business constitutes a direct transfer from businesses to the NHS and forms part of the total cost recovery of £220 million, the remainder of which falls on individuals (through private motor insurance) and the public sector.

- The overall impact on motor insurance premiums is small compared to the total value of motor insurance industry which was over £11 billion in 2011-12

Statistics: NHS Cost Recovery	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£56.5 million
Estimated equivalent annual benefits to business	£0
Estimated equivalent annual net cost to business (EANCB)	£56.5 million
Impact To Society	
Estimated annual cost to other parties/wider society	£166.0 million
Estimated annual benefits to other parties/wider society	£220 million
Net estimated annual cost to other parties/wider society	£54.0 million
Notes: Administrative costs to business have not been calculated but are marginal. DWP already had a scheme in place for the recovery of benefits and they had strong relationships with the industry. NHS cost recovery uses this existing scheme which includes a website that insurers and compensators can access to fill in all forms electronically in relation to the primary claim (benefit recovery) and electronic links into the insurance industry CUE PI system (Claims Underwriting Exchange for fraud monitoring). Administrative costs to the Department of Health England have been calculated at £2.5 million. This is included in the cost to other parties figure above.	
Reliability rating: 3.5/5	

<u>Summary</u>

Out of 20 regulations:

- Eight are zombie regulations which have no impact. Action on these regulations will be subject to Cabinet Office discussions on zombie regulations.

- There is a case to retain the further eight regulations with no impact to business. Options for consolidating these regulations have not yet been explored.

- There is a case to retain the four regulations with impact to business, where the impact is proportional to the benefits in terms of funding to the NHS. Retention also supports the principle that that those responsible for causing injury should meet the costs of their actions in full.

4.2 NHS Litigation

Why we regulate

- The regulations provide statutory frameworks for schemes that allow NHS bodies (and in some circumstances other bodies involved in providing NHS care) to pool a range of financial risks.
- Membership of the schemes is voluntary
- Administration of the schemes is on a not-for-profit basis.

What we regulate

- There are four statutory schemes that provide assistance to members with a range of third party liabilities (predominantly clinical negligence, employers' and public liabilities) and damage to/loss of property.
- The schemes only apply to costs associated with functions provided as part of the health service.

Other policy instruments

- The schemes have been variously amended by regulation since they were established to keep abreast of changing NHS policy and architecture.

OIOO/OITO Status

- Thirteen regulations in the NHS Litigation policy area have been scrutinised for this Audit.
- The regulations establish the rules of the scheme and have no impact to business under One-in One-out rules.

List of NHS Litigation Regulations		
SI	**Title**	**Origin**
1996/251	National Health Service (Clinical Negligence Scheme) Regulations 1996	Dom
1996/686	National Health Service (Existing Liabilities Scheme) Regulations 1996	Dom
1997/526	National Health Service (Existing Liabilities Scheme) (Amendment) Regulations 1997	Dom
1997/527	National Health Service (Clinical Negligence Scheme) (Amendment) Regulations 1997	Dom
1999/1274	National Health Service (Clinical Negligence Scheme) (Amendment) Regulations 1999,	Dom
1999/1275	National Health Service (Existing Liabilities Scheme) (Amendment) Regulations 1999	Dom
1999/873	National Health Service (Liabilities to Third Parties Scheme) Regulations 1999	Dom
1999/874	National Health Service (Property Expenses Scheme) Regulations 1999	Dom
2000/2341	National Health Service (Clinical Negligence Scheme) Amendment Regulations 2000	Dom
2000/2342	National Health Service (Property Expenses Scheme) Amendment Regulations 2000	Dom
2000/2385	National Health Service (Liabilities to Third Parties Scheme) Amendment Regulations 2000	Dom
2002/1073	National Health Service (Clinical Negligence Scheme) Amendment Regulations 2002	Dom
2006/3087	National Health Service (Clinical Negligence Scheme) Amendment (No 2) Regulations 2006	Dom

Summary

- There is a case to retain these regulations in order to ensure the running of the scheme.
- Options for consolidating these regulations have not been considered as part of this audit.
- We have investigated whether clinical negligence scheme for trusts (CNST) which has been extended to the private sector from 1 April 2013 could be considered a benefit to business. Previously, some non-NHS bodies (who provide NHS services) benefited from the cover of CNST indirectly through the commissioning PCT's membership of the scheme. Amendments to the Regulations regularised the position of non-NHS providers by allowing certain non-NHS bodies who are providing NHS services to become members in their own right, to contribute directly to the scheme to cover their own risks. The explanatory memorandum on the NHS (CNS) Amendment Regulations stated that the impact on business, charities or voluntary bodies is thought to be broadly nil as the scheme provides an alternative way of indemnifying clinical negligence risks in the NHS and the cover provided is not comparable to insurance. We expect non-public sector providers to choose from the range of products across the market, and accept that CNST, which does not

provide the same risk transfer as insurance, may be considered unsuitable by some providers. The benefit that CNST provides is it is ‘another’ option for providers.

5. Public Health

- This section is further divided into the following areas:
  - Abortion;
  - Blood and Tissue;
  - Food composition, labelling, and safety;
  - Healthy Start and Welfare Food;
  - Health Protection;
  - Health Protection – Port Health and Travel;
  - Health Protection – Vaccinations;
  - Human Fertilisation and Embryology Authority (HFEA);
  - HIV/Venereal Disease;
  - National Child Measurement Programme (NCMP);
  - Radiation;
  - Surrogacy;
  - Tobacco; and
  - Other.

5.1 Abortion

Why we regulate

- The Offences Against the Person Act 1861 makes it an offence to intentionally procure a miscarriage, including for a woman to procure her own miscarriage. The Infant Life (Preservation) Act 1929 makes it an offence to intentionally kill a child, capable of being born alive, before it has a life independent of its mother.

- The Abortion Act 1967 creates exceptions to the offences of procuring a miscarriage and child destruction. The Act makes an abortion legal where the pregnancy is terminated by a registered medical practitioner and where two registered medical practitioners agree that the grounds specified in the Act are satisfied.

- It is accepted Parliamentary practice that proposals for changes in the law on abortion have come from back-bench members and successive governments have taken the view that such matters should be decided by members voting freely in accordance with their own conscience.

- The Government does however have a duty to see that the provisions of the Act are properly applied until, and unless, Parliament chooses to further amend that law. The 1967 Act specified the creation of regulations through statutory instruments (SI) that required the certification and notification of terminations. The first SI (1968/390) stated that certificates of opinion should be take the prescribed form and be retained for three years; and that notification should be sent to the Chief Medical Officer in a sealed envelope within seven days in a prescribed form. The form of certificates and notifications and restrictions on disclosure were amended in SIs in 1969, 1976, 1980 and 1991, when the previous regulations in the series were revoked. A further statutory instrument in 2002 allowed for electronic notification as well as paper notification; and extended the notification period from seven to fourteen days.

What we regulate

- Who can legally perform an abortion;
- The grounds and gestational time-limits for abortions;
- Where abortions can be performed – NHS hospitals or independent sector places approved by SoS;
- Conscientious objection to abortion; and
- Certification and notification of abortions.

Other policy instruments

- The Secretary of State for Health has a responsibility under Section 1(3) of the Abortion Act 1967, as amended by Section 37 of the Human Fertilisation and Embryology Act 1990, to approve places (other than places exempt by this section) for the purpose of treatment for termination of pregnancy (abortion). All places operated by non-NHS bodies must be approved. The approval procedures are set out in the document "Interim Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy (Abortion)", published in January 2013.
- The Secretary of State will consider the approval of places if proprietors undertake to comply with:
    - The Abortion Act 1967 and Regulations made under the Act – Abortion Regulations 1991.
    - The requirements set out in regulations under the Health and Social Care Act 2008 (these are set out in the Care Quality Commission guidance about compliance with the Essential Standards of Quality and Safety (March 2010));
    - The Care Quality Commission (Registration) Regulations 2009, SI 2009/3112 Part 4 Para 20 (these regulations set out the gestation limit and the need for two opinions);
    - The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (SI 2010/781 Schedule 1 Para 12) – this regulation makes the provision of termination of pregnancy a regulated activity and therefore in scope of CQC registration and regulation (this is covered in the CQC chapter);
    - The Required Standing Operating Procedures (RSOPs).
    - Any conditions on which the Secretary of State's approvals rest.
- The RSOPs cover the following:
    - Compliance with the Abortion Act – Completion of Forms,
    - Medical Terminations including Early Medical Abortion (EMA) – Delegation of Duties and Protocols,
    - Notification of Change of Provider,
    - Service Provision for Children, Vulnerable Children and Adults,
    - Gestational Limits,

- Professional Guidelines,
- Access to Timely Abortion Services,
- Information for Women,
- Contraception and Sexually Transmitted Infections (STI) Screening,
- Counselling,
- Disposal of Fetal Tissue,
- Performance Standards and Audit,
- Patient Feedback and Complaints,
- Staffing and Emergency Medical Cover,
- Duty Records,
- Confirmation of Professional Status,
- Risk Management,
- Maintenance of Equipment,
- Death of a Patient,
- Payment of Fees,
- Referrals from Bureaux,

List of Abortion Regulations		
SI	**Title**	**Origin**
1969	Abortion Regulations	Dom
2002/887	Abortion (Amendment) (England) Regulations	Dom
2008/735	Abortion (Amendment) Regulations	Dom
1999	Abortion SOPs	Dom
1979/29	Termination of pregnancy SOPs	Dom
1991/499	Abortion Regulations	Dom

OIOO/OITO Status

- Six regulations in the Abortion policy area have been scrutinised for this Audit. Of these, all six are believed to have an impact to business under the OIOO/OITO rules. The estimated impact of these regulations is set out below.

Summary

- There is a case for retaining these regulations in order to fulfil the Government's duty to see that the provisions of the 1967 Abortion Act are properly applied.

Statistics: Abortion	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£1.2 million
Estimated equivalent annual benefits to business	£0million
Estimated equivalent annual net cost to business (EANCB)	Up to £1.2 million
Impact To Society	
Estimated cost to other parties/wider society	Un-monetised
Estimated benefits to other parties/wider society	Un-monetised
Net estimated cost to other parties/wider society	Un-monetised
Notes: The approach to the costing of regulations is such that we need to measure this against where there are no regulations, which in this instance implies no controls or restrictions on gestation, grounds, or settings under which terminations are carried out.	
Reliability rating: 3/5	

5.2 Blood and tissue

Why we regulate

- The availability of human tissue is essential to a number of highly important "medical" activities, for example: research; determining the cause of death; establishing after a person's death the efficacy of drugs and treatment; and transplantation.

- Adequate availability of tissue and organs relies on the public being willing to donate. That willingness to donate is in turn dependent on public confidence that human tissue will be used safely and ethically and with proper consent.

- Regulations play a key part in defining the regulatory framework necessary to achieve public confidence, for example they describe the process whereby the Human Tissue Authority approves cases of living organ donation, they set out circumstances in which the storage of tissue may be exempt from the need for a licence, they set standards for the quality and safety of tissue used for treatment purposes

What we regulate

- The Human Tissue Authority (HTA) licences and inspects organisations that store and use human tissue for:
  - teaching about or studying the human body;
  - carrying out post-mortem examinations;
  - using human tissue to treat patients;
  - carrying out research on human tissue; and
  - displaying human bodies or tissue in public (eg in a museum).

- The HTA gives approval for donation of organ and bone marrow from living people to guard against the use of coercion or reward.

- The HTA, acting as the UK competent authority, regulates, from a health and safety perspective the quality and safety of tissue used for treatment purposes and organs for transplantation.

Other policy instruments

- The Human Tissue Act 2004
- Code of Practice 1 – Consent
- Code of Practice 2 – Donation of solid organs for transplantation
- Code of Practice 3 – Post-mortem examination
- Code of Practice 4 – Anatomical examination
- Code of Practice 5 – Disposal of Human Tissue
- Code of Practice 6 – Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
- Code of Practice 7 – Public display
- Code of Practice 8 – Import and export of human bodies, body parts and tissue
- Code of Practice 9 – Research

List of Blood and Tissue Regulations		
SI	**Title**	**Origin**
2006/1659	Human Tissue Act 2004 (Persons who lack Capacity to Consent and Transplants) Regulations 2006	Dom
2006/1260	Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, SI 2006/1260	Dom
2008/3067	Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and supply of Information about Transplants) Amendment Regulations 2008. SI 2008/3067	Dom
2006/538	Human Tissue Act 2004 (Power of Entry and Search: Supply of Information) Regulations 2006 SI 2006/538	Dom
2007/1523	Human Tissue (Quality and Safety for Human Application) Regulations 2007	EU
1993/587	Central Blood Laboratories Authority (Revocation) Order 1993, SI 1993/587	Dom
1954/448	Removal of Bodies Regulations 1954, SI 1954/448	Dom

OIOO/OITO Status

- Seven regulations in the blood and tissue policy area have been scrutinised for this Audit. Of these, one is believed to have an impact to business – SI 2006/1260. The estimated impact of this regulation is set out below.

- Of the remainder, one is European Union related regulation and four are not believed to have an impact on business under OIOO/OITO rules because they deal with aspects of the regulation that do not directly impose a cost to business. These are: 2006/1659, 2008/3067, 2006/538 and 1993/587. The latter is a revocation order, used to revoke other regulations. It is deregulatory.

- This leaves one regulation (1954/448) where the impact to business under OIOO/OITO rules is unknown. Indeed it is not known whether DH has responsibility for this regulation which deals with the removal of bodies from the UK and dates from 1954. Legal advice is being sought on this point.

- As part of the Government's response to the recommendations of the McCracken Review of the HTA and HFEA, the Department will undertake in 2013/14 a review of legislation governing the use of human tissue with the aim of reducing regulatory burden. This will encompass work already started which will consider, subject to consultation, exempting the requirement for a licence for the removal of tissue from the body of a deceased person for the purpose of research that has ethical approval. Other areas that we will look to review, again subject to consultation, will be the scope of the legislation in respect of the retention of certain types of tissue (e.g. urine, faeces and saliva) and in respect of the licensing requirements for tissue taken from living people for research.

Statistics: Blood and Tissue	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£0.9 million
Estimated equivalent annual benefits to business	Un-monetised
Estimated equivalent annual net cost to business (EANCB)	In order of £0.9 million
Impact To Society	
Estimated annual cost to other parties/wider society	£4.3 million
Estimated annual benefits to other parties/wider society	Un-monetised
Net estimated annual cost to other parties/wider society	Up to £4.3 million.
Notes: HTA regulates licenses under four sectors (anatomy, post mortem, public display and research) as a result of UK legislation (as well as another two sectors from EU legislation). The four sectors of interest span activities of a range of organisations. Within the public sector, there are around 310 licensees, including local government (for mortuaries), universities, the NHS and Public Health England. Given the difficulty in defining the boundary between universities in some areas of which sectors will be affected, the estimated annual cost is to the public sector as a whole.	
Reliability rating: 2/5	

Summary

Out of seven regulations:

- Legal advice sought on as to whether the four Human Tissue Act regulations (2008/3067, 2006/1260, 2006/1659 , and 2006/538) can be merged into one. Of these, only merger of 2008/3067 and 2006/1260 (both subject to negative procedures and have same enabling powers) would be feasible though this could be a disproportionate use of legal time. For the others, merger is not possible because they are subject to different parliamentary procedures (affirmative and negative) and this would give rise to procedural difficulties. Also three of the four require a duty to consult Northern Ireland and Wales, an added complication.

- There is a case for retaining the three remaining regulations to maintain public confidence that human tissue will be used safely and ethically and with proper consent. This is important to ensure willingness to donate.

5.3 Food composition, labelling and safety

Why we regulate

- EU legislation ensures that the particular nutritional needs of vulnerable groups (e.g. infants and young children) are met; that consumers are protected from being misled; and that there is a level playing field for food businesses operating in the EU.

- The DH regulates to protect consumer safety in relation to food and drink particularly in the absence of harmonised EU rules. To do this the DH works with consumer organisations and food businesses in the UK.

What we regulate

- The DH is the Competent Authority in the UK for some EU legislation on food labelling and the nutritional composition of certain foodstuffs.

- EU legislation relevant to the DH's remit includes that on: nutrition and health claims made on foods; the composition and labelling of food supplements; foods for particular nutritional uses (such as infant formula); and fortified foods.

- The DH is also responsible for two pieces of domestic food safety legislation on the use of Kava-kava and Tryptophan in foods.

Other Policy Instruments

- Guidance documents published on the DH website are intended to help food businesses comply with the legislation;

- Engaging with trading standards officers to help ensure consistent enforcement of the legislation; and

- Seeking views from food businesses during policy development.

List of Food Composition, Labelling, and Safety Regulations		
SI	**Title**	**Origin**
2007/2080	Nutrition and Health Claims (England) Regulations 2007	EU
2003/1387	Food Supplements (England) Regulations 2003	EU
2009/3051	Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes)(England) Regulations 2009	EU
2010/295	Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2010	EU
1997/2182	Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997	EU
2010/2281	Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010	EU
2007/3521	Infant Formula and Follow-on Formula (England) Regulations 2007	EU
2000/845	Medical Food (England) Regulations 2000	EU
2007/181	Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007	EU
2003/3207	Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003	EU
2005/2630	Tryptophan in Food (England) Regulations 2005	Dom
2002/3169	Kava-kava in Food (England) Regulations 2002	Dom
2007/1631	Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007	EU
2010/1768	Nutrition and Health Claims (England) (Amendment) Regulations 2010, SI 2010/1768	EU

OIOO/OITO Status

- Fourteen regulations in the Public Health: Food Policy area have been scrutinised for this Audit. Of these, 12 are European Union related Regulations.

- The remaining two are believed to have an impact on business under OIOO/OITO rules. Their impact is estimated to be negligible on the basis that if sale was permitted, the potential demand for these products (Kava Kava and Tryptophan) is unknown and likely to be low at least in the first instance. These regulations were recently reviewed by the Committee on Toxicology, which recommended that they should be retained.

Summary

- There is a case for retaining the two domestic regulations in order to protect the public from harmful substances.

- The review of the eight EU regulations under Council Directive 2009/39/EC on foodstuffs intended for particular nutritional uses is currently underway. The European Commission's objective is to simplify existing legislation in this area.

5.4 Healthy Start and Welfare Food

Healthy Start

Why we regulate

- To improve nutrition during pregnancy and early childhood.

- Poor nutrition during pregnancy and early childhood can harm health. There is evidence that poor nutrition and poverty go hand in hand.

What we regulate

- The Healthy Start scheme provides vouchers to spend on fruit and vegetables, milk and formula milk to almost 600,000 pregnant women and children under four in very low income families throughout the UK, helping them to have a safe and healthy diet.

- The regulations underpin contractual relationships between the scheme and retailers who choose to take part, assuring them that they will be paid in full for vouchers they accept towards the cost of Healthy Start foods. Almost 30,000 retail outlets, including small and micro businesses as well as large businesses, voluntarily accept the vouchers and so benefit from Healthy Start sales.

Other policy instruments

- The Welfare Food Regulations 1996 enable children under five attending Early Years childcare settings in Great Britain to benefit from a free daily drink of milk.

- The School Fruit and Vegetable Scheme provides a daily piece of fruit or vegetable to children aged 4-6 in primary schools in England.

Welfare Food (Nursery Milk)

Why we regulate

- The provision of Nursery Milk is a statutory obligation of the Secretary of State. The Prime Minister has made a public commitment that the scheme will continue.

- The Nursery Milk scheme is governed by legislation – enabling powers are in S13 of the Social Security Act 1988 and the principle regulations are the Welfare Food Regulations 1996.

- We regulate to ensure that it is only those who qualify for Nursery Milk can receive it; to govern the process of reimbursing those who put in claims for payment regarding Nursery

Milk; to ensure that the correct type of milk is claimed for and reimbursed; to facilitate the working of a statutory scheme.

- The Welfare Food Regulations 1996 (GB wide) are reserved to Westminster. However, the devolved administrations in Scotland and Wales fund milk supplied through the scheme to children in their countries. Northern Ireland provides its own, similar, scheme.

- Going forward – The way the Scheme operates is being changed. We will regulate to ensure that the new Scheme continues to deliver on its obligations under the Welfare Food Regulations and provides an efficient, quality service and value for money.

What we regulate

- The Nursery Milk Scheme - which currently funds free milk for around 1.5 million children under five years old, in 55,000 childcare settings throughout Great Britain.

Other policy instruments

- Although it has been running largely unchanged since the 1940s, the Scheme is not financially viable or sustainable in its current form.

- We are therefore currently looking at ways to improve the operation of the scheme, and legislation (albeit amended/modified/simplified) will still be required to enable the operation of the scheme.

List of Healthy Start and Welfare Food Regulations		
SI	**Title**	**Origin**
2005/3262	Healthy Start and welfare food (amendment) regulations 2005	Dom
2006/589	Healthy Start Scheme and Welfare Food (Amendment) Regulations 2006	Dom
2006/2818	Healthy Start and Welfare Food Scheme (Amendment No 2) Regulations 2006	Dom
2007/505	Healthy Start Scheme and Welfare Food (Amendment) Regulations 2007,	Dom
2008/408	Healthy Start Scheme and Welfare Food (Amendment) Regulations 2008,	Dom
2009/295	Healthy Start Scheme and Welfare Food (Amendment) Regulations 2009,	Dom
2010/434	Healthy Start Scheme and Welfare Food (Amendment) Regulations 2010,	Dom
1996/1434	The Welfare Food Regulations 1996	Dom
2005/2279	Health and Social Care (Community Health and Standards) Act 2003 (Savings) Order 2005,	Dom

OIOO/OITO Status

- Nine regulations in the healthy start and welfare milk policy area have been scrutinised for this Audit.

- The Welfare Food Regulations 1996 (SI 1996/1434) are not considered to have an impact upon business based on the published Explanatory Note accompanying the legislation. This states that the regulations "…do not impose a charge on business."

- The introduction of the Healthy Start scheme (SI 2005/3262) did impact upon business. There was discussion of whether the costs would be positive in the Regulatory Impact Assessment in the Explanatory Memorandum published alongside the legislation. It has not been possible to retrieve the estimated costs to business for this Audit.

- The remaining regulations are not considered to have an impact to business in and of themselves. SIs 2006/589 and 2006/2818 amend the Healthy Start scheme and the Welfare Food Regulations. For 2006/589, the published EN States: "A full regulatory impact assessment has not been produced for this instrument as it has no impact on costs of business." For 2006/2818, any impact on business is considered to be second order and therefore out of scope of OIOO/OITO rules.

- SIs 2007/505, 2008/408, 2009/295 and 2010/434 make (annual) technical amendments to increase the limits to entitlements to benefits. They are not considered to have impacts to business as stated in the ENs accompanying the published legislation.

Costs and benefits

- Details of the estimated costs to business have not been located. It has not been possible to locate a key reference to these estimates produced at the time the legislation was made.

- Costs and benefits have been estimated based upon disparate sources (see notes, below).

Summary

- It is not clear on the basis of the available evidence as to whether removal of these regulations would yield an OUT. This is due to a lack of conclusive evidence on the costs to business. Further detailed work would be required to explore this.

- There is scope to simplify and/or consolidate the regulations. A programme of work is planned to update the regulations in phases to reflect welfare reform, and then to consolidate regulations with all amendments, between 2012/13 and 2018/19.

- The Healthy Start regulations will be amended between 2013/14 and 2017/18 in response to the staged implementation of welfare reform (and specifically the introduction of Universal Credit). The Department will be considering the opportunities to regulate for, and implement, digital voucher solutions within the context of the overall welfare agenda – and taking account of longer term cross-government strategy on the relationship between Universal Credit and passported benefits. Over the next three years, our priorities are to explore further scope to digitising the scheme's "back office " functions, and to work with the retail sector to increase the efficiency of paper vouchers – e.g. by achieving efficiencies through improved use of barcoding. This will provide a sound platform for introducing digital vouchers in future, and an evolutionary approach to digitisation will also ensure that small and micro businesses are not driven out of the scheme.

- The DH is aiming to make the Nursery Milk regulations more fit for purpose to help effectively deliver a scheme that is efficient, sustainable, and gives better value for money.

Statistics: Healthy Start and Welfare Food	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£7million (Healthy Start) plus £8million (Nursery Milk) = £15million
Estimated equivalent annual benefits to business	Un-monetised
Estimated equivalent annual net cost to business (EANCB)	Up to £15 million but may be ZERO NET COST (see notes)
Impact To Society	
Estimated annual cost to other parties/wider society	Un-monetised
Estimated annual benefits to other parties/wider society	Un-monetised
Net estimated annual cost to other parties/wider society	Un-monetised
Notes: It should be noted that over 90% of all the retail businesses registered to accept Healthy Start vouchers are small businesses (over 15,000 businesses) and they take a much smaller proportion of the vouchers as around 80% are taken by major supermarkets. These small businesses voluntarily register to be part of this scheme, suggesting that they do not regard the cost burden on them as onerous. The estimated equivalent annual benefits to business have not been quantified but we expect these to be the estimated profits to business from sales. Total sales revenue is in the region of £109 million, but we do not have evidence on total cost to calculate profits. Sources: Administrative Burden Measurement Exercise 2006, published Impact Assessments and Regulatory Impact Assessments.	
Reliability rating: 2/5	

5.5 Health Protection

Why we regulate

- Before being amended by the Health and Social Care Acts (2008 and 2012), the Public Health (Control of Disease) Act 1984 was out of date, containing measures dating back to Victorian times reflecting social conditions and scientific understanding then, and did not provide adequate health protection powers to meet modern requirements.

- The new Health Protection measures in the Health Protection regulations and the amended Act allow action to deal with infections or contamination that present a significant risk to human health. They take an “all hazards” approach to health protection, which is also

reflected in WHO's International Health Regulations, rather than focusing on specified infectious diseases.

- They provide a balanced set of powers, which local authorities and Justices of the Peace (JPs) can use to protect human health against threats from infection or contamination, which meet modern human rights requirements.

What we regulate

The Health Protection (Notification) Regulations 2010, Health Protection (Local Authority Powers) Regulations 2010, and the Health Protection (Part 2A Orders) Regulations 2010:

- Extend the long-standing requirement on registered medical practitioners to notify the proper officer of a local authority of individual cases of specified infectious diseases (notifiable diseases) by also requiring them to notify cases of other infections or of contamination which they believe present, or could present, a significant risk to human health;

- Require diagnostic laboratories to notify Public Health England of specified causative agents they identify in tests on human samples;

- Provide local authorities with wider, more flexible powers to deal with incidents or emergencies where infection or contamination presents, or could present, a significant risk to human health. Some powers, relating to specific circumstances, can be exercised directly by local authorities. In other circumstances, local authorities can apply to a justice of the peace (JP) for a Part 2A Order to impose restrictions or requirements to protect human health.

Other policy instruments

- None

OIOO/OITO Status

- Seven regulations in the Health Protection policy area have been scrutinised for this Audit.

- Three of these regulations (SIs 2010/659, 2010/657, 2010/658) stem from a new part (2A) of the Public Health (Control of Disease) Act 1984. They are a recent modernisation of previous legislation and are related to revisions of the International Health Regulations (2005) by the World Health Organisation. As such these should be considered to be exempt for OIOO/OITO as they fulfil UK commitments to International Agreements.

- Four regulations (SIs 2005/408, 2005/525, 2007/1624, 2010/2540) have been revoked as part of the implementation of the Health and Social Care Act 2012. They are not believed to have had an impact to business – as set out in ENs accompanying the published legislation.

List of Health Protection Regulations		
SI	**Title**	**Origin**
2010/659	Health Protection (Notification) Regulations 2010	Int
2010/657	Health Protection (Local Authority Powers) Regulations 2010	Dom (but implementing IHR 2005)
2010/658	Health Protection (Part 2A Orders) Regulations 2010	Int
2005/408	Health Protection Agency Regulations 2005	Dom
2005/525	Health Protection Agency Act 2004 (National Radiological Protection Board and Health Protection Agency Special Health Authority (Consequential Provisions) Order 2005	Dom
2007/1624	Health Protection Agency (Amendment) Regulations 2007	Dom
2010/2540	Health Protection Agency (Amendment) Regulations 2010	Dom

Costs and benefits

- The estimated costs and benefits presented below relate to SI 2010/659. These are presented for completeness although, as set out above, this regulation relates to an International Agreement and is therefore technically out of scope (exempt) for OIOO/OITO.

Statistics: Health Protection	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£0.1 million
Estimated equivalent annual benefits to business	Un-monetised
Estimated equivalent annual net cost to business (EANCB)	£0.1 million
Impact To Society	
Estimated annual cost to other parties/wider society	£0.1 million
Estimated annual benefits to other parties/wider society	£0.2 million
Net estimated annual cost to other parties/wider society	- £0.1 million
Notes: N/A	
Reliability rating: 2/5	

Summary

- Seven regulations in the Health Protection policy area have been scrutinised for this Audit.
- Three are a recent modernisation of previous legislation and are considered to be exempt from OIOO/OITO as they fulfil UK commitments to International Agreements.

- Four have recently been revoked.

- There is limited scope for further regulatory reform in this area.

5.6 Health Protection – Port Health and Travel

Why we regulate

- DH is responsible for ensuring there is adequate public health protection at UK ports and airports to prevent the spread of infection or contamination in the general population and to ensure that the UK is compliant with the WHO's International Health Regulations to minimise the risk from cross border threats.

What we regulate

- The current regulations provide a contingency for use only when a passenger on a ship or plane entering the UK is suspected of having yellow fever, cholera, plague or smallpox and refuses to seek medical attention.

- The regulations include provisions for notification of such a case to the destination port health authority and provisions for detention of that person for the purpose of a medical examination. Given that such cases arise very rarely and that in most instances people with a serious infectious disease will actively seek medical attention, the impact of the regulations on business is considered to be extremely small.

- The regulations provide protection for wider society by providing a safeguard to prevent the spread of serious infectious diseases. Preventing or controlling the spread of infection can result in:
  - reduced morbidity and mortality, preventing unnecessary suffering in individuals and families;
  - reduced costs to individuals e.g. through loss of income or childcare;
  - reduced costs to the health service e.g. in-patient or outpatient care; and
  - prevented disruption to public services and other businesses due to employee sickness.

Other policy instruments

- None

OIOO/OITO Status

- Eleven regulations in the ports and travel policy area have been scrutinised for this Audit. All but one are international agreements and obligations and therefore fall outside of the OIOO/OITO rules.

- The last domestic regulation (SI 1995/267) is deregulatory, it revokes the Public Health (Aircraft) (Isle of Man) Order 1982 and the Public Health (Ships) (Isle of Man) Order 1982,

which extended to the Isle of Man, subject to exceptions and modifications, the Public Health (Aircraft) Regulations 1979 (S.I. 1979/1434) and the Public Health (Ships) Regulations 1979 (S.I. 1979/1435).

List of Health Protection, Port Health and Travel Regulations		
SI	**Title**	**Origin**
1965/617	London Port Health Authority Order 1965	Dom (but implementing IHR 2005)
1980/215	London Port Health Authority (Amendment) Order 1980	Dom (but implementing IHR 2005)
1974/215	Port Health Authorities (England) Order 1974	Dom (but implementing IHR 2005)
1991/1236	Channel Tunnel (Emergency Medical Services) (No 2) Order 1991	Dom (but implementing IHR 2005)
1994/311	Public Health (International Trains) Regulations 1994	Dom (but implementing IHR 2005)
2007/1603	Public Health (Aircraft and Ships) (Amendment) (England) Regulations 2007	Dom (but implementing IHR 2005)
1979/1434	Public Health (Aircraft) Regulations 1979	Dom (but implementing IHR 2005)
2007/1447	Public Health (Aircraft) (Amendment) (England) Regulations 2007	Dom (but implementing IHR 2005)
1979/1435	Public Health (Ships) Regulations 1979	Dom (but implementing IHR 2005)
2007/1446	Public Health (Ships) (Amendment) (England) Regulations 2007	Dom (but implementing IHR 2005)
1995/267	Public Health (Ships and Aircraft) (Isle of Man) (Revocation) Order 1995	Dom

Summary

- The ports and travel regulations are enforced in a contingency situation when passengers or transport vehicles are infected and the passengers/transport owners refuse to seek treatment / disinfection. Therefore, while private sector companies would be subject to these regulations in the event of an outbreak, they would only apply in the case of an outbreak so the overall costs on business are negligible. Therefore, the case to retain these regulations is strong.

- Five regulations will be removed and replaced with simpler, more flexible and up-to-date regulations (SI 2007/1603, SI 1979/1434, SI 2007/1447, SI1979/1435, SI 2007/1446). The new regulations will be overall cost-neutral and will impose no new burdens on the public sector or on industry.

- We have aimed to adopt a balanced approach in the regulations between the need to protect public health and the need to avoid hindering international travel or trade. Overall, there will be a deregulatory effect, with fewer powers applying to the public and fewer requirements imposed on industry. New Department for Transport regulations, following a requirement to meet an EU transport directive, will introduce a new mechanism for notifications that is likely to supersede one aspect of these regulations in relation to ships.

5.7 Health Protection – Vaccinations

Why we regulate

- The Regulations give a statutory basis to the NHS Constitution's right for patients and the public to have access to national NHS-provided immunisation programmes, as recommended by the independent expert Joint Committee on Vaccination and Immunisation (JCVI), subject to cost-effectiveness having been demonstrated.

- To date, under these Regulations, the Secretary of State has asked JCVI to advise on immunisation against rotavirus; varicella (chickenpox); herpes zoster (shingles); hepatitis B; respiratory syncytial virus; and seasonal influenza (potential extension to current programme); and meningococcal B.

- The Regulations and the NHS Constitution help ensure that measures are taken to protect the health of the nation against vaccine preventable diseases through national immunisation programmes.

What we regulate

- How advice from JCVI about new national programmes or changes to existing national immunisation programmes is requested and responded to by the Secretary of State.

Other policy instruments

- Public Health (Control of Disease) Act 1984, as amended by the Health and Social Care Act 2008, under which these regulations have been made.

- NHS (Standing Advisory Committees) Order 1981 (SI 1981/597), which establishes JCVI as the Standing Advisory Committee on Immunisation.

- The Vaccine Damage Payments Scheme (including associated legislation), which is a Department of Work and Pensions lead.

List of Health Protection Regulations (vaccinations)		
SI	**Title**	**Origin**
2009/38	Health Protection (Vaccination) Regulations 2009	Dom

OIOO/OITO Status

- This regulation requires the Secretary of State to implement any recommendation that the Joint Committee on Vaccinations and Immunisations (JCVI) has made on national vaccination programmes. This is in line with the pledge set out in the NHS Constitution. There are no costs to business from this regulation.

Summary

- One regulation in the Health Protection (Vaccinations) policy area has been scrutinised for this Audit. There are considered to be no costs to business from this regulation.

5.8 Human Fertilisation and Embryology Authority (HFEA)

Why we regulate

- To protect the health and welfare of women and their children by ensuring that the provision of fertility treatments, related services and the use of human embryos in research are conducted in a safe and ethical manner.

What we regulate

- The provision of fertility treatments involving the creation of embryos outside the body and/or the use of donated gametes (sperm and eggs) and embryos, plus the collection and use of data about those treatments.

- Who will be recognised as the legal parents of a child born as a result of assisted reproduction, including surrogacy, and where donated gametes or embryos have been used, what information the child can access about the donor(s) from age 16 years onwards.

- Related services involving the donation, procurement, testing, processing, preservation, storage (including storage time limits) and distribution of gametes and embryos.

- The creation and use of human embryos and human admixed embryos (human/animal hybrid embryos) for research purposes.

- Day to day licensing of establishments carrying out these activities and on-going monitoring is the responsibility of the UK wide national regulatory body, the Human Fertilisation and Embryology Authority (HFEA).

Other policy instruments

- Human Fertilisation and Embryology Authority Code of Practice.

- Surrogacy Arrangements Act 1985, as amended.

List of HFEA Regulations		
SI	**Title**	**Origin**
2004/1511	The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004	Dom
2007/1522	The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007	EU
Primary	Human Fertilisation and Embryology Acts 1990 (as amended) and 2008	Dom
2009/1891	The Human Fertilisation and Embryology (Appeals) Regulations 2009	Dom
2009/1397	The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009	Dom
2009/2088	The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) (Amendment) Regulations 2009	Dom
2009/1918	The Human Fertilisation and Embryology (Special Exemption) Regulations 2009	Dom
2009/2581	The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Amendment) Regulations 2009	Dom
2009/1582	The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009	Dom
2009/2478	The Human Fertilisation and Embryology (Supplementary Provision) Order 2009	Dom
2009/1892	The Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order	Dom
2010/985	The Human Fertilisation & Embryology (Parental Orders) Regulations 2010	Dom
2010/995	The Human Fertilisation & Embryology (Disclosure of Information for Research Purposes) Regulations 2010 SI 2009/995	Dom
2010/986	The Human Fertilisation and Embryology (Parental Orders) (Consequential, Transitional and Saving Provisions) Order 2010	Dom
2010/726	The Human Fertilisation and Embryology (Procedure on Applications and Execution of Warrants) Regulations 2010	Dom
1993/746	Access to Health Records (Control of Access) Regulations 1993, SI 1993/746	Dom

<u>OIOO/OITO Status</u>

- Sixteen regulations in the human fertility and embryology policy area have been considered for this Audit. Of these, two are believed to have an impact to business under OIOO/OITO rules. These are the Human Fertilisation and Embryology Acts 1990 (as amended) and 2008, and SI 2010/995. The estimated combined impact of these regulations is given in the table below.

- Of the remainder, thirteen are not believed to have an impact to business under OIOO/OITO rules because they deal with aspects of the regulation that do not directly impose a cost to business. These are SIs 2009/1891, 2009/1397, 2009/2088, 2009/1918,

2009/1582, 2009/2478, 2009/1892, 2010/985, 2010/986, 2010/726, 2004/1511, 2009/2581 and 1993/746.

- The remaining regulation transposes a European Union directive.

Statistics: HFEA	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£5.0 million
Estimated equivalent annual benefits to business	Un-monetised
Estimated equivalent annual net cost to business (EANCB)	Up to £5.0 million
Impact To Society	
Estimated annual cost to other parties/wider society	£2.5 million
Estimated annual benefits to other parties/wider society	Un-monetised
Net estimated annual cost to other parties/wider society	Up to £2.5 million
Notes: The annual costs to other parties/wider societies has been estimated as the costs to the NHS. Approximately 2/3 of HFEA business relates to the private sector, whilst the other 1/3 is NHS only.	
Reliability rating: 2/5	

Summary

Out of 15 regulations:

- Legal advice has been sought and received as below. The upshot is two regulations could be merged into one, reducing the number of regulations by one.
  - Legal advice sought on merging 2010/986 with 2010/985 – these cannot be merged because they are made using different powers.
  - Legal advice sought on merging 2009/1918, 2009/2581, 2009/1582 and 2009/2478. Of these only merger of 2009/2581 and 2009/1582 would be feasible and this could be a disproportionate use of legal time. For the others, merger is not possible because they are subject to different parliamentary procedures (affirmative and negative) and this would give rise to procedural difficulties. SI 2009/2478 is an order and therefore cannot be merged with the others.
  - Legal advice sought on merging 2009/1397 and 2009/2088. These regulations are not made by the Secretary of State but by the HFEA – therefore it does not fall to the Department to consolidate these.

- There is a case for retaining these regulations to protect the health and welfare of women and their children by ensuring that the provision of fertility treatments, related services and the use of human embryos in research are conducted in a safe and ethical manner.

- As part of the overall response to the recommendations of the McCracken Review of the HFEA and HTA, the HFEA will take action during 2013/14 to review the balance of its

regulatory focus and activities, and will clarify how it will work with other bodies such as the MHRA, CQC and Health Research Authority to reduce regulatory burden.

5.9 HIV / Venereal Disease

HIV

Why we regulate

- HIV is a long-term treatable condition for which there is no cure. In 1992 there was no effective treatment and there was a concern that individuals might be coerced into testing for a serious disease for which there was no effective treatment.

- From the outset (1980s) HIV has remained a stigmatised condition which is primarily transmitted sexually or through injecting drug use. In 1992 there were also concerns about the accuracy and appropriateness of individuals using testing kits designed for use by healthcare professionals.

What we regulate

- The sale or supply of an HIV testing kit to a member of the public;

- The sale or supply of an HIV testing kit without an accompanying warning notice;

- Providers of HIV testing service.

Other policy instruments

- None

Venereal Diseases

Why we regulate

- Patients self-refer to sexual health clinics. We regulate to safeguard patient confidentiality and anonymity and to limit the circumstances in which data or information collected by sexual health clinics can be shared with health professionals and others.

- Sexually transmitted infections attract considerable stigma which can deter people from accessing services if their very personal information, including their sexual history, is shared routinely with other healthcare professionals, even when it has no bearing on other health conditions. With the exception of HIV for which there is treatment but no cure, most STIs are treated and have few long-term consequences.

- Unless STIs are diagnosed and treated, new infections will occur, therefore on public health grounds there are compelling reasons for people to access services to test and be treated if they have an STI without fear that this information will be disclosed to others.

What we regulate

- Disclosure of patient information collected by PCTs, all NHS Trusts and SHAs on sexually transmitted infections

Other policy instruments

- None

List of HIV/Venereal Disease Regulations		
SI	**Title**	**Origin**
1988/047	AIDS (Control) (Contents of Reports) (No 2) Order	Dom
1974/29	National Health Service (Venereal Diseases) Regulations 1974, SI 1974/29	Dom
N/A 2000	The NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000	Dom
1992/460	HIV Testing Kits and Services Regulations 1992, SI 1992/460	Dom

OIOO/OITO Status

- Four regulations in the HIV / VD policy area have been scrutinised for the Audit. Of these, three are not believed to have an impact to business under OIOO/OITO rules because the affected parties are public sector bodies. These are SIs 1988/047 and 1974/29 and the 2000 directive.

- This leaves one regulation which is believed to have an impact to business under OIOO/OITO rules. The estimated impact of this regulation is set out below.

Summary

- The Department is currently looking to revoke SI 1992/460. It is anticipated that this will have a benefit equal to the current cost to business of the regulation, set out below. Substantial benefits to other parties of revocation are also estimated.
- There is a case for retaining the three regulations with no impact to business to safeguard patient confidentiality and anonymity. Options for consolidating these regulations have not been considered as part of this audit.

Statistics: HIV & VD	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£12.2 million
Estimated equivalent annual benefits to business	Un-monetised
Estimated equivalent annual net cost to business (EANCB)	£12.2 million
Impact To Society	
Estimated annual cost to other parties/wider society	Unquantified but estimated to be significant
Estimated annual benefits to other parties/wider society	Un-monetised
Net estimated annual cost to other parties/wider society	Unquantified but estimated to be significant
Notes: An assessment for the repeal of the ban on sale of HIV home testing kits contained a lower and upper estimate of the impact to business of £6.4 million and £18.6 million respectively, with a central estimate of £12.2 million. These estimates may be revised following a limited stakeholder consultation.	
Reliability rating: 1/5	

5.10 National Child Measurement Programme (NCMP)

Why we regulate

- Annually over 1 million children are measured in reception year and year 6. Over 99% of eligible primary schools in England take part. The data collected provide important public health information on the prevalence of excess weight of children that informs the development and delivery of national and local policy and services to reduce overweight and obesity in children. The data underpin the Public Health Outcomes Framework on excess weight in children.

- Regulations provide a legal basis for the weighing and measuring of children in primary and middle schools, and for the results to be sent to parents. The Regulations also stipulate key aspects of how the programme should be delivered.

- The regulations are important for ensuring that the programme is conducted in a consistent manner, so that the data are robust, accurate and comparable between years and areas, providing a reliable year-on-year data set to assess trends and progress.

What we regulate

- The regulations set out critical requirements regarding the delivery of the programme, including:
  - the eligible cohort of children whose heights and weights are measured as part of the NCMP;
  - information to be collected;
  - how the information should be collected, and who is responsible for the programme locally; and,

- exemptions to the programme and restrictions regarding the onward processing of data arising from the programme.

Other policy instruments

- Since April 2013, the surveillance component of the NCMP is a mandated function of Local Authorities, as set out in the "Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2012".

List of NCMP Regulations		
SI	**Title**	**Origin**
2013/218	Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013	Dom

OIOO/OITO Status

- One regulation relating to the NCMP has been scrutinised for this Audit. Because involvement in the scheme for schools is voluntary the regulations impose no cost to business under OIOO/OITO rules. The regulation has recently replaced the NCMP Regulations 2008 (SI 2008/3080) and came into force on the 1 April 2013.

Summary Status

- There is a case for retaining regulation as it underpins the NCMP programme and does not impose a cost to business.

5.11 Radiation

Why we regulate

- DH holds the UK responsibility for implementing the requirements of the Medical Exposure Directive 97/43. This Directive is implemented into UK regulation by means of the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) and Regulation 32 in the Ionising Radiations Regulations 1999.

- The Care Quality Commission enforces the IRMER in England. The Devolved UK Governments have their own enforcement organisations.

- The aim of the regulations is to control the exposure of patients with medical radiation such as x-rays and CT scanning. There are a number of fundamental radiation protection principles applied with in the regulations such as justification – this is the process of balancing the risk of the radiation with the benefit of the image produced for diagnosis.

- DH is continually involved with the stewardship of professional bodies to produce and update guidance. The overall aim being to protect public health by minimising the justified exposure to medical radiation.

- DH holds the responsibility for regulation of access to sunbeds under the Sunbeds (Regulation) Act 2010.

What we regulate

Ionising Radiation (Medical Exposure) Regulations 2000 (Plus the 2006 and 2011 Amendments)

- Medical exposure means any exposure to which the following applies and involves any individual being exposed to ionising radiation:-

    - the exposure of patients as part of their own medical diagnosis or treatment including any exposure of an asymptomatic individual;
    - the exposure of individuals as part of occupational health surveillance;
    - the exposure of individuals as part of health screening programmes;
    - the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic research programmes; and
    - the exposure of individuals as part of medico-legal procedures.

- Each exposure has to be individually justified by a practitioner as defined in the regulations who bases that decision on a number of scientific and clinical factors. This practitioner has to be a trained, competent individual who understands the potential benefits and detriments from the exposure. Additionally, only persons who are adequately trained may carry out tasks associated with medical exposures to ionising radiation.

Medicines (Administration of Radioactive Substances) Regulations 1978 – 1995 Amendment

- The main work of this regulation is undertaken by the statutory Administration of Radioactive Substances Advisory Committee (ARSAC). The Secretariat is run by PHE Chilton. This committee authorises and revokes permission by means of a certificate to doctors and dentists. DH attends as an assessor.

Sunbeds (Regulation) Act 2010

- This regulation restricts access to sunbeds by those under 18 years of age, makes provision for the restriction on the sale of hire of sunbeds, provides for the posting of safety information for users, specifies the need for protective eyewear and allows for the regulation of sunbed establishments by local authorities, generally trading standards.

Other policy instruments

- None

One in One Out Status

- Six regulations in the ionising radiation policy area have been scrutinised for this Audit. All of these regulations are European Union related regulations and therefore fall outside of the scope of One-in One-out. The Basic Safety Standards (for ionising radiation) Directive has

recently been revised, due to go the EU Council of Ministers in September 2013 for sign off. Once this Directive has been adopted there will be a three year implementation period. This opportunity will be taken to rationalise regulation in this area and to produce that are fit for purpose and to the best current standards, ensuring no gold plating. Officials are already in discussion on proposals to take this forward.

- The sunbeds regulation is necessary to protect the public from unscrupulous use of sunbeds and, as such, is necessary to protect the public. When this was introduced in 2010 it was an "IN" with no corresponding "OUT" (see Annex E). The potential to revise the sunbed regulation has been investigated with DH lawyers who advised against changing the law where the regulation is very new. The DH plans to re-examine the burden on business and to examine how it might be reduced in this area.

List of Radiation Regulations		
SI	**Title**	**Origin**
2000/1059	Ionising Radiation (Medical Exposure) Regulations 2000	EU
2006/2523	Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006	EU
2011/1567	Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011	EU
1995/2147	Medicines (Administration of Radioactive Substances) Amendment Regulations 1995, SI 1995/2147	EU
1978/1006	Medicines (Administration of Radioactive Substances) Regulations 1978	EU
2006/2806	Medicines (Administration of Radioactive Substances) Amendment Regulations 2006	EU
Primary	Sunbeds (Regulation) Act 2010	Private members Bill

Summary

- Six regulations in the Ionising Radiation policy area have been scrutinised for this Audit.

- There is a case for retaining these regulations as they protect the public and ensure we meet EU regulations. However, those relating to medical exposures to ionising radiation will be revised and up-dated in line with the new Basic Safety Standards Directive once it has been adopted by the EU Council of Ministers with an implementation date of 2016. The DH also plans to re-examine the burden on business and how this might be reduced for sunbeds.

5.12 Surrogacy

Why we regulate

- The Surrogacy Arrangements Act 1985, which came into force on 16th July 1985, regulates certain activities in connection with an arrangement for a woman to carry a child for other person(s), with the intention that the child will be passed to those person(s) after birth. The purpose of the Act is to ensure that surrogacy is not undertaken on a commercial basis.

- The Act defines key terms such as Surrogate Mother and Surrogacy Arrangement. It also determines that a surrogacy arrangement, once made, is not legally enforceable.

- The Act prohibits the activities of commercial agencies or individuals aiming to make a profit out of a surrogate arrangement and applies to all forms of surrogacy.

- The Act makes it a criminal offence for anyone to play any part in setting up a surrogacy arrangement on a commercial basis, to advertise or compile information to promote or assist surrogacy arrangements.

What we regulate

- Certain activities in connection with an arrangement for a woman to carry a child for other person(s), with the intention that the child will be passed to those person(s) after birth.

Other policy instruments

- It is an offence to offer (and accept) an overt payment to the surrogate for her services, although case law has held that payments may be made to cover expenses and to compensate the surrogate for her time and inconvenience. However, this is derived (i.e. not set out expressly) from provisions in section 95 of the Adoption Act 2002 – this is not DH led legislation.

List of Surrogacy Regulations/Acts		
SI	**Title**	**Origin**
	The Surrogacy Arrangements Act 1985	Dom

OIOO/OITO Status

- This act is not thought to have any impact to business because it is not known what impact removing the act would have therefore any impact to business would be second round.

5.13 Tobacco

Why we regulate

- Tobacco is a uniquely dangerous consumer product and warrants special regulatory treatment. Smoking kills half of all long-term users. For this reason, tobacco is regulated differently to other goods; for example, through picture warnings and specific taxes.

- Tobacco use is a significant public health challenge and tobacco control has an essential part to play in delivering the commitment to reduce the number of people who die prematurely. It is also one of the most significant causes of health inequalities.

- One in two long-term smokers will die from a smoking-related illness, making smoking the single biggest cause of preventable death in England, causing nearly 80,000 premature deaths each year.

- There is a natural tension between the public health aim to reduce smoking prevalence and the vested interests of businesses that profit from the manufacture and sale of tobacco products.

- These factors have led to the World Health Organization's Framework Convention on Tobacco Control (FCTC) to which the UK is a Party. The FCTC is an evidence-based treaty that sets out obligations across a wide range of areas, including taxation, packaging and labelling, education, tobacco cessation, illicit trade, sales to minors, protection from exposure to second-hand smoke and the need to protect tobacco control policies from the financial and other vested interests of the tobacco industry.

- The nature of the public health challenge means that regulation makes a vital contribution to the overall comprehensive strategy. The international obligation to protect policy from vested interests means that voluntary or self-regulated approaches to tobacco control as alternatives to legislation are not effective or appropriate.

- For these reasons it is vital to maintain the established framework of tobacco control legislation.

- The primary aims of all recent legislation have been:
  - to reduce the number of young people recruited to the ranks of smokers;
  - to support quitters;
  - to reduce exposure to second-hand smoke.

What we regulate

- DH is responsible for tobacco control legislation contained in provisions in four different Acts and twenty two sets of regulations, as set out in the table below.

Other policy instruments

- HMT and HMRC are responsible for further legislation on tobacco products relating to matters such as taxation and excise duty.

List of Tobacco Regulatory Measures			
	Act	**Statutory Instrument Number**	**Statutory Instrument Title**
1	Age of Sale Children and Young Persons Act 1933 Ss 7, 12A-12D		
2		2007/767	Children and Young Persons (Sale of Tobacco etc.) Order 2007
3	Children and Young Persons (Protection from Tobacco) Act 1991		
4		1998/3228	The Protection from Tobacco (Display of Warning Statements) Regulations 1992
5	Tobacco Advertising and Promotion Act 2002		
6		2004/1824	The Tobacco Advertising and Promotion (Brandsharing) Regulations 2004
7		2004/1277	The Tobacco Advertising and Promotion (Specialist Tobacconists) Regulations 2004
8		2004/765	The Tobacco Advertising and Promotion (Point of Sale) Regulations 2004
9		2003/77	The Tobacco Advertising and Promotion (Sponsorship) Transitional Regulations 2003
10		2006/2369	Tobacco Advertising and Promotion Act 2002 (Amendment) Regulations 2006
11	Smokefree Health Act 2006 Sections 1-12		
12		2006/3368	The Smoke-free (Premises and Enforcement) Regulations 2006
13		2007/765	The Smoke-free (Exemptions and Vehicles) Regulations 2007
14		2007/764	The Smoke-free (Penalties and Discounted Amounts) Regulations 2007
15		2007/760	The Smoke-free (Vehicles Operators and Penalty Notices) Regulations 2007
16		2007/923	The Smoke-free (Signs) Regulations 2007
17		2012/1536	The Smoke-free (Signs) Regulations 2012 Deregulatory in effect, following the Red Tape Challenge.
18	Tobacco Advertising and Promotion Act 2002 Ss 7A, 7B and 7C (as inserted by s.21 Health Act 2009).		[Regulating displays of tobacco products]
19		2010/445	Tobacco Advertising and Promotion (Display)(England) Regulations 2010
20		2010/863	Tobacco Advertising and Promotion (Display of Prices)(England) Regulations 2010

21		2010/446	Tobacco Advertising and Promotion (Specialist Tobacconists)(England) Regulations 2010
22		2011/1256	The Tobacco Advertising and Promotion (Display and Specialist Tobacconists) (England) (Amendment) Regulations 2011 Deferring commencement to give businesses longer to prepare, following Ministerial review
23		2012/677	The Tobacco Advertising and Promotion (Display and Specialist Tobacconists) (England) (Amendment) Regulations 2012 Deregulatory in effect following Ministerial review of the tobacco display legislation
24		2010/864	The Protection from Tobacco (Sales from Vending Machines)(England) Regulations 2010
25		2002/3041	Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002
26		2007/2473	Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007
27		1992/3134	Tobacco for Oral Use (Safety) Regulations 1992

<u>OIOO/OITO Status</u>

- Twenty-seven regulatory measures (Acts and S.I.s) on tobacco control have been scrutinised in this Audit (table above). A further two regulations were identified relating to taxation and excise duty of tobacco products (SIs 2006/1787 and 2001/1712) but considered to be out of scope of this Audit as they are the responsibility of HMT and HMRC.

Exempted regulations:

- Eight regulations (SIs 2004/1824, 2004/1277, 2004/765, 2003/77, 2006/2369, 2002/3041, 2007/2473, 1992/3134) and one Act (Tobacco Advertising and Promotion Act 2002) are considered to be exempt under OIOO/OITO rules as they transpose EU Directives. There is not considered to be any gold plating of these regulations.

- Tobacco Advertising and Promotion Act (TAPA) 2002 implements Directive 2003/33/EC and fulfils UK commitments under FCTC making tobacco advertising and sponsorship illegal. Regulations 25 and 26 implement Directive 2001/37/EC and fulfil FCTC commitments requiring cigarette packets to carry health warnings in text and pictures; requiring compliance with maximum yields of tar, nicotine and carbon monoxide and stating yields on packets; forbidding carrying suggestions that they are less harmful than others; requiring manufacturers to provide Government with annual statements about product ingredients. Regulation 27 implements Directive 89/622/EEC prohibiting sale of tobacco for oral use.

- Regulation 9 (SI 2003/77) provided time limited exceptions to the TAPA 2002 and has now lapsed.

In scope:

- The remaining 18 regulatory measures are technically in scope of OIOO/OITO and have been considered as such by the RPC although it should be noted that they fulfil UK commitments to the WHO FCTC and are arguably exempt as International agreements.

- All tobacco control legislation has been reviewed under the Red Tape Challenge.

- In 2010, Government Ministers (Andrew Lansley, Oliver Letwin and Vince Cable) reviewed in detail the tobacco display legislation (Regulations 18-23). This resulted in the display regulations being amended to make them less burdensome and more practical for businesses to implement. To give businesses longer to prepare, and in keeping with the moratorium on new regulation for micro and small businesses, the start dates were deferred (supermarkets and other large shops have had to comply since 6 April 2012, small shops and all others will have to comply from 6 April 2015).

- Under the display legislation, two of the regulations listed above (SI 2004/1277 and SI 2004/765) will be revoked once the tobacco display regulations (SI 2010/446) take full effect on 6 April 2015.. SI 2010/446 was itself amended (by SIs 2011/1256 and 2012/677) which simplified the requirements and delayed commencement of the display legislation. A reduced IN was registered as a result (against SI 2011/1256), reported in SNR3.

- Age of sale regulations (Regulations 1-4). Since 1908 it has been illegal to sell tobacco to anyone under 16 years of age; this age was raised to 18 years in October 2007. These regulatory measures have been reviewed under the Retail RTC theme and their retention agreed.

- Smokefree legislation has eliminated second-hand smoke from virtually all indoor public places, working places and work vehicles (Regulations 11-17). These regulatory measures have been reviewed under the Hospitality RTC theme and their retention agreed. This resulted in the Smoke-free Signs Regulations being amended to make the requirements for no-smoking signs less onerous on business. Regulation 16 (SI 2007/923) has therefore been revoked by regulation 17 (SI 2012/1536) which was deregulatory in effect. An OUT was registered as a result and reported in SNR4.

- Sales of tobacco products from vending machines stopped in October 2011 (Regulation 24). This regulatory measure has been reviewed under the Hospitality RTC theme and its retention agreed. The introduction of this regulation had an associated IN as assessed and agreed by the RPC/RRC which was reported in SNR3.

<u>Costs and Benefits</u>

- Costs and benefits have been estimated where possible for the tobacco control regulatory measures where these are considered to be in scope of OIOO/OITO.

- Costs and benefits to business are estimated using strict EANCB methodology.

- Impacts to society are estimated based on economic costs and benefits. See Annex G for further information and breakdown of costs and benefits.

<u>Summary</u>

- There is limited scope for further regulatory reform on tobacco control legislation.

- Some 18 regulatory measures (for which DH has responsibility) fall within scope of the OIOO/OITO rules, although some have already been considered as in scope by the RPC. it

is arguable that they are necessary to fulfil UK international obligations under the WHO FCTC.

- These measures have been scrutinised extensively in recent years. As set out above, the display legislation has been the subject of ministerial review (and agreement). The age of sale, smokefree and vending machine legislation has been reviewed within the RTC Retail and Hospitality themes and their retention has been agreed by Oliver Letwin and Mark Prisk at Cabinet Office/BIS.

- Regulation 9 (SI 2003/77) could be revoked as this provides a time limited transitional arrangement which has now lapsed. There would be no OUT associated but this would constitute a simplification as it would remove a source of potential confusion.

- There is a robust cost-benefit case for the retention of the remaining tobacco control regulations as evidenced in the estimates of costs and benefits. Through the effects of the full range of tobacco control initiatives, adult smoking rates have reduced from over 45% in the early 1970s to around 20% in 2012.

- Experience shows that initiatives to reduce smoking prevalence work best in combination, with cumulative effects over time. *Healthy Lives, Healthy People: a Tobacco Control Plan for England* (March 2011) includes three national ambitions to reduce smoking rates among adults, young people and pregnant women and sets out the Government's comprehensive, evidence-based, strategy to achieve these ambitions, with initiatives across the six strands of work recognised internationally as required for effective tobacco control –
  - stopping the promotion of tobacco
  - making tobacco less affordable
  - effective regulation of tobacco products
  - helping tobacco users to quit
  - reducing exposure to second-hand smoke
  - effective communications for tobacco control.

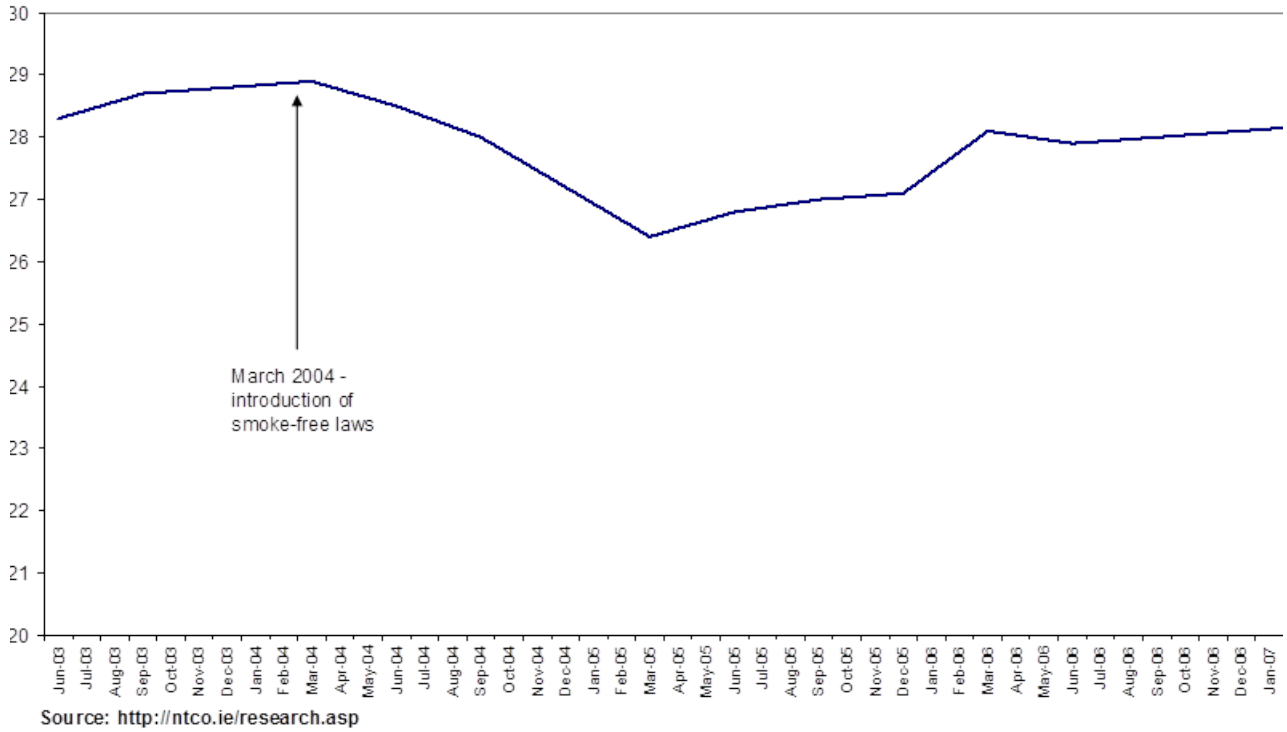
- The progress made over the decades since the 1970s, has been achieved through successive policies, consolidating and building on earlier progress. The different activities and initiatives tend to reinforce and amplify the impact that each one has.

- If implementation of tobacco control initiatives is not sustained, evidence from other countries shows that rates of smoking prevalence are likely to increase again. For example, data from the Republic of Ireland shows that while smoking prevalence fell by 2.5 percentage points over the 12 months following the introduction of smokefree legislation in March 2004, in the absence of sustained downward pressure from further tobacco control initiatives, prevalence rose again over the subsequent 2 years (Figure 1).

- Also, because tobacco control measures are mutually reinforcing, it is difficult, retrospectively, to disentangle the impact of single initiatives, particularly when they have been implemented as part of comprehensive strategies, the effects of which have built up over the years.

Summary Statistics: Tobacco	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£16 million of which 11.9 yet to be incurred
Estimated equivalent annual benefits to business	£0
Estimated equivalent annual net cost to business (EANCB)	£16 million of which 11.9 yet to be incurred
Impact To Society	
Estimated annual cost to other parties/wider society	£1,700 million
Estimated annual benefits to other parties/wider society	About £5,000 million
Net estimated annual cost to other parties/wider society	£3,300 million
Notes: Costs yet to be incurred relate to tobacco display phased entry	
Reliability rating: 4/5	

Figure 1: Smoking prevalence - Ireland (% of population aged 15+)



Source: http://ntco.ie/research.asp

5.14 Other

Family Practice Committees (FPCs)

- Two regulations relating to FPCs have been scrutinised for this Audit. The legal status of these regulations regarding whether they are still operative or in force has not yet been confirmed.

List of FPC Regulations		
SI	**Title**	**Origin**
1985/39	Family Practitioner Committees (Consequential Modifications) Order 1985, SI 1985/39	Dom
1985/497	Family Practitioner Committees (Consequential Modifications) Amendment Order 1985, SI 1985/497	Dom

National Patient Safety Agency

- Four regulations in the NPSA policy area have been scrutinised for this Audit. We have been advised that all four of these are due to be revoked as part of the implementation of The Health and Social Care Act 2012. These are listed in the table below.

List of NPSA Regulations		
SI	**Title**	**Origin**
2001/1742	National Patient Safety Agency Regulations 2001	Dom
2001/1743	National Patient Safety Agency (Establishment and Constitution) Order 2001	Dom
2003/1077	National Patient Safety Agency (Establishment and Constitution) Amendment Order 2003	Dom
2005/504	National Patient Safety Agency (Establishment and Constitution) Amendment Order 2005	Dom

Thermometers

- One regulation has been scrutinised for this Audit (listed below). This regulation is a European Union regulation and therefore falls outside of the OIOO/OITO rules.

List of Thermometers regulations		
SI	**Title**	**Origin**
1993/2360	Clinical Thermometers (EEC Requirements) Regulations 1993	EU

Voluntary Hospitals

- One regulation relating to Voluntary Hospitals has been scrutinised for this Audit. The legal status of this regulation regarding whether it is still operative or in force has not yet been confirmed.

List of voluntary hospitals regulations		
SI	**Title**	**Origin**
1936/1025	Rules, dated 15 September 1936, under Section 5(1) of the Voluntary Hospitals (Paying Patients) Act 1936 (1936)	Dom

6. Professional Standards

- This section covers professional regulation. Thirty-four different professions are regulated in law on a UK wide basis by eight separate independent regulatory bodies. These are listed in Annex B along with a full list of the relevant regulations.

Why we regulate

- Professional Regulation is part of the Government's overarching strategy to improve the safety and quality of care that patients and the public can expect to receive. Together with regulation by the Care Quality Commission (CQC), Monitor and the NHS Trust Development Agency (NHSTDA), professional regulation aims to ensure that respectful, compassionate care and safe and effective health and social care are considered the norm. The primary purpose of professional regulation is to ensure that an individual's practice and behaviour is safe for patients and service users, whether they work in the NHS or in private and civil society settings.

What we regulate

- Professional regulation is delivered through the regulatory bodies listed in Annex B which have a statutory duty to protect the public by:

    - Setting standards of education and training for the professions they regulate;
    - Maintaining a register of those who demonstrate they meet these standards;
    - Setting standards of conduct, ethics, and competence required to remain on the register;
    - Investigating concerns about professionals who are registered and taking appropriate action where individuals might present a risk; and,
    - Taking action against those falsely claiming to be a registered professional.

Other policy instruments

- Each of the regulatory bodies has been established through an Act of Parliament or an Order made by the Privy Council. The main legislation is:
    - Medical Act 1983;
    - Dentists Act 1984;
    - Opticians Act 1989;
    - Chiropractors Act 1992;
    - Osteopaths Act 1993;
    - Nursing and Midwifery Order 2001;
    - Health and Care Professions Order 2001;
    - Pharmacy Order 2010.

- Since 1999, these Acts and Order have been amended many times through an Order made by the Privy Council. These are:
    - Dentists Act 1984 (Amendment) Order 2001;
    - Dentists Act 1984 (Amendment) Order 2005;
    - General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010;

- Health Care and Associated Professions (Miscellaneous Amendments) Order 2008;
- Health Care and Associated Professions (Miscellaneous Amendments and Practitioner Psychologists) Order 2009;
- Health Professions (Hearing Aid Dispensers) Order 2010;
- Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006;
- Medical Act 1983 (Amendment) Order 2000;
- Medical Act 1983 (Amendment) Order 2002;
- Medical Professions (Miscellaneous Amendments) Order 2008;
- Nursing and Midwifery (Amendment) Order 2008;
- Opticians Act 1989 (Amendment) Order 2005;
- Postgraduate Medical Education and Training Order of Council 2010.

- Each of the regulatory bodies is empowered under this legislation to make rules setting out their operating procedures, the constitution of their Councils, and Committees, and the fitness to practise process.

- Before these rules can come into force however, they must be approved by the Privy Council and laid in both Houses of Parliament. Each set of rules made by a regulatory body is therefore set out in a separate statutory instrument.

<u>OIOO/OITO Status</u>

- Two hundred and seven regulations in the professional standards area have been scrutinised for this Audit. The degree to which any individual regulation places an impact to business has not been scrutinised for this audit. The regulations have been taken as a whole and their overall impact assessed.

- The Law Commission has recently consulted on a proposal to replace the existing legislation related to professional regulation with one overarching Act which would streamline the processes of the regulatory bodies (including their powers to make rules which would no longer require parliamentary or privy council approval) and ensure a consistent approach to regulation across the regulatory bodies.

- We expect the proposals to result in a reduction in the number of current pieces of legislation by around 90%. We have said that we will legislate at the earliest possible opportunity to make these changes, which would result in a considerable reduction in legislation and bureaucracy. As a result of the changes to their legal framework, regulatory bodies would be able to streamline their operating systems and processes quickly and effectively. This may result in benefits to businesses as more efficient processes, in for instance Fitness to Practise procedures, are likely to lead to a reduction in overall costs to regulators which could result in a reduction in fees for registrants. We will investigate this further as part of the process of designing and implementing the changes.

- In terms of the Statutory Instruments covering the rules made by the regulatory bodies, no impact assessment will have been made by DH. This is because responsibility for policy development, consultation and impact analysis is the responsibility of the regulatory body. The DH's role in advising the Privy Council whether to approve the rules or not is restricted to ensuring that the rules meet the requirements of public law and are consistent with the regulatory body's powers and responsibilities.

Statistics: Professional Standards	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£10 million
Estimated equivalent annual benefits to business	Un-monetised
Estimated equivalent annual net cost to business (EANCB)	Up to £10 million
Impact To Society	
Estimated annual cost to other parties/wider society	Un-monetised
Estimated annual benefits to other parties/wider society	Un-monetised
Net estimated annual cost to other parties/wider society	Un-monetised
Notes: The estimated equivalent annual cost to business is an average based on the low and high estimated costs (£9 million and £11 million respectively). This cost is an overestimate as it has not been possible to exclude GPs from the costing who are out of scope of OIOO/OITO as per BIS convention. The figure does however exclude Dentists, who again are out of scope of OIOO/OITO by BIS convention.	
Reliability rating: 3/5	

Summary

- Of the 207 regulations in this policy area one has already been revoked. Eighteen are obsolete, spent or superseded and two are transitional. These are listed below. Legal services have been asked to confirm whether these can be revoked and over what timetable.

- We expect that the Law Commission proposals will result in a reduction in the number of current pieces of regulation by around 90%. We will seek to legislate at the earliest possible opportunity to implement the proposals.

- The Law Commission's own Impact Assessment of its proposals concluded that there would be no impact on business.

List of Professional Standards regulations spent, revoked etc		
SI	**Title**	**Status**
1991/1706	Dental Auxiliaries (Amendment) Regulations 1991	Spent
1996/2998	Dental Auxiliaries (Amendment) Regulations 1996	Spent
1999/3460	Dental Auxiliaries (Amendment) Regulations 1999	Spent
2002/1671	Dental Auxiliaries (Amendment) Regulations 2002	Spent
2003/3105	Dental Auxiliaries (Amendment) Regulations 2003	Spent
2006/1671	Dentists Act 1984 (Amendment) Order 2005 Transitional Provisions Order of Council 2006	Transitional provisions
1981/432	European Communities (Medical, Dental and Nursing Professions) (Linguistic Knowledge) Order 1981	Superseded – Second round
1999/1857	General Chiropractic Council (Registration During Transitional Period) Rules Order of Council 1999	Revoked
2006/1664	General Dental Council (Appointments Committee and Appointment of Members of Committees) Rules Order of Council	Obsolete
1986/149	General Medical Council (Registration (Fees) Regulations) Order of Council 1986	Obsolete
1995/2786	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 1995	Obsolete
1997/1884	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 1997	Obsolete
2000/3194	General Medical Council (Registration (Fees) (Amendment) No 2 Regulations) Order of Council 2000	Obsolete
2004/3409	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 2004	Obsolete
2005/399	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 2005	Obsolete
2001/1744	General Social Care Council (Appointments and Procedure) Regulations 2001	Obsolete
2004/561	General Social Care Council (Description of Persons to be Treated as Social Care Workers) Regulations 2004	Obsolete
2004/562	General Social Care Council (Registration) (Description of Social Care Workers) Order 2004	Obsolete
2004/2525	Health Professions Order 2001 (Transitional Provisions) Order of Council 2004	Transitional
1968/271	National Assistance (Professions Supplementary to Medicine) (Amendment) Regulations 1968	Obsolete
1964/939	National Assistance (Professions Supplementary to Medicine) Regulations 1964	Obsolete

Annex B – Professional Standards additional information

List of Registered Professions

Regulator	Registered professions
General Chiropractic Council	Chiropractors
General Dental Council	Dentists
	Dental Hygienists
	Dental Therapists
	Clinical Dental Technicians
	Orthodontic Therapists
	Dental Nurses
	Dental Technicians
General Medical Council	Doctors
General Optical Council	Dispensing Opticians
	Optometrists
General Osteopathic Council	Osteopaths
General Pharmaceutical Council	Pharmacists
	Pharmacy Technicians
Health and Care Professions Council	Arts Therapists
	Biomedical scientists
	Chiropodists/Podiatrists
	Clinical scientists
	Dieticians
	Hearing Aid Dispensers
	Occupational Therapists
	Operating Department Practitioners
	Orthoptists
	Orthotists/Prosthetists
	Paramedics
	Physiotherapists
	Practitioner psychologists
	Radiographers
	Speech and language therapists
	Social Workers
Nursing and Midwifery Council	Nurses
	Midwives

Full List of Professional Standards Regulations

All domestic apart from 2 regs - 1981/432, 2004/1947 which are EU related.

SI No.	Title of SI or Act
2008/2927	Council for Healthcare Regulatory Excellence (Appointment, Procedure etc) Regulations
2002/922	Council for Professions Supplementary to Medicine (Transfer of Staff and Property etc
1991/1706	Dental Auxiliaries (Amendment) Regulations 1991, SI 1991/1706
1996/2998	Dental Auxiliaries (Amendment) Regulations 1996, SI 1996/2998
1999/3460	Dental Auxiliaries (Amendment) Regulations 1999, SI 1999/3460
2002/1671	Dental Auxiliaries (Amendment) Regulations 2002
2003/3105	Dental Auxiliaries (Amendment) Regulations 2003
1998/1546	Dentists Act 1984 (Amendment) Order 1998, SI 1998/1546
2001/3926	Dentists Act 1984 (Amendment) Order 2001
2006/1671	Dentists Act 1984 (Amendment) Order 2005 Transitional Provisions Order of Council 2006, SI 2006/1671
2005/2011	Dentists Act 1984 (Amendment) Order 2005, SI 2005/2011
1981/432	European Communities (Medical, Dental and Nursing Professions) (Linguistic Knowledge) Order 1981, SI 1981/432
2004/1766	European Nursing and Midwifery Qualifications Designation Order of Council 2004, SI 2004/1766
1996/1591	European Primary Medical Qualifications Regulations 1996, SI 1996/1591
2004/1947	European Qualifications (Health and Social Care Professions and Accession of New Member States) Regulations 2004, SI 2004/1947
2008/462	European Qualifications (Health and Social Care Professions) (Amendment) Regulations 2008, SI 2008/462
2007/3101	European Qualifications (Health and Social Care Professions) Regulations 2007, SI 2007/3101
2003/3148	European Qualifications (Health Care Professions) Regulations 2003, SI 2003/3148
2010/234	General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010, SI 2010/234
1999/1856	General Chiropractic Council (Registration) Rules Order of Council 1999, SI 1999/1856
1999/1857	General Chiropractic Council (Registration During Transitional Period) Rules Order of Council 1999, SI 1999/1857
1999/3071	General Chiropractic Council (Professional Indemnity Insurance) Rules Order 1999, SI 1999/3071
2000/2265	General Chiropractic Council (Appeals Against Decisions of the Registrar) Rules Order 2000, SI 2000/2265
2000/2866	General Chiropractic Council (Functions of Medical Assessors) Rules Order 2000, SI 2000/2866
2000/2916	General Chiropractic Council (Investigating Committee) Rules Order 2000, SI 2000/2916
2000/3214	General Chiropractic Council (Health Appeal Tribunal) Rules Order 2000, SI 2000/3214
2000/3290	General Chiropractic Council (Professional Conduct Committee) Rules Order of Council 2000, SI 2000/3290
2000/3291	General Chiropractic Council (Health Committee) Rules Order of Council 2000, SI 2000/3291
2002/2704	General Chiropractic Council (Registration of Chiropractors with Foreign Qualifications) Rules Order of Council 2002, SI 2002/2704
2000/2822	General Chiropractic Council Judicial Committee Rules 2000
2000/2865	General Chiropractic Council (Functions of Legal Assessor) Rules 2000
2004/1877	General Chiropractic Council (Continuing Professional Development) Rules Order of Council 2004, SI 2004/1877
2006/1630	General Chiropractic Council (Professional Conduct Committee and Health Committee) Amendment Rules Order of Council 2006, SI 2006/1630
2008/3047	General Chiropractic Council (Constitution) Order 2008

2009/26	General Chiropractic Council (Constitution of the Statutory Committees) Rules Order of Council 2009, SI 2009/26
2009/27	General Chiropractic Council (Registration of Chiropractors with United Kingdom Qualifications that are not Recognised Qualifications) Rules Order of Council 2009, SI 2009/27
2009/2305	General Chiropractic Council (Registration) (Amendment) Rules Order of Council 2009, SI 2009/2305
2009/2738	General Chiropractic Council (Constitution of the Statutory Committees) (Amendment) Rules Order of Council 2009, SI 2009/2738
2004/68	General Dental Council Continuing Professional Development Committee (Procedure) Rules Order of Council 2003 (2004), SI 2004/68
2006/1440	General Dental Council (Professions Complementary to Dentistry) Regulations Order of Council 2006, SI 2006/1440
2006/1663	General Dental Council (Fitness to Practise) Rules Order of Council 2006, SI 2006/1663
2006/1664	General Dental Council (Appointments Committee and Appointment of Members of Committees) Rules Order of Council 2006, SI 2006/1664
2006/1667	General Dental Council (Professions Complementary to Dentistry) (Dental Hygienists and Dental Therapists) Regulations Order of Council 2006, SI 2006/1667
2006/1668	General Dental Council (Registration Appeals) Rules Order of Council 2006, SI 2006/1668
2006/1669	General Dental Council (Professions Complementary to Dentistry) (Qualifications and Supervision of Dental Work) Rules Order of Council 2006, SI 2006/1669
2006/1670	General Dental Council (Professions Complementary to Dentistry) (Business of Dentistry) Rules Order of Council 2006, SI 2006/1670
2008/1822	General Dental Council (Continuing Professional Development) (Dentists) Rules Order of Council 2008, SI 2008/1822
2008/1823	General Dental Council (Continuing Professional Development) (Professions Complementary to Dentistry) Rules Order of Council 2008, SI 2008/1823
2009/1808	General Dental Council (Constitution) Order 2009, SI 2009/1808
2009/1813	General Dental Council (Constitution of Committees) Rules Order of Council 2009, SI 2009/1813
2007/1884	General Dental Council Health (Overseas Registration Examination Regulations) Order of Council 2007, SI 2007/1884
2005/3354	Nursing and Midwifery Council (Education, Registration and Registration Appeals) (Amendment) Rules Order of Council 2005, SI 2005/3354
1986/149	General Medical Council (Registration (Fees) Regulations) Order of Council 1986, SI 1986/149
1995/2786	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 1995, SI 1995/2786
1997/1884	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 1997, SI 1997/1884
2000/2141	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 2000, SI 2000/2141
2000/3194	General Medical Council (Registration (Fees) (Amendment) No 2 Regulations) Order of Council 2000, SI 2000/3194
2001/3668	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 2001, SI 2001/3668
2003/1074	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 2003, SI 2003/1074
2004/2607	General Medical Council (Fitness to Practise) (Disqualifying Decisions and Determinations by Regulatory Bodies) Procedure Rules Order of Council 2004, SI 2004/2607
2004/2608	General Medical Council (Fitness to Practise) Rules Order of Council 2004, SI 2004/2608
2004/2609	General Medical Council (Voluntary Erasure and Restoration following Voluntary Erasure) Regulations Order of Council 2004, SI 2004/2609
2004/2611	General Medical Council (Constitution of Panels and Investigation Committee) Rules Order of Council 2004, SI 2004/2611
2004/2612	General Medical Council (Restoration following Administrative Erasure) Regulations Order of Council 2004, SI 2004/2612
2004/2625	General Medical Council (Legal Assessors) Rules 2004, SI 2004/2625
2004/3410	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 2004, SI 2004/3410

2005/399	General Medical Council (Registration (Fees) (Amendment) Regulations) Order of Council 2005, SI 2005/399
2005/402	General Medical Council (Constitution of Panels and Investigation Committee) (Amendment) Rules Order of Council 2005, SI 2005/402
2005/896	General Medical Council (Legal Assessors) (Amendment) Rules 2005, SI 2005/896
2007/3168	General Medical Council (Fitness to Practise) (Amendments in Relation to Undertakings) Rules Order of Council 2007, SI 2007/3168
2008/1256	General Medical Council (Fitness to Practise) (Amendment in Relation to Standard of Proof) Rules Order of Council 2008, SI 2008/1256
2008/2554	General Medical Council (Constitution) Order 2008, SI 2008/2554
2009/1913	General Medical Council (Fitness to Practise) (Amendment) Rules Order of Council 2009, SI 2009/1913
2009/2739	General Medical Council (Licence to Practise) Regulations Order of Council 2009, SI 2009/2739
2009/2751	General Medical Council (Constitution of Panels and Investigation Committee) (Amendment) Rules Order of Council 2009, SI 2009/2751
2009/2752	General Medical Council (Registration Appeals Panels Procedure) (Amendment) Rules Order of Council 2009, SI 2009/2752
2009/2763	General Medical Council (Voluntary Erasure and Restoration following Voluntary Erasure) (Amendment) Regulations Order of Council 2009, SI 2009/2763
2009/2764	General Medical Council (Restoration following Administrative Erasure) (Amendment) Regulations Order of Council 2009, SI 2009/2764
2009/2765	General Medical Council (Fitness to Practise) (Disqualifying Decisions and Determinations by Regulatory Bodies) Procedure (Amendment) Rules Order of Council 2009, SI 2009/2765
2010/474	General Medical Council (Constitution of Panels and Investigation Committee) (Amendment) Rules Order of Council 2010, SI 2010/474
2010/475	General Medical Council (Applications for General Practice and Specialist Registration) Regulations Order of Council 2010, SI 2010/475
2010/476	General Medical Council (Registration Appeals Panels Procedure) Rules Order of Council 2010, SI 2010/476
2010/477	General Medical Council (Marking of the General Practitioner Register) Regulations Order of Council 2010, SI 2010/477
	General Medical Council (Constitution)(Amendment) Order 2012
2012/2685	General Medical Council (Licence to Practise and Revalidation) Regulations 2012
1985/856	General Optical Council (Rules on the Fitting of Contact Lenses) Order of Council 1985, SI 1985/856
1994/70	General Optical Council (Testing of Sight by Persons Training as Ophthalmic Opticians Rules) Order of Council 1994, SI 1994/70
1999/2897	General Optical Council (Testing of Sight by Persons Training as Ophthalmic Opticians Rules) (Amendment) Order of Council 1999, SI 1999/2897
2005/1475	General Optical Council (Fitness to Practise Rules) Order of Council 2005, SI 2005/1475
2005/1477	General Optical Council (Registration Appeals Rules) Order of Council 2005, SI 2005/1477
	General Optical Council (Committee Constitution) Rules 2005
2005/1478	General Optical Council (Registration Rules) Order of Council 2005, SI 2005/1478
2008/2690	General Optical Council (Fitness to Practise) (Amendment in Relation to Standard of Proof) Rules Order of Council 2008, SI 2008/2690
2008/3113	General Optical Council (Committee Constitution) (Amendment) Rules Order of Council 2008, SI 2008/3113
2009/442	General Optical Council (Constitution) Order 2009
	General Optical Council (Continuing Education and Training) Amendment Rules 2012 (Order of Council)
1998/1020	General Osteopathic Council (Conditional Registration) Rules Order of Council 1998, SI 1998/1020
1998/1328	General Osteopathic Council (Registration) Rules Order of Council 1998, SI 1998/1328
1998/1329	General Osteopathic Council (Professional Indemnity Insurance) Rules Order of Council 1998, SI 1998/1329
1998/2695	General Osteopathic Council (Conditional Registration) (Amendment) Rules Order of Council 1998, SI 1998/2695
1999/1846	General Osteopathic Council (Fraud or Error and Appeals) Rules Order of Council 1999, SI 1999/1846
1999/1847	General Osteopathic Council (Investigation of Complaints) (Procedure) Rules Order of Council 1999, SI 1999/1847

1999/1848	General Osteopathic Council (Legal Assessors) Rules Order of Counciul 1999
1999/1879	General Osteopathic Council (Medical Assessors) Rules Order of Council 1999, SI 1999/1879
2000/241	General Osteopathic Council (Professional Conduct Committee) (Procedure) Rules Order of Council 2000, SI 2000/241
2000/242	General Osteopathic Council (Health Committee) (Procedure) Rules Order of Council 2000, SI 2000/242
2000/243	General Osteopathic Council (Health Committee) (Appeals) Rules Order of Council 2000, SI 2000/243
2000/1037	General Osteopathic Council (Restoration to the Register of Conditionally Registered Osteopaths) Rules Order of Council 2000, SI 2000/1037
2000/1038	General Osteopathic Council (Application for Registration and Fees) Rules Order of Council 2000, SI 2000/1038
2000/1281	General Osteopathic Council (Recognition of Qualifications) Rules Order of Council 2000, SI 2000/1281
2006/3511	General Osteopathic Council (Continuing Professional Development) Rules Order of Council 2006, SI 2006/3511
2009/263	General Osteopathic Council (Constitution) Order 2009
2009/468	General Osteopathic Council (Constitution of the Statutory Committees) Rules Order of Council 2009, SI 2009/468
2009/1993	General Osteopathic Council (Registration of Osteopaths with United Kingdom Qualifications that are not Recognised Qualifications) Rules Order of Council 2009, SI 2009/1993
2012/1101	General Osteopathic Council (Appllication for Registration and Fees) (Amendment) Rules 2012
2010/300	General Pharmaceutical Council (Constitution) Order 2010
2010/1614	General Pharmaceutical Council (Appeals Committee Rules) Order of Council 2010, SI 2010/1614
2010/1615	General Pharmaceutical Council (Fitness to Practise and Disqualification etc Rules) Order of Council 2010, SI 2010/1615
2010/1616	General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010, SI 2010/1616
2010/1617	General Pharmaceutical Council (Registration Rules) Order of Council 2010, SI 2010/1617
2010/1618	General Pharmaceutical Council (Transfer of Property, Rights and Liabilities, Fees and Grants) Order of Council 2010, SI 2010/1618
2011/1367	General Pharmaceutical Council (Continuing Professional Development and Consequential Amendment) Rules 2011
2001/1744	General Social Care Council (Appointments and Procedure) Regulations 2001
2004/561	General Social Care Council (Description of Persons to be Treated as Social Care Workers) Regulations 2004
2004/562	General Social Care Council (Registration) (Description of Social Care Workers) Order 2004
2008/1774	Health Care and Associated Professions (Miscellaneous Amendments) Order 2008
2009/1182	Health Care and Associated Professions (Miscellaneous Amendments and Practitioner Psychologists) Order 2009
2010/233	Health Professions (Hearing Aid Dispensers) Order 2010
2003/1571	Health Professions (Parts of and Entries in the Register) Order of Council 2003, SI 2003/1571
2004/2033	Health Professions (Operating Department Practitioners and Miscellaneous Amendments) Order 2004
2004/2522	Health Professions (Parts of and Entries in the Register) (Amendment) Order of Council 2004, SI 2004/2522
2006/1996	Health Professions (Parts of and Entries in the Register) (Amendment) Order of Council 2006, SI 2006/1996
2003/1575	Health Professions Council (Conduct and Competence Committee) (Procedure) Rules Order of Council 2003, SI 2003/1575
2003/1574	Health Professions Council (Investigating Committee) (Procedure) Rules Order of Council 2003, SI 2003/1574
2003/1576	Health Professions Council (Health Committee) (Procedure) Rules Order of Council 2003, SI 2003/1576
2003/1577	Health Professions Council (Functions of Assessors) Rules Order of Council 2003, SI 2003/1577
2003/1579	Health Professions Council (Registration Appeals) Rules Order of Council 2003, SI 2003/1579
2003/1572	Health Professions Council (Registration and Fees) Rules Order of Council 2003, SI 2003/1572

2009/272	Health Professions Council (Registration and Fees) (Amendment) Rules Order of Council 2009, SI 2009/272
2010/479	Health Professions Council (Registration and Fees) (Amendment) Rules Order of Council 2010, SI 2010/479
2004/2524	Health Professions Council (Registration and Fees) (Amendment) Rules Order of Council 2004, SI 2004/2524
2007/1280	Health Professions Council (Registration and Fees) (Amendment) Rules Order of Council 2007, SI 2007/1280
2005/1625	Health Professions Council (Practice Committees and Registration) (Amendment) Rules Order of Council 2005, SI 2005/1625
2009/1345	Health Professions Council (Constitution) Order 2009
2009/1355	Health Professions Council (Practice Committees and Miscellaneous Amendments Rules) Order of Council 2009, SI 2009/1355
2003/1573	Health Professions Council (Screeners) Rules Order of Council 2003, SI 2003/1573
2002/1124	Health Professions Council (Transitional Provisions) Order 2002
2002/254	Health Professions Order 2001
2003/1590	Health Professions Order 2001 (Consequential Amendments) Order 2003
2003/1578	Health Professions Order 2001 (Legal Assessors) Order of Council 2003, SI 2003/1578
2003/1700	Health Professions Order 2001 (Transitional Provisions) Order of Council 2003, SI 2003/1700
2004/2525	Health Professions Order 2001 (Transitional Provisions) Order of Council 2004, SI 2004/2525
2010/913	Hearing Aid Council (Transfer of Property, Rights and Liabilities) Order 2010, SI 2010/913
1991/2770	Hearing Aid Council Investigating and Disciplinary Committee Rules Approval Instrument 1991, SI 1991/2770
1993/3052	Hearing Aid Council Monetary Penalty (Increase) Order 1993, SI 1993/3052
2006/1914	Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006
2000/1803	Medical Act 1983 (Amendment) Order 2000
2004/1731	Medical Act 1983 (Amendment) Order 2002 (Saving Provision) Order of Council 2004, SI 2004/1731
2004/2610	Medical Act 1983 (Amendment) Order 2002 (Transitional Provision) Order of Council 2004, SI 2004/2610
2002/3135	Medical Act 1983 (Amendment) Order 2002, SI 2002/3135
2007/2796	Medical Act 1983 Amendments (Further Transitional Provisions) Order of Council 2007, SI 2007/2796
2007/1886	Medical Act 1983 Amendments (Transitional Provisions Relating to Postgraduate Training) Order of Council 2007, SI 2007/1886
2008/3131	Medical Profession (Miscellaneous Amendments) Order 2008, SI 2008/3131
2010/2841	Medical Profession (Responsible Officers) Regulations 2010, SI 2010/2841
1968/271	National Assistance (Professions Supplementary to Medicine) (Amendment) Regulations 1968, SI 1968/271
1964/939	National Assistance (Professions Supplementary to Medicine) Regulations 1964, SI 1964/939
2002/253	Nursing and Midwifery Order 2001
2004/1765	Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004, SI 2004/1765
2006/1015	Nurses and Midwives (Parts of and Entries in the Register) Amendment Order of Council 2006, SI 2006/1015
2008/1485	Nursing and Midwifery (Amendment) Order 2008
2002/923	Nursing and Midwifery (Transfer of Staff and Property etc) Order 2002, SI 2002/923 – (this is listed 3 times in RTC list)
2008/2553	Nursing and Midwifery Council (Constitution) Order 2008
2004/1767	Nursing and Midwifery Council (Education, Registration and Registration Appeals) Rules Order of Council 2004, SI 2004/1767
2005/3353	Nursing and Midwifery Council (Fees) (Amendment) Rules Order of Council 2005, SI 2005/3353
2007/1885	Nursing and Midwifery Council (Fees) (Amendment) Rules Order of Council 2007, SI 2007/1885
2004/1654	Nursing and Midwifery Council (Fees) Rules Order of Council 2004, SI 2004/1654
2007/893	Nursing and Midwifery Council (Fitness to Practise) (Amendment) Rules Order of Council 2007, SI 2007/893
2004/1761	Nursing and Midwifery Council (Fitness to Practise) Rules Order of Council 2004, SI 2004/1761

2009/2894	Nursing and Midwifery Council (Midwifery and Practice Committees) (Constitution) (Amendment) Rules Order of Council 2009, SI 2009/2894
2008/3148	Nursing and Midwifery Council (Midwifery and Practice Committees) (Constitution) Rules Order of Council 2008, SI 2008/3148
2007/1887	Nursing and Midwifery Council (Midwives) (Amendment) Rules Order of Council 2007, SI 2007/1887
2004/1764	Nursing and Midwifery Council (Midwives) Rules Order of Council 2004, SI 2004/1764
2004/1763	Nursing and Midwifery Order 2001 (Legal Assessors) Order of Council 2004, SI 2004/1763
2006/1441	Nursing and Midwifery Order 2001 (Transitional Provisions) (Amendment) Order of Council 2006, SI 2006/1441
2002/1125	Nursing and Midwifery Order 2001 (Transitional Provisions) Order 2002
2004/1762	Nursing and Midwifery Order 2001 (Transitional Provisions) Order of Council 2004
2012/3026	Nursing and Midwidery Council (Fees) Amendment) Rules 2012 (order of council)
2007/564	Approved European Pharmacy Qualifications Order of Council 2007, SI 2007/564
2012/3025	Nursing and Midwifery Cooucil (Midwives) Rules 2012 (order of council)
2009/2722	Office of Health Professions Adjudicator Regulations 2009, SI 2009/2722
2005/848	Opticians Act 1989 (Amendment) Order 2005
2005/1472	Opticians Act 1989 (Transitional Provisions) Order 2005
2010/2150	Pharmacy Order 2010 (Appeals--Transitional Provisions) Order of Council 2010, SI 2010/2150
2010/1620	Pharmacy Order 2010 (Approved European Pharmacy Qualifications) Order 2010, SI 2010/1620
2010/1619	Pharmacy Order 2010 (Registration--Transitional Provisions) Order of Council 2010, SI 2010/1619
2009/385	Postgraduate Medical Education and Training Board (Fees) Rules Order 2009, SI 2009/385
2004/3410	Postgraduate Medical Education and Training Board (Members--Removal from Office) Rules Order 2004, SI 2004/3410
2010/473	Postgraduate Medical Education and Training Order of Council 2010, SI 2010/473
2003/2462	Registered Health Care Profession (Designation No 2) Order 2003
2003/2461	Registered Health Care Profession (Designation) Order 2003
1998/2252	Royal College of Ophthalmologists (Charter Amendment) Order 1998
1999/667	Royal College of Physicians of London (Charter Amendment) Order 1999, SI 1999/667
2007/442	Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc Rules) Order of Council 2007, SI 2007/442
2007/561	Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Registration Appeals Committees and their Advisers Rules) Order of Council 2007, SI 2007/561
2008/1553	Royal Pharmaceutical Society of Great Britain (Registration Amendment Rules) Order of Council 2008, SI 2008/1553
2007/441	Royal Pharmaceutical Society of Great Britain (Registration Rules) Order of Council 2007, SI 2007/441
2010/231	The Pharmacy Order 2010, SI 2010/231

Annex C - Research Approach

Overview

The purpose of this Audit is to provide a thorough overview of all the regulations for which DH has responsibility that are thought to have an impact to business. A regulation is a Statutory Instrument or Act that sets out “guidance with which failure to comply would result in the regulated entity or person coming into conflict with the law or being ineligible for continued funding, grants and other applied for schemes”. Acts have been treated as regulations in some sections (e.g. tobacco) where the Red Tape Challenge treated them as regulations in their own right. In other areas (e.g. CQC) Acts are mentioned and used to group SIs but are not treated as an individual regulation in their own right. The Audit describes why we have the regulations, their estimated costs and where possible benefits. The Audit has been conducted with a view to also identifying regulations that should be removed or consolidated to reduce the regulatory burden the DH places on business and Civil Society Organisations (hereafter “Business”) as well as reducing the number and scope of our regulations.

Research Stages

Phase One

In a Cabinet Office trawl 1,248 regulations were linked to the Department. Of these many were found in fact to be owned by Other Government Departments, only to have effect in a non-England geography (e.g. Wales only) or clearly only to impact on the public sector.

The first phase of the Audit (Dec 2012-Feb 2013) narrowed the focus to the regulations that directly impact upon business or Civil Society Organisations. About 650 relevant regulations were identified across 6 broad policy areas and their potential impact on business was assessed in broad terms. Less than 100 lines of regulation were considered likely to impact significantly upon business at the end of phase I.

Phase Two

The second phase (March – May 2013) focussed on setting out the rationale for regulation in each policy area, estimating the costs and, where possible, the benefits of each of the regulations thought to have an impact to busines, as well as identifying regulations which may be removed or consolidated.

Reconciling numbers with Medicines and Healthy Living and Social Care Red Tape Challenge themes

The two Red Tape Challenge (RTC) themes, Medicines and Healthy Living and Social Care listed 774 unique regulations. Of these, 214 regulations have been consolidated or revoked. As this had already been reported, after the RTC Medicines theme, these regulations were not considered in this Audit. As part of the Audit we identified a further number of regulations with potential impact on business, including for example MHRA regulations on medical devices and additional lines of secondary legislation that complement or adjust existing policies. Adding these in we came to a total of 651 regulations which were examined in the Audit. This is set out in Table 1.

Table 1 - Breakdown of Derivation of Audited Regulations

Total regulations identified by Cabinet Office	1248
CO identified regulations not entered into RTC (work is being undertaken to check whether we should revisit these)	474
Entered in to RTC phase 1 (Medicines)	255
Entered in to RTC phase 2 (Healthy Living and Social Care)	521
Phase 2 had 2 duplicates, true total is:	519
A = total unique regulations entered in 2 RTC phases	**774**
B = Revoked/ consolidated following RTC phase one so not audited	**214**
Unique RTC regulations minus revoked / consolidated (A - B)	560
C = Additional regulations identified by policy teams and added in for Audit (see lists by area below)	**91**
Pre-Audit total number of regulations believed to have impact on business = A + C	865
Total Audited Regulations = A + C - B	**651**

Table 2 - Breakdown of C - Additional regulations identified by policy teams and added in for Audit

Policy Area	**Regulations identified**
Public Health	40
NHS	5
Quality	11
Prof Regulation	12
MHRA	23
Total	**91**

Estimating costs and benefits

Analysts across the DH were asked to provide estimates of the costs and benefits of regulations by policy area under the following categories:

- Estimated equivalent annual cost to business;
- Estimated equivalent annual benefits to business;
- Estimated equivalent annual net cost to business (EANCB);
- Estimated annual cost to other parties/wider society;
- Estimated annual benefits to other parties/wider society; and
- Net estimated annual cost to other parties/wider society.

The sources for these estimates were most often impact assessments or were based on expert judgement and available data. In many cases it was not possible to estimate the benefits to business or other parties/wider society as there was insufficient information available to provide credible estimates. In these instances, these impacts have been left un-monetised.

In several policy areas the regulatory measures were judged to be out of scope of OIOO/OITO rules as set out on the OIOO/OITO Methodology document (July 2011). These rules are listed in table three below. In most cases the measures fell under i, ii, x and xi. In particular this explains why the impact to business of Medicines, Pharmacy, Dental and Ophthalmic services and the Medicines and Healthcare Products Regulatory Agency (MHRA) are considered to be zero or very small.

Table 3

Measures that are out-of-scope of the OIOO/OITO Rule, include:	
i.	Regulation that does not impact on business or civil society organisations;
ii.	European Union Regulations, Decisions and Directives;
iii.	International agreements and obligations;
iv.	Tax - central and local;
v.	Tax administration - this is being taken forward separately by the Office for Tax Simplification and is therefore out-of-scope of OIOO/OITO;
vi.	Civil emergencies regulation - those measures which would be classified as an emergency under the Civil Contingencies Act 2004. This Act forms the basis of the COBRA powers to deal with emergency situations in the UK (e.g. a foot and mouth outbreak);12
vii.	Spending decisions - including benefits, grants and subsidies;
viii.	Specific enforcement action - individual enforcement or inspection activities, or actions to ensure compliance with regulations;
ix.	Fines and penalties - even if levied on a regulated entity for non-compliance with a regulation;
x.	Fees and charges - except where they result from an expansion or reduction in the level of regulatory activity;
xi.	Contractual obligations - costs associated with obligations on business and civil society organisations which result from negotiating or entering into contractual arrangements with government and public sector organisations;
xii.	Court or tribunal cases - where the conclusion of a court or tribunal case has resulted in a change in the interpretation of a regulation;
xiii.	Environmental tax - environmental measures which have been classified by the Office for National Statistics as environmental tax;
xiv.	Financial systemic risk- measures which deal with issues falling under the OECD (2004) definition of financial systemic risk. However, the OIOO/OITO Rule does apply to all other areas of financial services regulation, including financial crime regulation (such as anti-money-laundering) and conduct of business regulation; and
xv.	Regulations that have a temporary and short lifespan i.e. up to 12 months and include an automatic sunset clause.

Reliability rating

The available evidence is better in some cases than others and there is significant uncertainty regarding some of the evidence. In order to reflect this uncertainty, estimates provided by analysts across the DH were quality assured by DH Strategy Group and assessed against a reliability rating. The reliability ratings used were adopted from Defra's 2011 publication – *The Costs and Benefits of Defra's Regulatory Stock*, as follows:

- **1** – Impacts not fully understood, hard to predict, heroic assumptions;
- **2** – Impacts not fully understood – (e.g. some behavioural responses not clear) but all or most estimates informed by relevant experts;
- **3** – Impacts well understood, estimates rely largely on expert judgement informed by some real-world data;
- **4** – Impacts well understood and estimates are informed largely by real-world data or directly applicable research - or if not expert judgement;
- **5** – Impacts very well understood and all or almost all estimates are evidenced by real-world data.

In some cases, work is underway to improve the estimates provided.

Annex D – NHS regulations thought to have no impact to business

There are a number of primarily NHS related regulations that are not thought to have an impact to business which have been included in the DH Red Tape Challenge process. A legal opinion on these has been sought as to whether they are spent and whether they can be revoked. These regulations are listed below along with some notes. These are all Domestic in origin.

NHS Regulations with no impact to business – legal advice received – retain

Legal advice has been received on the 11 regulations listed below. They should be retained as they underpin existing NHS structures and practices. They are not thought to have any impact to business.

2002/1438	Health Service (Control of Patient Information) Regulations 2002	A Regulatory Impact Assessment has not been prepared for these Regulations. In general the Regulations enable the flow of information and impose no obligations. Where obligations are imposed, they are imposed primarily on those performing functions for public authorities and so any burden imposed on business is considered negligible.
2004/696	Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004	NHS Reorganisation team.
2004/906	Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004, SI 2004/906	Retain- no impact to business
2006/305	Health Service Commissioner for England (Special Health Authorities) Order 2006, SI 2006/305	Retain as NHS Business Authority remains in existence and subject to investigation by the Health Service Commissioner
1991/590	Statutory Maternity Pay (National Health Service Employees) Regulations 1991, SI 1991/590	Retain - Amended but not abolished by Schedule 2 para 16 of the National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013:
1996/1023	Employment Protection (Continuity of Employment of National Health Service Employees) (Modification) Order 1996, SI 1996/1023	Retain - Amended but not abolished by Schedule 2 para 16 of the National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013:
2005/604	National Health Service Liabilities Schemes amendment regulations 2005	Still in force if the NHS Litigation Service still operates outside of Wales and England
1996/707	Health Authorities (Membership and Procedure) Regulations 1996, SI 1996/707	Still in force - no impact to business
2011/1556	The National Health Service (Charges to Overseas Visitors) Regulations 2011	Still operative - no impact to business
1992/3182	Residential Accommodation (Determination of District Health Authority) Regulations 1992	Retain- no impact to business
1993/582	Residential Accommodation (Determination of District Health Authority) Regulations 1993	Retain- no impact to business

NHS Regulations with no impact to business – legal advice received – spent/ no longer operative or in force

Legal advice has been received on the 41 regulations listed below. They are considered to be spent or no longer operative or in force. They come under the Cabinet Office definition 'zombie'. They do not impact on anyone and may for example come under an act which has now been abolished or have been time limited in nature. Legal advice as to whether they can and should be revoked is being sought. These are all Domestic in origin.

1994/2773	Isles of Scilly (National Health Service) Order 1994, SI 1994/2773	no longer in force
1996/638	Employment Protection (National Health Service) Order 1996, SI 1996/638	No longer operative
1999/946	Health Authorities (Membership and Procedure) Amendment Regulations 1999, SI 1999/946	No longer operative
2001/3744	Abolition of the NHS Tribunal (Consequential Provisions) Regulations 2001, SI 2001/3744	No longer operative
2002/556	Health Authorities (Membership and Procedure) Amendment (England) Regulations 2002, SI 2002/556	No longer operative
2004/17	Health Authorities (Membership and Procedure) Amendment Regulations 2004, SI 2004/17	No longer operative
2001/540	Isles of Scilly (Primary Care) Order 2001, SI 2001/540	No longer operative
2000/694	Health Act 1999 (Supplementary, Consequential etc Provisions) (No 2) Order 2000, SI 2000/694	Spent
2000/90	Health Act 1999 (Supplementary, Consequential etc Provisions) Order 2000, SI 2000/90	Spent
1981/1473	Isles of Scilly (National Health Service) Order 1981, SI 1981/1473	Spent
1985/1876	Health Service Supply Council (Abolition) Regulations 1985, SI 1985/1876	Spent
1985/1877	Health Service Supply Council (Abolition) Order 1985, SI 1985/1877	Spent
1989/947	Boards for Special Hospitals (Abolition) Order 1989, SI 1989/947	Spent
1994/1831	Authorities for London Post-Graduate Teaching Hospitals (Abolition) Order 1994, SI 1994/1831	Spent
1996/2310	Health Authorities Act 1995 (Transitional Provisions) Amendment Order 1996, SI 1996/2310	Spent
1996/511	Authorities for London Post-Graduate Hospitals (Abolition) Order 1996, SI 1996/511	Spent
1996/512	Authorities for London Post-Graduate Hospitals (Revocation) Regulations 1996, SI 1996/512	Spent
1996/709	Health Authorities Act 1995 (Transitional Provisions) Order 1996, SI 1996/709	Spent
1996/971	Health Authorities Act 1995 (Amendment of Transitional Provisions and Modification of References) Order 1996, SI 1996/971	Spent
1998/3149	Health Service Commissioner for England (London Post-Graduate Teaching Hospitals Designation Orders) Revocation Order 1998, SI 1998/3149	Spent
1999/2541	Health Act 1999 (Fund-holding Practices) (Transfer of Assets, Savings, Rights and Liabilities and Transitional Provisions) Order 1999, SI 1999/2541	Spent

2001/4045	Health Authorities (Membership and Procedure) Amendment (England) (No 3) Regulations 2001, SI 2001/4045	Spent
2001/751	Health Authorities (Membership and Procedure) Amendment (England) Regulations 2001, SI 2001/751	Spent
2001/834	Broadmoor Hospital Authority (Abolition) Order 2001, SI 2001/834	Spent
2002/559	Ashworth Hospital Authority (Abolition) Order 2002, SI 2002/559	Spent
2005/251	Health Service Commissioner for England (Special Health Authorities) Order 2005, SI 2005/251	Spent
2005/3428	Health Service Commissioner for England (Special Health Authorities) (No 2) Order 2005, SI 2005/3428	Spent
2005/502	Special Health Authorities (Abolition) Regulations 2005, SI 2005/502	Spent
2006/1393	Health Authorities (Membership and Procedure) Amendment (England) Regulations 2006, SI 2006/1393	Spent
2006/3332	Health Service Commissioner for England (Special Health Authorities) (Revocation) Order 2006, SI 2006/3332	Spent
2006/635	Special Health Authorities (Abolition) Order 2006, SI 2006/635	Spent
2009/618	Dudley and Walsall Mental Health Partnership National Health Service Trust (Originating Capital) Order 2009, SI 2009/618	Spent
2009/883	Health Service Commissioner for England (Authorities for the Ashworth, Broadmoor and Rampton Hospitals) (Revocation) Order 2009, SI 2009/883	Spent
2000/179	Health Authorities Act 1995 (Rectification of Transitional Arrangements) Order 2000, SI 2000/179	Spent
2000/604	Health Education Authority (Abolition) Order 2000, SI 2000/604	Spent
2001/2630	Health Authorities (Membership and Procedure) Amendment (England) (No 2) Regulations 2001, SI 2001/2630	Spent
2004/1772	General Medical Services (Transitional Measure Relating to Non-Clinical Partners) Order 2004, SI 2004/1772	No longer operative
2004/291	National Health Service (General Medical Services Contracts) Regulations 2004, SI 2004/291	No longer operative
2004/433	General Medical Services Transitional and Consequential Provisions Order 2004, SI 2004/433	No longer operative
2004/865	General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004, SI 2004/865	Spent
2005/1622	Health and Social Care (Community Health and Standards) Act 2003 (Public Health Laboratory Service Board) (Consequential Provisions) Order 2005, SI 2005/1622	Spent

<u>NHS Regulations with no impact to business – legal advice received – revoked</u>

Legal advice has been received on the 10 regulations listed below. They have been revoked. They are not thought to have had any impact to business. These are all Domestic in origin.

1989/1893	Health and Medicines Act 1988 (Superannuation) (Savings for Retired Practitioners) Regulations 1989, SI 1989/1893	Revoked
1989/306	National Health Service (Charges to Overseas Visitors) Regulations 1989, SI 1989/306	Revoked
1991/438	National Health Service (Charges to Overseas Visitors) Amendment Regulations 1991, SI 1991/438	Revoked
1994/1535	National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 1994, SI 1994/1535	Revoked
2000/602	National Health Service (Charges to Overseas Visitors) Amendment Regulations 2000, SI 2000/602	Revoked
2000/909	National Health Service (Charges to Overseas Visitors) Amendment (No 2) Regulations 2000, SI 2000/909	Revoked
2001/3788	Care Trusts (Applications and Consultation) Regulations 2001, SI 2001/3788	Revoked
2004/614	National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 2004, SI 2004/614	Revoked
2006/3306	National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 2006, SI 2006/3306	Revoked
2008/2251	National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 2008, SI 2008/2251	Revoked

NHS Regulations – awaiting legal advice

Legal advice has not yet been received on the two regulations listed below.

1998/2621	Health Authorities (Membership and Procedure) Amendment Regulations 1998
2010/720	Health Act 2009 (Powers in Relation to NHS Bodies--Consequential Amendments) Regulations 2010

Annex E - the Department of Health's closing position on Statement of New Regulation Five

The Department of health has a deficit on its closing position on Statement of New Regulation Five (SNR 5) of £20.03 million. The Departmen't position at SNR 5 is given in table one below. Table two then outlines the current position in more detail. A proportion of the deficit is accounted for by the introduction of sunbed related legislation in 2011 following a private members bill.

Table One

Presentation of Departments' closing One-in, One-out performance (from January 2011 to December 2012)	Department	Net Cumulative Value of Measures (£m)
1	Department for Work & Pensions / Health & Safety Executive	-£681.04
2	Department for Environment, Food & Rural Affairs	-£142.71
3	Department for Business Innovation & Skills	-£131.89
4	HM Treasury	-£30.05
5	Department for Education	-£11.11
6	Department for Culture, Media & Sport	-£9.77
7	Department for Communities & Local Government	-£4.96
8	Department of Energy & Climate Change	-£2.51
9	Food Standards Agency	-£0.13
10	Cabinet Office	£0.00
11	Ministry of Justice	£0.00
12	Department for Transport	£4.06
13	**Department of Health**	**£20.03**
14	Cross-Government[4]	£57.00
15	Home Office / Government Equalities Office	£97.03

Source: Table 4, Statement of New Regulation (SNR5), Department for Business, Innovation and Skills, December 2012.

Table 2

Title of the measure	IN/OUT	Due in force	IN Net Cost (£m)	OUT Net Benefit (£m)
Year One - SNR1&2				
The Medical Profession (Responsible Officers) Regulations 2010	IN	Jan-11	1.78	
The Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2010	IN	Jan-11	0.00	
Regulation of Sunbeds	IN	Apr-11	7.50	
Amendments to the Primary Medical Services (Electronic Prescription Service Authorisation) Directions 2008	IN	Apr-11	0.00	
IR(ME)R Amendment Regulations 2011	IN	Oct-11	0.05	
Prohibition on the sale of tobacco from vending machines	IN	Oct-11	9.80	
Three Year Rule for New Pharmacies	OUT	Oct-11		0.07
Year One Total			**19.13**	**0.07**
Year Two - SNR3&4				
Prohibition of the display of tobacco at point of sale	IN	Apr-12	2.41	
Care Quality Commision registration	OUT	Jun-12		0.42
Consolidation of UK Medicines legislation	OUT	Jun-12		0.94
Smoke free signs	OUT	Oct-12		0.07
Year Two Total			**2.41**	**1.43**
Year Three - SNR5				
Medical Profession (Responsible Officers) Regs Language Skills	IN	Apr-13	0.00	
SNR5 Total			**0.00**	**0.00**
Overall Total			**21.54**	**1.50**
Balance			**20.04**	
Footnote: Tobacco Displays is a phased entry. £2.41m now, £14.79m in 2015 Total IN of £17.20m				

Annex F – Full tables of regulations in and out of scope and potential to revoke by policy area

Regulations in and out of scope of OIOO/OITO by policy area

		Number of regulations	Regulationsconsidered out of scope of OIOO/OITO	Regulations with impact to business - in scope of OIOO/OITO	Unknown - either not apportioned or legal advice sought
Care quality	CQC	21	17	4	
	Mental Health: Mental Capacity Act (2005)	12	3	9	
	Mental Health: The Mental Health Act (1983)	8	8		
	Mental Health: The Mental Health Act (2007)	1	1		
	Mental Health: Part of the Community Care Act 2003	3	3		
	Social Care (Isles of Scilly)	10	10	0	
	Social Care: Other	8	8	0	
MHRA	Blood	9	9		
	Clinical Trials	3	3		
	Devices	13	13		
	Fees	13	13		
	Good Laboratory Practice	2	2		
	Herbals	6	5	1	
	Homeopathics	1	1		
	Pharmaceuticals	14	14	0	
	Transmissible Spongiform Encephalopathies	1	0	1	
MPI	Charges and benefits	14	14	0	
	Dental	7	7	0	
	General Pharmaceutical services	23	23	0	
	Ophthalmology	30	30	0	
	NICE	8	8	0	
	Statutory Pricing	7	7	0	

NHS	cost recovery	20	16	4	
	NHS Litigation	13	13		
	Other	64	64		
Public health	Abortion	6	0	6	
	Blood and tissue	7	5	1	1
	Food composition, labelling, and food safety;	14	12	2	
	Healthy Start and Welfare Food	9	8	1	
	Health Protection	7	7		
	Health Protection (inc ports and travel)	11	11		
	Health Protection vaccinations	1	1		
	HFEA	16	14	2	
	HIV / VD	4	3	1	
	National Child Measurement Programme	1	1		
	Radiation	7	6	1	
	Surrogacy	1	1		
	Tobacco control	27	9	18	
	Family Practice Committee	2	2		
	National Patient Safety Agency	4	4		
	Thermometer	1	1		
	Voluntary Hospitals	1	1		
Professional Standards	Professional Standards	207	0		207
TOTAL		637	378	51	208

14 regulations audited do not belong to DH, 9 are DWP (vaccine damage payments – not mentioned elsewhere in document, 3 DfE – mentioned in social care other and 2 HMRC – mentioned tobacco related)

Total regs audited = 651

Categorisation of all regulations out of scope by policy area

		EU	Intl	contractual	fees	no impact to business	other	Total Regs considered out of scope of OIOO/OITO
Care quality	CQC	0	0	0	0	17	0	17
	Mental Health: Mental Capacity Act (2005)	0	0	0	0	3	0	3
	Mental Health: The Mental Health Act (1983)	0	0	0	0	8	0	8
	Mental Health: The Mental Health Act (2007)	0	0	0	0	1	0	1
	Mental Health: Part of the Community Care Act 2003	0	0	0	0	3	0	3
	Social Care (Isles of Scilly)	0	0	0	0	0	10	10
	Social Care: Other	0	0	0	0	8	0	8
MHRA	Blood	8	0	0	1	0	0	9
	Clinical Trials	3	0	0	0	0	0	3
	Devices	1	0	0	4	8	0	13
	Fees	0	0	0	12	1	0	13
	Good Laboratory Practice	2	0	0	0	0	0	2
	Herbals	0	0	0	0	5	0	5
	Homeopathics	1	0	0	0	0	0	1
	Pharmaceuticals	0	0	0	0	14	0	14
	Transmissible Spongiform Encephalopathies	0	0	0	0	0	0	0
MPI	Charges and benefits	0	0	0	14	0	0	14
	Dental	0	0	2	0	5	0	7
	General Pharmaceutical services	0	0	23	0	0	0	23
	Ophthalmology	0	0	13	0	17	0	30
	NICE	0	0	0	0	8	0	8
	Statutory Pricing	0	0	7	0	0	0	7
NHS	cost recovery	0	0	0	0	16	0	16
	NHS Litigation	0	0	0	0	13	0	13
	Other	0	0	0	0	64	0	64
Public health	Abortion		0	0	0		0	0

	Blood and tissue	1	0	0	0	4	0	5
	Food composition, labelling, and food safety;	12	0	0	0		0	12
	Healthy Start and Welfare Food	0	0	0	0	8	0	8
	Health Protection	0	3	0	0	4	0	7
	Health Protection (inc ports and travel)	0	10	0	0	1	0	11
	Health Protection vaccinations		0	0	0	1	0	1
	HFEA	1	0	0	0	13	0	14
	HIV / VD	0	0	0	0	3	0	3
	National Child Measurement Programme	0	0	0	0	1	0	1
	Radiation	6	0	0	0	0	0	6
	Surrogacy	0	0	0	0	1	0	1
	Tobacco control	8	0	0	0	1	0	9
	Family Practice Committee	0	0	0	0	2	0	2
	National Patient Safety Agency	0	0	0	0	4	0	4
	Thermometer	1	0	0	0	0	0	1
	Voluntary Hospitals	0	0	0	0	1	0	1
Professional Standards	Professional Standards	0	0	0	0	0	0	0
TOTAL		44	13	45	31	235	10	378

Regulations with potential to revoke by policy area

		Number of regulations	Have already been revoked/ repealed	Potential to revoke pending legal advice	consolidated or potential to consolidate	No change
Care quality	CQC	21	2	5	2	12
	Mental Health: Mental Capacity Act (2005)	12	0	0	0	12
	Mental Health: The Mental Health Act (1983)	8	0	0	0	8
	Mental Health: The Mental Health Act (2007)	1	0	0	0	1

	Mental Health: Part of the Community Care Act 2003	3	0	0	0	3
	Social Care (Isles of Scilly)	10	1	0	0	9
	Social Care: Other	8	4	0	0	4
MHRA	Blood	9	0	0	0	9
	Clinical Trials	3	0	0	0	3
	Devices	13	0	8	0	5
	Fees	13	1	0	0	12
	Good Laboratory Practice	2	0	0	0	2
	Herbals	6	0	0	0	6
	Homeopathics	1	0	0	0	1
	Pharmaceuticals	14	0	3	0	11
	Transmissible Spongiform Encephalopathies	1	0	0	0	1
MPI	Charges and benefits	14	0	0	9	5
	Dental	7	2	0	0	5
	General Pharmaceutical services	23	0	0	15	8
	Ophthalmology	30	11	6	0	13
	NICE	8	0	8	0	0
	Statutory Pricing	7	1	0	3	3
NHS	cost recovery	20	0	8	0	12
	NHS Litigation	13	0	0	0	13
	Other	64	10	43	0	11
Public health	Abortion	6	0	0	0	6
	Blood and tissue	7	0	0	2	5
	Food composition, labelling, and food safety;	14	0	0	0	14
	Healthy Start and Welfare Food	9	0	0	0	9
	Health Protection	7	4	0	0	3
	Health Protection (inc ports and travel)	11	0	0	5	6
	Health Protection vaccinations	1	0	0	0	1
	HFEA	16	0	0	2	14
	HIV / VD	4	0	1	0	3
	National Child Measurement Programme	1	0	0	0	1
	Radiation	7	0	0	0	7

	Surrogacy	1	0	0	0	1
	Tobacco control	27	3	1	0	23
	Family Practice Committee	2	0	2	0	0
	National Patient Safety Agency	4	4	0	0	0
	Thermometer	1	0	0	0	1
	Voluntary Hospitals	1	0	1	0	0
Professional Standards	Professional Standards	207	1	206	0	0
TOTAL		637	44	292	38	263

Annex G – Tobacco Control Additional information on costs and benefits

Tobacco control legislation has significantly contributed to the overall fall in smoking prevalence and the related health benefits that have accrued from that reduction in smoking. Figure 1 shows the timeline of regulation since 1980 alongside the trajectory of smoking prevalence in England (age 16+).

Deregulation would not necessarily give rise to savings in costs to business equivalent to the costs of implementation estimated at the time the law was introduced. There may also have been significant costs to business of making changes (sunk costs). The costs presented below are recurrent costs only and do not include sunk costs which would not be recovered in a case where the legislation was repealed.

Tobacco control legislation broadly falls into three categories:

a) made under the Coalition Government's regulatory framework, including OIOO/OITO (regulating tobacco displays, ending sales from vending machines, deregulating no-smoking signs)
b) made prior to June 2010 (age of sale, smokefree)
c) transposition of EU Directives (ban on advertising and sponsorship, ban on oral tobacco, regulating tobacco products, e.g. requirements for health warnings etc)

a) Legislation made under the Coalition Government's regulatory framework

Regulation of displays of tobacco products

Recurring costs to business (per annum):	
Additional serving time (large shops)	£1.3 million
Additional serving time (small shops)	£9.1 million (yet to be incurred – scheduled for 6 April 2015)
Maintaining price lists (large shops)	£0.4 million
Maintaining price lists (small shops)	£2.8 million (yet to be incurred – scheduled for 6 April 2015)
TOTAL	£13.6 million (£11.9 million yet to be incurred – scheduled for 6 April 2015)
Health benefits	£1.2 billion per annum (£0.89 billion adults, £0.31 billion young people)
Wider costs (lost duty)	£70 million per annum

See: Department of Health (2011). Impact assessment on the prohibition of display of tobacco products at the point of display in England. London: Department of Health.

Prohibition of tobacco sales from vending machines

Recurring costs to business (per annum):	None.
Health benefits	£0.4 billion per annum (£0.05 billion adults, £0.09 billion young people)
Wider costs (lost duty)	£32 million per annum £19 million per annum (consumer surplus)

See: Department of Health (2012). Impact assessment for the prohibition on the sale of tobacco from vending machines. London: Department of Health.

De-regulation of no smoking signs

Recurring costs to business (per annum):	
Maintenance of signs	-£0.1 million (small benefit to business because of change to rules on no smoking signs 2012)
Health benefits	Nil
Wider costs (lost duty)	Nil

See: Department of Health (2012). Impact Assessment of the effect of repealing the Smoke Free sign Regulations (2007).

b) Legislation made prior to June 2010

Age of sale – estimates made on raising the age of sale from 16 to 18 in 2007

Impact on Business	This excludes revenue impact to tobacco companies, subsequently ruled out of scope for OIOO/OITO and is unquantified. Raising the age of sale to 18 meant that retailers had one age limit for the majority of age-restricted goods.
Benefits	Ongoing savings of between £0 and £6m (midpoint £3m used) a year in the treatment of smoking-related diseases and annual gains to the economy from lives saved of between £0 and £226m (midpoint £113m used).
Wider costs (lost duty)	£30.65m per annum

See: Department of Health (2007). Final Regulatory Impact Assessment for regulations to be made under powers in Part 1, Chapter 2 of the Health Act 2006 (power to amend for age of sale of tobacco etc.).

Smoke-free legislation

Impact on Business	£0-5 million annual costs (midpoint of £2.5 million used.
Benefits	£2.7bn in health benefits, £100m reduction in NHS costs, £70m-£140m reduced sickness absence (midpoint £105m) , £340m-£680m production gains (midpoint £510m), £63m safety benefits (damage, fire, injuries etc.), £100m reduced cleaning and maintenance (all annual figures) .
Wider costs	£30m Enforcement, £1m Education, £859m Duty, £113m Duty, £430m Productivity, £155m Consumer's surplus = total £1.588 bn.

See: Department of Health (2007). Final Regulatory Impact Assessment for regulations to be made under powers in Part 1, Chapter 1 of the Health Act 2006 (Smoke-free Premises, Places and Vehicles).

Studies have reported a reduction of 1200 emergency admissions for myocardial infarction[1] in the year following the introduction of smoke-free legislation in England and 1900 fewer emergency admissions for asthma[2] in each of the first three years after legislation was introduced.

[1]Sims M, Maxwell R, Bauld L, Gilmore A (2010). Short-term impact of smoke-free legislation in England: retrospective analysis of hospital admissions for myocardial infarction. BMJ 340:c2161.

[2]Sims M, Maxwell R, Gilmore A (2013). Short-term impact of the smokefree legislation in England on emergency hospital admissions for asthma among adults: a population-based study. Thorax: 1-6.

c) Transposition of EU directives – Not included

Prohibition of tobacco advertising and sponsorship

a) Tobacco Advertising and Promotion (Point of Sale) Regulations 2004

b) Tobacco Advertising and Promotion (Brandsharing) Regulations 2004

Prohibition of Oral Tobacco

Regulation of Tobacco Products

a) Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002

b) The Introduction of Picture Warnings on Tobacco Packs

Total impact

Impact on Business	Total recurrent costs £16 million of which £11.9m yet to be incurred– scheduled for 6 April 2015)
Costs to other parties/wider society	£1.7 billion
Benefits to other parties/ wider society	£5.0 billion
Net benefit to other parties/ wider society	£3.3 billion.

Summary Statistics: Tobacco	
Costs/Benefits To Business	
Estimated equivalent annual cost to business	£16 million of which 11.9 yet to be incurred
Estimated equivalent annual benefits to business	£0
Estimated equivalent annual net cost to business (EANCB)	£16 million of which 11.9 yet to be incurred
Impact To Society	
Estimated annual cost to other parties/wider society	£1,700 million
Estimated annual benefits to other parties/wider society	About £5,000 million
Net estimated annual cost to other parties/wider society	£3,300 million
Notes: Costs yet to be incurred relate to tobacco display phased entry	
Reliability rating: 4/5	

Note - the potential sunk costs associated with legislation that have yet to be incurred are not included for consistency with the other areas scrutinised in this Audit and because the legislation underpinning the change has already been reviewed by the RPC.

Annex H – Deregulatory measures

Deregulatory regulations

Chapter	Explanation	SI numbers	Count
1.1 Care Quality Commission (CQC)	two regulations with impact to business in fact reduce the burden on businesses	2012/1513, 2010/496, 2012/921	3
2.8 Pharmaceuticals	Two regulations are revocation orders which are used to revoke other regulations. They are deregulatory.	1996/3269, 1997/1727	2
5.2 Blood and tissue	One regulation is a revocation order which is used to revoke other regulations. It is deregulatory.	1993/587	1
3.3 General Pharmaceutical Services, Local Pharmaceutical Services, Controlled Drugs, Responsible Pharmacist and non-medical prescribing	Non-medical prescribing regulations are deregulatory in effect - two regulations	2006/913, 2003/699	2
	Under the Medicines Act 1968, each registered community pharmacy must have a pharmacist in charge of the pharmacy. This applies across the UK. Previously, the Act did not define "personal control" nor how the pharmacist is to comply with this requirement. However, it was commonly interpreted that the pharmacist had to be physically present in the pharmacy to enable the sale or supply or all medicines to continue, including those designated as general sale list medicines (which can be sold from a variety of retail outlets, not just pharmacies). The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 and section 72 of the Medicines Act from which they are derived are therefore required to introduce the concept of a "Responsible Pharmacist" (RP) and outline RP's duties including when the RP may be absent from the premises during the pharmacy's business hours. These measures were deliberately cautious in their deregulatory nature as they needed to be agreed across all four countries.	2008/2789	1
5.6 Health Protection – Port Health and Travel	SI 1995/267 is deregulatory, it revokes the Public Health (Aircraft) (Isle of Man) Order 1982 and the Public Health (Ships) (Isle of Man) Order 1982, which extended to the Isle of Man, subject to exceptions and modifications, the Public Health (Aircraft) Regulations 1979 (S.I. 1979/1434) and the Public Health (Ships) Regulations 1979 (S.I. 1979/1435).	1995/267	1
5.13 Tobacco	The Smoke-free (Signs) Regulations 2012 Deregulatory in effect, following the Red Tape Challenge. An OUT was registered as a result and reported in SNR4.	2012/1536	1
	The Tobacco Advertising and Promotion (Display and Specialist Tobacconists) (England) (Amendment) Regulations 2012 Deregulatory in effect following Ministerial review of the tobacco display legislation	2012/677	1
	Under the display legislation, two of the regulations listed above (SI 2004/1277 and SI 2004/765) will be revoked once the tobacco display regulations (SI 2010/446) take full effect on 6 April 2015. SI 2010/446 was itself amended (by SIs 2011/1256 and 2012/677) which simplified the requirements and delayed commencement of the display legislation. A reduced IN was registered as a result (against SI 2011/1256), reported in SNR3.	2011/1256	1
Annex D	Four revocation orders that are now spent identified	1996/512 , 1998/3149, 2009/883, 2006/3332	4
		total noted	17