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Regulation

Regulation and regulatory effectiveness in public health

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Much of the global success of 19th century sanitary reform in developed economies was built upon the prescriptive, but effective, regulation of: urban water quality and sewage disposal; food safety; burials and mortuaries; noxious trades; and housing and building standards.[1] Within New South Wales (NSW) these regulations were supported by a trained inspectorate and a system of governance at local government level, which endured more or less unchanged for 100 years after the first NSW *Public Health Act* of 1896.

Since the 1970s, regulatory modernisation in all arms of government has been driven by a need to reduce administrative red tape without compromising regulatory effectiveness. This modernisation accepted that regulators would be more likely to succeed by being responsive to the context, conduct and culture of those being regulated, and by invoking escalating sanctions; that is, soft words before hard words, and carrots before sticks.[2]

Health departments have been slow to embrace regulatory reform, perhaps because many of these regulatory activities are now marginal and, to a degree, alien to the culture of health-care delivery. It is, however, significant that regulatory reform has transformed the domains of environment protection, food safety and occupational health and safety, all of which originated in health departments and continue to have primary public health objectives.

This transformation began with the publication of the Robens Report in the United Kingdom in the 1970s.[3] Robens argued that occupational health and safety regulation had become a complex mass of technical rules for workers to follow and inspectors to enforce. Not only were the regulations not understood by workers, they also undermined responsibility for safety throughout organisations by inviting the impression that safety was imposed from outside the workplace.[4] As a result of regulatory reform, organisations were to be given general duties of care for their employees' occupational health and safety. Such duties were to be discharged by collaborating with the workforce to develop, document, implement and improve auditable safety management systems.

The new style of regulation seeks to use its power of command in a way that is more analogous to good management – it seeks to encourage excellence at the same time as setting a standard, below which performance shall not fall.

Responsive regulation can be viewed as a regulatory pyramid comparable to the principle of a hierarchy of control of occupational or environmental hazards:[5]

- Voluntarism is based on an individual or organisational undertaking to do the right thing without any coercion.
- Self-regulation occurs where an organised group regulates the behaviour of its members (e.g. by establishing an industry-level code of practice).
- Economic instruments involve economic sanctions or incentives, or measures that give more power to consumers.

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- Meta-regulation involves an external regulatory body (e.g. ensuring that health-care providers implement safety and quality programs and practices).
- Command and control involves enforcement by government (e.g. ensuring compliance with rules for licensing facilities).

Over the last few years, some of these principles of responsive regulation and modern approaches to regulatory governance have found application not only in the more traditional public health fields such as environmental health, but also in areas as diverse as clinical safety and quality and research governance.

This edition of the *Bulletin* includes articles demonstrating the successful contribution of regulatory governance to public health. Byleveld and others assess the impact over the last 7 years of a responsive, regulatory framework to improve the quality of drinking water in rural NSW; Bloom and Frew outline the gains made in the regulation of clinical research. These contributions share the conclusion that the application of frameworks and systems rather than an elaborate and prescriptive list of requirements are vital to effective regulation.

Tutt provides a local perspective of tobacco control in his report of the enforcement of laws related to selling tobacco products to minors. He reminds us that all regulatory effort must be accompanied by the support of field staff in what is sometimes difficult work and by a commitment to the ongoing evaluation of the effectiveness of regulatory programs.

There is a need for constant vigilance and innovation in the development of public health regulatory frameworks. The regulation of the built environment has been a cornerstone of public health practice, but both technological progress and the increasing importance of chronic disease prevention are changing the nature of this task. I have discussed this aspect of public health regulation in a separate article.

Using the example of proposed future directions in tobacco regulation, especially the adoption of economic instruments to regulate unhealthy products, Penman provides some important and timely insights into how regulatory initiatives in public health should be framed so that they attract the support both of the community and our political representatives.

Regulation has become more common with the growth of private entrepreneurs and the introduction of market mechanisms into the public sector. These new bodies are seeking flexible, participatory and devolved forms of regulation, in addition to traditional enforcement such as inspections.[5] A review of the NSW *Public Health Act 1991* is currently underway and the articles in this issue provide some evidence of the growing awareness of both the utility and possibilities of modernised and effective public health regulation.

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