equality for all

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JOINT SUBMISSION: METHODOLOGY FOR CONFORMING WITH INTERNATIONAL BENCHMARKS OF THE PRICES OF MEDICINES

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Introduction

Government Notice 2007 of 2005 (*Government Gazette* No. 28214 of 11 November 2005) calls for submissions – amongst other things – on a methodology for conforming with international benchmarks of the prices of medicines. According to the notice, the methodology will be determined and published by the Minister of Health ("the Minister") in terms of regulation 5(2)(e) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances ("the pricing regulations"). We welcome the opportunity to provide input into this important process and hope that our recommendations will assist the Pricing Committee and the Minister in their deliberations.

This joint AIDS Law Project (ALP)/Treatment Action Campaign (TAC) submission is based on our support for the development and implementation of the methodology as an integral component of a range of regulatory tools that are designed to ensure access to a sustainable supply of affordable essential medicines. We continue to welcome government's efforts to increase access to medicines, an integral part of the right of access to health care services that is entrenched in section 27 of the Constitution. In particular, we recognise the importance of regulating private sector medicine prices. By expanding access to health care services through the reduction of medicine prices, appropriate private sector regulation has the potential to relieve the burden of disease on the public sector. This is increasingly important in the context of an expanding HIV/AIDS epidemic that is already placing extreme pressure on a weak public health system.

Focus of this submission

Following the Constitutional Court's decision in *Minister of Health v New Clicks SA (Pty) Ltd*,[1] in which former Chief Justice Chaskalson referred to the methodology as "an essential part of the pricing system",[2] regulation 5(2)(e) now provides as follows:

> "The Minister on the recommendation of the Pricing Committee must determine and publish in the Gazette a methodology for conforming with international benchmarks, taking into account the price, and factors that influence price, at which the medicine or Scheduled substance, or a medicine or Scheduled substance that is deemed equivalent by the Minister on the recommendation of the Pricing Committee, is sold in other countries in which the prices of medicines and Scheduled substances are regulated and published and the single exit price of each medicine or Scheduled substance must, within 3 months of publication of such methodology in the Gazette conform with international benchmarks in accordance with such methodology".

Regulation 5(2)(e) thus requires the development of a framework that will regulate the way in which the single exit price ("SEP") of each medicine[3] conforms with international benchmarks.[4] But what is meant by the phrase "conform with

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[1] 2006 (1) BCLR 1 (CC), also available online at http://www.constitutionalcourt.org.za/site/pharm.html
[2] At paragraph 279
[3] Unless expressly mentioned or the context indicates otherwise, any reference to medicines in this submission should be understood to include a reference to scheduled substances.
[4] The task of developing the methodology thus rests with the Pricing Committee. Any recommendation of the Pricing Committee should then be presented to the Minister for her

international benchmarks". To conform means to match, agree with, correspond, fit or be consistent with. Benchmarks are standards, yardsticks, levels, targets, scales or points of reference. In other words, SEPs will have to be set at levels that are consistent with relevant international pricing scales, assuming that such comparisons can indeed be found. The methodology to be adopted should therefore set out the ways in which this consistency should be achieved, taking into account the price – and the factors that influence price – at which a relevant medicine or equivalent is sold in other countries where medicine prices are regulated.

While some may question the wisdom of subjecting all medicines to an international benchmarking exercise, particularly in those circumstances where it is possible to ensure sufficient competition amongst pharmaceutical companies,[5] regulation 5(2)(e) makes it plain that the "single exit price of <u>each medicine or Scheduled substance</u> must … conform with international benchmarks".[6] This does not mean, however, that the methodology should adopt a one-size-fits-all solution.[7] Indeed, such an approach has the potential to fall foul of various provisions of the Constitution.[8]

Because the call for input on the international benchmarking methodology was made in the absence of any draft proposals, it is not possible for this submission to be anything but limited in its focus. Instead of concrete proposals on a methodology, this submission will instead focus on the following:

- The meaning and implications of section 25(1) of the Constitution, which protects against the arbitrary deprivation of property;[9]
- Unpacking the detail of regulation 5(2)(e); and
- Pragmatic considerations for using international benchmarking.

In so doing, this submission aims to assist the Pricing Committee in developing a draft methodology that will be published for comment before it is finalised and presented to the Minister for her consideration. Given the partially successful constitutional challenge that followed the promulgation of the pricing regulations, resulting in the significant delay of the full and proper implementation of the Medicines and Related Substances Act, 101 of 1965 (as amended), we are of the view that every attempt should be made to ensure that this process runs as

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consideration. Thereafter, she may either accept the recommendation (and then publish the methodology in the *Government Gazette*), or reject it and refer it back – with comments – to the Pricing Committee for reconsideration.

[5] Competition would ordinarily arise following patent expiry, the grant of voluntary and/or compulsory licences in respect of patented products, or the express commitment of an exclusive rights holder not to enforce such rights in the patent concerned. This is not, however, always the case. For example, whilst Bristol-Myers Squibb's essential medicine Fungizone® is no longer under patent protection, generic amphotericin B has yet to be placed on the South African market. Amphotericin B is the antifungal agent of choice to treat cryptococcal meningitis, a common cause of death amongst people living with HIV/AIDS in Africa having a mortality rate of between 25 and 40 per cent.

[6] Emphasis added

[7] Instead, it simply means that no medicine may be exempt from compliance with the international benchmarking methodology.

[8] In particular, section 25(1) dealing with property and section 27 dealing with access to health care services. These issues are considered in more detail below.

[9] The section 25(1) analysis takes into account the state positive constitutional obligations in respect of health care services.

smoothly as is reasonably possible in the circumstances. In short, this means following fair, open and accountable processes, as well as adopting a methodology that is developed with the state's constitutional obligations firmly in mind.[10]

Meaning and implications of section 25(1) of the Constitution

As any restriction on the setting of medicine prices would appear to be a limitation of property rights, it is important to develop and implement an international benchmarking methodology in a manner that complies with the Constitution in general and the provisions dealing with property in particular. In this regard, section 25(1) provides that "[n]o one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property." In relation to the proposed international benchmarking methodology, the following questions thus need to be addressed:

- Is the ability to charge whatever the market will bear for a medicine to be considered as property for the purposes of section 25?
- Will the methodology to be determined and published by the Minister in terms of regulation 5(2)(e) of the pricing regulations constitute a law of general application?
- Is price regulation in the form of mandatory international benchmarking a form of property deprivation, and if so, how can it be done so as to render it "non-arbitrary" and therefore constitutional?

It is highly likely – and therefore wise to assume – that placing regulatory limits on medicine prices constitutes the deprivation of property.[11] In other words, the methodology should comply with the requirements of section 25(1) of the Constitution: it should take the form of a law of general application, and in substance, it should be "non-arbitrary". The former requirement will clearly be met by the proposed determination and publication of the methodology in terms of regulation 5(2)(e). The latter requirement is somewhat more demanding.

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[10] In our view, the Pricing Committee would be wise to assume that the international benchmarking methodology may well be subject to legal challenge if it has the potential to achieve its goal – that is, to exert real downward pressure on the prices of medicines. Because of this, every attempt should be made to insulate the methodology from legal challenge. This does not mean, however, that the methodology should be conservative in its goals. It simply means that it should be carefully tailored to comply with the Constitution.

[11] See *First National Bank of SA Ltd t/a Wesbank v Commissioner, South African Revenue Service*; *First National Bank of SA Ltd t/a Wesbank v Minister of Finance* 2002 (4) SA 768 (CC) at paragraphs 51 and 57 respectively, where Ackermann J states as follows:

> "At this stage of our constitutional jurisprudence it is, for the reasons given above, practically impossible to furnish – and judicially unwise to attempt – a comprehensive definition of property for purposes of section 25."
>
> "In a certain sense any interference with the use, enjoyment or exploitation of private property involves some deprivation in respect of the person having title or right to or in the property concerned."

See also *Mkontwana v Nelson Mandela Metropolitan Municipality* 2005 (1) SA 530 (CC) at paragraph 32 (footnotes omitted):

> "Whether there has been a deprivation depends on the extent of the interference with or limitation of use, enjoyment or exploitation. … [A]t the very least, substantial interference or limitation that goes beyond the normal restrictions on property use or enjoyment found in an open and democratic society would amount to deprivation."

In *First National Bank of SA Ltd t/a Wesbank v Commissioner, South African Revenue Service*; *First National Bank of SA Ltd t/a Wesbank v Minister of Finance* ("the FNB case"), Ackermann J held as follows:

> "In its context 'arbitrary', as used in section 25, is not limited to non-rational deprivations, in the sense of there being no rational connection between means and ends. It refers to a wider concept and a broader controlling principle that is more demanding than an enquiry into mere rationality. At the same time it is a narrower and less intrusive concept than that of the proportionality evaluation required by the limitation provisions of section 36. This is so because the standard set in section 36 is 'reasonableness' and 'justifiability', whilst the standard set in section 25 is 'arbitrariness'. This distinction must be kept in mind when interpreting and applying the two sections. …
>
> Having regard to what has gone before, it is concluded that a deprivation of property is 'arbitrary' as meant by section 25 when the 'law' referred to in section 25(1) does not provide sufficient reason for the particular deprivation in question or is procedurally unfair."[12]

In short, the methodology must "provide sufficient reason" for the extent to – and the manner in – which it regulates medicine prices, and must be procedurally fair. A low level of regulation for all medicines may satisfy compliance with this requirement, but

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[12] See *FNB*, above note 11 at paragraphs 65 and 100. Paragraph 100 continues as follows:

"Sufficient reason is to be established as follows:

(a) It is to be determined by evaluating the relationship between means employed, namely the deprivation in question, and ends sought to be achieved, namely the purpose of the law in question.
(b) A complexity of relationships has to be considered.
(c) In evaluating the deprivation in question, regard must be had to the relationship between the purpose for the deprivation and the person whose property is affected.
(d) In addition, regard must be had to the relationship between the purpose of the deprivation and the nature of the property as well as the extent of the deprivation in respect of such property.
(e) Generally speaking, where the property in question is ownership of land or a corporeal moveable, a more compelling purpose will have to be established in order for the depriving law to constitute sufficient reason for the deprivation, than in the case when the property is something different, and the property right something less extensive. This judgment is not concerned at all with incorporeal property.
(f) Generally speaking, when the deprivation in question embraces all the incidents of ownership, the purpose for the deprivation will have to be more compelling than when the deprivation embraces only some incidents of ownership and those incidents only partially.
(g) Depending on such interplay between variable means and ends, the nature of the property in question and the extent of its deprivation, there may be circumstances when sufficient reason is established by, in effect, no more than a mere rational relationship between means and ends; in others this might only be established by a proportionality evaluation closer to that required by section 36(1) of the Constitution.
(h) Whether there is sufficient reason to warrant the deprivation is a matter to be decided on all the relevant facts of each particular case, always bearing in mind that the enquiry is concerned with "arbitrary" in relation to the deprivation of property under section 25."

would in all likelihood constitute non-compliance with the state's positive obligations in respect of the right to have access to health care services in section 27(2) of the Constitution.[13] A high level of regulation, on the other hand, may be appropriate for certain medicines but not for others.

In effect, this means that the methodology must avoid a "one-size-fits-all" approach – it needs to differentiate according to the need for and the appropriateness of strict price controls. In our view, there are at least three clear bases upon which to differentiate:[14] the existence (or otherwise) of competition in the market for a particular medicine; the need to create sufficient incentives for pharmaceutical manufacturers to place new innovative products on the market;[15] and the burden of disease in respect of which a medicine is indicated (as a prophylaxis or treatment).

Existence or otherwise of competition

The need for an international benchmarking methodology speaks to the regular failure of market forces to regulate medicine prices appropriately. But while there is generally a need for price regulation in South Africa, its focus should be on what should be done in respect of medicines where there no competition, limited or insufficient (some but not enough) competition. Where there is adequate competition in the market, it should largely be free to perform.[16] In other words, where the market can work to keep prices in check, then it should be left to work.

But what is meant by no, limited, insufficient and adequate competition? For the purposes of the methodology, we submit that these terms be defined and propose the following:[17]

- No competition: where only a single version of a particular medicine is available for sale in South Africa, regardless of its patent status
- Limited competition: where only two versions are available for sale
- Insufficient competition: where three or four versions are available
- Adequate competition: where five or more versions are available

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[13] This is because it would leave the prices of many medicines insufficiently regulated, thereby limiting access to them.

[14] All of these comply with the requirements of the right to equality in section 9 of the Constitution, in particular the right in section 9(3) to be free from unfair discrimination.

[15] These incentives are not to be confused with the creation of incentives for innovation per se, which is supposed to lie at the heart of patent protection. In our view, high medicine prices in South Africa and/or the rest of Africa have little to no impact on the research and development agenda of research-based pharmaceutical companies. In this regard, see Edwin Cameron and Jonathan Berger, "Patents and Public Health: Principle, Politics and Paradox", (2005) 131 *Proceedings of the British Academy* 331 at 340 – 341.

[16] This applies in respect of price regulation only. Regulation for the purposes of ensuring quality, safety and efficacy cannot be left to market forces.

[17] This categorization is largely based on the "rule-of-five" which "holds that generic prices generally reach their minimum when there are at least five generic alternatives on the market". See World Health Organization, "Drug procurement – the principles for getting it right" in *Essential Drugs Monitor* N° 30 (2001), available online at http://mednet2.who.int/edmonitor/edition/edm30_en.pdf, at 15. For the purposes of the categorization, one competitor cannot be owned or controlled – in part or in whole – by another. Thus, for example, Novartis and its generic division Sandoz cannot be considered as competitors.

So how should the methodology deal, in general,[18] with each of these categories of medicines? While it is important to develop a system that responds appropriately to the need for regulation, section 25(1) of the Constitution does not require the degree of accuracy implicit in proportionality analysis. In other words, all that it requires is that there be sufficient reason for the differentiation. Further, because of the impossibility of designing a methodology that responds to medicines individually, we submit that all medicines in a single category be subjected to the same test, subject only to possible adjustments based on the level of innovation represented by that medicine and the burden of disease in respect of which the medicine is indicated.

Below we consider an appropriate option in respect of each category. Our approach, which is based on the need for simplicity of regulation, assumes that the methodology selects an even number of appropriately selected international comparators.[19] Our approach seeks to pair up the level of competition faced by a product in South Africa with an appropriate level of international benchmarking: the greater the competition, the lower the level of obligation; and similarly, the lower the level of competition, the greater the level of conforming.

No competition

In the ordinary course of events, the simple operation of the patent system results in a complete lack of competition for any registered medicine for the duration of the life of the patent.[20] It is respect of such products where there is the greatest need to restrict a manufacturer's ability to set medicine prices. But how should medicines that face no domestic competition have to respond to the international benchmarks? In our view, the price of such a medicine in South Africa should be no higher than the average of the bottom half of the international benchmarks. Thus if there are four benchmarks, the South African price should be no higher than the average of the two lowest benchmarks. Similarly, if there are six benchmarks, the South African price should be no higher than the average of the three lowest benchmarks.

Limited competition

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[18] This will be subject to other considerations regarding levels of innovation and incentives to place such products on the market. This issue is discussed below.

[19] The selection of comparators may have to be adjusted on a case-by-case basis. Take the case of India, for example, which prior to 2005 did not recognise medicine product patents. It may be difficult to compare products that may be patented in South Africa (and therefore subject to no competition) with the same products that have not been – nor have the possibility of being – patented in India.

[20] There are exceptions to this general rule. In some cases, one patented medicine – such as Pfizer's Viagra® – may be considered as fully (or largely) substitutable for another – such as Bayer's Cialis®. But in others – such as is ordinarily the case with highly active antiretroviral therapy (HAART) – the availability of other medicines in the same therapeutic class does not mean substitutability. In this regard, see Robin Wood, affidavit in *Hazel Tau and Others v GlaxoSmithKline SA (Pty) Ltd and Others*, in case no. 2002Sep226 before the Competition Commission of South Africa, available online at http://www.tac.org.za/Documents/DrugCompaniesCC/Tau_v_GSK--Wood_affidavit.doc, where the following is stated at paragraph 43:

> "The nature of HAART, coupled with a further narrowing of choices in respect of pregnant women and women of childbearing potential, children and people with TB and HIV co-infection, leads to only one reasonable conclusion—that ARVs, even within the same therapeutic class, cannot be considered as fully substitutable for each other. Because of the matrix of interconnected factors relating to toxicity and effectiveness of treatment, access to a wide choice of ARVs is required in order to effectively administer HAART. At present no single registered ARV is fully substitutable by another."

Where only two versions of a medicine are available for sale, as usually happens following patent expiry and the market entry of the first competitor, an important – but still wholly inadequate – initial price reduction is ordinarily observed. Because such medicines are under some competitive pressure, it is not appropriate to subject them to the same high standard as we have already submitted should be applied to medicines that do not face any competition. Because of this, it is our view that the price of such a medicine in South Africa should be no higher than the average of all the international benchmarks.

Insufficient competition

Where three or four versions of a particular medicine are available for sale, price reductions begin to become meaningful. Because such medicines are under significant (albeit insufficient) competitive pressure, it is not appropriate to subject them to the intermediate standard described above, but instead apply a somewhat lower standard. We therefore submit that the price of any medicine facing insufficient competition should be no higher than the average of the top half of the international benchmarks. Thus if there are four benchmarks, the South African price should be no higher than the average of the two highest benchmarks. Similarly, if there are six benchmarks, the South African price should be no higher than the average of the three highest benchmarks.

Adequate competition

Where there is adequate competition, the methodology should be least restrictive of a manufacturer's ability to set medicine prices. In our view, the price of a medicine that faces adequate competition in South Africa should be no higher than the highest of the international benchmarks.

Level of innovation and burden of disease

Within each category identified above, sufficient space must be created to allow for adjustments that respond to levels of innovation and the burden of disease. Largely underpinning such a proposal is the need to ensure that innovative products are placed on the market in South Africa, as well as the need to ensure the affordability – in particular – of medicines necessary to deal with public health priorities. This process, however, should not result in any significant variation from the generalized approach already articulated above, which is primarily based on the need for appropriate regulation to counter the partial or total lack of competition that often characterizes the market for medicines.

In our view, the methodology should allow for greater flexibility in respect of medicines that provide a breakthrough or a substantial improvement on what is currently available in the market.[21] Similarly, medicines necessary for dealing with public health emergencies – such as antiretroviral medicines for the prophylaxis and treatment of HIV-infection and AIDS-related illnesses (such as tuberculosis) – should be subjected to greater regulation than other medicines in the same category.[22] Clearly, a fine balance needs to be reached between keeping medicine prices down

[21] This would generally apply, however, only in respect of the "no competition" category. Once generics are placed on the market, the danger of innovative products not reaching the market has been removed.

[22] By category, we do not mean therapeutic class but rather category as defined by level of competition in the market.

and ensuring that new innovative products – especially those necessary for dealing with public health priorities – are placed on the South African market.[23] In practice, this may require a shift from the approach based on averages to one based on medians, or some other measure that allows for the broad thrust of the approach to remain whilst taking into account flexibility necessary for rewarding innovation and/or dealing with public health priorities.

Unpacking some of the detail of regulation 5(2)(e)

Regulation 5(2)(e) states that the methodology must take into account a range of issues. We are of the view that some of these issues need to be unpacked carefully, primarily to ensure that the methodology identifies appropriate international comparators. These issues are now discussed below in greater detail

Factors that influence price

While numerous factors influence price, the primary driver of high medicine costs is the lack of adequate competition in respect of any particular medicine. Limits on competition are in turn the result of a number of factors, including the following:

- The failure of many legal frameworks to give full and proper effect to the flexibilities and public health safeguards in the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs), as clarified in the *Declaration on the TRIPs Agreement and Public Health*,[24] and as supplemented by the decision on the *Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health*;[25]
- The TRIPs-plus commitments contained in the so-called free trade agreements between the United States of America and many developing countries;[26]
- Delays in drug registration by national drug regulatory authorities; and
- The failure of many generic companies to register certain off-patent (or unpatented) medicines and place them on the market.

In addition, prices may vary due to a range of additional factors, such as:

- The non-existence of patent protection in respect of certain products, whether as a result of a failure to file patents or as a result of pre-TRIPs patent regimes that did not recognise product patents;
- The extent to which the public sector covers the costs of medicines for middle- and upper-incomes persons;
- The ability of persons to purchase medicines, including the extent to which they are able to access private medical insurance or are reliant on out-of-pocket expenditure for medicines;
- The costs of production, including innovation in process and the costs of active pharmaceutical ingredients (APIs), raw materials and intermediates;

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[23] A further safeguard exists in the form of section 56 of the Patents Act, 57 of 1978. Where new innovations are not placed on the market, compulsory licences may be issued on the basis that the failure to "work" the invention constitutes an abuse of the exclusive rights in the patent concerned.

[24] WT/MIN(01)/DEC/2, 20 November 2001

[25] WT/L/540, 1 September 2003

[26] See, for example, the texts of the United States-Morocco Free Trade Agreement (available online at http://www.ustr.gov/Trade_Agreements/Bilateral/Morocco_FTA/FInal_Text/Section_Index.html) and the Central America-Dominican Republic-United States Free Trade Agreement (available online at http://www.ustr.gov/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/Section_Index.html).

- The existence (or otherwise) of an essential drugs list, its implications and the extent to which it is comprehensive;
- State procurement practices; and
- State-imposed cost drivers such as import duties and value-added tax.

Medicines deemed equivalent by the Minister
The methodology needs to provide guidance to the Pricing Committee and the Minister regarding an appropriate process for deeming medicines equivalent. In this regard, the test for substitutability – as ordinarily employed in market definition analysis in competition law – is a useful start. However, equivalency for the purpose of price regulation also needs to consider that even where a medicine may be considered as substitutable, other factors (such as the complexity of manufacture or the cost of the APIs) might render it an inappropriate comparator.

Comparator countries
The essential requirement in regulation 5(2)(e) is that comparators be found in countries where medicine prices are regulated and published. This is helpful, but inconclusive. In general, it would not suffice to compare medicine prices in South Africa with those in developed countries where medicine prices are regulated and published.[27] Instead, the focus should be on middle-income countries with significant disparities between the rich and the poor. However, even this approach is not without its complications. Even though Brazil is generally a good comparator, with similar levels of inequality and economic development, it is not a good comparator when it comes to the prices of post-TRIPs antiretroviral medicines. Because of the relatively small size of its HIV/AIDS epidemic,[28] Brazil does not "qualify" for the best prices offered in certain industry-driven differential pricing programmes.

Pragmatic considerations for using international benchmarking
A key consideration in the development and implementation of an international benchmarking methodology is the need to ensure that sufficient capacity exists within the Department of Health to implement such a methodology. Recognizing that regulation is resource-intensive, we submit that unless significant additional financial and human resources are made available for its implementation, the methodology should – as far as is reasonably possible – be simple to understand, apply and implement.

Some of the burden can – and indeed should – be placed on the manufacturers themselves, who are either in possession of or are reasonably able to access international pricing information, particularly in respect of their own products. However, the state cannot expect – nor should it allow – the private sector to shoulder the entire burden. This would be both unfair and counter-productive, as it would effectively place the process of regulation back into the hands of the very sector that has proven itself incapable of self-regulation.

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[27] There are exceptions to this rule. According to our research, the essential medicine Fungizone® (amphotericin B) was priced in the British National Formulary at UK£3.70 a vial (VAT inclusive) in early 2005. At the same time, the public sector price of the medicine in South Africa was R145.75 (VAT inclusive). At the exchange rate applicable at the time, the UK public sector price was just 29% that of the South African private sector price. See also above note 5.
[28] Relative to a high prevalence country such as South Africa

In addition, the methodology should include a requirement for an annual review of the appropriateness of the comparator countries, including a process for amending the list and the basis upon which such an amendment would be effected. Finally, the methodology should include a mechanism for enforcement, expressly allowing for interested parties to lodge formal complaints with the Department of Health if they have reason to believe that any pharmaceutical manufacturer is not acting in compliance with regulation 5(2)(e).

Conclusion

Once again, we welcome this opportunity to make written submissions and reiterate our support for the full and proper implementation of the Medicines and Related Substances Act, 101 of 1965, as amended by the Medicines and Related Substances Control Amendment Act, 90 of 1997 and the Medicines and Related Substances Amendment Act, 59 of 2002. Should the Pricing Committee and/or the Minister require any further input from either the ALP or the TAC in this initial process, we can be contacted through the author of this submission at (011) 717-8627 or bergerj@law.wits.ac.za.

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