

Government initiatives around better regulation

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting	Authority
Agenda item	10
Paper number	HFEA (20/01/2016) 784
Meeting date	20 January 2016
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Output:

For information or decision?	For information
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Recommendation	<p>The Authority is asked to:</p> <ul style="list-style-type: none"> • Note and comment on these emerging proposals from Government. • Note the forthcoming consultation on bodies having a duty under the terms of the Enterprise Bill, and that we do not make a case for exemption. • Endorse our proposed approach to fulfilling these duties (when enacted). • Endorse our proposed approach to continue to resist any duty to appoint a Small Business Appeals Champion.
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Resource implications	Opportunity cost
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Implementation date	During 2016–17 business years
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Communication(s)	Clinic Focus and other communication channels
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Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
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Annexes	N/A
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1. Background

- 1.1.** This paper seeks to outline several related aspects further to the Government's emerging regulatory agenda, for information and comment and for agreeing our response.
- 1.2.** Deregulation is a core part of this Government's commitment 'to boost UK productivity, and back British business' and includes a commitment to 'cut a further £10bn of red tape over this Parliament.'
- 1.3.** There has been a notable stepping up of the scale and pace of these initiatives, with the Department for Business, Innovation and Skills working with Government Departments on their obligations and, in turn, their regulators. The initiatives covered within this paper include:
- The Enterprise Bill incorporating the Business Impact Target and reporting duties relating to 'growth' and the Regulators' Code
 - Innovation Plans, further to the Government's productivity ambitions;
 - Further to the Small Business, Enterprise and Employment Act 2015, expectations on regulators to introduce a Small Business Appeals Champion.
 - Burden Reduction Plan

2. The Enterprise Bill

- 2.1.** This is a wide-ranging 'pro-business' Bill: Alongside those parts relating to regulation are other aspects - including the setting up of a small business commissioner to support small businesses (late payments, resolving disputes and so on); strengthening apprenticeships; prompt payments of insurance claims; reforming business rates; and capping exit payments for public sector workers.
- 2.2.** The regulatory parts already apply to Government Departments, further to the Deregulation Act 2015. The Enterprise Bill seeks to extend those obligations to all regulators across government including the HFEA. We are among 70 or so other regulatory bodies caught by these proposals. The Bill itself does not specify which regulators are being brought into scope; that will be set out in secondary legislation following a six-week public consultation, due to start this month. The Government's preference is for 'comprehensive view of coverage'. It includes 50 or so independent regulators including CQC and HTA.
- 2.3.** There are two main requirements. Firstly a reporting duty; and secondly the business impact target (BIT).

Reporting duty

- 2.4.** We will have to produce annual information on how we meet the requirements of the growth duty (how we have regard to the desirability of promoting

economic growth when exercising our regulatory functions). This duty (on Departments) was introduced in the Deregulation Act 2015. We will also have to report on how we have had regard to the Regulators' Code – the principles of better regulation, which we are bound by and on which we report our performance to Authority from time to time.

- 2.5.** The intention in doing so is to promote greater transparency, allowing Government and business to hold regulators to account on how they have performed in relation to these duties and encourage the sharing of best practice between regulators. Key features are:
- We are permitted to do so as part of our general reporting, for example annual report.
 - We must obtain the views of businesses on the effect the duties have had – for example in the post-inspection questionnaires.
 - If we don't do it properly the Minister may require us to provide more information to him/her.
- 2.6.** It is possible this requirement may apply to our performance in this year 2015/16 and be included in the annual report published in 2016 due to the retrospective nature of the Bill.
- 2.7.** We will be required to: Report our performance annually (within the HFEA annual report) as regards the 'growth duty' and the Regulators' Code.
- (ii) The business impact target (BIT)
- 2.8.** This is more challenging and for some regulators more problematic. If included in scope the HFEA must provide a *scored* assessment of the economic impact on *private business* of changes we make on our 'in-scope' regulatory policies and practices during a reporting period. The assessment we make must be verified (at a point to be determined) by an independent body the Regulatory Policy Committee. Further, we must provide a summary of out of scope activity within this period.
- 2.9.** Officials in BIS have reassured regulatory bodies that they are not being set a formal deregulation target or that it will impinge on our respective independence; more so the aim being to 'encourage smarter regulation through greater transparency around *business impacts*.'
- 2.10.** The following are likely to be out of scope:
- Public sector regulation – e.g. NHS clinics. In other words, our duty here applies only as to the effect we have on independently owned clinics;
 - The fees and charges we levy;
 - Measures that are introduced that have less than 12 months' (i.e. temporary) impact;
 - Areas of devolved competence.
- 2.11.** The following will also probably be out of scope:

- Casework such as specific investigation and enforcement activity, or individual decisions on licencing;
- Factual information that does not constitute guidance and individual compliance or best practice advice provided by inspectors or suchlike;
- Activity related to regulatory policy development, such as formal and informal consultations, policy reviews, ad hoc information requests; or
- Changes to the organisation and management of the regulator that are not determined in legislation, even where these result in costs to business.

2.12. Everything else is in scope, and could include:

- Changes in regulator costs resulting from some other (not fees policy) policy change - e.g. changes in number of inspections passed on to the business;
- Compliance activity associated with EU legislation;
- Enforcement policies – how investigations and enforcement will be conducted, such as changes to our Compliance & Enforcement policy;
- Changes in our approach to risk-based regulation;
- Anything that constitutes guidance (information for businesses on how to comply with regulations);
- Changes in policy resulting from consultation;
- Routine information requests, say treatment submissions.

2.13. Ministers have determined that the methodology for calculating impacts will be Equivalent Annual Net Cost to Business. They are not minded to set a de minimis level, but agree it should be proportionate. Ministers have not determined when verification of assessment should happen – just after a proposal has been developed; just after a decision to implement has been made; or after implementation of a decision.

2.14. We will be required to: Carry out assessments of the economic impacts to business of any change to our regulatory policies and practices in line with *Business Impact Target* duties and have these subject to scrutiny by the (independent) Regulatory Policy Committee.

3. Innovation plans

3.1. In July 2015 the Government published its Productivity Plan ‘Fixing the foundations: Creating a more prosperous nation’, and inter alia, stated

“The government will... require departments to work with regulators to publish Innovation Plans by spring 2016. These will set out how legislation and enforcement frameworks could adapt to emerging technologies and disruptive business models.”

3.2. We are advised this is to obtain assurance that UK regulatory framework is working effectively to support innovation and disruptive business models – and

that regulators are using innovation to deliver their own work more effectively, and to reduce burdens on business - in the form of innovation plans. It is stated the preparation of plans will also provide the opportunity for identification and sharing of good practice.

3.3. It is suggested that plans include the following:

- How legislation and enforcement frameworks could adapt to new technologies and disruptive business models to encourage growth;
- An assessment of how new technology is likely to shape the sectors being regulated;
- Actions for how regulators could better utilise new technologies to generate efficiency savings and reduce burdens on business.

3.4. We will be required to: Engage with stakeholders and publish an 'innovation plan' by March 2016.

4. Extending the Regulators' Code to include a requirement on regulators to consider small business appeals' process

4.1. The Small Business, Enterprise and Employment Act 2015 requires the appointment of an independent Small Business Appeals Champions for each national non-economic regulator – to scrutinise appeals and complaints processes, make recommendations, and report. Departments and regulators would be expected to consider any recommendations to improve processes made, and either implement them or explain, publicly, why they had decided not to do so.

4.2. We have made representations to the Department of Health and BIS officials jointly, explaining how the regulations for representations and appeals of regulatory decisions made by the Authority are set out in the Human Fertilisation and Embryology Act 1990 (as amended). Officials have agreed to seek Ministers views on exempting the HFEA from this measure. We understand that the Government will bring forward further proposals on implementation shortly.

5. Burden reduction plans

5.1. BIS Ministers have asked the Health and Social Care Information Centre (HSCIC), to work with ALBs (including the HFEA) to develop a plan for 2016/17 on our plans to reduce the regulatory 'burden' on licensed centres.

- 5.2.** HSCIC will have oversight of the plans, the content of which will be regularly reviewed, providing the evidence base contributing towards its measure of burden reduction activity

6. Risks and issues

- 6.1.** We see some risks and issues here at several levels. We and others have raised concerns as to the effect such requirements fetter our independence (and ability to enforce requirements robustly). For example, we may face challenge about the extent and scope of a future change to our policy in a particular when dealing with concerns say in a licensed centre about its compliance with regulatory requirements.
- 6.2.** Linked, is concern that a duty to promote growth (which in itself is unexceptionable) undermines the delicate balance that the HFEA has managed to strike, taking into account the interests of science and innovation and society's concerns about the nature and pace of such developments. This is perhaps best exemplified by the careful and sensitive approach taken to the introduction of mitochondrial transfer.
- 6.3.** As NHS services are exempt from such considerations the requirements engender a sort of two-tier consideration. This is problematic at a practical level that in, say, consulting with stakeholders we take a comprehensive approach rather than a stratified one where the NHS and independent sector is approached differentially.
- 6.4.** Finally, there is the not insignificant challenge to our capacity. Additional requirements placed upon us have a cost – and on the basis that there will be no easing of the restrictions placed upon us regarding headcount and operating budget, then there will be an opportunity cost. It is expected that the reporting duty and BIT requirements will be retrospective - to June 2015. We expect to take two or three proposals a year through the Regulatory Policy Committee (such as changes to the compliance and enforcement policy; operationalising of the new EU directives on coding and import) – all further activity to add to our tricky prioritising considerations.
- 6.5.** We have expressed these concerns at official level with colleagues from the Department of Health and BIS. BIS officials are firmly of the view in their arguments that the requirements are simply an extension of good practice; promote transparency; and that there are safeguards and exclusions are in place. They have also been clear in documentation and in person that Ministers have a strong preference for 'comprehensive' coverage.

Our working position

- 6.6.** Taking that into account and considering the prevailing landscape regarding Government's approach to regulation as a whole, the executive has adopted a working position, as follows.

- We welcome and support the need for any regulator to take into account its impact and the need for collaboration with the sector and for transparency - and we have worked hard at doing so over many years. For example, all Authority meetings are held in public with an audio recording published subsequent to each meeting; we hold three licensed centre's panel and fees' group meetings per year as well as other stakeholder events; we publish clinic focus directed to licensed centres every month; we undertake regulatory impact assessments for major changes to regulatory requirements; we consult formally and informally; we seek views about the impact of inspection at every inspection; we report to the Authority annually on the impact of compliance activity.
- Regarding the growth duty, and obligation to develop innovation plans, we have been held up (on the latter) by BIS as a centre of excellence regarding our work on mitochondrial donation. With some additional consultation, and building on the work undertaken at horizon scanning and our Scientific and Clinical Advances Advisory Committee, we can probably discharge our duty here relatively proportionately. That said, our initial innovation plan may be drafted as regards meeting the March 2016 deadline.
- Regarding our reporting duty, as stated above, we report our regulatory impact to Authority annually and within that set out (at relatively high-level) our performance in relation to the Regulators' Code. We will continue to do so and publish a summary of this within our Annual Report.
- Compliance with BIT duties will be more challenging. That said, we believe some of our proposals are simply too small to put through bureaucratic hoops. As such we would self-declare these as 'exempt' – report these as such and run a risk of challenge by BIS Ministers or others. We see this as unlikely.
- The Burden Reduction Plan commitments can be wrapped up in our IfQ proposals and to be set out in our Business Plan.
- We have grave concerns about being caught within the Small Business Appeals' Champion. As such, we welcome the commitment from BIS officials to seek an exemption.

7. Recommendation

7.1. The Authority is asked to

- Note and comment on these emerging proposals from Government.
- Note the forthcoming consultation on bodies having a duty under the terms of the Enterprise Bill, and that we do not make a case for exemption.
- Endorse our proposed approach to fulfilling these duties (when enacted).
- Endorse our proposed approach to continue to resist any duty to appoint a Small Business Appeals Champion.