Regulating the pharmaceutical sector: Coping with low capacity while maintaining regulatory independence

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Abstract

Drug regulatory agencies play a key role in ensuring that medicines available for use are safe and effective. South Africa has been at the forefront of recent debates about pharmaceutical regulation, adopting wide-ranging changes to its legislative frameworks, in order to ensure cheaper access to quality drugs through parallel importation and compulsory licensing. At the same time the drug regulatory agency has sought to improve its effectiveness while dealing with a substantial capacity shortage. As with all regulation, agencies have to maintain independence from private sector interests – in this case the powerful pharmaceutical industry. In many low and middle-income countries there is insufficient individual and organizational capacity to ensure that regulation is effective. Steps often taken to deal with the capacity shortages can lead to agency independence being compromised.

This paper describes: firstly, the capacity problems experienced in South African drug regulation over the period 1997-2003; secondly, steps taken remedy some of the problems; thirdly, the ways in which possible solutions, suggested by various stakeholders, are likely to affect the independence of the agency. Finally, the paper concludes with recommendations, drawing on the lessons from the South African experience for other low and middle-income countries struggling with similar issues.

Introduction

In most countries, the production and distribution of drugs is almost exclusively undertaken by the private sector, largely consisting of extremely powerful multinational corporations. Regulation of the industry is essential to ensure the production of safe and efficacious drugs. Recent efforts to improve access to medicines in the developing world has led to a focus not only prices and international barriers to trade, but on national drug regulatory agencies (DRAs), in their role in registering drugs for use (Gray 2004, Hill and Johnson 2004, Timmermans 2004).

Improperly functioning health regulatory systems have been observed in a range of LMICs (e.g. Zimbabwe, Tanzania, Lao PD) (Hongoro and Kumaranayake 2000, Stenson et al 1997, Kumaranayake et al 2000). Hongoro and Kumaranayake (2000) identify capacity as a key factor influencing the ability of regulation to achieve its stated goals. Regulatory agencies often face crippling manpower shortages that severely curtail their ability to perform designated tasks. A comparative 10-country study of drug regulation concludes that 'the shortage of qualified staff is the main problem faced by regulatory authorities' (Ratanawijitrasin and Wondemagegnehu 2002:133).

Countries have responded to capacity shortages in a variety of ways. Many developing countries employ part-time drug evaluators (e.g. Health Professions Council in Zimbabwe, Drug Control Council in Tanzania etc, and Medicines Control Council in South Africa). Some agencies accept approval decisions taken by other countries or international organizations, such as the International Conference on Harmonization (ICH). Some developed countries have introduced fees paid by the pharmaceutical industry per approval application, providing sufficient funds to increase staff numbers and salaries (e.g. Australia and the Netherlands)

Yet, these strategies to cope with inadequate capacity have the potential to threaten the independence of a regulator, through, for example, the reliance on fees from industry, or part-time evaluators. A key requisite for effective regulation is 'independence from regulatory capture' – the ability of the agency to take decisions that are guided by the interests of public health (Goddard 2003), and not shaped by the interests of industry or by a lack of government commitment (financial or otherwise).

Building on past work (a policy analysis of the process of legislative change by Gray et al 2002), this paper looks at how the South African agency has responded to capacity shortages, while trying to ensure the independence of its decisions. Capacity here is defined as being individual, organizational, and broader institutional context capabilities.) South Africa has been at the forefront of recent debates about pharmaceutical regulation as it has adopted wide-ranging changes to its legislative frameworks allowing parallel importation and compulsory licensing. At the same time the regulatory agency has sought to improve its functioning while dealing with a substantial capacity shortage. The South African experience highlights, for other low and middle-income countries struggling with similar issues, how commonly suggested measures to deal with inadequate capacity, can jeopardize the ability of the regulator to impose its authority. From this experience recommendations are made. This paper contributes to the small existing literature on drug regulation in developing countries, and even more so on associated capacity issues within regulation.

The paper is structured as follows. The next section describes the methods used in the study and the analytical frameworks that guided investigation. Subsequent sections present an overview of the South African pharmaceutical environment, the key capacity problems experienced over the last eight years, how the regulatory authority has responded, and discusses how suggested solutions to capacity issues might affect independence. Finally, the conclusion highlights the lessons for other low and middle-income countries in dealing with capacity problems in regulation.

Methods

Document reviews

Documents accessed for this analysis can be classified into three categories. A limited number of documents were analysed from the general literature on the subject of regulation. A bibliographic search was conducted using MEDLINE and the Social Science Citation Index for the years 1998-2004 using the terms 'drug regulation' and 'pharmaceutical regulation'. Several peer-reviewed publications that address the subject of regulation within a health sector context were also reviewed. Finally, documents dealing with the specific subject of regulating the pharmaceutical sector in South Africa were examined. The main piece of legislation forming the backdrop of regulation in the pharmaceutical sector is the Medicines and Related Substances Control Act. This legislation, and its various amendments, was analysed. Other key documents analysed include the "Guidelines for Good Manufacturing Practice for Medicines in South Africa" prepared by the MCC and available on its website at www.mccza.com, and a recent review of South African pharmaceutical regulatory environment.

Interview data

Data for this analysis were collected through semi-structured interviews and group discussions during 2002-2003. The research team first drew on inside knowledge of the pharmaceutical environment to identify a core group of interviewees considered to be significant role players. Subsequently, additional interviewees were identified through the snowball technique. 13 in-depth semi-structured interviews were conducted with representatives from the regulatory authority, industry associations, generic and original pharmaceutical companies, and other key individuals who are knowledgeable about the pharmaceutical environment and current developments within it. (Ethics approval was obtained from the University of Witwatersrand Committee for Research on Human Subjects.)

During interviews specific emphasis was placed on actors' experiences of the drug approval and registration process, and the capacity of the group of organizations involved. Two discussions were conducted with selected members of the regulatory authority, aimed at obtaining first hand information on the regulators' experiences in relation to capacity.

Analysis

Data from all interviews were coded and analysed by one researcher and two senior researchers. The coding was based on common themes emerging from the interviews. Interview data were triangulated by testing themes across the interviewees representing differing actor interests. South African document data were triangulated with the interview data. Two internal workshops were held by the researchers to interrogate the validity of identified themes, and the main researchers also shared preliminary findings with colleagues at an international workshop held in London in May 2003. These discussions assisted in maintaining rigour in the analysis. Preliminary findings were also shared with the regulatory authority to obtain feedback on the accuracy and relevance of the analysis. Results from these discussions then informed the final stages of analysis.

The Hilderbrand and Grindle (1997) framework of organizational capacity was used to guide data collection and analysis. This framework broadens the focus of capacity beyond individuals and their skills to organizational capacity (for example to retain skilled staff), and the ability of the various organizations to interact effectively. The five dimensions of organizational capacity identified are: the action environment, the institutional context of the public sector, the task network, the organization and finally, human resources.

The action environment: The situation or system within which entities implement their activities. It comprises factors such as the policy values of the country, the role of public and private sectors, political stability, overall human resource development, social conflict etc. (Hilderbrand and Grindle 1997, Milen 2001).

The institutional context of the public sector: Broader than the organizational level, it includes the rules and procedures that shape the management of a public organisation, and resources available to support its tasks.

The task network: is the set of organizations involved in accomplishing a task. Their performance will be affected by whether such networks facilitate communication and coordination. The performance of one within the network is dependent on others executing responsibilities effectively.

The organization: This dimension includes the structure and processes of an organsiation, such as mission, strategy, culture, management styles, structures, finances, information sources and infrastructure (Milen 2001).

Human resources: The focus is on fit between knowledge and skills of staff and the needs of a task, focusing on technical, professional, managerial and communication and networking aspects of knowledge and skills. It also deals with attracting people to the organisation, utilization of their knowledge and skills and retention of individuals.

Regulating the pharmaceutical sector in South Africa: an overview

The organizations involved in regulating the pharmaceutical sector, both the regulators and those affected by regulation, and their context are presented in Figure 1 below, using the Hilderbrand and Grindle framework.

Fig 1: The organizations involved in pharmaceutical regulation, and their context, using the Hilderbrand and Grindle framework
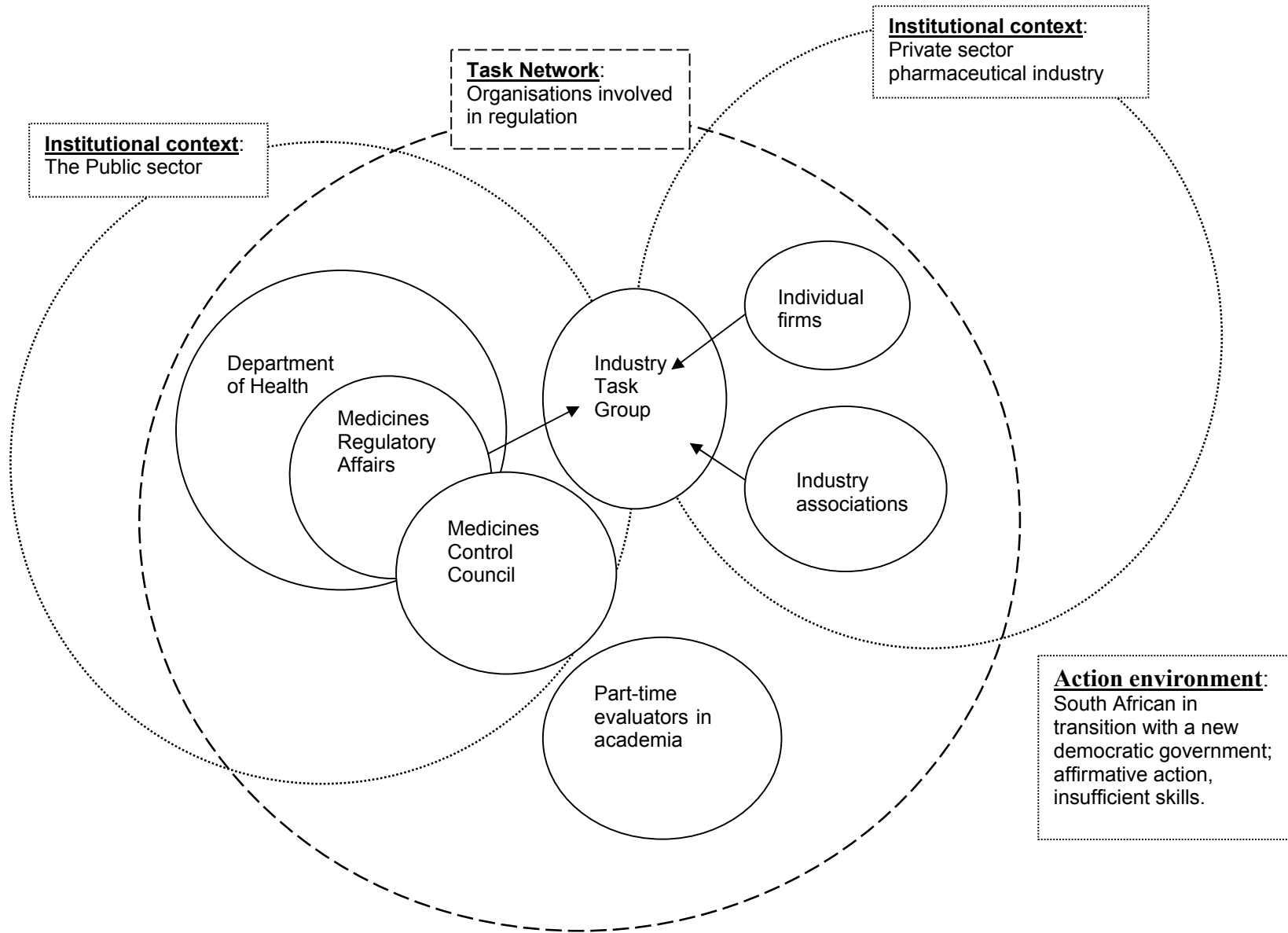
Organisations within the task network, and their institutional contexts.

The regulatory agents

The Medicines Control Council (MCC) is the public sector body tasked with regulating pharmaceutical products in South Africa. 11 expert committees, that evaluate the safety and efficacy of a drug submitted for approval, inform the decisions of the MCC. Apart from the Registrar of Medicines, all members of the MCC committees are engaged on a part time basis, including the evaluators who are often in full-time employment elsewhere. The Medicines Regulatory Affairs (MRA) comprises 4 units, namely: inspectorate and law enforcement, operations and administration, clinical and medicines registration. These units perform an administrative and coordinating role, facilitating the work of the expert committees (interview data, MCC representative).

Both the MRA and MCC are public sector bodies that work within, and are influenced by, the public sector institutional context. Features of this context that have particular influence over the organizational capacity of the regulatory agencies include: the human resource practices of the civil service (recruitment procedures, salary levels etc); the hierarchical and rule-bound culture; and, the widespread need for urgent reform due to need to redress the inequities of apartheid (Gilson et al 1999, Gray et al 2002).

The pharmaceutical industry

As a middle-income country, South Africa has a significant pharmaceutical industry (Gray et al 2002). The Pharmaceutical Manufacturers Association (PMA) represents the interests of international companies operating in South Africa whereas the National Association of Pharmaceutical Manufacturers (NAPM) represents local manufacturers. Neither of these associations is a statutory body, and it is not compulsory for a drug manufacturer to belong to either.

Joint industry and regulatory organization

The Industry Task Group (ITG) was established in order to create a forum to bring together industry representatives and the pharmaceutical regulators. Its initial aim was to improve communication and enhance regulatory effectiveness.

Key capacity problems

Through the interviews the following problems were identified as having a key impact on capacity during 1997-2003.

Action environment: Widespread legislative reform and affirmative action

In an attempt to address the inequities, and policy shortcomings of the apartheid era, the new South African government have introduced wide spread policy and legislative reform – including drug regulation (Gray et al 2002). In most instances, legislative changes have been implemented expeditiously only to be met with fierce challenges from actors with powerful interests. This reform has taken place in parallel with affirmative employment policies – ensuring the civil service reflects the demographic profile of the country – that has essentially changed the face of both the MCC and MRA. The current analysis was undertaken at a time of immense, and unique, political and societal transition in South Africa. This transition has inevitably affected policy implementation throughout the health sector (Gilson et al., 1999; Gray et al., 2002).

Task network: Legal conflict over regulatory policy leading to poor relationships

Widespread controversy accompanied new regulations allowing for compulsory licensing and parallel importation (Gray et al 2002). The pharmaceutical industry engaged the state in extensive litigation. But in 2002, it was forced to withdraw its challenge to the new regulations due to pressure emanating from global opinion on the role of the industry in the face of the HIV/AIDS epidemic. The lengthy legal battles have led to a deterioration of the relationships between industry and the regulator.

Institutional context of the public sector: Medicines Control Council situated with in the Department of Health.

The physical location of the MCC within the Department of Health is perceived by stakeholders to be a significant limiting factor on its ability to meet its responsibilities (interview data, regulator, industry).

Firstly, poor remuneration of part-time evaluators has for a long time been identified as one of the contributing factors in slowing down the registration of products. It is argued that because evaluators do not get adequate compensation for their time and expertise, they are not motivated to prioritise evaluation. Although fully aware of the problem, the MCC can do little to address it. All payments for doing work of statutory boards are governed by established guidelines of the National Treasury. The MCC is, therefore, not able to improve remuneration as a way of motivating evaluators either to do more work or to speed up the process. Similar problems are experienced in recruiting and retaining staff within the MRA. All staff are paid according to established salary bands for the entire public service. Consequently, MRA is unable to use salary to attract and retain some of the skills that would strengthen the regulatory role. Most observers attribute the failure by the MCC to retain staff to its inability to match salaries paid by industry as a result of civil service rules. In illustrating the impact of low MCC salaries on the rate of staff turnover an industry insider commented "*I pay more tax than those guys earn as a gross salary*".

Secondly, as all MRA staff are employed by the NDoH they do not always work solely on tasks of the MCC. Often, they get caught up in other activities and occasionally get delegated to take part in other functions of the Ministry that may have nothing to do with regulating the pharmaceutical industry (interview data, regulator).

Organisations: The lack of adequate organizational processes

The need to restructure the civil service, such that it represented the demographic profile of the country, was an important consideration in public sector recruitment after 1994 (the action environment), and a driving factor during the period of high turnover in the MCC/MRA. During this period, individuals who had been with the MCC/MRA for decades gave way to new leadership, but the process was not always smooth and some cases of dismissal ended up in the labour courts (Gray et al 2002). Strained relations between personnel meant there was no opportunity for the systematic handover of regulatory functions. Compounding the problem was failure on the part of MRA to recruit new staff quickly enough to minimize disruption in the regulatory process. Existing organizational systems could not withstand to the loss of experienced staff, leading to a failure of organizational processes. The transitional situation prompted some stakeholders in the private sector to perceive the new leadership as being obsessed with change without careful consideration of all implications. According to an industry interviewee it was like "*any change will do because we need change*". It became

clear that input was required from some of the people who had left the MCC. According to an interviewee the new leadership began to realize that "*we have thrown the baby out with the bath water…let's get the baby back…the baby is drowning*".

Human resources: Inadequate regulatory skills

During the period 1997 – 2000 both the MCC and MRA experienced a high rate of turnover of skilled staff. Interviewees suggest that the MRA Directorate lost close to 80% of its staff within this 3-year period (interview data). While the newly recruited personnel came with relevant qualifications they still needed experience to become effective regulators. An interviewee from industry commented "*you can't be an inspector through a textbook or through somebody who has been an academic.... That only comes through experiential learning*".

Yet the MCC/MRA was not the only organization facing a lack of regulatory skills. A view held by the MCC is that delays in the registration process can to some extent be attributed to poor quality submissions made by industry. Pharmaceutical manufacturers acknowledge the existence of shortcomings within themselves in this regard. An industry insider admitted, "*there's a lot of new people in industry itself. They also have to be trained*". (Industry interview)

Responses to capacity problems

The responsiveness of an organization is a key element of capacity and effectiveness. Organizations with a problem-solving culture are likely to perform better (Hilderbrand and Grindle 1997). Table 2 sets out the main capacity constraints outlined in the previous section, using the Hilderbrand and Grindle framework. The third column highlights how 'responsive' the regulator has been to these constraints, through the following actions: promotion of the ITG; use of a consultancy firm to improve organizational processes; establishing more formal contracts with part-time evaluators; developing legislation to make the regulatory agency a statuary body separate from the Department of Health; and, establishing strong new leadership.

Table 2: Capacity issues in regulating the South African pharmaceutical sector

Hilderbrand & Grindle framework	Capacity-related problems in South Africa	'Responses' of the regulator since 1997
Action environment (South African in transition)	• Period of South African transition to a new democratic government, with explicit policies of affirmative action • Limited number of personnel in the country with appropriate pharmaceutical skills	• Training, but no policies to encourage trained staff to remain in the country, or in the regulatory body.
Task network (Regulatory bodies, Department of Health, pharmaceutical industry and industry bodies)	• Conflictual relationship between government and industry over previous policy issues • Poor communication between those in the task network • Part-time evaluators, with insufficient time for the workload that is required	• Set up ITG to allow efficient communication between government and industry, to explain internal problems that the regulator is facing, and to rebuild relationships after conflictual phase • Establishing contracts with part-time evaluators in order to reduce delays
Public sector Institutional context	• Pursuing substantial legislative and policy change in all government departments, despite limited capacity, leading to involvement of regulatory officials in other areas of DoH work. • Lower salary levels in the public sector in comparison to the private sector, encouraging a loss of staff	• Developed legislation to make the regulatory body a separate juristic body from the National Department of Health, (to be able to set its own salary levels, raise funds, avoid pressures of other unrelated demands.) This process appears to have been stalled due to unresolved debates about the most appropriate source of funding for an independent body.
Organisations (MCC, MRA)	• Change in leadership of the regulatory body, in a drawn out conflictual process • High levels of turnover of staff • Weak organisational processes that were sustained by individuals detailed knowledge of the process and the industry. The substantial loss of staff lead to a failing of organisational processes	New strong leadership by an individual who knew the regulatory process well Engagement of a consultancy firm to improve the organisational processes to improve efficiency.
Human resources	• Insufficient skills in pharmaceutical regulation • Demotivated staff due constant pressure from industry, and failure of the organizational processes to help staff meet their workload	Training Strong leadership Improved communication through ITG that reduced pressure from the industry on individual staff members.

In the past the MCC/MRA had to deal with each individual manufacturer when queries arose in the approval process. It became apparent, however, that problems were similar across the different applicants. In order to become more efficient the MCC/MRA recommended to industry that it organize itself into a single forum that would facilitate communication. This recommendation led to the birth of the Industry Task Group (ITG), acknowledged as a positive development by industry. An interviewee submitted, "*the MCC/MRA was actually very instrumental in starting the ITG by saying that they were so tired of speaking to all the different role players and basically giving them the same message*".

The existence of the ITG is credited with most of the improvements that have been achieved in the relationship between the pharmaceutical industry and the MCC. An industry insider observed, "*we have actually proceeded in building a better relationship between the industry and the regulatory authority*". However, there is widespread contention within industry that the ITG is not serving its intended purpose. The industry perceived that the ITG would be a forum that would lay "*open routes* (for) *discussion and debate*". Industry has criticized the MCC for using the ITG as a platform just for making announcements rather than allowing two-way discussions about how to improve the regulatory framework. One interviewee stated, "*it is more of a monologue rather than a dialogue*".

Although consultation is important, ultimately the regulator, not the industry, has to decide on the regulatory framework. To some extent the industry has unrealistic expectations of its possible role in policy-making. The role of the various parties needs to be clarified to deal with any misunderstanding and expectations, and hopefully, the ITG will become a useful forum to exchange views and debate possible collaborations. Given the limited reach of a regulatory agency, engagement in collaborative relationships where others are used as informants or agents of change, can assist the regulator.

The MCC has also initiated other more internally focused strategies to address challenges in the regulatory process. To try and address the limiting factor of being located organizationally within the Department of Health and civil service frameworks, recent legislation will enable the MCC to become an independent juristic body. The main advantage of this development is likely to be the ability to recruit and retain high calibre regulatory personnel, through offering higher salaries. This would also extend to part-time evaluators (interview data, regulator). However, this initiative is apparently stalled due to debates about the sources of funds.

Even more intense has been the effort to reform the internal processes of the MRA, which serves as the administrative unit of the MCC. A detailed situation analysis revealed several problems with the existing system, including:

- An excessive amount of paper handling associated with each drug approval application, with some steps, e.g. screening, often thought to be unnecessary and duplicative;

- Gaps in responsibility, where one unit of the MRA was under the impression that another was undertaking a particular task, only to realize too late that in fact no one was doing anything about the issue;

- Too many computer systems that did not complement each other;

- Lack of a tracking system for applications to determine how far an application had progressed.

The MCC has put several initiatives in place to address these problems. In 2002 Industry already gave testimony to the fruits of these initiatives in that they applications for drug approvals were being completed faster. In the words of an industry interviewee, "*We already see the commitment. We see things coming through faster. The MRA have been cutting out all kinds of internal bureaucratic processes that slowed things down*". (Industry interview data)

Possible solutions to remaining capacity problems

Despite attempts to deal with poor capacity within the task network, the key obstacle of being unable to recruit and retain skilled staff in the regulatory authority remains. Several suggestions were made by interviewees to deal with the problem: the creation of the MCC/MRA as a separate juristic body outside of the Department of Health; the reliance on industry fees to fund the regulatory agency allowing salaries of regulatory officials to be raised; shifting towards a compliance rather than deterrence approach; or, relying on the approval decisions of other agencies or international conventions. Each of these possible solutions – discussed below – have potential implications for the independence and authority of the regulator.

Task network: Shifting towards compliance to reduce capacity bottlenecks

According to their own judgments, and the evaluators, pharmaceutical manufacturers generally comply with the regulatory framework (interview data, evaluators, industry). This high level of compliance is not attributed to the MCC being a firm regulator or stiff penalties for noncompliance. Rather, manufacturers comply because, they argue, it is good for business. In the words of a manufacturer "*you are not going to put a product that is substandard out there because it can kill someone….then your reputation as a company is shot and no one will buy your products. It is not in the industry's best interests to put a product that is of substandard quality, that doesn't work and is not safe*".

In the opinion of industry, a more compliance-based approach with reduced regulatory requirements would alleviate some of the capacity bottlenecks (Industry interview data). For example, is the same regulatory process necessary whether a company is applying to change a package insert or the chemical composition of a drug? Industry argues that the former qualifies as a minor amendment that could be delegated to the manufacturer to implement. The MCC would then be left to approve applications for the latter, which is considered a major amendment.

In spite of the goodwill that the pharmaceutical industry has accumulated over the years in South Africa, internationally it unfortunately still has a reputation for concealing adverse

information on a drug or outright flouting of regulation when it is convenient for it to do so. [1] The excessive profits made by pharmaceutical manufacturers have also compounded the problem, with the industry being viewed, in South Africa and internationally, as opportunistic and self-interested. Even with changes to the package insert it is possible that misleading information could be passed on to doctors and patients that may result in fatal consequences. It therefore is difficult to recommend that this aspect of the regulatory process is amenable to self-regulation in spite of the suggested advantages.

Task network: The role of international conventions in drug approval decisions

The industry within South Africa has argued strongly for South Africa's participation in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human use (ICH) – allowing a single international process for approval rather than individual processes. *"We have got the situation where drugs have been approved in Europe. They are even on the market in Europe and here in South Africa they put them through an over-burdened committee structure"*. (Industry interview data) This again would have the effect of reducing capacity requirements for having in place highly qualified personnel to evaluate drugs. Despite the involvement of many national regulatory authorities, industry is a key force behind the harmonization process – in order to increase its access to worldwide markets. There are examples of less stringent requirements for drug approval at the international level than at national level with regard to: a) expedited reporting of adverse drug reactions; b) the use of carcinogenicity testing before patients are exposed to new drugs; c) reducing the minimum length of a clinical trial to 6 months from 12 months (Gordon 1994) Such evidence suggests there should be some caution in accepting international standards (Timmermans 2004).

Task network: Retaining skilled part-time evaluators

Part-time valuators often wish to maintain their research careers with involvement in the development of new drugs. This can be beneficial for regulation as evaluators remain abreast of new research, increasing their evaluation skills. However, conflicts of interest may compromise the independence of the evaluator's decision. Funds for research are often only

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[1] For instance, an editorial in the Lancet (October 2004) cast serious doubts about the sincerity of a drug company's (Merck and Co) announcement that it was withdrawing from the market a leading drug for control of acute pain (Rofecoxib/Vioxx) after fatal adverse reaction events were discovered. The editorial argued that apparently evidence had existed for a long time of these adverse events but was ignored. The suggestion is that whereas the drug company knew about existence of potentially fatal side effects, it continued to extract profits from the drug and after it had benefited immensely, it then withdrew it from the market.

available from drug companies, so a negative decision on the approval of one drug may influence an evaluator's ability to secure funding. Anonymity of the evaluators, and declaration of associations with industry, are key to prevent approval decisions from being compromised. (Although commercial secrecy agreements can lead evaluators not to declare their associations.)

Institutional context: Creating a separate, juristic regulatory agency

With the creation of a separate, juristic body, the MRA/MCC would have more control over how it carries out its objectives. At the time of writing this paper, a period of more than two years had elapsed since the change in the legal framework to allow a separate body, and doubts were already beginning to emerge as whether the MCC will eventually assume quasi-independent status or not. Providing a budgetary allocation to the MCC enables the Department to retain accountability, and maintain control over the regulator. If independence from government leads to a fall in budgetary support, and an increase in the reliance on registration fees from industry, this may present an opportunity for pharmaceutical manufacturers to have more influence over regulation. (Currently, registration fees collected have no bearing on the budgetary allocation to the MCC since all funds are channeled to the Treasury Department.) Reliance on industry fees may make regulators more likely to see the industry as its constituency to which they are primarily responsible, not the public (Gray 2004).

The experience of Europe provides an example of the negative effects of agency reliance on industry fees. The combination of the harmonization of approval processes (one country's approval being accepted by other agencies), and drug registration fees, meant European agencies had to compete with one another for industry business, severely compromising the independence of the regulators. In order to deal with this problem the European Commission now allocates applications to a national agency (Lewis and Abraham 2001, Abraham 2002, Wiktorowicz 2000)

Human Resources: Raising salaries of regulatory officials

A key assumption from the interview data is that the salary discrepancies between the public and private sectors is the root cause of the inability of the regulatory authority to retain skilled staff. Similar salary levels in both regulator and regulatee may lead to the regulator being

able to recruit staff, but it will not prevent the movement of staff between the two organisations. Many of those who left the MCC/MRA in the 1997-2000 period moved to industry. The 'revolving door' exists where regulatory officials begin their careers in industry, work for some years in the regulatory authority, and then return to industry at a higher level than when they left. For example, although the FDA, the US regulatory authority, is the best resourced in the world, it has many senior regulators with a background in industry, and who are likely bring values that are sympathetic to the pharmaceutical industry (US Congress) – enabling industry to 'penetrate into the heart of the regulatory political subculture' (Abraham 2002, p1498). With such flows of staff, the ability of the regulator to prevent 'regulatory capture' by industry and ensure that public is it's primary constituency is limited.

Conclusion

The South African analysis affirms a common experience: pharmaceutical regulation is a difficult and contested arena. It demonstrates that regulatory capacity can be developed over time, even in the face of antagonistic relationships and during a time of intense societal transition. The MCC/MRA's actions over the last few years show that it is a versatile organization that has demonstrated willingness to address its capacity problems. Real improvements have already been made as well as building the foundations for more effective regulatory implementation in the future.

However, improving regulatory capacity cannot be considered in isolation. Any possible solution will have ramifications of the independence of the agency. Capacity and independence have to be considered together. Short cuts that reduce the need for capacity, such as international harmonization, increasing regulatory revenues from registration fees, or a more compliance-orientated approach, may simply compromise the independence of the regulator.

Retaining and recruiting the right calibre of staff for the MCC/MRA is critical to ensuring that the regulator stays a step ahead of industry. The desperate lack of capacity compounded with high levels of staff turnover between industry and the regulator are issues that might be addresses by rewarding staff appropriately, structuring suitable career paths and allowing part-time evaluators an opportunity to develop research careers without dependency on industry. An important strategy might be to foster organizational values focused on the protection and advancement of public health, rather than responding to the demands of a vocal industry. There is already considerable evidence of such values with the willingness of the South African regulatory authorities to insist on parallel importation and compulsory licensing legislation, despite lengthy legal opposition from the international drug industry. Articulating and developing those values further, along with an explicit awareness of the dangers of regulatory capture, might help to ensure the objectives of public health are not compromised by the inability of the authorities to 'filter out' the noisy demands of industry.

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