Department of Health

Reviewing Regulation: DH commitments

Post-Implementation Review Schedule

May 2016

Title: Reviewing Regulation: DH Commitments
Author: FC&NHS / GFM / IA&BR / 17560
Document Purpose: Corporate Report
Publication date: 6th May 2016
Target audience: Business & DH stakeholders
Contact details: DH Better Regulation Unit. E: mb-ias-and-consultations@dh.gsi.gov.uk

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Reviewing Regulation: DH commitments

Post-Implementation Review Schedule

Prepared by the Department of Health

Contents

Introduction

This document sets out the Department of Health's commitments to review regulations, as at April 2016.

Successful delivery of the Better Regulation Agenda is not only measured by our efforts prior to and upon implementation of regulations but also through careful consideration of the correct form of regulatory intervention and post-implementation evaluation of any legislative measures.

Post-implementation evaluation is critical in ensuring that our regulatory interventions are delivering the intended outcomes, in identifying any unintended consequences and in re-evaluating our estimates of the costs and benefits, to ensure these accurately reflect the impacts to business and society. Reviewing regulation also enables us to learn lessons from previous interventions and apply these to future regulations.

Our commitment to reviewing regulation comes in two forms: statutory review commitments in legislation, and other public commitments, for example in impact assessments. As part of a transparent policy making process, it is important that those who are affected by regulations know what is due to be reviewed and when. We shall update this list on a regular basis with information about new commitments or the delivery of existing commitments.

We welcome your feedback on this document and our wider efforts to implement the Better Regulation agenda. You can email us at mb-ias-and-consultations@dh.gsi.gov.uk

DH Better Regulation Unit

April 2016

Why does the Department of Health regulate?

The Department is responsible for key areas of public protection, including patient safety in hospitals and care homes. Many of its regulations are therefore essential to protect patients and the public by ensuring essential standards are maintained.

The Government wants to ensure all regulation is fair and effective. The Government's Principles of Regulation state that it will regulate to achieve its policy objectives only where:

- it is demonstrated that satisfactory outcomes cannot be achieved by alternative, self-regulatory, or non-regulatory approaches;
- analysis of the costs and benefits demonstrates that the regulatory approach is superior by a clear margin to alternative, self-regulatory or non-regulatory approaches; and
- the regulation and the enforcement framework can be implemented in a fashion which is demonstrably proportionate, accountable, consistent, transparent, and targeted.

Departments and partner bodies are required to produce impact assessments (IAs) assessing the costs and benefits of regulatory changes prior to consultation, enactment and implementation. The evidence and analysis used within IAs are scrutinised by the Regulatory Policy Committee. The flow of new regulation was initially subject to a One In, One Out rule, meaning that the costs to business of any new regulation had to be matched by an equal deregulatory measure. In 2013, the deregulatory requirements doubled to produce a One In, Two Out rule. In 2015, the business savings requirement has been ratcheted up to One In, Three Out, meaning that for a measure costing £50m to business, we would need to find £150m business savings to offset the cost.

DH 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 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.

Why review our regulations?

Post Implementation Reviews (PIRs) are a key element of better regulation and will provide an evidence based evaluation of the effectiveness of a measure after it has been implemented and operational (after an appropriate period of time). A PIR will review: the original policy objectives, the extent to which the measure is achieving its intended effects / meeting its objectives; whether there have been any unintended consequences; how well it is working; and the reasons why. It will also assess whether the objectives could be achieved with a system that imposes less regulation.

The PIR evidence will support decisions about the next steps for a measure, which are:

- Renewal - measure continues without change;
- Amendment - measure remains but changes are made to improve it;
- Removal - measure is removed without replacement; or
- Replacement - measure is replaced or redesigned substantially.

There are 2 types of reviews:

- ☐ statutory reviews – where the commitment to undertake a review is set out in legislation, either primary or secondary
- ☐non-statutory reviews – which are not set out in legislation, but the Department has committed to undertake in other published documents, e.g. impact assessments and responses to reports.

DH has identified 18 reviews which need to take place over the next five year period, all of which are statutory reviews.

In reviewing these regulations the Department will take a proportionate approach, focusing attention and impact on legislation with the highest costs to business. The Department will make full use of best practice learning and guidance from across all government departments and all our PIRs will be reviewed by the Regulatory Policy Committee to ensure that the evidence presented to Ministers is fit for purpose.

Department of Health review commitments

Year	SI	Title	Origins	EANDCB[1] (£M)	Deadline for publication	Status
2012	921	The Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012	Domestic	0	17/06/2017	Unpublished
2012	1426	The Medical Devices (Amendment) Regulations 2012	EU	Unknown	30/06/2017	Unpublished
2012	1513	The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012	Domestic	-0.42	01/07/2017	Unpublished
2012	1916	The Human Medicines Regulations 2012	EU	-0.9	13/08/2017	Unpublished
2012	1501	The Quality and Safety of Organs Intended for Transplantation Regulations 2012	EU	0.324	26/08/2017	Unpublished
2013	349	The National Health Service (Pharmaceutical and	Domestic	0	31/08/2017	Unpublished

[1] Equivalent Annual Net Direct Cost to Business - formerly the EANCB but retitled to clarify that only direct costs and benefits are scored.

		Local Pharmaceutical Services) Regulations 2013				
2013	1855	The Human Medicines (Amendment) Regulations 2013	EU	1.891	19/08/2018	Unpublished
2013	2269	The National Health Service (Cross-Border Healthcare) Regulations 2013	EU	0	25/10/2018	Unpublished
2014	1878	The Human Medicines (Amendment) (No. 2) Regulations 2014	EU	0	01/01/2019	Unpublished
2014	1788	The Care Quality Commission (Reviews and Performance Assessments) Regulations 2014	Domestic	0	01/10/2019	Unpublished
2013	2327	The Medical Devices (Amendment) Regulations 2013	EU	0	31/12/2019	Unpublished
2013	373	The Controlled Drugs (Supervision of Management and Use) Regulations 2013	Domestic	0	31/03/2020	Unpublished
2014	2936	Fit and proper persons requirement for directors	Domestic	1.41	01/04/2020	Unpublished
2014	2936	Duty of Candour	Domestic	1	01/04/2020	Unpublished
2014	2936	Review of CQC registration requirements	Domestic	-0.3	01/04/2020	Unpublished
2012	677	The Tobacco Advertising and Promotion (Display and Specialist Tobacconists) (England) (Amendment) Regulations 2012	Domestic	28.1	05/04/2020	Unpublished

2013	2881	The Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013	Domestic	3.4	01/01/2021	Unpublished
2015	829	The Standardised Packaging of Tobacco Products Regulations 2015	Domestic	36.78[2]	20/05/2021	Unpublished

[2] Originally assessed at 2009 prices. On review, assessed against 2014 prices, the EANDCB becomes £48.4m