ANALYSIS OF THE TASK TEAM REPORT AND COMPARISON WITH THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2008

On 2 June 2008, the Medicines and Related Substances Amendment Bill, 2008[1] – which seeks to amend the Medicines and Related Substances Act, 101 of 1965 ("the Medicines Act") – was published in the *Government Gazette*. On 17 June 2008, this published version was formally introduced to Parliament as the Medicines and Related Substances Amendment Bill [B 44—2008] ("the Bill"). In addressing the issue of consultation, the explanatory memorandum on the objects of the Bill provides as follows:

> 5. CONSULTATION
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> The Ministers of Finance, of Trade and Industry, for Agriculture and Land Affairs, and of Environmental Affairs and Tourism, after consultation with the Minister of Health, identified senior officials in their respective Departments to represent their Departments on the Ministerial Task Team. The Task Team's recommendations were achieved by consensus. Members of the various Departments were asked to engage discussions with their principals so that the consensus within the Task Team would have the support and approval of their relevant Departments.
>
> The Social Sector Cluster was also consulted.

Amongst other things, the *Ministerial Task Team on the Restructuring of the Medicines Regulatory Affairs and Medicines Control Council* ("the MTT") was set up "to make recommendation[s] for a new regulator[y] authority for health products in South Africa."[2] As such, and as suggested by the explanatory memorandum to the Bill, one would have expected the Bill largely to give effect to the MTT's recommendations.

Yet this is not the case. There is a significant disconnect between the recommendations of the report of the MTT ("the Report") on the one hand and the Bill on the other. Simply put, a substantial – indeed foundational – part of the Bill is not supported by the Report. If anything, much of the Bill actually serves to undermine many of the Report's findings and recommendations.

PURPOSE OF THIS SUBMISSION

The purpose of this submission is twofold.[3] First, it addresses the following concerns in relation to the MTT's work:

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[1] Government Notice No. 611, *Government Gazette* No. 31114 (2 June 2008)
[2] Report of the MTT, at page 36
[3] Concerns regarding the substantive provisions of the Bill have – in effect – already been raised in the "Joint Submission on the draft Medicines and Related Substances Amendment

- Composition of the MTT;
- Consultation process;
- Terms of reference; and
- Failure to address the Constitution, its obligations on the state and its implications for the regulation of health products.

Second, it considers the relationship between the Report and the Bill, focusing on the timing of the Report's publication and the manner in which the Bill both departs from and undermines the MTT's recommendations.

CONCERNS REGARDING THE MTT'S WORK

Composition of the MTT

Until the Report was published, the MTT's composition was not a matter of public record. In addition, the very existence of the MTT – as far as we have been able to determine – had also not been made a matter of public record. Its existence was brought to our attention by some of those consulted as part of the MTT's work. As is discussed in the next section, we are of the view that the consultation process itself was severely flawed, and that the MTT's role weakened as a result.

Of greater concern, however, is the appropriateness of the MTT's composition. It is not so much a question of who was included – even though it is questionable whether the chief executive officer (CEO) of a multinational pharmaceutical company should have been part of the MTT – but rather about who was excluded. In particular, the MTT did not include people with expert skills, knowledge of and/or expertise in constitutional law and law enforcement. Nor did it include any representation from civil society, in contrast to the space given to private sector representatives.

Consultation process

The Report does not give a comprehensive list of who was consulted as part of the MTT's work. Instead, it lists a number of groups who provided "assistance, cooperation and contributions", all but one of whom fall into one of the following four categories:[4]

- Pharmaceutical industry bodies;[5]
- Pharmaceutical industry-aligned bodies;[6]
- Other industry bodies;[7] and
- Statutory councils.[8]

Bill, 2008", available online at http://www.tac.org.za/community/node/2306. This is because the Bill is largely indistinguishable from the previous draft published by the DoH for comment.

[4] The Medicines Regulatory Affairs (MRA) directorate was also thanked

[5] Pharmaceutical Industry Association of South Africa (PIASA); Innovative Medicines South Africa (IMSA); National Association of Pharmaceutical Manufacturers (NAPM) and National Association of Pharmaceutical Wholesalers (NAPW)

[6] South African Clinical Research Association (SACRA) and Physicians of the Pharmaceutical Industry (PPI)

[7] Health Products Association of South Africa (HPA) and South African Medical Device Industry Association (SAMED)

Once again, our concern is not that these important groupings should not have been consulted, but rather that additional groupings – in particular from civil society – should have been consulted. As organisations that have been amongst the most vocal and active on issues of access to medicines, we find it somewhat disturbing that we were never consulted. To our knowledge, our partner organisations were similarly excluded.

Terms of reference

As set out in the Report, the MTT's terms of reference ("the ToRs") were to –

- Undertake a detailed background study and conduct a current situation analysis of the past and current Medicines Control Council (MCC) and Medicines Regulatory Affairs (MRA) and study all available resource documentation.
- Conduct a legal scan of the legislation regarding the MCC and the MRA of South Africa and of selected other related regulatory bodies globally.
- Investigate the roles and relationships of the MCC and the MRA and/or similar regulatory bodies.
- Undertake an analysis of regulatory bodies globally in terms of their organisational structures, functions, relationships and effectiveness. This must include bodies of various formations in selected countries including those in Africa.
- Study the organisational structure and operations of the selected bodies reviewed.
- Determine possible models for a regulatory authority inclusive of their formation, organisational structure, situation, function, outputs and efficiency.
- Consider the details of the regulation of Health Technology, Medical Technology and Medical Devices, and make recommendations for a single or a separate regulatory authority with regard to medicine and these technologies.
- Consider additional terms of reference as decided by the Minister and the Director-General and any further issues that may arise in the work of the task team during its work.
- Make recommendations with regard to an efficient regulatory authority body for Medicines and Health Technology, Medical Technology and Medical Devices for consideration by the Minister.

The Report provides our only reference point for determining the extent to which the MTT discharged its mandate. With this in mind, it appears as if the ToRs were only addressed in part. In our view, key aspects of the MTT's mandate that were not adequately addressed (if at all) include the following:

- Detailed background study of the MCC and related "resource documentation";
- Investigation of the roles and relationships of other regulatory bodies; and

[8] Pharmacy Council of South Africa (PCSA) and Medicines Control Council (MCC)

- Analysis of regulatory bodies globally in terms of their organisational structures, functions, relationships and effectiveness, including a study of their organisational structures and operations.

While the Report does provide some information regarding a background study of the MCC, it fails to address at least two important issues. First, it is completely silent on the South African Medicines and Medical Devices Regulatory Authority Act 132 of 1998 ("the SAMMDRA Act"), which was assented to by former President Mandela on 11 December 1998. Second, the legislative and executive history addressed in our previous submission (to the Department of Health (DoH)) is not captured at all.

The second omission is – to some extent – understandable, given that the person largely responsible for many of the attacks on the independence of the MCC is the person who appointed the MTT and to whom it reported. More surprising, however, is the complete exclusion of any reference to the SAMMDRA Act. At a bare minimum, the Report should have interrogated that statute and relevant supporting "resource documentation". In so doing, it should have sought to explain why the model chosen by Parliament in 1998 is no longer deemed appropriate.

While a legal scan of other regulatory bodies was indeed completed, there is nothing in the Report to suggest that the roles and relationships of these regulatory bodies were investigated in any detail. In addition, there is no analysis of any sort of the regulatory bodies surveyed. For example, there is no analysis of the appointment process in terms of which the Commissioner of the Food and Drug Administration (FDA) in the United States is appointed. So while he or she is required to report to the Secretary of Health, his or her appointment – made by the President – only takes place following public confirmation proceedings in the Senate.

Equally disturbing is the Report's failure to consider the various legislative and structural arrangements within their respective constitutional frameworks. As we argued in our previous submission, in relation to the lessons – if any – that could be learnt from the FDA and Health Canada:

> [South African] regulatory and oversight institutions are established and operate within the broad legal framework provided by the Constitution, which differs markedly from the foundational documents of other countries. Unlike ours, the US and Canadian Constitutions do not recognise a right to have access to health care services. They also do not recognise the principle of state accountability as does ours. Further, the US Constitution does not recognise positive obligations on the state in respect of fundamental rights.

Simply put, the Report merely provides a list of various relevant legal and other provisions but provides no analysis. In the result, we are left without any basis for making sense of the impact of the legal scan on the MTT's thinking and its recommendations. We are simply left to assume the analysis – if done at all – was thorough.

Constitution, state obligations and implications for regulation
The Report makes the following three references to the Constitution:

> The legal implications necessary for the implementation of the SAHRA are outlined in the Report. There are no constitutional implications of the recommendations.[9]
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> …
>
> The following questions have been specifically raised and we will deal with them in the order in which they appear:
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> 1. What existing legislation will require amendment?
> 2. What new legislation, if any, will need to be drafted?
> 3. What existing regulations, if any, need to be drafted?
> 4. What new regulations, if any, will need to be drafted?
> 5. Are there any constitutional matters that need to be dealt with?[10]
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> …
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> There are no constitutional matters arising. The fact that the SAHRA will report to the Minister reaffirms the constitutional principle that the executive authority of the Republic vests in the President and that the President exercises that authority together with members of Cabinet, the Minister of Health being central in this regard.[11]

These statements not only misrepresent the correct state of affairs, but also display a remarkable failure to understand that the Constitution is not solely about the limitations it imposes on the exercise of public power. Importantly, the Constitution also imposes positive obligations on the state, such as it does to ensure that rights are protected, promoted and fulfilled.[12] In other words, the "constitutional implications" of any proposed restructuring of a medicines regulatory authority are not solely those relating to what the Constitution prohibits or whether it does not permit legislation based on the MTT's recommendations.

Instead, the "constitutional implications" also include addressing the positive measures that the Constitution requires to ensure the timely registration of health products – including medicines – of proven quality, safety and efficacy. These include, but are not limited to ensuring that –

- The state budgets for and allocates sufficient resources;
- The medicines regulatory authority is both able and willing to attract and retain an adequate number of appropriately trained staff members;
- The mandate and governance structure of the regulatory authority, including the manner in which its CEO is appointed, supports its independence; and

[9] Page 11
[10] Page 112
[11] Page 115
[12] See section 7(2)

- Discretionary powers, including those assigned to the Minister of Health, are appropriately allocated and accompanied by statutory guidance regarding their use.

In fairness, the Report does address some of these issues, such as by providing details regarding proposed budgets and human resource requirements. However, this is done without recognising the constitutional significance of these matters. Moreover, the recommendations are silent insofar as the proposed regulatory authority's independence and discretionary powers are concerned. These matters are simply ignored, despite their significant importance. As is discussed later in this submission, the manner in which the Bill deals with these issues severely undermines critical aspects of the recommendations.

One final issue on this topic requires consideration – the Report's assertion that the obligation imposed on the proposed regulatory authority to report directly to the Minister "reaffirms the constitutional principle that the executive authority of the Republic vests in the President and that the President exercises that authority together with members of Cabinet, the Minister of Health being central in this regard." This suggests that a range of other regulatory bodies – such as the Independent Communications Authority of South Africa and the Council for Medical Schemes – do not affirm this principle, as they create independent juristic persons. This is simply incorrect.

The nature and extent of the executive's constitutional mandate does not necessarily require direct control over all aspects of regulation and the implementation of legislation. In fact, numerous constitutional norms and principles – such as the principle of accountability – may indeed require the opposite in many cases. As we have argued in our previous submission, many of the provisions that seek to ensure direct ministerial control over the operations of the proposed regulatory authority carry the real danger of undermining the effective and appropriate functioning of this body.

RELATIONSHIP BETWEEN THE REPORT AND THE BILL

Publication of the report

In our previous submission, we expressed concern that the Report had not yet been released for public comment. We explained:

> We are aware that Prof. Green-Thompson, special adviser to the current Minister, conducted an investigation and produced a report ("the Green-Thompson report") on the basis of which the draft Bill was ostensibly prepared. To date, it is not known who was consulted as part of this process. In addition, the Green-Thompson report has yet to be made public, *making it very difficult to understand the basis for the significant amendments proposed by the draft Bill*.[13]

We continued to explain that because of the DoH's failure to release the Report, we had "no option but to make a formal request for access to a copy

[13] At footnote 1 (emphasis added)

of the report." We further explained that such a request, which at that stage was to "be made in terms of the Promotion of Access to Information Act 2 of 2000", would "be lodged with the DoH in the near future." Fortunately, such action was not necessary. Two days after raising our concern directly with the DoH, the Report was published online.[14]

While we welcome the Report's publication, we are concerned that it was only released after the closing date for written submissions to the DoH on the draft Bill, and apparently only because of the threat of legal action that had the potential to delay the process significantly. Having read the Report, we now understand why it was not released. Simply put, the there is a large disconnect between the Report and its recommendations on the one hand and the Bill on the other.

Disconnect between the MTT's recommendations and the Bill

In our view, the Bill both departs from and undermines the MTT's recommendations. For example, the Report recommends that the proposed regulatory authority take the form of an independent agency – as opposed to a line function – within government. Yet the regulatory authority that the Bill seeks to create is a hybrid structure that exhibits characteristics more closely aligned with an ordinary line function within government. In so doing, the Bill allocates a range of broad discretionary powers to the Minister that have the potential to undermining the authority's independence.[15]

In this section, we consider the following six recommendations:

- A "single entity will be responsible for the regulation and registration of all health products in the country so as to ensure safe, quality and efficacious health products";
- The authority will be an independent agency;
- "Pricing will only be considered as part of the regulatory process should an NHI be established";
- "Memoranda of Understanding should be developed with selected regulatory authorities of other countries in specific areas so as to enhance efficiency and maximise resources utilisation";
- A series of specific recommendations dealing with the detail of the authority's structure and operations; and
- A requirement relating to the tabling of strategic plans and annual reports before the National Assembly.

In so doing, we also address those aspects of the Bill that have the effect of undermining the MTT's recommendations. In this regard, we focus on issues that may not have been addressed by the MTT but which nevertheless have a negative impact on its recommendations.

[14] At a meeting with senior DoH officials held in Pretoria on 20 May 2008, we requested that the Report be made available. At that meeting, to which we were invited by the DoH, Dr. Kamy Chetty promised to raise this particular concern with Prof. Green-Thompson.

[15] This is discussed in greater detail below.

Authority alone responsible for regulation and registration of products
The report's first recommendation covers the following three areas:

- The functions currently undertaken by the MCC and the MRA – which are to be expanded to cover all health products (as defined) – should fall under the same roof;
- Only the authority should be involved in the regulation and registration of health products; and
- Regulation and registration should be limited to ensuring quality, safety and efficacy.

The Bill only complies with the first part of this recommendation, by establishing a regulatory authority that is not limited to medicines. But it fails dismally in respect of the second and third legs of this recommendation, in particular by introducing the two-tier registration system – with certification by the authority followed by registration by the Minister.

We have already addressed our substantive concerns with this system in our previous submission. Here, we are further concerned by the manner in and the extent to which this system departs from the Report's first recommendation. In short, it –

- Locates the registration process partly outside of the authority, being directly under the Minister's control; and
- Introduces a range of factors – other than quality, safety and efficacy – that must be considered before a certified product can be registered.

Independent agency
As already mentioned above, the Bill seeks to create a hybrid structure that exhibits characteristics more closely aligned with an ordinary line function within government than with those suggestive of an independent agency. It does this in a number of ways, including by –

- Allocating a range of broad discretionary powers to the Minister relating to the core business of health product regulation; and
- Empowering the Minister to appoint the head of the authority without mandating any open and accountable process.

<u>Ministerial powers</u>
Our previous submission addressed our substantive concerns with the nature and location of such powers. Such concerns remain, as the Bill is largely indistinguishable from the previous version in respect of which our concerns were raised. In this submission, however, we focus on those powers that undermine the authority's independence, effectively turning it into a line function within the DoH.

Three particular powers come to mind.

The first – and most obvious – deals with the broad scope for refusing to register certified health products, purportedly if it is not in the "public interest"

for such products to be registered. This can be done after the following list of factors has been considered:

- Public health interests including national epidemiological trends;
- Economic interests in relation to health policies;
- Whether the product is supportive of national health policy and goals in the long term;
- Whether the product is likely to significantly improve access to health care for vulnerable groups within society;
- The experience of other countries concerning the marketing, distribution and use of the product; and
- Generally whether the public would be best served by such registration.

As our previous submission argued, registration itself should be limited to concerns of quality, safety and efficacy. Where this has been proven, we do not understand what harm could arise if such products were to be placed on the market – as is currently the case. To the contrary, placing a wider range of health products of proven quality, safety and efficacy on the market is likely to be beneficial in most if not all cases. But by empowering the Minister to have the final say on which products may be registered, on the basis of vague considerations,[16] the Bill removes the core function assigned by the MTT's recommendations to the authority. This seriously calls into question the authority's purported independence.

As we have stated before, we are not arguing against the DoH putting in place a reasonable statutory mechanism for determining whether products of proven quality, safety and efficacy should be provided in the public health sector. To the contrary, we support separate legislation that would codify such a process. Nor are we arguing against the DoH using its purchasing power to extract significant price reductions for the health products that it procures on behalf of the provinces.[17] We are simply opposed to these considerations being taken into account – by a Minister – in determining whether health products should be registered at all.

The second power – dealing with authorisations for the use of unregistered medicines – concerns an aspect of regulation that sits at the core of the functions against which political and commercial interference should be guarded. This power is ordinarily used to address a number of different situations, such as access to products registered elsewhere (but not yet in South Africa), access to experimental products for those who have exhausted their treatment options and authorisation for the use of products in clinical trials designed to determine their safety and/or efficacy. There is no reason why this important function should be carried out by anyone outside of the independent agency.

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[16] Whilst somewhat better drafted than in the previous version of the Bill, these provisions are still vague and uncertain.

[17] Not only do we strongly support the DoH acting in this way, but we also recognise its constitutionally mandated role to ensure that all health products are appropriately priced in the private sector.

The third power that has the potential to undermine the authority's independence is that which permits the Minister to exclude any product from part or all of the provisions of the Medicines Act. In this case, there are no considerations that need to be taken into account – the Minister may simply act "on the recommendation of the Authority". Because the authority reports directly to the Minister and has no independent governance structure of its own, it is particularly vulnerable to undue influence. The manner in which the MCC has come under undue pressure in the past suggests that our concerns in this regard are well founded.

Appointment process

The Bill merely requires the Minister to appoint a "suitably qualified" CEO for the authority. In turn, he or she appoints the authority's staff. The latter aspect of the appointment process is very much in line with the concept of an independent agency. But the appointment of the CEO flies in the face of pretensions at independence. In contrast, consider the appointment processes in relation to the following two statutory bodies: the Judicial Inspectorate of Prisons ("the Judicial Inspectorate") and the Media Development and Diversity Agency (MDDA).

The Judicial Inspectorate – soon to be known as the Judicial Inspectorate for Correctional Services – is headed by the Inspecting Judge. As a current or former judge, he or she – if appointed to the bench after 27 April 1994 – would have been through a public interview process. Upon recommendation by the Judicial Service Commission, the President would have made the appointment. The President appoints the Inspecting Judge.

The Correctional Services Amendment Bill [B 32F—2007] – the latest version of the most recent amendment to the Correctional Services Act, 111 of 1998 – introduces the office of the CEO, "responsible for all administrative, financial and clerical functions of the Judicial Inspectorate." After much debate, the Portfolio Committee on Correctional Services agreed on the following process in terms of which the CEO is to be appointed:[18]

> (1) The Inspecting Judge must identify a suitably qualified and experienced person as Chief Executive Officer, who—
> (a) is responsible for all administrative, financial and clerical functions of the Judicial Inspectorate;
> (b) is accountable to the National Commissioner for all the monies received by the Judicial Inspectorate; and
> (c) is under control and authority of the Inspecting Judge.
> (2) The person contemplated in subsection (1) must be appointed by the National Commissioner.

In other words, the Inspecting Judge identifies the suitably qualified CEO. The National Commissioner – the most senior official in the department – is then obliged to appoint the person identified by the judge, who is accountable to him or her only in respect of monies received. For

[18] New section 88A

everything else, the CEO reports to the judge. In this way, the Judicial Inspectorate retains its independence.

As is the case with many statutory bodies, an independent board heads the MDDA. That board is comprised of nine members:

- Six members appointed by the President on the recommendation of the National Assembly on the basis of –
  - Public participation in the nomination process;
  - Transparency and openness; and
  - The publication of a shortlist of candidates for appointment based on a set of clearly identified considerations; and
- Three other members appointed by the President taking into account another set of considerations. Of these three, "one must be from the commercial print media and another from the commercial broadcast media."

The first six, who would have been subjected to an open public hearing process in Parliament, must all be "committed to fairness, freedom of expression, openness and accountability on the part of those entrusted with the governance of the public service". When viewed collectively, they should be "representative of a broad cross section of the population" and should "possess suitable qualifications, expertise and experience in fields such as" –

- Community media;
- Social, labour and development issues;
- Media economics;
- Financial management and funding;
- Advertising and marketing;
- Journalism and broadcast programming;
- Media research;
- Media training, literacy and education;
- Media law; and
- Information and communication technology policy.

Whilst the two examples are quite different, they both provide examples of legislation providing significant detail regarding key appointments to statutory bodies. In both cases, a range of safeguards – including a separation between the appointing authority (in both cases the President) and the political head responsible for the operation of the body – is put in place to protect the integrity of the institutions and to ensure that appropriate appointments are made. In comparison, the Bill simply grants the Minister a seemingly unfettered discretion in this regard.

Pricing not ordinarily a part of the regulatory process

While recognising the role to be played by the proposed authority in assisting the DoH with its work in relation to the pricing of health products, the Report makes it plain that "[p]ricing will only be considered as part of the regulatory

process should an NHI be established".[19] In other words, unless and until South Africa has adopted a system of national health insurance, the regulatory process should not consider issues beyond quality, safety and efficacy. To date, policy makers in South Africa have neither agreed on what constitutes NHI nor have they committed to putting it in place.

Nevertheless, the Bill disregards the MTT's recommendations. In so doing, it also goes beyond the issue of pricing, with proposed new section 15(4)(c) listing six factors that are to be considered by the Minister in determining whether a certified product should be registered. Of these, only one – "economic interests in relation to health products"[20] – seems to deal directly with health product pricing. Others – including one dealing with "access to health care for vulnerable groups"[21] and another dealing with "the experience of other countries concerning the marketing, distribution and use of the product"[22] – at best seem to allude to considerations of pricing.

Engagement with other regulatory authorities
In its Report, the MTT recommended that –

> Memoranda of Understanding should be developed with selected regulatory authorities of other countries in specific areas so as to enhance efficiency and maximise resources utilisation. This will assist with scarce skills shortages. The MOUs will be signed by the Minister.[23]

This complements the recommendation in our first submission regarding the proposed recognition of other stringent regulatory authorities.[24]

Yet, once again, the Bill is silent. Without any empowering provision in the legislation, it is unlikely that the conclusion of such agreements – whether or not done in terms of any future regulations – would be lawful.

Detail of the authority's structure and operations
The Report provides a series of specific recommendations dealing with the detail of the authority's structure and operations. Yet in response, the Bill is – in the main – largely silent. Presumably, much of this detail is to be provided in regulations, albeit in the absence of any statutory guidance. In contrast, the organisational structure of the South African Medicines and Medical Devices Regulatory Authority (SAMMDRA) – a body that was required to "be independent and impartial in the performance of its functions"[25] – was set out in some detail in its empowering legislation. In particular, sections 16 to 20 provide significant detail on the following:

- Staff of SAMMDRA;
- Financing of SAMMDRA;

[19] Report at page 136
[20] Proposed new subsection (i)
[21] Proposed new subsection (iv)
[22] Proposed new subsection (v)
[23] Report at page 134
[24] See pages 9 and 10 of our previous submission
[25] Section 2(3) of the SAMMDRA Act

- Loans;
- Finances of SAMMDRA; and
- Banking account.

Yet the Bill simply states that the proposed authority is "a juristic person" and that it is "subject to the Public Finance Management Act, 1999" ("the PFMA").[26] In addition, it provides some detail regarding the CEO and his or her staff:

- CEO's term of office and benefits;[27]
- Performance agreement for the CEO and his or her lines of accountability and reporting;[28] and
- Broad responsibilities of the CEO, including –
    - General administration, management and direction of the activities of the authority;[29]
    - Appointment and supervision of staff,[30] including the power to "contract other suitably qualified persons to assist"[31] and to bring in "persons seconded or transferred from the public service"[32];
    - Compilation of business and financial plans and reports in terms of the PFMA;[33] and
    - Subject to the Minister's approval, the power to appoint committees "to investigate and report … on any matter within the purview of the Authority".[34]

Further, it proposes that all staff become members of the Government Employees' Pension Fund and be subject to a human resource policy – including a code of conduct – that is to be developed by the Minister after consultation with the Minister for Public Service and Administration.[35]

Thus on the issue of staffing, the Bill provides much direction. But in respect of the other key issues addressed in the SAMMDRA Act – financing, loans, finances and banking account – it is silent. The Bill's failure to provide such detail, particularly when much of it was already considered by the Report, calls into question the approach that any new regulations will take. Given the disconnect between the Bill and the Report, it is not unreasonable to fear that any new regulations may also depart from the MTT's recommendations.

Tabling of strategic plans and annual reports

The Report recommends that the proposed authority be required to table strategic plans and annual reports before the National Assembly. Yet once again, the Bill is silent. In so doing, it further reinforces the perception that the

[26] Proposed new section 2(2)
[27] Proposed new sections 3(2)(a) and (d) respectively
[28] Proposed new sections 3(2)(b) and (c) respectively
[29] Proposed new sections 3(2)(e) and (f) respectively
[30] Proposed new section 3(2)(g)
[31] Proposed new section 3(3)
[32] Proposed new section 3(5)
[33] Proposed new section 3(2)(h)
[34] Proposed new section 3(7)
[35] Proposed new section 3(4)

proposed authority is not an independent government agency but rather a simple line function within the DoH.

CONCLUSION

This submission has focused on two issues: concerns regarding the MTT's work, as well as the relationship between its recommendations – as set out in the Report – and the Bill. In so doing, it has shown that a central part of the DoH's consultation process was fundamentally flawed. When considered in the light of highly abbreviated timeframes for written submissions on the earlier version of the Bill, as well as a series of meetings with stakeholders that did not result in a single substantive change, we are left with the view that the DoH has largely failed to consult appropriately. With this in mind, we call on Parliament to ensure that the public is appropriately consulted. In our view, it would be well advised to return the Bill to the DoH so that a comprehensive consultation process can be restarted.