



## **SUBMISSION ON THE DRAFT METHODOLOGY FOR INTERNATIONAL BENCHMARKING OF MEDICINE PRICES IN SOUTH AFRICA<sup>1</sup>**

On 10 March 2006, the AIDS Law Project (ALP) and the Treatment Action Campaign (TAC) made a joint submission in response to the call for submissions – amongst other things – on a methodology for conforming with international benchmarks of the prices of medicines.<sup>2</sup> As was the case with that submission, the recommendations contained in this submission are based on our support for the development and implementation of an appropriate benchmarking methodology as one of a range of regulatory tools that are necessary for ensuring access to a sustainable supply of affordable essential medicines. Once again, 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.

Before we comment on and make recommendations in respect of the draft methodology for the international benchmarking of medicine prices (“the draft methodology”), we would like to consider the relationship between it and other available regulatory tools, particularly given the structural factors that result in unjustifiably high medicine prices. Notwithstanding our recognition that there is no magic bullet for ensuring a sustainable supply of affordable essential medicines, we are nevertheless of the view that the single most important challenge to address – the underlying cause of unjustifiably high medicine prices – is the lack of competition in respect of many (ordinarily patented) medicines. Simply put, the lack of competition is a result of one or more of the following factors:

- Market exclusivity as a result of patent protection;
- Delays in the market entry of generic competitors following patent expiry or the grant or issue of licences, including – but not limited to – delays in the drug registration process; and
- An insufficiently-sized “market”.

In all of the above cases, the market simply cannot be left to regulate itself. The primary role of government in this regard, *wherever appropriate*, is to facilitate an environment that permits the market entry of generic competitors:

- In relation to market exclusivity as a result of patent protection, the state’s primary role is to ensure a regulatory framework that – in appropriate cases – facilitates the granting and/or issuing of licences to generic competitors.
- Regarding regulatory delays, the state’s primary obligation is to ensure that the Medicines Control Council (MCC) has the requisite resources and operates within an appropriate regulatory framework that allows and compels it to assess the quality, safety and efficacy of medicines within a reasonable time period.

<sup>1</sup> This submission is endorsed by the TAC and the AIDS and Rights Alliance for Southern Africa (ARASA). The ALP is a founder member of ARASA. For further information regarding this submission, please contact Jonathan Berger on 011 356 4112 (tel), 011 339 4311 (fax), 083 419 5779 (cell) or [bergerj@alp.org.za](mailto:bergerj@alp.org.za).

<sup>2</sup> Government Notice 2007 of 2005, *Government Gazette* No. 28214 (11 November 2005). The submission is available online at <http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=282>

- Wherever possible and appropriate, the state should be “creating” the relevant market – by ensuring that medical schemes are obliged to fund the use of such medicines as part of the Prescribed Minimum Benefits and by providing the medicines as an integral part of the standard of care in the public sector.<sup>3</sup>

What then does this mean for the relationship between the draft methodology and other available regulatory tools, particularly when the state has a constitutional duty to “take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation” of the right to have access to health care services – which includes a right of access to essential medicines?

Where it is not possible to facilitate an environment that permits the market entry of generic competitors, because such forms of intervention are either not feasible or are practically impossible, the state is entitled – and indeed constitutionally mandated – to ensure that medicines are affordably priced by way of direct price regulation, such as by way of a benchmarking methodology. But before resorting to direct price regulation, which is resource (financial and human) intensive and runs the risk of the market being either under- or over-regulated, the state would be wise to explore all alternatives.<sup>4</sup>

Unfortunately, the draft methodology acts as a blunt tool, treating all medicines in the same undifferentiated way, regardless of the existence or otherwise of competition in the relevant market. At best, the methodology has the potential to under-regulate the market by bringing many of our excessively priced medicines in line with lower – but still unjustifiably high – medicine prices.<sup>5</sup> At worst, the methodology will over-regulate by opening up the door to the wholesale collapse of the local generic drug industry – primarily by guaranteeing originator medicines a 40% margin, regardless of current patent status.

## Summary of recommendations

This submission makes the following recommendations:

- Regulation 5(2)(e) of the medicine pricing regulations should be amended to address two concerns:
  - First, it should be amended so that it refers to the prices of medicines sold “in other comparable countries” rather than the price of medicines sold “in other countries in which the prices of medicines and Scheduled substances are regulated and published”; and
  - Second, it should be supplemented so that it empowers the Minister to exempt certain medicines or categories of medicines from the operation of the methodology where the Pricing Committee has reasonable grounds for believing that there is sufficient competition in respect of that medicine or category of medicines;
- The list of comparator countries – which only includes Australia, Canada, New Zealand and Spain – needs to be supplemented to include more appropriate

<sup>3</sup> Markets can also be created by removing inappropriate regulatory barriers that act as a disincentive to generic competitors entering the market. This includes, but is not limited to, inexcusable regulatory delays and proposals (such as is contained in the draft benchmarking methodology) that create inappropriate distinctions between generic and off-patent branded products. This is addressed below.

<sup>4</sup> This, in essence, was the underlying principle in our earlier submission – that “the methodology must avoid a ‘one-size-fits-all’ approach” and that “it needs to differentiate according to the need for and the appropriateness of strict price controls”.

<sup>5</sup> This is because of the comparator countries chosen, as well as the decision to base all benchmarks on the lowest price of the originator medicine in the benchmark countries.

comparators, in particular developing countries with similar levels of development and/or burdens of disease;

- The distinction between off-patent originator and generic medicines needs to be discarded, with some distinction being retained only in respect of originator medicines that are still under patent protection; and
- The benchmark prices need to be reconsidered:
  - There needs to be a single benchmark price for all medicines, regardless of whether it is an originator or generic medicine;
  - The benchmark price of a medicine that is still under patent in South Africa, irrespective of whether voluntary, non-voluntary or compulsory licences have been issued or granted, is the price of the cheapest originator version of that medicine in the comparator countries; and
  - The benchmark price of a medicine that is no longer under patent protection in South Africa is the price of the cheapest version of that medicine – recognised by a stringent drug regulatory authority or the World Health Organization as being of acceptable quality, safety and efficacy – in the comparator countries.

### **Structure of this submission**

This submission begins by comparing the prices of key essential medicines in South Africa with the prices of the same medicines in the proposed comparator countries. Once certain lessons have been drawn from this comparison, the submission addresses the following recommendations: supplementing the list of comparator countries and amending regulation 5(2)(e); and redefining the benchmark prices. Before concluding, the submission addresses a few other concerns we have about the text of the draft methodology.

### **Price comparisons**

The price comparison table below deals only with a few medicines in each of three categories: HIV-related (antiretroviral (ARV) medicines and opportunistic infection (OI) treatments), anti-cholesterol and anti-cancer medicines. While most of the products are still under patent,<sup>6</sup> some of these do face lawful generic competition.<sup>7</sup> All prices quoted are for a single tablet, capsule or vial of powder.<sup>8</sup> Each South African price quote is a single exit price (SEP), excluding VAT but including the logistics fee.<sup>9</sup> Australian, Canadian,<sup>10</sup> New Zealander and Spanish prices quoted are government-negotiated prices – retail prices have been used only where the relevant pharmaceutical benefit does not cover the medicine at all, resulting in it not being listed on the relevant benefit schedule.<sup>11</sup>

<sup>6</sup> Fluconazole and simvastatin are no longer protected by patent. Roche does not enforce its exclusive rights in the ganciclovir and valganciclovir patents.

<sup>7</sup> Stocrin (efavirenz) faces the threat of imminent generic market entry.

<sup>8</sup> All prices are in South African rands, based on the exchange rate of 20 February 2007 ([www.oanda.com](http://www.oanda.com)).

<sup>9</sup> The amount of the logistics fee in respect of many medicines is not yet publicly available.

<sup>10</sup> Each Canadian province negotiates separately. For this analysis, the lowest of the Ontario and Quebec prices have been considered, being the two largest drug programmes in the country.

<sup>11</sup> I am grateful to the following people for assistance in gathering this data: Marta Darder (Médecins Sans Frontières, South Africa); Carole Devine (formerly with Médecins Sans Frontières, Canada); Richard Elliott (Canadian HIV/AIDS Legal Network); Lai-Ling Lee (Médecins Sans Frontières, Canada); Carmen Pérez Casas, (Campaign for Access to Essential Medicines, Médecins Sans Frontières); Victoria Siu (Faculty of Pharmacy, University of Toronto); and Nora Uranga Celaya (Médecins Sans Frontières, Spain).

## Selected price comparisons

Drug and dosage	Australia	Canada	NZ	Spain	SA	Difference
<b>ARV medicines</b>						
Efavirenz (Stocrin) 600mg tab	84.81	81.53	<u>79.25</u>	83.73	4.72	– 94.04%
Lamivudine (3TC) 150mg tab	26.42	26.99	25.63	<u>23.48</u>	1.64	– 93.02%
Lamivudine (Generic) 150mg tab	-	-	-	-	0.65	– 97.23% (relative to 3TC)
AZT/lamivudine (Combivir) 300mg/150mg tab	54.20	58.28	55.66	<u>45.81</u>	5.35	– 88.32%
AZT/lamivudine (Generic) 300mg/150mg tab	-	-	-	-	3.67	– 91.99% (relative to Combivir)
<b>OI treatments</b>						
Fluconazole (Diflucan) 200mg cap	106.39	109.69	–	<u>82.74</u>	47.29	– 42.85%
Fluconazole (Generic) 200mg cap	106.39	59.63	<u>7.42</u>	71.46	8.81	– 89.35% (relative to Spanish Diflucan) – 81.37% (relative to SA Diflucan) + 18.73% (relative to generic)
Ganciclovir (Cymevene) 500mg vial for IV	314.77	252.84	(Not listed)	<u>180.90</u>	372.28	+ 105.79%
Valganciclovir (Valcyte) 450mg tab	210.39	<u>137.48</u>	–	198.32	214.12	+ 55.75%
<b>Cholesterol</b>						
Atorvastatin (Lipitor) 40mg tab	<u>5.75</u>	13.19	6.18	11.31	8.24	+ 43.3%
Simvastatin (Lipex or Zocor) 40mg tab	12.62	13.50	<u>3.00</u>	5.96	4.97	+ 65.67%
Simvastatin (Generic) 40mg tab	12.49	<u>6.75</u>	(Not listed)	(Not listed)	3.40	– 49.63% (relative to generic) + 13.33% (relative to Lipex)
<b>Cancer</b>						
Imatinib mesylate (Glivec or Gleevec) 100mg tab	176.70	<u>156.94</u>	200.22	164.05	160.24	+ 2.1%
Trastuzumab (Herceptin) 440mg vial for IV	16 986.07	17 475.26 (retail)	19 396.31	<u>16 471.98</u>	16705.41	+ 1.42%

The table above tells a multitude of stories, providing a strong basis for approaching the proposed benchmarking methodology with great caution. Quite clearly, there is a great disparity between the price comparisons between South Africa and the comparator countries in respect of the antiretroviral (ARV) medicines covered on the one hand, and opportunistic infection treatments such as ganciclovir and valganciclovir on the other. This simply begs the question: if South Africans can access ARV medicines at such reduced prices, why – for example – should they not be able to access other essential HIV-related medicines at similar price reductions?

For example, why is Diflucan – used to treat opportunistic infections such as candidiasis and cryptococcal meningitis – sold in South Africa at a price of about 43% lower than the price of the same product in Spain; whereas Cymevene – used to treat CMV retinitis – is sold for more than twice the Spanish price? The answer is simple: civil society action against Pfizer regarding the price of Diflucan has not yet been matched by similar action against Roche regarding the price of Cymevene. And while the draft methodology – if implemented in its current form – would result in a 51.4% reduction in the price of Cymevene, it simply leaves unanswered the question of whether the Spanish price of Cymevene is itself not unreasonably high when viewed in a South African context.

Consider the example of 3TC, which prior to the Competition Commission complaint brought by Hazel Tau and others against GlaxoSmithKline and Boehringer Ingelheim in 2002 retailed for R10.67 per 150mg tablet (VAT exclusive). The draft methodology – if it had been implemented at that time but based on the current prices of 3TC in the comparator countries – would have left the price untouched. Yet today, the retail price of 3TC in South Africa today is 85% lower than it was in 2002, with generic lamivudine retailing at a reduction of just under 94%. Public sector prices are even lower.

It may be tempting to argue that the regulatory framework that resulted in such price reductions could similarly be used to effect significant price reductions in respect of other medicines.<sup>12</sup> But the fact that it hasn't suggests that reliance on such civil society action is both unrealistic and unsustainable. For every HIV-related medicine that has been targeted by the ALP and the TAC – zidovudine, lamivudine and nevirapine;<sup>13</sup> fluconazole;<sup>14</sup> and amphotericin B<sup>15</sup> – there are many more that remained off the radar screen. And as the ALP and TAC litigation and legal action record over the past few years show, medicine pricing issues have largely taken a back seat as other treatment access battles have dominated the organizations' agendas.

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<sup>12</sup> But see Edwin Cameron and Jonathan Berger, "Patents and Public Health: Principle, Politics and Paradox" (2005) 131 *Proceedings of the British Academy* 331 at 364, where the authors argue that "[t]he manner in which access to certain generic ARVs has been assured is decidedly unsustainable in the long term."

<sup>13</sup> *Hazel Tau v GlaxoSmithKline South Africa (Pty) Ltd and Boehringer Ingelheim (Proprietary) Limited*, complaint before the Competition Commission of South Africa, case no. 2002Sep226 (settled on 9 December 2003). For further discussion of the complaint, see Jonathan Berger, "Advancing Public Health by Other Means: Using Competition Policy", in Pedro Roffe, Geoff Tansey and David Vivas-Eugui (eds.), *Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, London: 2005) and Tenu Avafia, Jonathan Berger and Trudi Hartzenberg, "The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries – Tralac Working Paper No 12" (University of Stellenbosch Printers, Stellenbosch: 2006), available at [http://www.tralac.org/pdf/20061002\\_Avafia\\_TRIPsandCompetitionLaw.pdf](http://www.tralac.org/pdf/20061002_Avafia_TRIPsandCompetitionLaw.pdf)

<sup>14</sup> The TAC's Christopher Moraka Defiance Campaign successfully targeted the unjustifiably high price charged by Pfizer for its then-patented version of fluconazole (Diflucan). For more information on the campaign, see <http://www.tac.org.za/Documents/DefianceCampaign/import.htm>

<sup>15</sup> Threatened legal action by the ALP on behalf of the TAC and the Southern African HIV Clinicians' Society resulted in public and private sector price reductions of 85% and 90% respectively. For more information on the threatened action, see <http://www.tac.org.za/Documents/AmphotericinB/bms.htm>

Reliance on civil society action may, to some extent, be justifiable in the HIV/AIDS context. But why should the existence or otherwise of well-organised and resourced organizations be the determinant of medicines access? Why, for example, should the weakness of consumer groups dealing with cancer be the reason that drugs such as Gleevec and Herceptin remain out of the reach of most of those in need?<sup>16</sup> In any event, the primary obligation to ensure access to a sustainable supply of affordable medicines lies with government. It has a constitutional duty to ensure that the regulatory framework it puts in place is capable – as far as is reasonably possible – of delivering on the promise of access to health care services, including access to essential medicines.

Another concern raised directly by the table is the crude and unhelpful distinction made by the draft methodology between originator and generic products. Applying the methodology to fluconazole would leave South African originator and generic prices untouched, regardless of the fact that the cheapest generic fluconazole sold in South Africa is still more than 18% higher than the cheapest generic in New Zealand. Yet the price of the cheapest generic zidovudine/lamivudine combination sold in South Africa would be forced down a further 12.5% (so that it is at least 40% lower than the South African price of 3TC), notwithstanding that it is already sold on the private sector at 8% of the lowest price of Combivir (the only version legally sold) in the comparator countries.

### **Supplementing the list of comparator countries and amending regulation 5(2)(e)**

The draft methodology claims that the Pricing Committee “wishes to ensure that South African citizens do not pay higher prices than their counterparts in other countries.” This simply begs the question – which counterparts, in which “other” countries? Regulation 5(2)(e) of the Pricing Regulations is not particularly helpful – it simply refers to “countries in which the prices of medicines and Scheduled substances are regulated and published”. While implicit in regulation 5(2)(e) is a requirement that these countries be appropriate comparators, particularly when understood in the context of section 25(1) of the Constitution,<sup>17</sup> the choice of countries suggests otherwise.

Consider the following statistics:<sup>18</sup>

- Position on the Human Development Index (highest to lowest): Australia (3); Canada (5); New Zealand (19); Spain (21); South Africa (120);
- Percentage of people living on less than US\$2/day: only South Africa (34.1%);
- Per capita gross national income (highest to lowest): Canada (US\$30 0660); Australia (US\$29 200); Spain (US\$25 070); New Zealand (US\$22 130); South Africa (US\$10 960); and
- Per capita government expenditure on health (highest to lowest): Canada (US\$2090); Australia (US\$1939); New Zealand (US\$1483); Spain (US\$1321); South Africa (US\$258).

In respect of burden of disease, there is significant variance. Consider, for example, HIV prevalence rates: New Zealand: 0.035%; Australia: 0.079%; Canada: 0.186%; Spain: 0.325%; and South Africa: 11.6%.

<sup>16</sup> Given the very high prices of these medicines in the comparator countries, the application of the benchmarking methodology would have a negligible impact on increasing access to them.

<sup>17</sup> In this regard, see our previous submission which deals with section 25(1) of the Constitution and the deprivation of property.

<sup>18</sup> These statistics are sourced from the Joint United Nations Programme on HIV/AIDS and are available online at [http://www.unaids.org/en/Regions\\_Countries/Countries/default.asp](http://www.unaids.org/en/Regions_Countries/Countries/default.asp).

In wealthy countries with low disease burdens and relatively well-resourced public health systems, one should not be surprised to find relatively high medicine prices. That we should consider them against which to benchmark our medicine prices is indeed surprising. In a country such as South Africa, relatively low levels of government funding for health care (relative to the comparator countries, not other developing countries) and limited access to public sector pharmaceutical services translate directly into out-of-pocket expenditure on medicines for many working class people. Where we have seen the greatest consumer advocacy in respect of medicine prices – HIV/AIDS – we are increasingly seeing greater public sector access. Where prices remain unjustifiably high, public sector access remains very low.

In addition, the specifics of the price control mechanisms adopted in at least two of the comparator countries undermine their relevance. In Canada, the Patented Medicine Prices Review Board only regulates the prices of originator medicines whilst still under patent protection.<sup>19</sup> In Australia, where most medicine purchases are funded by the state, a recent free trade agreement with the United States places extreme limits on the ability of the federal government to negotiate the prices of medicines. Australia's relevance as a comparator may indeed be waning.

It may well be that the wording of regulation 5(2)(e) precludes the adoption of relevant comparator countries where prices are either not published or regulated: it refers to “the price ... at which the medicine or Scheduled substance ... is sold in *other countries in which the prices of medicines and Scheduled substances are regulated and published.*”<sup>20</sup> If this is indeed the case, there is nothing stopping the Pricing Committee from recommending that the regulation be amended so that it simply refers to “other comparable countries”. It must be remembered that the wording of the regulation was originally proposed by the Pricing Committee, which retains a statutory power to recommend amendments to the regulations.

In addition, there is nothing preventing the Pricing Committee from recommending that the benchmarking methodology be limited in its application to medicines and Scheduled substances in respect of which there is inadequate competition. Recognising that competition is the primary means for reducing medicine prices, with price controls running the risk of over- or under-regulation, we propose a minor amendment to regulation 5(2)(e) that empowers the Minister, upon the advice of the Pricing Committee, to exempt a particular medicine or Scheduled substance (or category of medicines or Scheduled substances) from the operation of the methodology. Given that resources for regulating industry are indeed limited, it does not make sense to impose regulation in respect of issues that the market is in fact able to address.

In the result, we propose the following redrafted regulation 5(2)(e):

“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 comparable [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;

<sup>19</sup> See <http://www.pmprb-cepmb.gc.ca/>

<sup>20</sup> Emphasis added

provided that where the Pricing Committee has reasonable grounds for believing that there is sufficient competition in respect of a particular medicine or Scheduled substance (or category of medicines or Scheduled substances), the relevant single exit prices are exempt from conforming with international benchmarks.<sup>21</sup>

## Redefining the benchmark prices

In her address of 31 October 2006 entitled “Announcement of the New Dispensing Fee for Medicine”, the Minister of Health introduced the draft methodology by noting that “[t]he Pricing Committee has proposed two different methodologies to benchmarking since there are significant differences between generic and innovator medicines.”<sup>22</sup> In our view, the distinction between what the draft methodology refers to as originator medicines (medicines that are – or were – under patent protection) and generics is more apparent than real.

In terms of section 46 of the Patents Act, 57 of 1978 (“the Patents Act”), the duration of a patent is ordinarily 20 years from the date of the application therefore. Unless and until a Minister of State uses a patented invention (such as a medicine under patent protection) for a public purpose,<sup>23</sup> a compulsory licence is granted,<sup>24</sup> the patent is revoked,<sup>25</sup> or the state acquires the patent,<sup>26</sup> the holder of the patent – during this 20 year period – has “the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention.”

The benefit accorded to originator medicines – that being statutorily guaranteed market exclusivity – shields such medicines from competitive pressure. In so doing, it allows for prices to be kept unreasonably high. Once this monopoly ends, the innovator medicine must compete freely with generic equivalents.<sup>27</sup> It is for this reason that countries such as Canada restrict their medicine price control regimes to products that are still under patent protection, allowing the market to exert competitive pressure following patent expiry. Yet the draft methodology retains a distinction between originator and generic medicines when patents are no longer at issue.

This artificial divide creates an unjustifiable advantage for originator medicines after the expiry of the 20-year guarantee of market exclusivity. But in a regulatory framework that recognises mandatory generic substitution, as is the case in South Africa, would innovator medicines not simply be priced in accordance with generics, so as to guarantee market share? In theory, this should be possible. In practice, however, the distinction drawn by the draft methodology allows for originator medicines effectively to keep generic competition out of the market. Within a month of the SEP of an originator medicine having been set, the SEPs of generic medicines will be set – at a level at least 40% lower than the SEP of the originator medicine. It is possible, indeed quite probable, that innovator medicines will be priced at levels that make the market entry of generic competition unlikely or even impossible.

<sup>21</sup> Underlined text indicates a proposed addition; bolded text in square brackets indicates a proposed deletion.

<sup>22</sup> This address is available online at <http://www.doh.gov.za/docs/sp/2006/sp1031.html>. The draft was formally published in *Government Gazette* No. 29443 on 1 December 2006 as *Government Notice* No. R. 1211.

<sup>23</sup> Section 4 of the Patents Act

<sup>24</sup> Either in terms of section 56 of the Patents Act or section 58 of the Competition Act, 89 of 1998

<sup>25</sup> Section 61 of the Patents Act

<sup>26</sup> Section 78 of the Patents Act

<sup>27</sup> The only advantages it retains are a well-established brand and initial market dominance.

This much is recognised in the draft methodology, which allows for a company to “apply to the [pricing] committee (with supporting evidence) for relief from the methodology” in circumstances where “the benchmarking methodology results in a company having to sell a product at an unviable price”. But such a process is designed to deal with exceptional cases, being wholly unsuited to deal with the identified problem. Instead of being a methodology that keeps prices low, it is likely to be used as a tool for predatory pricing – the margin still allowing for comfortable profits whilst retaining de facto market exclusivity.

## Other concerns

Our other concerns include the following:

- While possibly the exception and not the rule, certain originator medicines have never been – and will never be – protected by patents.<sup>28</sup> Their mere existence, however, suggests that the definition of a generic product – a medicine that has “never been protected by patentcy legislation” – should perhaps be amended.
- The draft methodology suggests that “countries should contribute to the costs of research and development, so long as these costs are accurately estimated and according to their ability to pay.” We recommend that this be expanded to include a reference to that country's share of the global pharmaceutical market, given the relationship between the existence of markets and the current focus of research and development on diseases that affect such markets.
- The draft methodology states that where there is no comparator product in one of the four comparator countries, then the Pricing Committee will use the following criteria “to make a product-by-product determination”: “Other countries in which the medicine manufacturers sell the product”; “Burden of disease”; “Therapeutic class comparisons”; and “For multi-ingredient products, the sum of the cost of the individual ingredients”. The fourth criterion is clear – the other three are not: Which other countries? What will be done about burden of disease? Which therapeutic class distinction will be used? These factors are vague and ill-defined, having the potential to create uncertainty and invite litigation.
- Which rate will be used to convert foreign prices into South African rands? On which day will these conversions be made? On what basis?

## Conclusion

While the ALP recognises the value of putting an international benchmarking methodology in place, it nevertheless cautions the Department of Health (“the DoH”) against investing resources in a overly simplistic system that, at best, will have little real impact, and, at worst, will undermine the generic industry. In addition to addressing the express recommendations advanced, we suggest that the DoH directly engages relevant stakeholders – in terms of a process similar to that followed in developing the new *National HIV & AIDS and STI Strategic Plan for South Africa, 2007-2011* – for the purpose of reviewing and updating the National Drug Policy of 1996 (and the manner of its implementation) in light of domestic and international developments in the field of access to medicines over the past decade.

[ENDS]

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<sup>28</sup> Gilead's Viread (soon to be co-marketed with Aspen Pharmacare) falls into this category. Further, Roche has committed “[n]ot to file patents on new or investigational HIV medicines in Least Developed Countries and sub-Saharan Africa”. It does not enforce its exclusive rights in respect of its HIV medicines that are already under patent protection in any of these countries.