

## Department of Health – overview

	IN	OUT	ZNC	£IN	£OUT	Net
Department of Health	11	8	4	39.43m	-5.40m	34.03m

The Department of Health remains committed to the use of better regulation to achieve our objectives at the least cost to the economy, thereby promoting economic growth and prosperity. This is achieved by using, where possible, alternatives to regulation, for example the Responsibility Deal, and reviewing our existing regulations to remove unnecessary regulatory burdens on business where we can. When we do regulate, it is only where it is necessary to protect public health and to ensure provide safe, effective and compassionate care.

DH's role in protecting public health has required us to impose costly regulatory measures in the areas of preventing harm to children through the use of sunbeds – setting a minimum age for sunbed use – and in reducing tobacco use by banning sales of tobacco products from vending machines and banning the display of tobacco packs in retailers. DH worked hard to mitigate the impact of the tobacco display ban for small retailers by delaying the commencement of the regulations until SNR9. This has given shop keepers longer to prepare for the regulations and spread the cost of any necessary changes they have to make.

DH is committed to ensuring that the National Health Service becomes one of the best organisations in the world to deliver innovations to patient care faster, removing the barriers that prevent innovation and creating a climate where clinical pioneers have the freedom to make breakthroughs in treatment.

### De-regulation in action

Up to 100,000 people in the UK have HIV but around a quarter are living with it undiagnosed. By removing the 1992 ban on the sale of home testing kits, DH is encouraging earlier diagnosis of HIV by removing the stigma of going to a sexual health clinic, as well as allowing a new market to develop.

DH has also extended the use of abbreviated medicines advertisements to medicines intended for healthcare professionals, which reduces the burden on business by nearly £1m per year.

The MHRA, through the Accounting for Regulatory Impact (ARI) programme, introduced new ways of working for approval of variations to medicines licences, which was expected to save businesses at least £25m per year. MHRA has led the vanguard across Government on the ARI programme and has saved businesses a further £4m through reducing the number of instances where parallel import licences require assessment by moving towards a principle of “do and tell” notification.

In November 2012, the Department of Health launched the Healthy Living & Social Care theme. The Department crowd-sourced regulations affecting business and civil

society through the Red Tape Challenge website and comments from a range of different groups were received on a number of areas.

The Department looked at 555 regulations, covering four areas: public health, quality of care & mental health, NHS and professional standards, this builds on earlier work done to look at 255 regulations under the Red Tape Challenge Medicines theme.

We carefully considered the comments received through the Red Tape Challenge website and aligned this with an internal audit of Department regulations, the results of which have already been published on our GOV.UK site. Using this information and running a rigorous challenge process we identified the Healthy Living & Social Care regulations that could be scrapped or improved. Of the 555 regulations considered the Department proposes scrapping 128 regulations and improving 252 others. This means that 68% of the regulations under the Healthy Living & Social Care theme will either be scrapped or improved.

The Medicines theme identified six regulations that could be scrapped immediately and a further 209 that could be improved, 205 of which would save businesses time and money. This equates to 84% of medicines regulations being scrapped or improved.

As part of the Government's Red Tape Challenge the DH has undertaken work to map the regulatory requirements, guidance, codes, rules and instructions which health professionals have to comply with. The focus was on businesses operating in each sector, not just the professionals with the aim of identifying where the main burdens lie and the potential to reduce these burdens. The groups looked at were opticians, dentists, doctors, physiotherapists, nurses and the care homes sector.

Beyond SNR9, DH intends to put in place further protection for young people against taking up smoking, by introducing legislation on standardised packaging for tobacco and to set a minimum age of sale for nicotine inhaled products.

## Department of Health – all measures

Title of the measure	Purpose	OITO classification	Date from which measure is / is expected to be in force	Equivalent Annual Net Cost to Business (£m, 2009)
The Medical Profession (Responsible Officers) Regulations 2010	To introduce a responsible officer role, to evaluate the fitness to practise of doctors in designated organisations delivering healthcare, and those with a role in setting policy and standards for healthcare.	IN	01/01/2011	£1.78
The Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2010	To change the maximum prices of prescription-only branded medicines supplied to the NHS by companies which are not members of a voluntary scheme to control the prices of branded health service medicines.	Zero Net Cost	01/01/2011	£0.00
Regulation of Sunbeds	To prohibit the use of sunbeds for under 18 years old on commercial sunbed premises by requiring operators to display signs prohibiting the use of sunbeds by under 18 year olds.	IN	01/04/2011	£7.50
Amendments to the Primary Medical Services (Electronic Prescription Service Authorisation) Directions 2008	To enable the use of the Electronic Prescription Service by prescribers in a Primary Care Trust if that PCT is listed in the Directions.	Zero Net Cost	01/04/2011	£0.00
The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011	To remove any doubt that the exposure to medical x-rays of self-referred asymptomatic individuals are included in the Ionising Radiation Medical Exposure Regulations (IRMER).	IN	25/07/2011	£0.05
The Protection from Tobacco (Sales from Vending Machines) (England) Regulations 2010	This measure is a priority for the Government as it will help promote and improve public health and, change young people's perceptions regarding the social norms around smoking among their peers and others. Retailers are unlikely to voluntarily remove tobacco displays and therefore it is necessary regulation be put in place.	IN	01/10/2011	£9.20

The Medicines Act 1968 (Pharmacy) Order 2011	Remove restrictions on new pharmacies to allow pharmacists registered with the General Pharmaceutical Council via EC Directive 2005/36 to hold the position of responsible pharmacist in any registered pharmacy in Great Britain.	OUT	04/11/2011	-£0.06
The Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012	To remove the burden of regulation where it is not justified, this will allow CQC to become more focussed on where it can address the greatest risks to patients and people who use services.	OUT	27/03/2012	-£0.42
The Tobacco Advertising and Promotion (Display) (England) Regulations 2010	To prohibit the display of tobacco products in shops to help reduce smoking uptake by children and young people, and support adult smokers who want to quit.	IN	06/04/2012	£2.27
The Human Medicines Regulations 2012	To consolidate and simplify the fragmented legislation regulating medicines, saving time and costs for business, civil society organisations and the public sector in understanding and applying the law.	OUT	14/08/2012	-£0.91
The Smoke-free (Signs) Regulations 2012	To remove, through the Smoke-Free Signs Regulations 2012, the legislation that dictates location and design of no smoking signs, whilst maintaining the requirement to display no smoking signs.	OUT	01/10/2012	-£0.06
The Medical Profession (Responsible Officers) (Amendment) Regulations 2013	To amend existing regulations for new health structures. It will also set out the responsible officer role in ensuring the language skills of doctors.	Zero Net Cost	01/04/2013	£0.00
The Human Medicines (Amendment) Regulation 2012	To implement the falsified medicines directive 2011/62/EU to strengthen the medicines supply chain and reduce risk of counterfeits.	EU Out of Scope	01/07/2013	£0.00
Medical Devices (Amendment) Regulations 2013	To amend the Medical Devices Regulations 2002 to ensure that two new EU Regulations are enforceable in the UK.	EU Out of Scope	01/08/2013	£0.00

Implementation of Pharmacovigilance directive 2012/26/EU	To ensure that if a safety issue is identified, competent authorities are notified and co-ordinated action is taken in all member states where a product is marketed.	EU Out of Scope	01/10/2013	£0.00
The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2014	To allow infant formula to be made using goats milk.	EU Out of Scope	28/02/2014	£0.00
The HIV Testing Kits and Services (Revocation) (England) Regulations 2014	To repeal a ban on the sale of home testing kits in England.	OUT	06/04/2014	-£2.81
Healthcare and associated professions (Indemnity arrangements) – Cross border patients	To transpose Directive 2011/24/EU on Cross Border Patient Healthcare to require regulated healthcare professionals to have in place appropriate insurance or indemnity cover.	EU Out of Scope	07/07/2014	£2.10 [out of scope]
Healthcare and associated professions (Indemnity arrangements) – domestic patients	To require regulated healthcare professionals to have in place appropriate insurance or indemnity cover when providing healthcare for domestic patients.	IN	17/07/2014	£0.90
Abbreviated advertisements for human medicines	To amend the information requirements for advertisements for medicines targeted at prescribers and suppliers of medicines to extend the use of existing abbreviated formats.	OUT	01/10/2014	-£0.86
Relaxation on restrictions on asthma inhalers	To allow schools to hold stocks of asthma inhalers for use in an emergency.	OUT	01/10/2014	-£0.00 [not yet validated]
Tobacco Advertising and Promotion (Display) (England) Regulations	To extend the current display ban on tobacco products in large shops to all shops.	IN	06/04/2015	£14.79
Duty of Candour	To introduce a duty of candour for all organisations that register with CQC.	IN	06/04/2015	£1.00

Fit and proper persons requirement for directors (FPPT)	To ensure that all healthcare providers undertake the necessary checks to ensure that their directors are fit and proper for their positions.	IN	06/04/2015	£1.41
Market Oversight of difficult to replace care providers	To ensure continuity of care for vulnerable care service users in the event of financial distress and market exit of a major provider of care services.	IN	06/04/2015	£0.37
Displaying ratings	To enable patients and visitors to health and social care facilities to see, at a glance, what their rating is.	IN	06/04/2015	£0.16
Mitochondrial donation treatment	To remove the current ban on mitochondria donation treatment.	Zero Net Cost	06/04/2015	£0.00
Review of CQC registration requirements (fundamental standards)	To simplify the current regulations and to allow CQC to initiate prosecutions without issuing a warning notice first.	OUT	06/04/2015	-£0.30