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Guest Editorial

Better regulation in troubled times

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Regulatory climates are of central importance to participants in the health sector. Regulatory compliance costs are a key concern of all parties – from providers of front-line services to those developing new pharmaceutical products. Regulation, moreover, affects a myriad of activities, from the marketing of drugs to the supply of human organs. It is important, accordingly, to consider whether governments provide regulatory systems that are user friendly, conducive to certainty, and protective of relevant interests.

Looking at the United Kingdom regulatory environment, it is clear that these are interesting times. A number of changes are taking place, which may involve uncertainties for the health sector as much as for others. Most notably, the period 2005–06 is seeing a fundamental shift of the UK Government's rhetoric on regulation. The 'better regulation' movement is giving way to the 'regulatory reduction' rallying cry, and, as a result, British regulators now have to deal with a number of difficult messages from central government. It is worth outlining how this position has been arrived at and how this places modern regulation under considerable stress.

The 'better regulation' thrust within UK Government can be traced back to 1997. Before that time the prevailing concern was the Thatcherite desire to deregulate. In 1997, however, the switch from the language of 'deregulation' to that of 'better regulation' was made. Dr David Clarke, Chancellor of the Duchy of Lancaster, argued: 'Deregulation implies regulation is not needed. In fact good regulation can benefit us all – it is only bad regulation that is a burden' (Cabinet Office, 1997).

The better regulation agenda was pressed forward by the Better Regulation Task Force (which was established in 1997), the Regulatory Impact Unit was set up at the Cabinet Office, Regulatory Reform Ministers were appointed in each department of state, and a Ministerial Panel for Regulatory Accountability was created in order to improve the regulatory system. The UK's 'better regulation' rhetoric echoed that encountered in the European Union and the OECD, and the way to ensure better regulation was seen in terms of the need to develop and apply a series of regulatory improvement tools and policies. Central amongst the tools was Regulatory Impact Assessment – a process for the cost–benefit testing of new regulatory proposals.

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In March 2005, however, two important publications signalled a change in direction. The Better Regulation Task Force (BRTF) released its report, 'Regulation – Less is More' (Better Regulation Task Force, 2005a) and the Hampton Review on 'Reducing administrative burdens' (Hampton, 2005) was published.

The 'Less is More' Report (LIM) recommended the adoption of new steps to reduce administrative burdens on business, and, notably, it urged the introduction of the following measures:

- The new Dutch approach of introducing a target for reducing administrative costs to businesses.
- A 'one in, one out' rule for regulation, whereby new regulations have to be matched by deregulatory measures.

The Hampton Review recommended that regulators as a whole should use comprehensive risk assessments to concentrate resources on the areas that need them most.

The Hampton recommendations were endorsed by the Government in the March 2005 budget speech, and, in November 2005, the Chancellor, Gordon Brown, wooed the Confederation of British Industry (CBI) Conference by promising to publish new legislation to ensure that there will be 'no inspection without justification, no form filling without justification, and no information requirements without justification' (HM Treasury, 2005). Across government, departments have been told to set new targets for reducing (by fixed percentages) the information burdens that they impose on businesses.

The 'better regulation', 'less is more' and 'risk-based' messages involve a number of tensions, however, and these pose serious challenges for regulators in coming years. Three difficulties demand particular attention.

Better regulation versus smarter regulation

The thrust of better regulation is to improve regulation by testing it with tools such as Regulatory Impact Assessment. The lesson of the 'smart regulation' philosophy as expounded by Gunningham and Grabosky (1998),[1] is that the best regulatory systems involve optimal mixes of state controls, associational (or quasi-regulatory) controls and corporate constraints (i.e. controls within the corporation); and that mixtures of less coercive and more coercive regulatory instruments should be employed with an emphasis on less punitive, less formal controls as first options. Smart regulation thus envisages a movement away from restrictive, rule-based, 'command and control' regimes towards those that place more emphasis on alternative, less coercive methods as applied by a variety of institutions – be they regulators, professional bodies, or companies/service providers themselves.

1 See also Baldwin (2005).

The tension between better regulation and smart regulation is that better regulation gives centrality of place to regulatory impact assessment (RIA), whereas smart regulation advocates complex policy mixes and 'softer' styles of control that are extremely difficult to put through a RIA process. Such mixes are almost impossible to evaluate numerically in terms of costs and benefits because of their multi-instrumental and multi-institutional complexity. Any proponent of a new regulatory system who knows that a RIA process has to be negotiated will have a huge disincentive to put forward a smart regime and an almost irresistible imperative to opt for something closer to an old-fashioned command and control system. On the one hand, the Government advocates the use of more imaginative, 'alternative' and less restrictive approaches to regulation (Better Regulation Task Force, 2005b), whilst, on the other hand, it evaluates regulatory proposals with a process that is almost wholly unsympathetic to such approaches.

Better regulation versus less regulation

The Government is now keener than ever to avoid imposing new burdens on businesses. It wants to reduce quite significantly the burdens of supplying information that regulators impose on them. It also wants regulators to target their enforcement activities more precisely in order to take up less business time. The problems are, first, that targeting enforcement demands that inspections and other actions are based on intelligence, and second, that, if the obligations of businesses or health care bodies to supply information to regulators are reduced, it is increasingly difficult for regulators to engage in targeting without generating intelligence independently. Such independent generation of data may, of course, prove hugely expensive for regulators – indeed far more expensive for them than for the businesses/health care bodies that they are controlling (who may have the information quite readily to hand).

There is, indeed, a further danger in the burden-reducing policy thrust. This is that the potential savings made are likely to be hugely exaggerated and that the costs will be underplayed. This is likely to occur in the following way. If a business or health care body is asked to state what it costs to tell the regulator how often it changes the filters on a ventilation system, it is liable to look to the staff time and other resources spent in keeping records. Such costs are considerably more than those of e-mailing the records to the regulator. Let us suppose the record keeping costs are £5,000 a year and the e-mailing costs £20 per year. The burden-cutting saving is liable to be calculated at £5,020 per year. In fact the real saving is only £20 because the record keeping needs to be carried out as part of routine management. If, moreover, the obligation to supply the records is removed (in order to achieve the hoped-for £5,020 saving), the regulator will have to make investigations to uncover the relevant data. Those investigations will cost considerably more than £20.

Better regulation versus risk regulation

Risk-based regulation involves a targeting of enforcement at those businesses or service providers who pose greatest risks. As such, risk-based systems offer the prospect of a more efficient and less intrusive system of control than regimes that adopt, say, blanket or reactive approaches. Dangers arise, however, when ministers make statements that lead businesses or health care bodies to believe that all inspections will be justified according to risk assessments. A central such danger is that risk-based systems tend to be blind to new risks and risk creators. They make risk assessments on the basis of a given set of information on risks and their creators and, as a result, their inspection processes are locked into a focus on those risks and risk creators. They do not look to new hazards or new actors because these do not develop risk scores on the extant system (it was for such reasons that the Hampton Review suggested that risk-based systems should always be combined with a process of random inspection). It is random inspection (or another enforcement approach) that will uncover new issues, not the risk-based system. Regulators and ministers, accordingly, should be slow to assure businesses, health care bodies or others that all inspections will be based on prior evidence of risk.

Conclusions: regulation and health care

These are, indeed, extremely interesting times for regulation, and particularly for regulators. Within government there exist a number of vigorous policy thrusts, but these are not in complete harmony and many regulators may fear that they are being asked to straddle a number of horses. An optimistic view of recent developments is that the Government is shaking up regulation and that, together with current concerns about burdens, this is likely to produce more effective, 'lighter-touch' controls than were encountered formerly. The pessimistic analyst may, however, suggest that obsessions with Regulatory Impact Assessments, burden reductions, and risk-based enforcement systems are likely to stand in the way of user-friendly regulation, and that these obsessions may increase regulatory compliance costs and lower the levels of protection that are currently found across economic and social activity. In the health sector, as in other areas, a particular worry may be that tensions within and between regulatory strategies tend to produce uncertainties unless they are handled astutely. Such uncertainties affect not only the ability of health service providers to plan investments – they also impact on compliance costs, the development of new products or services, and the welfare of patients. The UK Government may eventually manage to resolve the tensions discussed above, but many health sector participants will be watching the regulatory climate with some anxiety over the next few years.

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