

## **Regulatory excess: The role of regulatory impact assessment and the Competition Commission**

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### Abstract

South Africa is undergoing a major regulatory reform phase. On the one hand, state owned enterprises are being restructured in various ways, including the introduction of competition. This requires a rethink of the regulatory regime to take into account new developments in the market. On the other hand, there has been a proliferation of new legislation and regulations with which business, both big and small, has to comply. These range from environmental regulations, to labour laws, to tax laws and to price regulations. Many, if not all of these new regulations have been imposed without a pragmatic analysis to take into account the impact of such laws on the ability of firms to perform optimally. The lack of regulatory impact assessment is a flaw in the formulation and implementation of regulations.

Taking the pharmaceutical industry as a case study, this paper will draw attention to the regulatory web entangling firms and to highlight the crucial necessity of assessing regulations before and after implementation. The paper will also highlight the vital role of the Competition Commission, through its advocacy function, in assessing the competition impact of new laws and regulations, and in ensuring a proper regulatory regime during the transition to market liberalization.

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## 1 Introduction

The OECD (1996) defines regulation broadly as a full range of legal instruments by which governing institutions, at all levels, impose obligations or constraints on private sector behaviour. Regulation can also be defined as “the sustained and focused control, normally by a public agency, over activities that are valued by a community.”<sup>2</sup> For purposes of this paper, regulation is assumed to encompass all laws, regulations, and requirements placed by government on business and society.

Regulation can be divided into two main forms, economic and social. Economic regulation is concerned with the regulation of prices, profits, revenue, output, service delivery or market entry by firms (Guasch & Hahn: 1997). The rationale for economic regulation stems from market failure, that is, the belief that under certain conditions the market system may not lead to desirable outcomes. Such conditions include the presence of natural monopolies, public goods, externalities and a skewed distribution of income. In such circumstances, the state is required to intervene with corrective measures.

Social regulation focuses on issues as such environmental and safety standards, the treatment of workers and eliminating discriminatory practices against minorities. It may also be aimed at giving opportunities to previously disadvantaged communities (ESMAP Report: 1999). The purpose of all regulation is to prevent undesirable behaviour, actions and activities while at the same time enabling and facilitating desirable ones. Thus, most government regulation has a public interest slant and, its objectives and purposes are, in most instances, laudable. However, regulations have what are called ‘unintended consequences’, or side effects, that may manifest in the form of inhibited business competitiveness, reduced investment, decreased competition, derailed economic growth, heightened job losses and an increased cost of doing business. A cost benefit analysis is thus imperative in ensuring that the benefits of regulation justify its costs.

South Africa is undergoing a major regulatory reform phase. State owned enterprises are being restructured along the lines of market liberalization in some instances; public-private partnerships and concessionings are taking place in others. This requires a rethink of the regulatory regime to take into account new developments in the market. On the other hand we have a proliferation of new legislation and regulations with which business, both big and small, have to comply. These range from environmental regulations, to labour laws, tax laws and to price regulations. Again, this requires a pragmatic approach to take into account the impact of such laws on the ability of firms to perform optimally.

What is of concern is that, instead of reviewing past laws and evaluating proposed ones, laws are being developed faster than they can be implemented. For instance, close to eight hundred new acts of parliament<sup>3</sup> have been passed in South Africa since 1994 in addition to countless regulations, provincial laws and municipal by-laws. Despite an

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<sup>2</sup> <http://www.unescap.org/tctd/pubs/files/econreg.ch1.pdf>

<sup>3</sup> Including amendments to existing legislation

obvious and apparent regulatory excess, governments continue passing legislation that may not be needed and keeping a lot that is redundant.

The purpose of this article is to highlight the crucial necessity of assessing regulations before and after implementation, for purposes of accountability, transparency, consistency, efficiency and effectiveness. It also seeks to draw attention to the vital role that the Competition Commission (Commission) plays in assessing the competition impact of new laws and regulations and in ensuring a proper regulatory regime during the transition to market liberalization as part of its advocacy function. The next section discusses the costs and benefits of regulation and the need to weigh these costs against the envisaged benefits. Section 3 looks at impact assessment studies, focusing on a widely accepted scientific method of appraising regulations. Issues around the regulation of the pharmaceutical industry are discussed in section 4, using the South African industry as a case study. The role of the South African Competition Commission in assessing regulations and advocating for competition during the process of restructuring state owned enterprises is discussed in section 5. Section 6 outlines some policy recommendations and draws a conclusion.

## **2 Costs and benefits of regulation**

Whilst the objectives of regulations are highly appreciated and the public interest they serve well understood, it is not always clear at what cost these benefits are attained. Evidence, even though sometimes anecdotal, suggests that legislators do not always factor in the cost of the regulations they impose on business and society at large. The cost of regulation involves compliance costs borne by businesses and implementation costs borne by government.

### **2.1 Cost to business**

The costs to business associated with regulation are outlined as follows: compliance costs, industrial concentration costs, transition costs, impact on international competitiveness, product prices and managerial time.

#### *Compliance costs*

The cost of complying with legislation increases the transactions cost of doing business, which impedes productivity, competitiveness, job creation and economic growth. Luus (2004) identifies over-regulation as one of the growth inhibitors in South Africa. Furthermore, companies have to employ what are called ‘compliance officers’ whose sole mandate is to help them comply with a myriad of laws, to avoid prosecution for noncompliance. Because of their size and limited resources, regulations seem to weigh more heavily on small and medium sized entities. Some small businesses may even choose to remain small and informal to avoid getting entrapped in the regulatory net. This entails an indirect cost to society in the form of forgone jobs, investment, innovation and growth. The American Bankers Association estimates the compliance costs borne by the banking industry in America to be in the region of US\$16 billion per annum<sup>4</sup>. Although

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<sup>4</sup> [http://www.aba.com/Industry+Issues/Issues\\_Reg\\_Burd\\_Menu.htm](http://www.aba.com/Industry+Issues/Issues_Reg_Burd_Menu.htm)

one is not aware of similar studies that have been undertaken in South Africa, it can safely be concluded that in most instances the benefits of regulation do not justify the costs.

#### *Industrial concentration costs*

Where regulation takes the form of licencing or long patent periods, society pays the cost of industrial concentration ((Chinloy: 1989). Licences and patents create artificial barriers to entry. This results in highly concentrated or monopolistic industries, which are accompanied by higher product prices due to lack of competition. This is not to say that patents are necessarily bad. There must be a trade-off between the benefits of patent protection (allowing firms to earn a return on their investment) and the cost to society of maintaining a monopoly (high prices) and the restrictions on information-spread. On the one hand government wants to encourage innovation and R&D expenditure by say, pharmaceutical industries, and on the other it wants to discourage them from charging exorbitant prices. For the former, government relies on patent protection and for the later it relies on competition or price regulation.

#### *Transition costs*

The costs of regulation are not limited to the compliance costs borne by companies and the implementation and enforcement costs borne by government. Companies also incur what are called transition costs that come with the introduction of new laws or changes to existing regulations. Dorfman (1997) defines transition costs as the costs of adapting to a change in circumstances. The introduction of a regulation or an amendment to an existing regulation disturbs the equilibrium position of the industry concerned. Before industry can settle at a new equilibrium point, there is an intervening time when changes have to be made and costs incurred. These costs will not recur once equilibrium has been reached. For instance certain changes would have to be made to a company's capital equipment, to comply with, say, a new emissions policy.

#### *International competitiveness*

At a time of accelerated globalisation, South African firms may be at an international competitive disadvantage vis-à-vis their counterparts in other countries who may not be subject to similar regulations. An intrusive regulatory environment dampens the spirit of entrepreneurship.

#### *Product prices*

To the extent that all these costs form part of the operational costs of firms, they are passed on to consumers in the form of higher prices (Louw: 2004). Products are made expensive by regulation.

#### *Managerial time*

Indirect costs include the distraction of executives to ensure compliance with regulation. A lot of human resources and time are expended in dealing with regulations. The opportunity cost of these resources is their next best alternative use. Time, labour and money that could have been spent in innovation projects are now spent in regulatory compliance programmes.

The Doing Business in 2004 Report<sup>5</sup> provides an indication of the regulatory costs in different countries in terms of the hurdles that business have to overcome in order to start a business, hire and fire workers, obtain credit, enforce contracts and wind up a business. The specific regulations and policies surrounding these indicators have important implications for investment, productivity and growth. In terms of starting a business in South Africa, firms must expect to spend an average of 38 days and to go through 9 steps compared with the regional average of 64 days and 11 steps and the OECD average of 25 days and 9 steps. The flexibility of our labour laws compares favourably with those of the region and the OECD in all but one of the four indices. This goes against the popular belief that South Africa has one of the most stringent labour laws in the world. The World Competitiveness Yearbook<sup>6</sup> measure of the extent to which government policies are conducive to competitiveness ranked South Africa 15<sup>th</sup> in 2003 out of 30 countries, down from 12<sup>th</sup> in 2002. Although this is not an unfavourable ranking, the three-place fall may be attributed to the many laws that are coming through the legislature.

## **2.2 Cost to government**

Government employs multitudes of bureaucrats who are employed to churn out, implement and monitor compliance with legislation. The result is heightened red tape and increased government expenditure. Further, more enforcement measures are needed in today's era of regulatory inflation and this entails a cost to government.

A proliferation of regulations reduces compliance in three ways:

- Regulatory complexity decreases awareness – when regulations and legislation are coming in fast and furious, companies are likely to lose track and fall foul of non-compliance.
- Compliance burden reduces voluntary compliance – when faced with too many regulations, firms' willingness to voluntarily comply decreases.
- Effective enforcement is difficult as the quantity and complexity of requirements increases – government may find it difficult to enforce a multitude of laws.

## **2.3 Benefits of regulation**

Although it is not uncommon to hear the private sector complaining about the potential cost of environmental regulations, occupational health and safety regulations and municipal zoning laws, the truth of the matter is that some amount of regulation is necessary to rein-in unbecoming behaviour by firms and to correct imbalances caused by the market system; sometimes to the benefit of the private sector participants. In the absence of regulation, firms would not invest in processes that result in external benefits to society. For example, although an improvement in air quality accrues to all members of society, firms would not necessarily adopt cleaner technologies voluntarily unless there is a direct benefit to the firm of doing so. Governments then intervene to ensure that firms meet certain minimum environmental or occupational health safety standards.

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<sup>5</sup> See the World Bank's 'Doing Business in 2004 report'

<sup>6</sup> See the IMD World Competitiveness Yearbook, 2003

Whereas such regulation may improve total social welfare due to higher safety and better health, the cost of doing business increases when executives have to spend time dealing with government officials and complying with legislation.

An illustration of the importance of regulation is the US proposals aimed at improving the system of testing for mad cow disease. Industry and other lobbyists opposed the regulations as too radical, onerous and costly for farmers and consumers (Holmes: 2004). However, when the disease was discovered in the State of Washington, the US Department of Agriculture had to reverse its decision and immediately implemented the regulations. Had the industry adopted them earlier, they would have saved billions of dollars in lobbying and fighting against the regulations, as well as the cost of lost exports and the negative publicity following the discovery of the disease.

In his analysis of the regulatory impact in Ghana, Ahortor (2003) observes that businesses in Ghana do not view safety regulations, business licensing requirements and labour laws as infringements on their economic freedoms, but rather as opportunities for creating a competitive environment and attracting foreign investment. In other words, instead of competing on price and product quality only, firms could also compete on regulatory compliance. This may offer some firms a competitive edge. Unfortunately, in South Africa, the general sentiment around regulations is negative. Despite complaints of over-regulation and too much red tape, Hudson (2003) contends that much of the criticism is speculative and based on perception rather than hard core evidence.

#### **2.4 Measuring the costs and benefits of regulation**

A cost-benefit analysis involves summing up all the gains, or positive benefits, created by a change, and then comparing that sum to the total costs of producing the change plus any potential losses or negative benefits induced by the change (Campbell: 1974). Benefits can be measured by the individual's willingness to pay the extra cost brought about by the regulation as reflected in the higher product price. Certain benefits are psychic and can only be experienced by individuals. Such benefits are difficult to quantify. Where quantification is possible, a common measure such as a monetary value is required to sum up the gains and losses. In other words, gains and losses must have a common measurement unit for comparison. In calculating the net benefits of regulation, the benefits of fewer accidents and a healthier workforce are set against the higher cost of doing business which include the direct costs of investing in cleaner technologies and managers' time spent in complying with legislation, an indirect cost (Chinloy: 1989).

### **3 Impact assessment studies**

Impact assessment studies are carried out to evaluate the effect of particular public or private sector conduct and decisions on society, the environment or the economy. The common impact analyses are social impact analyses, environmental impact analyses and regulatory impact analyses.

### **3.1 Social impact assessment**

A social impact analysis can be defined as a process of predicting the manner in which a proposed course of action is likely to affect the way people live, work, interact and function as individuals and as members of society. For instance, an alteration on land use patterns may cause stress, anxiety, social disruption and hunger, among other things. At the beginning of 2000 the Gauteng provincial government announced a proposal to introduce a rapid train service that would link the Johannesburg, Pretoria and the Johannesburg International Airport. Bohlweki Environmental was commissioned to undertake an EAI, which included a social impact assessment study. Although the consultants gave the project the green light, a number of red flags were raised, warranting further investigation. The project is likely to directly affect some 650 homes, which have to be expropriated. This is in addition to the noise, vibration, traffic, archaeological and heritage effects (Davie: 2003). These are social costs, which must be weighed against the benefits of the project.

### **3.2 Environmental impact assessment**

Most private sector and public sector projects have an adverse effect on the environment. Examples include the development of a mining site on land used for other purposes, the development of infrastructure like roads and railway lines or the erection of telecommunication and electricity lines.

Environmental impact assessment is a formal process or set of activities or planning tools used to identify, evaluate or predict the environmental consequences of a proposed development project. The essence of an EIA is environmental protection and sustainable development. It attempts to integrate the environmental protection and economic decisions at the early stages of planning. Society receives net benefits whenever the societal benefits of better health or cleaner air have a greater value than the costs of the pollution reduction (Luken: 1992).

The department of Environmental Affairs and Tourism recently published for public comment a new set of regulations on EIA in terms of the National Environmental Management Act. According to the Minister of Environmental Affairs and Tourism, Marthinus Van Schalkwyk, the new regulations will ensure a more streamlined EIA process, which will speed up the decision making process and reduce the time it takes to process an EIA by 20% over the next three years<sup>7</sup>. This is an example of the importance of assessment studies.

### **3.3 Regulatory impact assessment**

As already alluded to, past experience suggests that legislation is often developed and implemented with little regard to its impact on the economy. This is the essence of legislative inefficiency. Policy makers either overlook or simply do not explore other

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<sup>7</sup> Van Schalkwyk, M. Speech during National Assembly debate on Budget Vote 28: Environmental Affairs and Tourism, in Parliament, 17 June 2004.

options of achieving the same results. For instance, it might be that there are other ways of ensuring low prices for consumer products than price regulation, or there may be other ways to mitigate job losses with less adverse effects on economic performance than stringent labour laws (Mihlar: 1998). Simply put, policy makers rarely employ a cost-benefit analysis or a regulatory impact assessment (RIA) of proposed and existing regulations. This leads to a proliferation of ineffective, inappropriate and unnecessary laws that do not stand up to scrutiny, and lots that are sometimes never implemented. All this is a sheer waste of much needed resources that could be employed productively elsewhere. According to Medalla (2000), government policies appear to erect barriers to entry or affect the state of competition when government intervenes with such policies. Such policies can be grouped into three: government regulation of an industry; direct government equity participation and; other regulatory restrictions. These regulations serve important objectives and at times can even be pro-competitive. However, there is a need to evaluate and review such policies and regulations pass them through a competition test or at least justify them on public interest grounds (Medalla: 2000).

A regulatory impact assessment, also known as a regulatory impact analysis, is a form of a cost-benefit analysis tool, a means of appraising the costs and benefits of proposed regulation and evaluating the performance of existing ones (Kirkpatrick: 2003). Smith (1998) defines RIA as the systematic ex ante estimation of the effects of regulatory proposals. The use of RIA helps policy makers to ask questions such as is there a need for this law? Will it meet its objectives? Is it the most cost-effective method of protecting the public interest? Will it have unintended side effects? What are the likely benefits of this law? What about the costs to firms/society? etc.

Most countries, at different stages of development, now have RIAs in place that allow lawmakers to justify whatever law they propose by enabling them to compare various options, identify costs and benefits for each option and choose the option with the least cost, whose benefits exceed the costs. It is time that South Africa should use the same approach. Moreover, at a time when governance is a top priority for both the private and public sectors across the globe, RIAs can also be used as processes that contribute to better governance, by improving transparency and the accountability of public decision-making.

According to Kirkpatrick (2003) about 20 OECD countries had some form of RIA in place at the beginning of 2001. Jacobs (1998) also notes that many countries in Europe and outside have adopted measures and programmes in the past several years to simplify or reform their regulatory processes. These programmes range from sector specific measures like the reform for taxi competition in Sweden and the Netherlands, to general reform programmes focusing on reducing the administration burden caused by paperwork required for company registration, statistical information requirements and tax filings.

### Formal stages in the legislative process in SA

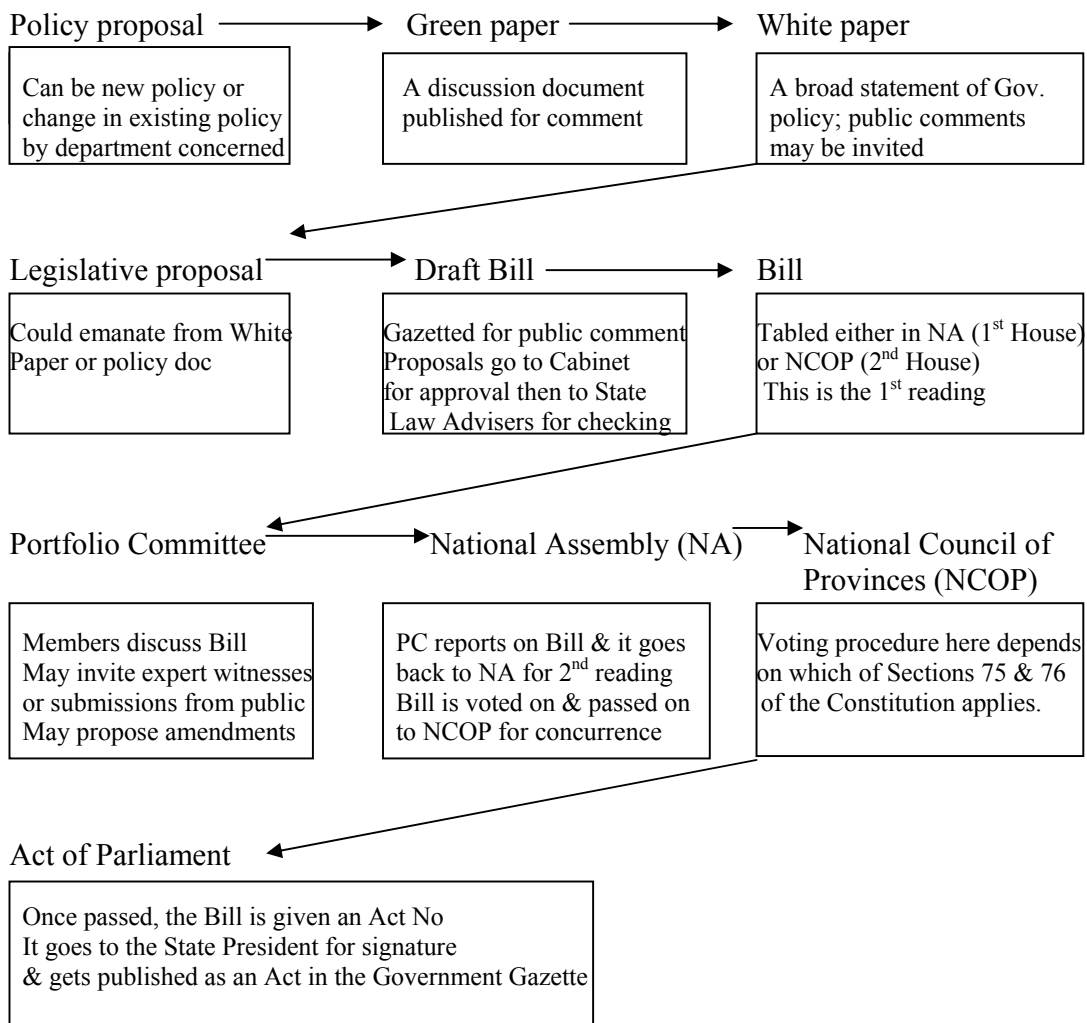


Fig 1<sup>8</sup>.

The above figure illustrates the legislative process in South Africa. The conspicuous absence of an impact assessment criterion is apparent. Although the process involves some form of public consultation and debate at the National Assembly, it is not clear to what extent the views, comments and objections of interested parties and the public are taken into account. What is more worrying is that in certain instances no research documents or background information to the policy or legislative proposals are available<sup>9</sup>. In some countries a Cabinet checklist is used to ensure quality of legislation. Such a checklist, as exists in Ireland and other OECD countries, includes questions such as:

<sup>8</sup> Adapted from Legilink and Parliamentary Monitoring Group websites

<sup>9</sup> Efforts to obtain research or background documents to the DTI's scrap metal policy introduced and withdrawn within 3 months early this year were not fruitful.

1. Is this legislation absolutely necessary? Are there other means of attaining the same objectives?
2. Will the legislation affect market entry, restrict competition and result in administrative burden?
3. Outline the consideration given to sunseting and review date.
4. Outline the extent to which interested/affected parties have been consulted (OECD: 2001).

Van Kreveld (1998) identifies ten requirements for legislative quality: Legislation and regulations should be:

- ✓ Issued only if necessary and should be proportional
- ✓ Stable and predictable
- ✓ Compliant, applicable and enforceable
- ✓ Effective
- ✓ Consistent and coherent with the whole body of legislation
- ✓ Simple, clear and transparent
- ✓ Founded upon careful consideration of all relevant facts, interests and alternatives
- ✓ Easily accessible to the public together with an explanatory memorandum
- ✓ Subject to superior law
- ✓ Subject to the primacy of parliament

The use of a regulatory impact assessment would ensure that for every proposed regulation, the economist or policy maker interrogates the following: How would the regulation affect the supply of a particular product? How will it affect product prices? What about the export potential of firms in the industry? Will it be possible to import products and at what price? What would happen to product quality? How will the availability of substitutes and their prices be affected?

The importance of RIA lies in its ability to predict whether a regulation would yield a net benefit to society. Applied to a range of competing policy options, it can guide choice towards that likely to have the greatest net benefits. The need for RIA arises partly because many policy impacts are indirect and not easily identifiable. It is also an important mechanism for ensuring that policy choice is not industry biased by strong interest groups. RIA is crucial to regulatory quality. Dynamic quality is assured by applying RIA to existing regulation as part of the wider review process. RIA focuses on efficiency achievements of regulatory objectives at least cost.

Other advantages of using a RIA include the protection of independent regulators from political interference, the establishment of regulatory legitimacy and the assurance to government, business, consumers and stakeholders of the logic of regulatory decisions. In short, a properly formulated RIA should help to achieve the following pillars of an efficient regulatory system:

- ✓ Accountability - Regulators should be able to justify and account for their actions and decisions to the general public.
- ✓ Transparency – The public should know why and how certain decisions are taken by government and should be free to participate in the decision making process.

- ✓ Consistency - The purpose of legislation is to provide guidance and direction. Thus, the application of regulations should be uniform, consistent and predictable.
- ✓ Independence – Regulatory agencies should execute their tasks and make decisions without external pressure or influence.
- ✓ Proportionality – The tightness or looseness of the regulation should correspond with the degree of market failure in question.
- ✓ Targeting – Regulations should be aimed at the problem at hand and spillovers to other unintended areas should be avoided.
- ✓ Representation/Inclusivity - The policy making process should take into account the views and concerns of all stakeholders for easy buy-in.

When it comes to methodology, there is no single or right way of conducting a RIA. Some methodologies consider the monetary values only in their estimations whilst others use a combination of quantitative and qualitative data. However, RIAs should be used as an aid to decision making rather than a mechanism for reaching a single definitive answer to a policy problem. In other words, it should be used with some flexibility and not as a strict methodology to be followed at all cost. In terms of structure, a RIA unit can be housed within a commerce department like the departments of trade and industry, finance or public enterprises. Alternatively it can be the function of the parliamentary accounts committee. Other countries have stand-alone units that evaluate all laws in the country while others leave it up to individual regulators or government departments to do their own RIAs. Whatever the structure or methodology used, the fact of the matter is that RIAs should be an integral part of any modern public governance structure.

Central to the issue of governance is how well the link between policy formulation, co-ordination and implementation is managed. If this link is well managed, the results are a more predictable policy framework and better regulation. The recent UNDP Report on South Africa (UNDP: 2003) notes that the post-1994 period has been characterized by wide-ranging and fundamental policy and legislative reforms. However, it further notes, that whilst hundreds of policies and laws have been developed, implementation remains a major hurdle. One of the reasons for this implementation gap can be traced to a lack of a proper appraisal of the policies and legislation developed.

A properly conducted RIA should help identify other means of attaining the same goal as regulation. The following are possible alternatives to regulation<sup>10</sup>:

*Hands-off approach* – In certain instances, regulation could be the last thing needed. This may be the case where regulation is likely to compound the problem. It may also be the case where the market is evolving; that is, over time, the problem would diminish. Also, there is no point in passing regulations where enforcement seems difficult. Doing nothing is, thus, sometimes the best antidote.

*Creating a market* – opening up an industry to competition could take care of a number of problems like inefficiency, high prices, lack of investment etc. This could involve removing barriers to entry, both legal and institutional.

*Use of market instruments* – Where intervention is inevitable, the use of market-based instruments like subsidies, user charges and taxes, is recommended.

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<sup>10</sup> <http://www.cabinet-office.gov.uk/regulation/ria-guidance/content/alt-regulation/index.asp>

*Use of common laws*– Many activities in the economy are subject to countless overlapping regulations including common laws. In some cases the use of common laws only, or other existing laws may suffice.

*Self-regulation* – Most industries have codes of practice/ethics that govern the behaviour of players in that industry. Membership of professional associations can play an important regulatory role.

*Information dissemination* – Addressing information asymmetries between buyers and sellers may actually resolve the problem of policy failure with no recourse to regulation.

## **4 Pharmaceutical industry regulation**

The manufacture, registration and sale of drugs have been the subject of strict regulations and administrative procedures for decades the world over. The regulation of pharmaceuticals relates to the control of manufacturing standards, the quality, efficacy and safety of drugs, labeling and information requirements, distribution procedures and consumer prices. Cumbersome business registration requirements might act as barriers to entry and exit, thus affecting the structure of the industry and therefore the amount of competition. Licensing requirements also restrict the number of players in a particular market, and so do intellectual property rights laws.

### **4.1 The case for and against pharmaceutical regulation**

The case for regulating the manufacture and sale of drugs stems from the state's paternalistic responsibility. In terms of public economics theory, the state has a role to play in the economy, including that of protecting its citizens. Because consumers do not always have sufficient information to make informed decisions, and because firms do not always have the best interest of consumers at heart, governments often take it upon themselves to play the guardian by requiring firms to abide by certain standards in order to protect consumers.

An abdication of this role can be disastrous to society. Two historic cases illustrate the case for government regulation of drugs very well. These are the Elixir Sulfanilamide tragedy, which occurred in the US in 1937 and the Thalidomide disaster, which occurred in Europe in 1961. The former case involved a concoction of the drug Sulfanilamide. Under the existing drug regulations, pre-marketing toxicity testing was not required and in this case was never done. 105 people, mainly children died as a result. This led to the passage of the 1938 Federal Food, Drug and Cosmetic Act requiring pharmaceutical companies to submit new drug applications to the Food & Drug Administration (FDA) showing drug safety and efficacy before distribution. In the latter case, Thalidomide, a drug developed as a sedative and anti-anxiety medication was widely prescribed during pregnancy. Thalidomide was patented in 1957 and marketed in Europe in 1958 after toxicity studies in lab animals as well as human beings showed it to have very low toxicity levels. However, no studies were carried out to determine the likelihood of the drug causing abnormal development of the embryo. By 1961, many complaints had been received from users, but thousands of babies had already been born with malformations.

Dukes and Broun (1994) identify seven reasons why pharmaceuticals require regulation:

- a) Users do not exercise choice. Doctors or health care workers make prescriptions.
- b) Where consumers can make a choice, they lack the ability to compare different drugs on quality, efficacy, suitability and even price.
- c) Pre-marketing studies on safety and efficacy are sometimes contradicted by the results of drug use.
- d) The user is often insulated from the price consequences of drug consumption through the public or private sector medical insurance systems.
- e) Assessment of the efficacy of the drug is made difficult by a number of intervening factors that contribute to the ailment.
- f) The patient's hopes and expectations also influence objective assessment.
- g) The fear of illness creates an unreasonable demand for drugs.

Despite the benefits of government regulation in pharmaceuticals, free marketers and libertarians would argue that paternalism belongs in the home. Individuals should be given the right to choose and drug companies should be given the space to innovate. The case against drug regulation is strengthened by the fact that efforts to regulate the industry have at times been counterproductive in most countries around the world. Instead of improving the system, regulations have often led to new inefficiencies and heightened bureaucracy. Where no consultation or negotiation has taken place in adopting certain policies, they have led to conflicts between government and industry. Where registration processes and requirements are cumbersome, multinationals are wary of registering new drugs in these countries. It is believed that India's drug price regulations in the 1970s and 1980s led to a decrease in investment, productivity, capacity utilisation, R&D and overall profitability (Chinloy: 1989). Rigid, time consuming and elaborate testing and registration processes may lead to a slowdown in innovation. As a result, new drugs and vaccines are sacrificed on the altar of regulation. Extreme process regulation creates incentives to locate production elsewhere. At the end of the day consumers again are the main losers as they are denied access to essential drugs.

Since firms compete on various aspects including product quality, it can be argued that in the absence of regulation, reputation becomes the most important guarantor of high quality and standards<sup>11</sup>. Companies have a lot to lose from a fall out with consumers as a result of sub-standard or harmful products. Where reputation matters, firms will strive for high standards. The problem with regulation is that it can result in moral hazard. When consumers equate regulation to safety, they are likely to be relaxed and careless when dealing with a regulated industry or product. They tend to find solace in the fact that government requirements have been met therefore the product is assumed to be safe. Officials working at pharmaceutical regulatory institutions can make human errors in their judgements. There are two types of errors likely in this case: Type 1 error could occur where an official does not approve a product that is safe and efficacious. Type 2 error involves the approval of a product that is not safe or efficacious. Therefore in order to 'play it safe', officials could turn down applications or stall for time by requiring more research by the drug company (Higgs: 2004, Chinloy: 1989). The forgone benefits of

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<sup>11</sup> <http://www.samizdata.net/blog/>

regulatory induced delays in obtaining new drugs must be weighed against the benefits of less exposure to drug toxicity.

Nonetheless, pharmaceutical companies have been subjected to two broad categories of regulation: 1) the registration and administrative process and 2) the regulation of quality; manufacturing standards; efficacy; information disclosure; competence of drug prescribers and dispensers; pricing and cost control; access and expenditures. The pharmaceutical industry in South Africa is no exception. The following two sections will discuss the drug registration process and the regulation of prices and cost in South Africa.

#### **4.2 The drug registration process in SA<sup>12</sup>**

The Medicines and Related Substances Control Act No. 101 of 1965 (the Medicines Act), as amended, is the principal act governing the manufacture, registration and sale of drugs in South Africa. The Medicines Act makes provision for the publication of numerous Regulations and Guidelines by the Medicines Control Council (MCC), the pharmaceutical regulatory authority. There are fifty general regulations that accompany the Medicines Act. The MCC is also required to publish Guidelines. These are categorized into five main sections: Good Manufacturing Practice; Human Medicines; Veterinary Medicines; Licencing and; Miscellaneous. Altogether there are about 52 guidelines issued by the MCC currently. These guidelines are meant to assist the industry in complying with the requirements of the Medicines Act. The registration of medicines is governed by Regulation 22. The Medicines Act requires that the MCC shall register every medicine before it may be sold or marketed. Companies are required to submit applications for the registration of medicines for evaluation and approval.

The Medicines Control Council may speed up the registration process for medicines under the 'essential drugs' list or those that are already registered in countries with whom the MCC has some kind of understanding, or those considered essential but not appearing on the 'essential drugs' list. The MCC operates through expert committees manned by specialists from various institutions around the country. There are 11 such committees at present that evaluate volumes of data submitted by drug companies for registration purposes. Since the MCC is a juristic person, it can sue and be sued. This impacts on the decision making process, since individuals become cautious in making decisions for fear of being sued.

The process of getting a new drug on to the pharmacy shelf starts with preliminary research by the drug company. Pharmaceutical companies spend a major portion of their budgets on research and development. Pre-clinical and clinical trials are undertaken to determine the safety and efficacy of drugs. Animal tests are done to determine the toxicity of the drug. Healthy human tests are used to determine the levels and rates of absorption, distribution around the body, excretion, metabolism, efficacy and the like. The MCC regulates three aspects of drug use: safety, quality and efficacy. When applying to register a drug manufacturers are required to furnish the MCC with a dossier of information including the purpose of the drug, its efficacy, side effects, contra-

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<sup>12</sup> <http://www.mccsa.co.za>

indications, warnings on usage by children or during pregnancy, storage and disposal. The application procedure is very elaborate involving strict compliance with the administrative information requirements, labeling requirements, information on pre-clinical and clinical trials, information on manufacturing standards, safety, etc. An audit of the factory where the drug is manufactured may also be done, to assess manufacturing standards. According to MCC policy only medicines manufactured, packed and quality controlled at sites compliant with the current principles of Good Manufacturing Practice (GMP) as prescribed will be considered for registration.

The MCC makes use of expert committees that go through huge amounts of data. These experts are not necessarily full time employees of the MCC, but are drawn from academia, industry and government. There are no statutory time lines for the processing of applications for registration purposes. However, time is of the essence in the pharmaceutical industry. Firms have to have new products to survive. Generic manufacturers are in turn dependent on innovation by brand manufacturers. A slow registration process impacts negatively on the firms' operations. Firms are not the only ones that are affected. Patients are deprived the benefit of new drugs that may ease their suffering or those benefits come later rather than sooner. After assessing the application, the expert committees have to compile reports for the MCC. These expert reports also follow strict procedures. The MCC is a juristic person that can sue and be sued. This impacts on the decision making process, since individuals become cautious in making decisions for fear of being sued. However, like many government institutions it also suffers from a lack of resources and this is reflected through its turnaround times. Although the MCC claims that the registration process takes between 12 to 18 months, statistics show that this figure can range between 3 to 5 years with a yearly average figure of 33 months in 2000, 38 months in 2001, and 39.8 months in<sup>13</sup>.

### **4.3 Price regulation**

Section 22g of the Medicines Act allows the Minister of Health, on recommendation by the Pricing Committee, to make regulations relating to:

- a) the introduction of a transparent pricing system for all medicines and scheduled substances sold; an appropriate dispensing fee to be charged by pharmacists and dispensing doctors/registered nurses;
- b) an appropriate fee to be charged by wholesalers, distributors and other sellers of scheduled substances.

According to the Medicines Act, the transparent pricing system shall include a single exit price (SEP), which shall be published as prescribed. The SEP shall be the only price at which manufacturers shall sell medicine and scheduled substances to any person other than the state. On the 16<sup>th</sup> of January 2004, the Department of Health (DOH) published the pricing regulations in the Government Gazette for public comment. The regulations aimed at reducing pharmaceutical product prices, introduce transparency in the pricing system and do away with a system of bonuses, rebates and discounts. Whilst the need for

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<sup>13</sup> Statistics compiled by Pharmnet as published by the MCC for submissions and registration dates.

transparency within the distribution chain and low prices for consumers is recognized, it is not clear whether the use of direct price control as a means of achieving this is appropriate. In their original form the regulations proposed a 50% reduction of the Blue Book prices, thus effectively capping the SEP at 50% of the Blue Book prices. The idea behind this regulatory proposal was based on the belief that pharmaceutical product prices are inflated by rebates, bonuses, discounts and the lack of transparency therein. However, of concern to the industry was the fact that the 50% reduction to be applied across all types of pharmaceuticals assumed that there were equal markups applied to all products, whereas this was surely not the case. Pharmaceutical manufacturers stated that discounts offered vary on a company by company and on a product by product basis and in some cases a 50% reduction in prices would not be possible without losses being sustained. As a matter of fact, industry research found bonuses and rebates to be in the region of about 15%. Thus, to assume that all pharmaceutical product prices are inflated by the same amount, without empirical evidence was too simplistic. Therefore, not only did the 50% figure appear to have been chosen arbitrarily, but also it would have affected different products and different manufacturers differentially.

According to industry sources<sup>14</sup>, firms spent a lot of time and resources consulting and lobbying government. Manufacturers had to make presentations to the Department of Health. They used the services of consultants to undertake research and employed independent auditors to verify their cost structures and pricing processes in order to convince government that manufacturing prices are not as high as alleged and that the proposed 50% across the board reductions in manufacturers' prices would be unjustified. This entails a cost to the industry. Implementing the SEP required certain logistical configurations. Again, this is a form of transition cost to the industry.

Regardless of the level of the SEP, the fact of the matter is that it is a form of price control. It caps the maximum price at which pharmaceutical products may be sold. Maximum prices are set in order to, among other things, keep the prices of essential goods/services low and avoid excessive pricing and exploitation of consumers. However, where there is a need to intervene in prices, price regulation theory indicates that subsidies are preferable to maximum or minimum prices. Since maximum prices are set below equilibrium price, not only would they distort the market by creating excess demand but also they have the potential of limiting competition in the market. Actually, the SEP removes the benefit of price competition along the supply chain. Whether the forgone benefits of competition and the costs of a distorted market are outweighed by the benefits of transparency and low prices, cannot be ascertained without an extensive assessment.

The regulations also put an exact value on the services of wholesale, distribution and retail, regardless of the size of delivery, the remoteness of the buyer, and the value of the medicines (above a fairly low rand value). These stipulations also amount to a form of price control and will affect the viability of the various players in the supply chain of pharmaceuticals in possibly unintended ways.

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<sup>14</sup> An interview was held with Maureen Kirkman, head of Scientific and Regulatory Affairs at the Pharmaceutical Manufacturers' Association in Jhb.

It is clear that the Pricing Committee did not have enough time or resources to go through all the data submitted in order to make an informed decision on pricing regulations. It was argued that government couldn't use a one-size-fits-all approach by requiring all manufacturers to cut their prices by 50% because not all middlemen made huge margins along the chain. There have been legal challenges. All this could have been avoided through a consultative process. In the meantime, manufacturers have implemented the single exit price. Pharmacists have not implemented the regulations pending a court case where they are arguing that the set margins would render them unviable. In the meantime they are charging the usual mark ups. Medical schemes on the other hand can only reimburse at the SEP. Consumers are having to pay the difference between what the medical aid scheme pays and what the pharmacy charges.

Other regulations that have been proposed in this industry are found in the National Health Bill and relate to the doctors' certificate of need and the prevention of doctors from dispensing medicines unless there is no chemist nearby. The doctors' certificate of need regulation, although supposedly serving the public interest by forcing doctors to locate their practices in rural and other under-served areas, is a form of market allocation and, therefore, also against the principles of competition. Doctors should be able to practice wherever they so desire based on their own assessment of demand and supply conditions. Government should therefore consider offering certain incentives to lure doctors to practice in the under-served areas instead of using heavy-handed regulation to prevent them practicing in areas of their own choice. The wisdom behind the dispensing restrictions was to ensure that pharmacies remain viable on volumes since they could no longer impose margins. High volumes could then be guaranteed if doctors are prevented from dispensing. All this gives the impression that the Government thinks it knows better than the market as to who should be selling medicines, where and at what price.

## **5 The role of the Competition Commission**

The Competition Commission has a crucial advocacy role to play in the regulatory reform process. With regard to the restructuring and privatization of state-owned enterprises, the commission has to ensure that the process leads to a competitive outcome. The resultant market structures should be such that new entrants can compete fairly with incumbents. In other words, for these industries to be fairly contestable, the playing field between the incumbents and new entrants must be leveled. To do this, previous benefits like tax exemptions, preferential access to scarce inputs and discriminatory subsidies enjoyed by these former state-owned enterprises ought to be phased out. It's not enough to simply substitute private monopolies for public ones.

The need for continued access, economic, safety and technical regulation has necessitated the establishment of more regulatory bodies to undertake these functions. Where new regulators are established, these must be independent, efficient and effective. Also, a consolidation of multiple regulators into one regulator in industries such as energy, transport and communications is advisable in order to, among other things, reduce

regulatory costs and avoid overlaps, duplication and jurisdictional conflict. The founding legislations of these bodies must spell out their functions and powers clearly, in order to give assurance to the investment community. The following regulatory functions are crucial during the transition from state ownership to market liberalization and after (Davidson: 2002):

1. Competition regulation - controlling anti-competitive behaviour and assessing mergers and acquisitions;
2. Access regulation - ensuring non-discriminatory access to essential facilities and necessary inputs;
3. Economic regulation - adopting measures to control monopoly pricing in cases where competition is either non-existent or limited; and
4. Technical regulation - setting standards to address privacy, safety, and environmental protection concerns.

These functions raise the age-old question of regulatory jurisdiction, that is, who is best suited to deal with which type of regulation? Whilst it is clear from government policy (Department of Public Enterprises: 2000) that competition authorities in South Africa should undertake competition regulation, there is still a lot of new legislation that mandates sector regulators to deal with competition matters. Although concurrent jurisdiction can work under certain circumstances, it has its own demerits, which include forum shopping, double jeopardy and inter-organizational conflict.

With regard to new laws and regulations, the Commission is also mandated to play an active role. In terms of section 21 (1)(k) of the Competition Act, the Commission is responsible to, “over time, review legislation and public regulations, and report to the Minister concerning any provision that permits uncompetitive behaviour.” Whilst the Act is clear about the Commission’s advocacy function in this regard, the 2003 OECD Peer Review Report<sup>15</sup> notes that “most of the efforts of the Commission have been aimed at raising public awareness of the Act, rather than studying and advising about the effect of laws and regulations on competition.” However, it is heartening to note that there has been a paradigm shift since the release of this report, as evidenced by the number of parliamentary and government departmental submissions made by the Commission on various legislative and policy proposals during 2003. During the past 18 months or so, the Commission has actively participated and influenced the outcomes of the following legislative and policy making processes: The Liquor Bill, the Petroleum Pipelines Bill, The Petroleum Products Amendment Bill, the BEE Bill, the National Ports Authority Bill, the Mining Royalties Bill, the Convergence Bill, the Cooperatives Bill, the drug pricing regulations, the scrap metal policy proposal, the electricity pricing policy proposal as well as being involved in other sector specific policy making processes. Section 41(1) of the constitution of the Republic, reinforces the idea of cooperative governance by encouraging organs of state to consult on matters of common interest, to co-ordinate their actions and legislation with one another and to avoid legal proceedings against one another. Notwithstanding this, we continue to witness a number of laws being passed with little regard to their impact on competition.

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<sup>15</sup> Oecd Global Forum on Competition Peer Review: Paris, 11 Feb 2003.

The pricing regulations were of concern not only from an industry perspective but also from a competition policy viewpoint. The Commission thus welcomed the opportunity to submit written comments on the regulations to the DOH. In its submission the Commission pointed out that it has not been made aware of prior research to warrant the drastic steps being taken by the DOH. Nevertheless, the Commission recommended that other means of ensuring low prices should be explored and where they exist they should be used more extensively before embarking on price controls. These include parallel importation, generic substitution, more information dissemination, removing import duties on pharmaceutical products and equipment, removing barriers to entry in the industry as well as streamlining the registration process. Although government went ahead with the introduction of the SEP, the aspect of a compulsory 50% reduction in all product prices was dropped in favour of a requirement that incentives, discounts, etc be removed from pharmaceuticals prices on a product-by-product basis. Although manufacturers can now determine the SEP of each product, they nevertheless will henceforth not be able to implement price rises at will; instead they will have to motivate these to the DOH, which still amounts to a form of price control.

The use of a RIA in this instance would have ensured that a competition assessment of the proposed regulations was done. A simple competition assessment would have looked at whether the proposed regulations are likely to affect the structure of the industry concerned, or the behaviour of firms in that industry and their ability to compete effectively. It would also look at the effect of the price regulations on firm viability. The negative effects of the regulations would then be weighed against the benefits of low and stable consumer prices and transparency in the system. Price regulations inhibit the ability of firms to compete on prices. They can also impact on competition by, for example, affecting the firms' cost structures.

The Commission has intervened successfully in the past where proposed legislation and policies would have inhibited the ability of firms to compete freely. Whereas such interventions have been limited to the competition impact of these laws, government appraisal would go a step further to consider the effects thereof on employees, consumers, the environment, civil society, etc.

## **6 Policy recommendations/ conclusion**

In light of the above discussion, perhaps it is time for government to pause and ponder as to the effectiveness of past laws and the necessity of proposing new ones. The Minister of Finance, in his budget speech<sup>16</sup> identified the easing of the regulatory burden on the small business sector as a key microeconomic reform strategy. President Mbeki added his voice to this call, in his state-of-the-nation address<sup>17</sup>, by stating that as a means of helping small businesses, government “will carry out a comprehensive review of the regulatory framework that impacts on this sector, to facilitate its further growth and development.” Such a review should not only be limited to the regulatory institutions or to small

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<sup>16</sup> Budget speech. Minister of Finance, Trevor Manuel. February 18, 2004.

<sup>17</sup> Address of the President of South Africa, Thabo Mbeki, to the first joint sitting of the third democratic parliament, Cape Town, May 21, 2004.

businesses, but should include a review of all the laws that impact on the economy as a whole. Also, in light of government's ten year review process it would be beneficial as part of the exercise to review, amend, and/or eliminate existing laws/regulations as the case may be using a RIA criterion.

Where regulations are justified, the drug pricing regulations debacle illustrates the importance of consultation, engagement, compromise, flexibility and an objective evaluation process of the proposed course of action. In addition, the following proposals cited by Mihlar (1998) can be used to reform the regulatory process in South Africa:

- Write regulations that are simple and easy to understand;
- Provide a sunset clause in all regulations to allow review after a certain period;
- Study the economic impact of proposed regulations;
- Encourage market-driven responses in place of regulation
- Prioritize regulations using a comparative risk assessment.

In order to promote an efficient and effective regulatory regime and without perpetrating a regulatory state, government should pass a "Regulatory Impact Assessment Bill" that will make it compulsory for public servants to justify the need for any proposed law and evaluate all existing ones using a cost/benefit analysis approach. Until then, the Commission should reinforce its advocacy function and play a more aggressive role in assessing, not only the competition effects, but also the economy-wide impact of proposed legislation and policies.

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