



MEMORANDUM ON CONCERNS RELATING TO THE 2008 ANTIRETROVIRAL MEDICINE TENDER SPECIFICATIONS¹

Background

In September 2007, the AIDS Law Project (ALP) submitted a memorandum to the Office of the Presidency setting out “various issues that the ALP believes should be considered by government in preparing for and running the 2008 antiretroviral (ARV) medicine tender”.² We explained our motivation for doing so:

Our recommendations are based – in large part – on our analysis of the shortfalls of the 2004 tender process and our experience regarding access to medicines work more broadly. In addition, our approach is primarily informed by the right to have access to health care services – including access to medicines – and the corresponding obligations that the right places on the state regarding its progressive realisation.

On 18 January 2008, the Joint Civil Society Monitoring Forum (JCSMF)³ hosted a public meeting in Cape Town that also focused attention on the 2008 ARV tender. The meeting’s resolutions record as follows:⁴

The theme of the meeting was *Drug Supplies, the 2008 Antiretroviral Tender and Availability*. The meeting was attended by approximately 60 people from 35 different organisations representing a wide cross-section of sectors and interests.

The meeting was addressed by experts who reviewed the experiences and lessons learnt with the first antiretroviral (ARV) tender, current international consensus regarding first line ARV regimens and a number of inter-related issues such as registration of new products and intellectual property licensing agreements. All these have considerable bearing on the prospect of achieving universal access to sustainable anti-retroviral treatment programmes and services in future.

The JCSMF resolutions were circulated to all members of the Programme Implementation Committee (PIC) of the South African National AIDS Council (SANAC) in advance of the PIC meeting held on 7 February 2008 meeting in Cape Town. Unfortunately, that meeting ran out of time to address the resolutions. Instead, the PIC suggested that its Technical Task Team on Treatment, Care and Support address the tender issue at its forthcoming meeting. At that meeting, concerns relating to the tender were indeed discussed. Unfortunately, the PIC has not yet had an opportunity to discuss the task teams considerations. Nor has the SANAC plenary had a chance to discuss the tender, as its 4 March 2008 meeting was postponed a few days before the meeting was scheduled to take place.

Purpose of this memorandum

This memorandum focuses narrowly on our main substantive concerns with *Special Requirements*

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² This document is available online at <http://196.212.109.36/ALPtendermemo.pdf>

³ The ALP is a founder member of the JCSMF.

⁴ The JCSMF resolutions are available online at <http://196.212.109.36/12JCSMFResolutions.pdf>

and Conditions of Contract: The Supply of Antiretroviral Drugs, the primary National Treasury document detailing specifications for the ARV tender for the period 01 June 2008 to 31 May 2010 (“the ARV tender specifications”). It does not address any of the procedural concerns – such as the lack of openness, transparency, accountability and public participation – that were warned against in the 2007 ALP memorandum and the JCSMF resolutions. These concerns – which include what appears to have been a deliberate bypassing of SANAC procedures by those responsible for drafting and publishing the ARV tender specifications – have been tabled for discussion at various SANAC committees.

In particular, the following substantive concerns are addressed in this memorandum:

- Type and quantity of ARV medicines to be procured;
- Contract period;
- Legislative requirements (relating to registration and licensing concerns);
- Lack of clarity regarding the points system;
- The “cost” of local production;
- Price qualification;
- Labels, packaging and package inserts;
- Counter offers; and
- Adverse drug reactions.

Type and quantity of ARV medicines to be procured

In the absence of revised ARV treatment guidelines, it is very difficult to provide much input on the types and quantities of drug choices. Unless and until the revised guidelines are finalised and published, this will generally remain the case.⁵ It is important to note that concerns regarding the delay in publishing these guidelines have already been raised in a number of different forums, including the JCSMF and various SANAC committees. In particular, these concerns address the Department of Health’s failure to systematize any guideline review process. To date, the process of reviewing guidelines takes place on an ad hoc basis, ordinarily following civil society advocacy. The speed at which developments in the field of ARV treatment are taking place requires an annual review process.

Perhaps of greater concern, however, is that the ARV tender specifications appear to have been decided in the absence of consultation with experts regarding a range of relevant issues, such as appropriate drug regimens, the latest available evidence on treatment options and an analysis of treatment outcomes almost four years after the public sector programme began. In addition, the lack of consultation – which would have been averted had an expert committee been set up to advise government on the issue (as recommended in the 2007 ALP memorandum and the JCSMF resolutions) – appears to have resulted in the ARV tender specifications anticipating lower patient demand than contemplated by the targets of the national *HIV & AIDS and STI Strategic Plan for South Africa, 2007-2011* (NSP).

Contract period

The contract period is for 24 months, commencing on 01 June 2008. This period may have been appropriate if adequate provision had been made to address the dynamic nature of the ARV “market” – with many new chemical entities and new formulations and combinations of existing

⁵ The exception in this regard is an apparent mismatch between what is asked for in the case of zidovudine and nevirapine for the purposes of the prevention of mother-to-child transmission of HIV (PMTCT) and what is currently available and registered. We have been advised that 20ml zidovudine and nevirapine oral liquids, which the tender specifications itemize, are simply not available.

products coming to market on a regular basis.⁶ Yet paragraph 13.d – which allows the state “to purchase its requirements elsewhere outside the contract” – does not make provision for the market entry of new products. Instead it is limited to the following circumstances:

- “the minimum packing or minimum order quantity specified by the contractor ... [is] more than that of an institution’s requirements”;
- “the item(s) are urgently required and [are] not immediately available”;
- “an emergency arises”; and
- “it is more economical to purchase small quantities from local sources”.

As the ARV tender specifications are for products that comply with exact descriptions only, paragraph 13.d therefore does not permit the following:

- Any future amendments to existing protocols that would require the procurement of chemical entities other than those already listed;⁷
- The use of fixed-dose combinations other than zidovudine/lamivudine (seemingly only for post-exposure prophylaxis to prevent HIV transmission following rape or occupational exposure) and lopinavir/ritonavir (the only combination in which lopinavir is marketed) – even in respect of chemical entities and combinations that are already listed (such as stavudine/lamivudine/nevirapine, the combination used by about 30% of patients currently initiating ARV treatment in the public sector)); and
- The use of co-packaged products.

It would be very difficult ordinarily to characterize these products as “urgently required” or necessary to address an emergency. An emergency would only arise if all stocks of a particular product were to be recalled (such as was the case in 2007 with the protease inhibitor nelfinavir) and a replacement ARV drug – from the same therapeutic class – were to be procured instead.

Legislative requirements

Two concerns in this regard have been identified:

- Possession of valid registration certificates “at the closing date and time of bid”; and
- Compliance with the requirements of intellectual property legislation, in particular the Patents Act 57 of 1978.

We recognise that there can be no compromise on the issue of registration – the public sector simply cannot procure products that are not registered for use. But what could be permitted is the opportunity for companies to participate in the tender in respect of products where registration is imminent,⁸ or in respect of which registration has been granted but registration certificates have yet to be issued. It is generally understood that certificates may take up to three weeks to be issued following registration. In addition, the Medicines Control Council is expected to register a number of ARV medicines at its next meeting, which is only scheduled to take place in early April 2008. These medicines will be registered too late for procurement.

On the issue of compliance with intellectual property legislation, it is interesting to note that tenders

⁶ In addition, the market entry of generic competition has been shown repeatedly to have a downward pressure on price – lengthy tenders have the effect of locking in high prices.

⁷ Paragraph 23 does seemingly allow the state the right to negotiate with successful bidders regarding regimen changes. Such a right, however, does not necessarily mean a right to procure from other suppliers.

⁸ In the 2004 ARV tender, products in respect of which registration was imminent were considered. On this basis, Aspen Pharmacare secured contracts in respect of products that had not yet been registered at the time tender bids were due.

ordinarily do not require bidders to produce documentary proof of patent status or the existence of an agreement in terms of which the patentee has licensed the bidder in respect of the patented product. Instead, bidders are simply required to assure the state that it will not be responsible for any possible infringement of intellectual property rights. In other words, the state cannot be sued for patent infringement if it procures registered products from a company that is not licensed by the patentee. The 2004 ARV tender was the first – and to date only – tender that introduced such a requirement. There does not appear to be any reasonable basis for departing from the ordinary tender process.

While the state may run the risk of supply problems if it were actually to procure unlicensed generic products, it is counterproductive to exclude potential competitors from the bidding process. Such competitors may, in fact, be in the final stages of securing licensing agreements. This was indeed the case in 2004, when Cipla-Medpro was unable to bid on products in respect of which they were subsequently licensed. The company concluded licensing agreements after the due date for tender bids but significantly in advance of the actual award of the tender. In the result, for example, multinational company GlaxoSmithKline secured 20% of the tender for lamivudine – a drug used by every person initiating ARV treatment – at a price more than 20% higher than what Cipla-Medpro would most likely have charged.

Points system

Other than in respect of the issue of local production, which is addressed separately below, there are two concerns raised by the points system:

- Paragraph 2.1.b, which allows – “on reasonable and justifiable grounds” – for a contract to “be awarded to a bid that did not score the highest number of points”. The ARV tender specifications do not give any indication of what may be considered as reasonable and justifiable in the circumstances.
- Paragraph 2.1.g, which allows for a contract to “be awarded to the bidder scoring the highest number of points for the specified goals” – BEE and local production – in the event that two or more bids have scored equal total points. In the event that two or more bids are indistinguishable, “the award shall be decided by the drawing of lots.”

These provisions do not sit comfortably with paragraph 13.e, which allows for the state “to arrange contracts with more than one contractor for the same drug, where the continuous supply of that drug is of critical importance.” It is beyond question that the continuous supply of all ARV drugs “is of critical importance”. Where contracts are to be split, paragraph 13.e provides the following formula:

- Where overall points (including pricing, BEE and local production) are equal, the tender should be split 50/50;
- Where there is a difference of between 0.1 and 5 percentage points, the tender should be split 70/30; and
- Where there is a difference of between 5.1 and 10 percentage points, the tender should be split 80/20.⁹

In our view, the ARV tender specifications should remove this lack of clarity, which may lead to unnecessary litigation by an unsuccessful bidder. In turn, this may have a negative impact on ARV medicine procurement.

Local production

We recognise the importance of an industrial policy that supports a local pharmaceutical

⁹ Implicit in this formula is that tenders are not split if the margin is greater than 10 percentage points.

manufacturing industry and note that an appropriate industrial strategy recognises that the development of a strong domestic industry requires more than a procurement preference for locally produced goods. In particular, it requires the taking of steps that enable local producers to be internationally competitive, such as considerations of export incentives and support for the vertical integration of the industry (to reduce reliance on imported active pharmaceutical ingredients (APIs)). Having access to export markets, as is currently the case with companies such as Aspen Pharmacare, reduces the cost of production.

Where procurement is used to support local industry, this should – as far as is reasonably possible – shy away from the use of actual subsidies for higher priced products. Instead, for example, local manufacturers may be given the opportunity to match lower priced bids from importing competitors. Thus tenders could expressly permit counter offers. In our 2007 submission to the Office of the Presidency, we therefore raised concerns about the manner in which a preference for local production would be given effect. In particular, we were concerned that this could translate into the procurement of significantly higher priced medicines that would have to be funded by an already defined health budget – in other words, fewer drugs would be purchased using finite funds that had already been allocated for this purpose.

These concerns appear largely to have been addressed, save for the concern regarding the budget out of which higher priced local products are to be procured.¹⁰ The ARV tender specifications give a maximum of nine points for local production – where the local content is 50% or more of the bid price. At best, generic manufacturers who formulate locally using imported APIs – the current state of the industry – add in the range of 20 – 30% local value. It is therefore safe to assume that neither of the two local producers in the ARV market – Aspen Pharmacare and Adcock Ingram – will get more than two points for local manufacture.¹¹ This is likely to result in locally produced products being procured at a premium of less than 5%.

Price qualification

Paragraph 8.a suggests that prices may be adjusted subject only to exchange rate variations. In other words, the state will not be able to take advantage of significant price reductions, which are always a strong possibility in the dynamic field of ARV drugs. On the other hand, the tender does protect against significant price increases (outside of the context of exchange fluctuations). However, these have yet to be seen in this dynamic market.

Labels, packaging and package inserts

Paragraph 15.c addresses the issue of patient-ready packs. However, given that there is a separate tender number in respect of each ARV drug and that there is no guidance in the ARV tender specifications regarding the assessment of bids in relation to co-packaged products, it must be assumed that co-packaged products are not sought. This is to be regretted and seems to run counter to the outcomes sought by paragraph 15.c – easy-to-use products that assist in patient adherence.

Counter offers

Paragraph 21 states that “counter offers with regard to any of the abovementioned Special Conditions will invalidate such bids”. It is unclear how far this provision goes. For example, would it invalidate bids in respect of three separate ARV drugs where a bid in respect of a co-packaged

¹⁰ We remain of the view that the Department of Health’s budget should either be expanded to address industrial policy considerations, or additional funds should be made available by the Department of Trade and Industry for this purpose. Either way, the relevant budget should be amended to address higher priced medicines that are produced locally.

¹¹ In addition, a maximum of one point is allocated to address black economic empowerment (BEE) considerations. Only one of the two local producers is likely to score a BEE point (or part thereof). Of the importers, only Cipla-Medpro – a wholly owned subsidiary of Enaleni Pharmaceuticals – will score a BEE point (or part thereof).

product containing the three separate drugs has also been lodged?

Adverse drug reactions

It is unclear if this provision, which allows the state to reconsider its contract regarding drugs in respect of which adverse drug reactions have been experienced, extends beyond the known adverse drug reactions in respect of any particular drug. This overly broad provision would seem to permit the state to cancel the entire tender.

Conclusion

The deadline for tender bids is Thursday, 20 March 2008. Almost three weeks ago (on 29 February 2008), a range of civil society organisations requested a meeting with key government officials to discuss their concerns. So far, not a single government department has agreed to meet. Yesterday, we received the only substantive response to date, which unfortunately fails to engage appropriately with the issues raised. Implicit in that letter is a failure to recognise the negative impact of the state's failure to consult appropriately. Instead, the response provides us with information on the tender in respect of which we were already largely familiar. This is to be regretted. Instead of open engagement with those in civil society who are well placed to ensure that the tender fully supports the goals and targets of the NSP, the response from government is one that is characterised by a lack of openness, accountability, transparency and public participation, arguably in conflict with the spirit and letter of the Constitution.

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