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Review

Solving of complex regulatory matters in the method of current practices

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Abstract

MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and efficacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the manufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is known that no drug product is completely safe or is 100% safe for use, but MHRA tries to minimize as many problems regarding the drug so that patients will be provided with the best drug with minimal risk.

Keywords: MHRA, United Kingdom, Product license, eCT

INTRODUCTION

Regulation seeks to make such improvement by changing individual or organisational behaviour in ways that generate positive impacts in terms of solving societal and economic problems. At its most basic level, regulation is designed to work according to three main steps:
1. Regulation is implemented, which leads to changes in
2. The behaviour of individuals or entities targeted or affected by regulation, which ultimately leads to changes in
3. Outcomes, such as amelioration in an underlying problem or other (hopefully positive) changes in conditions in the world.

Evaluating regulation therefore entails an inquiry, after regulation has been put in place, into how it has changed behaviour as well as, ultimately, its impacts on conditions in the world.

The word "regulation" itself can mean many things. At its most basic level, -regulation‖ is treated as synonymous with "law". Regulations are rules or norms adopted by government and backed up by some threat of consequences, usually negative ones in the form of penalties. Often directed at businesses, regulations can also take aim at nonprofit organisations, other governmental entities, and even individuals. Regulations can also derive from any number of institutional sources –parliaments or legislatures, ministries or agencies, or even voters themselves through various kinds of plebiscites. Given their variety, regulations can be described using many different labels: constitutions, statutes, legislation, standards, rules, and so forth.

Individual rules versus aggregations of rules

Regulation can refer either to individual rules or collections of rules. Similarly, an evaluation of regulation could focus either narrowly on how well an individual rule works or more broadly on the impacts of collections of rules. Although the scope of any evaluation may fall along a spectrum, it will be helpful to distinguish between the following two ways that regulatory evaluations can be focused.

Individual rules. An evaluation can focus on the impact of a specific rule. An evaluation of an individual rule could focus on a single command, such as a new speed limit. Or it could also focus on a discrete legal document, such as a motor vehicle safety standard adopted by a transportation bureau on a specific date. To the extent that a single legal document contains more than one command, it may be meaningful to treat these commands as effectively one individual rule, to the extent they are closely intertwined. For example, if a legal document were written to say that "there shall be established a speed limit of a maximum of 60 km/h which shall be posted on a sign no smaller than 1.5 meters in diameter," the document would actually contain two closely integrated commands: one to drivers about maximum speed and the other to the highway authority about the size of signs. Such a legal document, though, could presumably still be evaluated as a single rule for most purposes.

Collections of rules. To the extent that a legal document contains many discrete, separable commands – such as with a sprawling, multifaceted piece of legislation – its evaluation will no longer be considered narrow. However, a regulatory evaluation can attempt to encompass a combination, collection, or system of rules. For example, instead of just focusing on a specific speed limit rule, an evaluator might seek to determine the effects of all the rules related to traffic safety adopted within a particular jurisdiction. In a similar vein, the evaluator could assess all the rules related to health care delivery, banking solvency, occupational safety, or any number of regulatory domains. As with occupational safety, which could be evaluated either within or across industrial sectors, evaluations of collections of rules could aim at a single industry (e.g., insurance regulations) or at rules that cut across different sectors (e.g., environmental regulations).

Regulation and its effects

Even a well-defined, individual regulation will often comprise a complex chain of interventions, interactions, and impacts. At its most basic level, regulation seeks to change behaviour in order to produce desired outcomes. When regulation stems from a good faith effort to advance the public interest, those desired outcomes will be improvements in problematic conditions in the world. A regulation "works" when it solves, or at least reduces or ameliorates, the problem or problems that prompted government to adopt it in the first place.

With regulation responding to problematic conditions in the world, understanding and mapping the state of the world helps in understanding how a regulation can lead to desired outcomes. The world consists of numerous and complex causal relationships that contribute to social and economic problems; regulations take aim at one or more steps on the causal pathways leading to those problems. Consider a simple example of automobile safety regulation. The fatalities, injuries, and property damage associated with automobile accidents are the problems that animate regulation. The accidents that give rise to these problems in turn arise from myriad causes such as driver error, road conditions, and mechanical failure. Regulation takes aim at these various causes of accidents by imposing requirements for driver training, vehicle operation, and engineering design.

Of course, policy makers and the public typically care about more than just solving the animating problem underlying a regulation. They do not generally accept solving a problem at any cost. To use auto safety again as an illustration, a regulation could mandate all vehicles be constructed as heavy and solid as tanks, or that drivers drive no faster than 5 kilometers per hour. Although such extreme safety regulations might prove exceedingly effective at eliminating fatalities from automobile accidents, they would presumably come at the substantial cost of keeping most people from driving because of the expense or impracticality of transportation that complied with the rules. To ―work,‖ regulation will not only change behaviour to achieve desired outcomes but it will also avoid or limit undesired outcomes.

The basic elements of regulation, behaviour, and outcomes (both desired and undesired) form the core of any model of how regulation is supposed to work. Figure 1 builds on those core elements to present a relatively simple

schematic of regulation and its impacts. The figure maps out in a general way the relationships between distinct steps in the development and implementation of any regulation, leading to its eventual effects. The schematic shows that regulation itself comprises not only a rule – but also that its effects will be influenced by how that rule is implemented and enforced. In addition, the schematic makes clear that both the rule and its implementation are products of a regulatory process, carried out by decision makers in specific regulatory institutions who must operate under their own set of rules and practices. Finally, regulation not only affects the behaviour of those targeted by a rule and its implementation, but the behavioural change induced by a regulation can lead to several different kinds of outcomes, desired and undesired, intermediate and ultimate.

Evaluating regulatory policy

Government officials and members of the public rightfully seek to know not only how well their regulations work, but also how well their regulatory policy works. That is, do the procedural requirements that call for analysis or transparency in the development of new regulations make a difference? To assess the regulatory policy directed at how regulations are developed, evaluations will actually need to follow a framework identical to that for evaluating regulations themselves.. Regulatory policy is, after all, itself a type of regulation – a way of ―regulating the regulators‖ (Viscusi, 1996) or of what can be called ―regulation inside government‖ .The aim of regulatory policy, as with any regulation, is to change behaviour to improve outcomes, with the only difference being that the behaviour sought to be changed by regulatory policy is that of the regulatory institution or its members. Given the similarity in the causal logic of both regulation and regulatory policy, anything that can be said about evaluating regulation will apply to evaluating regulatory policy. Regulation and regulatory policy are both ―treatments,‖ to use the parlance of program evaluation. As such, although the framework developed in this report is primarily presented in terms of the evaluation of regulation, the framework applies as well to evaluations of regulatory policy.

Choosing to present a framework in terms of evaluating regulations, rather than separately for regulations and regulatory policy, is not merely a matter of convenience or ease of presentation. Rather, it reflects the reality that any complete evaluation of regulatory policy will entail the incorporation of evaluations of individual regulations. Regulatory policy imposes requirements on regulatory officials with the expectation that they will lead those officials to make better regulations (OECD, 1995; 1997; 2005). Regulatory policy is ―designed to maximise the efficiency and effectiveness of regulation‖. Its ―main assumption … is that a systematic approach to regulation making – embodied in high quality regulatory policies – is the key to ensuring successful regulatory outcomes‖ .

If better outcomes from regulations are the ultimate outcome of concern for regulatory policy, the only way to evaluate such policy will be to determine whether the regulations themselves are better. For example, a complete evaluation of regulatory impact analysis (RIA) requirements, which aim to promote efficient or at least cost-effective regulations (Coglianese, 2002), will need to include an evaluation of the cost-effectiveness or efficiency of the regulations adopted under such requirements. Similarly, in order to determine if transparency requirements really do improve the substantive outcomes of regulations by making it more difficult for officials to adopt inefficient or ineffectual regulations that favor special interests, then an inquiry must be made into the substantive quality of regulations. As long as regulatory policy seeks to improve regulation, nested within a full evaluation of regulatory policy will be an evaluation of regulations themselves. For this reason, methods of evaluating regulatory policy are not just analogous to methods of evaluating regulation, they actually depend on them.

This is not to say that the only outcomes of concern for regulatory policy will be the substantive improvement of regulations. Sometimes regulatory policy will aim to advance other goals, such as procedural legitimacy. Transparency requirements, for example, might seek to reduce public cynicism over governmental decision making or to increase public participation, something which might be valued for its own sake irrespective of how it affects the substantive quality of regulation. In those (rare) instances where regulatory policy seeks solely to advance procedural legitimacy or another objective divorced from the substantive performance of regulations, then the framework in this report should indeed be treated as just analogous to a framework used to evaluate regulatory policy, and one could essentially substitute the words ―regulatory policy‖ every time the word ―regulation‖ is used. However, on the altogether reasonable assumption that regulatory policy often, if not even always, concerns itself at least to some degree with the substantive performance of regulation, the evaluation of regulation itself will be more than just analogous to the evaluation of regulatory policy. It will be integral to it.

A. **Regulatory enforcement and inspections should be evidence-based and measurement-based: deciding what to inspect and how should be grounded on data and evidence, and results should be evaluated regularly.**

1. Getting the policy settings right and deciding which inspection bodies and regulatory enforcement or regulatory delivery institutions should exist, and with what mandate, is essential. To achieve this existing structures, budget

allocations, human and material resources, mandates and functions of enforcement and inspecting agencies need to be reviewed systematically using a transparent set of well defined criteria.

2. For most countries, the existing institutional structures and resources allocation have evolved over many years, incrementally through legislative and governmental decisions focusing on one particular issue at a time (often reacting to a particular emergency or event), without the benefit of a comprehensive perspective. As a result, government structures often have many overlapping or partly duplicating functions. Many inspection institutions also have a mandate that corresponds to issues that may have come to present little risk, or where inspections are not an effective compliance strategy. This provides an opportunity for countries to learn from the experience of other jurisdictions in those cases where regulatory compliance has been found to be effectively promoted through other means.
3. Likewise, resource allocation is often based to a large extent on decisions taken long ago, in a different context. Institutions were set up with a given budget and staffing, and these evolve from year to year based on budget constraints and policy priorities – but the allocation across the executive branch, between different enforcement and inspection areas, is not usually reviewed using a cost-benefit analysis and considering what hazards are being addressed by each structure, and at what cost. Such cost-benefit analysis should become a central element in the assessment and development of inspection and enforcement functions.
4. A principle of evidence-based enforcement and inspections would require that inspectorates' actions and their effectiveness should be regularly evaluated, against a set of well-defined indicators, and based on reliable and trusted data. Collecting data on activities and outputs (e.g. how frequently an agency conducts inspections, how many entities are subject to inspections, how much time, private or public is taken up with inspections – and what are the administrative sanctions or criminal prosecutions that may follow) is important to assess resource use and burden on businesses. However, these should not be taken as a reflection of the effectiveness (or lack thereof) of an agency.
5. Comparative research has shown that a high number of inspections do not guarantee greater levels of compliance, and many sanctions do not necessarily safeguard the public. On the other hand a small number of checks or prosecutions do not mean that compliance is high, as it may just reflect a lack of inspection resources, or lax enforcement. It is acknowledged that properly assessing the effectiveness of enforcement and inspection agencies is difficult, because improvements or worsening outcomes (health, safety etc.) cannot directly be attributed to their activities because of the vast number of other, often more important, factors. Nonetheless, it remains crucial to monitor such outcomes in order to judge whether enforcement is having any positive contribution. Overall, enforcement agencies should aim at a combination of:
    - improved or maintained outcomes, all other things being equal (i.e. taking into account whether major externalities may have affected the level of outcomes)
    - ensuring that the strong majority of regulated subjects are broadly compliant with all requirements that are critical to ensuring outcomes (such as safety, health, environmental protection, state revenue).

B. The potential of market forces, private sector and civil society actions to support compliance and enforcement should be explored wherever possible: inspections and enforcement cannot be everywhere and address everything, and there are many other ways to achieve regulations' objectives.

1. 1.While regulations of economic activities have existed for a very long time, the emergence of specialized institutions tasked with verifying compliance and enforcing rules has only been a gradual process, and in many cases a relatively recent one. It should not be assumed that each and every rule issued by the state needs to have a specific enforcement unit following up on compliance by businesses.
2. In many cases, even if the regulation is both needed and cost-effective, there may cases where there is no need to assign state resources to control compliance and enforce it, because other mechanisms may be used for lesser cost and burden. In particular, when regulations apply to market relationships and services to be provided, it may be possible to rely on liability provisions for suppliers, combined with adequate insurance requirements for one or both parties. Governments, before deciding upon whether to assign inspection and enforcement resources to a specific regulation or set of regulations, should follow clearly stated criteria, such as:

• Would violation of these regulations potentially cause immediate, irreversible harm – or would there be possibility to later on repair or compensate the damage adequately, once violation is identified? Alternatively, would remediating this harm be possible, but so difficult and so considerably more expensive than preventing it that there is a very clear case for preferring direct inspection and enforcement as a tool to try and avoid it?

- Are there possibilities to rely on market mechanisms and providers of conformity assessment services, so that conformity can be verified by (adequately regulated and supervised) private sector entities, rather than directly by the state (and would this prove more cost-efficient for the state and for taxpayers)?
- Can the potential liability in case of violation of regulations and subsequent harm be adequately covered through a mandatory insurance mechanism?

3. If the conclusion is that non-compliance would not immediately cause irreversible harm, and that remediating any potential harm would not be prohibitively difficult or expensive, and alternative mechanisms are found to be applicable, governments should consider using market-based mechanisms rather than direct inspections and enforcement actions. Even when only some of these points are met, such mechanisms can be considered if, for instance, direct control by the state would pose an excessive burden on state resources or would result in major bottlenecks for the economy.
4. Likewise, if the harm that could arise from non-compliance with regulations is assessed to be very low, and regulations nonetheless exist (in cases where OECD principles would rather recommend *not* to use state regulation), inspections and enforcement resources should generally not be allocated.
5. Use of alternative means is not, by definition, appropriate for all types of regulations. The fundamental criteria should be the possibility of harm occurring that would be irreversible, or extremely costly and difficult to remediate. There are, in fact, many regulated fields that are very unlikely to cause such harm – and are nonetheless on the books. An easy to grasp example are the regulations on state language – while their aim may be considered as legitimate, it may not always be necessary to create a specific inspectorate to look after them.

C. **Enforcement needs to be risk-based and proportionate: the frequency of inspections and the resources employed should be proportional to the level of risk and enforcement actions should be aiming at reducing the actual risk posed by infractions.**

1. All enforcement activities should be informed by the analysis of risks. Each activity and business should have their level of risk assessed. Enforcement resources should then be allocated accordingly. Each set of regulations should likewise be given a level of priority commensurate to the risks they are trying to address. Risk should be understood here as the combination of the *likelihood* of an adverse event (hazard, harm) occurring, and of the potential *magnitude* of the damage caused (itself combining number of people affected, and severity of the damage for each). Governments should ensure that a consistent definition of risk is used throughout all inspectorates, and that it forms the basis for allocation of resources and targeting.
2. Such risk-analysis should be used at all steps of the regulatory process – when designing regulation, enforcing it, and evaluating it. It is particularly important at the enforcement stage, because it is physically impossible for governments to inspect each and every business or object, and because even attempting to do so (while not being necessarily effective) would result in massive and unnecessary administrative burden. Thus, because prioritization in inspection and enforcement actions is indispensable, governments should make sure that it is done on the basis of risk-analysis and assessment of businesses' risk profile.
3. In practical terms, this means that governments should ensure that each inspectorate develops/collects and uses the following:
   - Criteria to assess the risk of individual businesses and rank them according to assessed risk level;
   - Data on all (or at least most) businesses allowing to effectively assess their individual risk level ;
   - Planning and resource allocation mechanisms so that inspection visits are effectively planned based on the risk level, and resources are rationally allocated
   - Updating process so that the risk-profile of each business is regularly updated to incorporate new information, and risk criteria are modified based on new statistical data on hazards, possible damages etc.
4. In addition to the allocation of inspection resources, the follow up actions taken based on inspections findings, should also be proportional to risk. Governments should adopt rules requiring all inspectorates to develop and implement enforcement policies based on risk-proportionality so that:
   - Types of violations are reviewed, analysed, and ranked according to the potential risk they present;
   - Guidelines are given to inspectorate staff prescribing to always assess the actual risk level presented by each recorded violation or set of violations before deciding on a sanction;
   - As a result of these steps, sanctions taken when violations are found are proportional to the potential magnitude of hazard – thus ensuring deterrence in the most hazardous situations but also reducing burden for minor shortcomings.

5. Governments should ensure that risk criteria, policies, guidance, etc. are clearly communicated and explained to the public, and regularly reviewed based on results and available data, so that evolutions in hazards and threats are properly addressed.

D. **Enforcement should be based on "responsive regulation" principles: inspection enforcement actions should be modulated depending on the profile and behaviour of specific businesses**

1. The "responsive regulation" approach suggests that regulators should adopt a differentiated enforcement strategy based on the behaviour and history of the businesses they deal with. Used properly, responsive enforcement promotes compliance more effectively, while reducing the burden posed on the "best performing" businesses. Because businesses are informed about this policy, they have an incentive to improve their compliance and cooperate with regulators, because they know this will lead to less burdensome oversight. In this perspective, governments should promote the use of responsive enforcement approaches by regulators where possible and monitor their use.
2. The following approach is suggested:
   - Businesses that show a pattern of systematic and repeated violations of regulations are assigned a higher risk level, and accordingly checked more frequently;
   - Businesses which commit repeated and systematic violations are also showed no leniency when significant violations are found, and enforcement may immediately escalate to sanctions, and possibly suspension of operations, rather than just giving an improvement notice;
   - On the contrary, businesses which have a history of compliance should be gradually inspected less often (their risk level being rated lower) – and for first-time violations, inspectors should also generally start with improvement/warning notices or (in the case of lesser violations) verbal warnings, except in cases of major, imminent hazard;
   - Recently created businesses should be similarly first given a chance to improve, rather than immediately resorting to sanctions, so as to promote a culture of openness on their side (except, once again, if violations are seen to be particularly dangerous and/or were clearly committed intentionally, on purpose).
3. In order for such a "responsive" approach to be effective, and as the necessary complement to compliance promotion approaches, the sanctions available to regulators need to be sufficient for deterrence. Whenever relevant to the type of violation, penalties should be set up in such a way as to at least capture the economic benefit that the violator obtained by failing to comply with regulations (if the violation did lead to an economic benefit). In all cases, enforcement agencies should have a range of penalties at their disposal (be they administrative sanctions that can be imposed directly, or penalties that can only be imposed by courts following successful prosecution) that allow to properly differentiate between minor and major violations, and to punish severely the most egregious violations, and those that create (or may have created) the most harm.

E. **Governments should adopt policies on regulatory enforcement and inspections: clear objectives should be set and institutional mechanisms set up with clear objectives and a long-term road-map.**

1. Regulatory enforcement and inspections are functions that have a major bearing on regulatory effectiveness overall, on the intended effects of regulations in terms of public goods, and on the burden they pose to businesses and the economy. Thus, recognizing them officially as a distinct priority is a first essential step. Transforming regulatory enforcement and inspections practices and processes requires time – and therefore it is essential to have as much as possible continuity in goals and political support. The breadth of issues and institutions involved also makes it necessary to establish an overall framework or mechanism to steer improvements and reforms across the board. Governments should thus adopt official policies on reform, oversight and continuous improvement of enforcement and inspections.
2. An official government vision on enforcement and inspections is important because: *i)* it recognizes the similarities between all functions and structures that deal with these issues, regardless of the sector, and thus to address problems and issues in a consistent way, as well as to tackle overlaps and duplications – *ii)* it can serve as basis and anchor for all inspection and enforcement reform initiatives in specific institutions and sectors. It also helps to mobilize public support for transformations by lending more visibility to the topic.
3. The policy on regulatory enforcement and its reforms should be based on clearly articulated overarching goals (e.g. combining safety and economic growth) as well as specific objectives (e.g. improving efficiency, minimizing burdens, concentrating resources and efforts where they can deliver the most results, improving transparency and responsiveness). The reform efforts should be regularly evaluated, and be updated where needed.

4. The objectives should aim at addressing the issues that have been identified in each given jurisdiction as particularly relevant or problematic. These are likely to include excessive numbers of inspections or of institutions covering the same issues (at least for some types of businesses and sectors), unclear requirements and expectations, insufficient focus of resources on risk, and proportionality of sanctions to risk, lack of coordination and information sharing, limited (if any) provision of compliance supporting advice, evaluation systems treating outputs (inspections) as results, among the most typical problems. They may also include in some areas a problem of *under*-inspection, due to lack of resources, resulting in enforcement gaps in some critical areas (which resource reallocation and consolidation could help address). In all cases, it is essential to consider the actual situation in terms of risks and current outcomes in the country, to spot the areas of good and less good performance. Based on the analysis of the situation in their country, governments should developed detailed, specific objectives based on the OECD principles presented in this document.
5. In addition, mechanisms are needed to drive the change process, evaluation framework and, if necessary, exert pressure. Governments should create an institutional set up that provides for co-ordinating and driving the change process, evaluation framework and, if necessary, exert pressure. This mechanism should ensure that all relevant ministries, agencies and structures (regulators, inspectorates etc.) are involved in a co-ordinated manner. A strong political leadership must be ensured as in case of all policy reforms.

F. Inspection functions should be co-ordinated and, where needed, consolidated: less duplication and overlaps will ensure better use of public resources, minimise burden on regulated subjects, and maximise effectiveness.

1. One of the most important institutional changes to improve the efficiency of inspections and decrease the costs and burden they represent is to restructure enforcement agencies so that functions are consolidated, duplications and overlaps removed. Existing institutional structures are in many countries a result of *ad hoc* creations (when new legislation was adopted), or of policy changes focused on one sector but without a comprehensive perspective. Therefore, there are areas where more than one agency control and enforce regulations simultaneously, generally without coordination and in an inconsistent manner – and often with different sets of regulations. Governments should in this respect identify main areas of overlap and duplication among existing institutions authorized to inspect and enforce regulations with the aim to minimise those where necessary.
2. Institutional arrangements will inevitably be diverse, depending on constitutional and other contexts. However, international experience shows that there is only a limited number of different types of risks, that should form the basis for restructuring. One of the possible approaches is an institutional structure close to a "one risk, one inspectorate" model, while of course accommodating local priorities and acknowledging that sometimes mergers can be very difficult and improved coordination can be an acceptable solution.
3. The suggested most important core inspection and enforcement functions that should serve as foundation for such a structure include:
   -Food safety
   -Non-food products safety
   -Technical and infrastructure/construction safety
   -Occupational safety and health
   -Environmental protection
   -State revenue
   -Transportation safety
4. It should be noted that there is a trade-off between consolidation (and thus rationalization) and specialisation, which can help deliver better results in very narrow, high-hazard areas. Thus, governments may decide to split some of these core functions to keep some higher levels of specialization (including e.g. between financial services, banking, insurance – or to keep aviation separate from other transportation means). In other cases, the added value of resource-sharing and coordination may be deemed more important, and additional consolidation can take place (e.g. merging food and non-food safety, or even setting up a single inspectorate for most technical safety functions, with different internal departments looking at specific issues but under a joint management).
5. The aim of such re-organisation should be not only to remove duplications (thus decreasing costs and burden) but also to improve coordination and focus, and allocation of resources. Thus, the new structure should be implemented alongside a review of the resource repartition between enforcement areas (in line with principles 1 and 3). It should also be an opportunity to improve coordination and information sharing, and to improve governance (in line with principle 7).
6. An important aspect of potential duplication, and need for coordination, is the interaction between national (or federal) level inspectorates, and local ones (at whichever level of local jurisdiction). It is needed to consider both

levels when reviewing functions and competences, so as to ensure that there is no duplication of work, nor additional burden due to repeated checks by different levels, and that coordination and exchange of information between these different levels are fully effective.

Best Regulatory Practice[10]

There are commonly accepted practices connected with regulatory activity at all levels of government.

Consider Best Practices

If council has decided that regulation is the method that will achieve the highest level of compliance, staff will carry out an analysis of specific terms and conditions, leading to the writing of a draft bylaw. In doing this, there are a number of practices to consider. These have been sourced from related literature and are grouped under the following headings – A Solid Start, A Rigorous Assessment and A Clear Conclusion. Rather than prescribing the "best practice", this guide poses a number of questions associated with each topic for consideration by everyone involved.

A Solid Start

One of the key elements of good regulatory practice is being well prepared. Here are three practices that governments commonly use at the front end of developing new or updated regulations.

Check on legal authority. Does the government have authority to proceed with a regulatory measure? Is there any potential overlap with another level of government?

Define the problem. Are the causes and the symptoms of the issue identified? Is this documented in a report to council? Is this information publicly accessible?

Involve those affected. Is there a communications and consultation process for involving those who are affected by the problem and, potentially, affected by the outcome? Is there a publicly accessible report that outlines this process?

A Rigorous Assessment

Best practice suggests that a thorough and systematic assessment be undertaken, particularly when issues are complex or contentious. The five practices identified below are ones that should likely be undertaken during the assessment period.

Generate options Have a variety of terms and conditions been considered that would result in the best outcome for most people? Has research been undertaken that would help inform the options being considered? Have other municipalities been contacted, particularly neighbouring municipalities that may have experienced similar problems? Have non-prescriptive approaches been fully considered?

• **Compare and assess options**. Have the options been analyzed in terms of shortand long-term costs and benefits? Have unintended outcomes and consequences been anticipated? Has stakeholder input been fully taken into account? Has the option that will achieve the highest level of voluntary compliance been selected? If not, why not? Is the analysis documented in a report to council? Is this information publicly accessible?

Re-evaluate the "final draft" option. This is a central aspect of finalizing any regulatory measure. The evaluation should address commonly accepted principles of good regulatory practice. An evaluation tool is presented at the end of this section.

• **Make costs of complying reasonable**. Are proposed licence fees or fines reasonable relative to the significance of the matter? How do they relate to the actual costs of administration and enforcement? How do they compare with nearby municipalities? What are the consequences of too high or too low a fine or licence fee? Will too low a penalty result in people ignoring the regulation? Have the cumulative indirect costs of compliance been considered?

• **Ensure reliable enforcement**. Have steps been taken to ensure that those who administer the bylaw have the resources to respond in a timely way? Does the municipality have bylaw enforcement officers to accommodate the anticipated new responsibilities? Or, if there are going to be new administrative requirements, does staff have the capacity to add these to their work program?

After assessing and selecting terms and conditions, municipal administrators will give direction for bylaw drafting. Best practice research addresses this key element and also points the way to further processes. Here are five practices that municipal governments may consider.

Write in plain language. Is the bylaw clearly written and easy to understand? Will complexity lead to unintended consequences? Will citizens and businesses understand the rules and their impact?

• **Explain the reasons for a decision.** Is it clear what factors were taken into account in the decision-making process? Can the decision be publicly justified? How has the outcome reflected public and stakeholder input?

• **Consider other ways to increase compliance**. Would a regulatory bylaw benefit from complementary measures such as a companion education program or third party monitoring? When the bylaw comes into effect, would a news release and media backgrounder be helpful to assist in an understanding of the issue and its resolution?
• **Set up a way to evaluate effectiveness**. Have measures of effectiveness been identified? Has a monitoring system been established? Is there a commitment to report back on the effectiveness of the new (or amended) regulatory bylaw after a reasonable period of time?
• **Commit to a review**. Will this regulation be regularly reviewed to ensure that it is still appropriate and necessary? Is there a "sunset clause" in the bylaw? Or, has another expiry provision been incorporated? If not, what are the reasons why either provision cannot or should not apply?

Involve those affected
"Involve those affected" by the issue is one of the best practices dentified in Consider best practices. It is expanded upon here.

A Communications and Consultation Process
There is much to gain when regulation is approached in an open and transparent manner. Consultation increases opportunities for effective problem-solving by engaging those with interest and ideas. It also helps to air opposing interests and practical problems. And, importantly, because the issue is to be openly discussed, it may increase voluntary compliance and reduce enforcement costs.
When a municipality – or group of municipalities – is considering regulation as the principal means of problem-solving, staff will generally develop a communications and consultation plan and submit this to council(s) for review.

A typical communications and consultation process usually includes:
- the identification of interested parties. This will include those individuals, businesses and organizations potentially affected by any form of regulation, groups that have a wider interest and, perhaps, other levels of government. And importantly, if the municipality has its own internal review processes – staff committees, standing advisory committees – these need to be identified;
- the proposed means of communicating with interested parties on an early and ongoing basis. This may involve media relations, paid advertising, newsletters, mailings, web site, and local radio talk shows. The identification of a spokesperson is also important. This could be a member of council or a senior staff person; and
- the proposed means of consulting with interested parties. This may involve stakeholder meetings, an ongoing advisory group, public meetings, open houses and surveys, or a combination of these. Dates and venues for events benefit from being scheduled well in advance.
- the identification of what written and web-based information is needed. As much information as possible should be provided to ensure informed input and decisionmaking. This would likely include background information used for defining the problem, any resource material from other municipalities that have tackled the issue, and any work done on the costs and benefits of alternative regulatory approaches.
- a clear and defined time frame for consultation, along with an identification of any milestones and a general date for reporting back to council. At times, processes become unnecessarily complex or time consuming if the time frame is not clearly defined at the outset.
- the anticipation of costs. These are important considerations for council, particularly if the current budget did not anticipate the need for this process. Staff costs will include time for organization of the consultation process, analysis of the input and an assessment of any unintended consequences.
- the identification of how to be accountable. When a decision is made – or regulatory bylaw is adopted or amended – those who had input into the consultation process want to understand how their input influenced the outcome. A public report that describes the consultation process and the input and feedback received is one way of demonstrating accountability.

Case Studies of Regulatory Practices
A scan of municipalities in British Columbia revealed a number of relatively high profile local issues that, ultimately led to consideration of a regulatory approach, leading to a council-adopted bylaw. While any one of these might have represented an interesting case study, only three were chosen: Dogs off-leash; Noise Abatement; and Business Licensing. Each is based on a real situation, but each is an example of an issue that may arise in communities of all sizes in any part of the province. The case studies give background on the issue and describe the process that led to the specific regulatory outcome. Legal considerations are also discussed, including an analysis of how regulatory

authority could be used from the Community Charter. A commentary note forms the end to each case study. This is provided as a way to link the case study to the principles of good regulatory practice and, where appropriate, to suggest ways in which the process could have been enhanced or modified.

CONCLUSION

Any medicinal agent to be marketed in the United Kingdom has to follow the guidelines and regulations framed by MHRA, a regulatory authority which approves the drug products. The objective of this review article is to highlight information regarding the requirements, the different types of submissions for the registration of a medicinal product in a market in the UK. It also includes all the details about the fee for the application and the time period for the approval of the application after the submission of the application. By knowing the requirements of the MHRA guidelines and regulations, it is easy for a product to get into the UK market. Those rules, procedures and practices that govern the rule-making process itself are intended to improve regulators' decisions, and hence to deliver both substantive and process outcomes. Unfortunately regulatory policies have until now been far too often recommended without serious evaluation to support them. They may well be justified, but to correct for the paucity of systematic, causally oriented research on regulatory policy, governments will need to evaluate the substantive outcomes of their regulations using the framework of indicators and research designs. They also need to apply that same framework to evaluate the distinctive process outcomes that regulatory policy aims to achieve.

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