SAHRC PUBLIC HEARINGS ON THE RIGHT TO HEALTH:

ENSURING ACCESS TO A SUSTAINABLE SUPPLY OF AFFORDABLE MEDICINES

A. What are the key considerations?

1. Defining access to medicines

   a. Availability, affordability and sustainability of supply
   b. Of safe and effective medicines of good quality
   c. Combined with access to appropriate information on the basis of which informed choices may be made

2. The state's constitutional obligations

   a. Source and nature of the right

   - Right of access to health care services includes a right of access to medicines – *Minister of Health v New Clicks South Africa (Pty) Ltd*[1]
     - "In 1997 measures were introduced into the … [Medicines Act] towards making medicines more affordable. This, to give effect to the state's constitutional obligation to provide everyone with access to health care services."[2]
     - "The purpose of section 22G of the Medicines Act read in the context of the Medicines Act as a whole is to enhance the accessibility and affordability of medicines. This is an obligation of the state which in terms of section 27 of the Constitution is obliged to take reasonable measures to enhance access to health care."[3]
     - "The right to health care services includes the right of access to medicines that are affordable. The state has an obligation to promote access to medicines that are affordable."[4]

   - Obligations are set out in sections 7(2) and 27(2) of the Constitution
     - Section 7(2): "The state must respect, protect, promote and fulfil the rights in the Bill of Rights."
     - Section 27(2): "The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of … [this right]."
     - Read together: the state must take reasonable measures aimed at respecting, protecting, promoting and fulfilling the right

[1] 2006 (2) SA 311 (CC)
[2] Per the court at paragraph 1 (footnotes omitted)
[3] Per Chaskalson CJ at paragraph 314
[4] Per Ngcobo J at paragraph 514

b. Negative obligations

- Respect: state must not limit access unreasonably or unjustifiably
  - Registration processes should not address issues other than quality, safety and efficacy
  - Procurement policies should not result in unnecessary delays or exclude products from consideration on irrelevant or unreasonable grounds
  - Industrial policy should not undermine access

c. Positive obligations

- Protect: state must develop, implement and enforce an appropriate legal framework to prevent third parties from limiting access unreasonably and unjustifiably
  - Promotion of untested remedies and the making of false and exaggerated claims should be prohibited
  - Imports, production and sale of counterfeits (not to be confused with generics) to be prohibited

- Promote: state must develop, implement and enforce an enabling legal framework to ensure that medicines are available and affordable and that supply is sustainable
  - This will allow people to access medicines through their own actions and ensure that the state has access to the medicines that it needs to provide in the public sector
  - The legal framework should – amongst other things – address the following issues:
    - Registration: ensure that applications for registration are processed efficiently, with priority given to essential medicines and priority health needs
    - Pricing concerns: patent legislation that takes full advantage of the flexibilities in the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) – particularly insofar as these relate to health products – and price controls where necessary (including possible caps on mark-ups at all stages of the supply chain)
    - Sustainability of supply: for high demand conditions (such as HIV/AIDS), ensure that the legal framework allows for a sufficient number of suppliers to produce and/or import medicines
    - Procurement: a flexible, transparent and accountable system that is context-specific and needs-driven
    - Research: need a regulatory environment that facilitates the pursuit of alternatives to exclusive rights in intellectual

property to ensure research into drugs for neglected diseases; the development and commercialisation of more appropriate dosages and formulations for our purposes; and appropriate African Traditional Medicine (ATM) research

- Fulfil: state must provide medicines to those who would otherwise not be able to access them

3. Key availability, affordability and sustainability of supply barriers

a. Availability

- Registration:
  - Very slow pace of registration
    - Largely as a result of lack of capacity and reliance on expertise that largely lies outside of the Medicines Control Council (MCC) and not within its own staff
    - Partly as a result of full registration process, including inspections of manufacturing plants already approved by numerous stringent drug regulatory authorities
  - Fast-track registration procedures are not working
    - Nine-month time period frequently overrun
  - Lack of transparency and accountability
    - Inappropriate interpretation of section 34 (secrecy clause) of the Medicines Act
    - Probable unconstitutionality of section 34

- Procurement
  - The manner state tenders are sometimes run (as was the case with the 2004/5 antiretroviral (ARV) medicine tender) – which is not required by the relevant legal framework – may result in outcomes that limit access
    - Prices may be fixed for a few years, despite the real possibility that they could come down (as has been the case with ARV medicines since 2000)
    - Newer and better medicines and/or formulations of existing medicines may come to market but not be used because tender awards span too many years
    - Tenders take time and are not useful (or required) where potential suppliers are very limited
  - Tender rules may unreasonably exclude potential suppliers
    - The ARV tender required generic companies to be licensed when submitting their bids, but only required proof of registration at the time the tender was awarded

- The result was that potential suppliers who were licensed at the time of the award of the tender (and whose products were already registered) were excluded.

- Research
  - Largely global reliance on the patent system and the private sector for developing new medicines
    - Delivers drugs for diseases and conditions prevalent in developed countries, which often also affect the developing world (such as HIV/AIDS and heart disease)
    - Fails to deliver drugs for diseases that do not affect developed countries (such as tropical diseases) or are no longer of major concern (such as TB)
    - Often fails to deliver appropriate formulations of existing drugs, such as paediatric formulations (there is almost no paediatric AIDS in the US, for example) and formulations for public-health programme
  - Limited domestic public funding of drug research and development
    - Limited research into ATMs, in particular their safety, efficacy and interaction with registered drugs (such as ARV medicines)
    - Reliance on foreign donor or private sector funding for non-private sector research (such as clinical trials), which raises concerns regarding research priorities and the sustainability of research projects

b. Affordability and sustainability of supply

- Unjustifiably high levels of patent protection translate directly into a lack of competitive pressure on the prices of patented medicines and threats to the sustainability of supply
  - Failure to implement TRIPs flexibilities in respect of health products
    - WTO's Doha Declaration on TRIPs and public health and the Paragraph 6 system
    - Revised guideline 6 of UNAIDS/UNHCHR International Guidelines on HIV/AIDS and Human Rights
    - Gaborone Declaration (October 2005): African Ministers of Health undertook "to making full use of the flexibilities in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) and the Doha Declaration on TRIPS and Public Health"
  - Failure to make use of TRIPs-compliant provisions
    - State has failed to use a government-use provision to license manufacturers and/or importers of generic medicines

- Limited use of third-party provisions to ensure market entry of generic medicines, in large part because of unreasonably limited standing provisions and grounds for third-party compulsory licensing applications

- Ineffective and/or inappropriate price control mechanisms
  - Pricing regulations have focussed largely on retailers (pharmacists) and not manufacturers (the primary drivers of excessive prices)
  - Unresolved dispensing fee – the revised dispensing fee (adopted after the Constitutional Court decision in *New Clicks*) is subject to further legal action
  - Process in terms of which the Director-General (DG) determines the reasonableness of prices has no remedy – the DG has no power to take remedial action following a finding of unreasonable pricing
  - Inappropriate draft international benchmarking methodology (refer to two submissions)
    - At best, limited impact on prices
    - At worst, undermine the generic industry

- Limited primary domestic manufacturing capacity
  - Over-reliance on imported products, in particular active pharmaceutical ingredients (APIs)

B. What is the way forward?

1. Current policy processes and legal developments

a. AU Pharmaceutical Manufacturing Plan for Africa

- Plan adopted by 3rd Ordinary Session of the Conference of African Ministers of Health (11 April 2007)
- Concerns regarding the highly centralised nature of the plan that seems to ignore pragmatic realities regarding private sector generic drug production (see attached "talking points")
- Terms of reference are sufficiently broad for the expert committee to address these concerns

b. Domestic policy processes

- International benchmarking methodology
  - Second call for submissions (see attached ALP submissions)
    - First call in the absence of draft regulations
    - Second call with draft regulations
  - Deadlines shifted twice (19 February to 19 March to 30 April)

- Development of a Pharmaceutical Sector Strategy (under NEDLAC)

- Falls within ASGI-SA process led by the Deputy President
- Government, business, labour and community all represented
- Tight timelines

▪ Regulation of complementary medicines
- According to the MCC, manufacturers were requested to submit their products for evaluation – 14 000 of 20 000 products had been assessed by 14 September 2006
- Draft regulations, which were previously published for comment, are in the process of being reviewed
- A Complementary Medicines Committee, which has been established within the MCC, is said to be developing guidelines for registration and regulation of complementary medicines

▪ Problematic state-appointed task teams
- Presidential Task Team on ATM (chaired by Professor Herbert Vilakazi, special advisor to the Premier of KwaZulu-Natal)
  - Appointed on 11 October 2006
  - Terms of reference do not expressly refer to the regulation of ATMs
  - No timeframes to the task team's work
- Review of the MCC (chaired by Professor Ron Green-Thompson, special advisor to the Minister of Health)
  - Non-transparent process
  - Industry – but not civil society – has been consulted

c. Domestic litigation

▪ Competition Commission complaint against MSD and Abbott
- Based on companies' refusals to license companies to produce and/or import generic efavirenz and lopinavir/ritonavir products
- Complaint to be filed by the end of May 2007

▪ *TAC v Matthias Rath and Minister of Health*
- Allegations that Rath has violated various provisions of the Medicines Act, while the Law Enforcement Unit of the Department of Health (DoH) has failed to enforce the Act
- Matter set down for argument in Cape High Court on 26 April 2007

2. <u>Developing and implementing a reasonable plan for ensuring access</u>

a. Short-term

▪ Registration
- Minor amendment to Medicines Act to allow for automatically authorised use of medicines registered by a stringent drug

regulatory authority (such as the US Food and Drug Administration (FDA)) or prequalified by the World Health Organization (WHO), pending registration in South Africa
    - Could be limited to medicines for the prevention and treatment of priority diseases
    - Regulations could specify which diseases and/or regulatory authorities
- Fast-track approval procedures must be prioritised
    - MCC must report on how the process is or is not working
    - May require additional resources to get the process working

- Reducing prices and/or ensuring sustainability of supply of priority drugs
    - Pricing regulations to be finalised
        - Dispensing fee
        - International benchmarking methodology
    - State must engage pharmaceutical industry on the need to issue licences on key medicines for priority diseases, failing which it should be prepared to license generic manufacturers and/or importers in terms of section 4 of the Patents Act

b. Medium-term

- Review of National Drug Policy, 1996, and amendment of relevant legislation in accordance with South Africa's TRIPs obligations, the Doha Declaration, the Paragraph 6 system and the Gaborone Declaration
    - Patents Act
        - May not be a need for a general amendment to the Act – could limit the scope of amendments to public health products, rather than reducing patent protection generally
        - Need to focus on more than compulsory licensing, including scope of patentability, pre-grant opposition procedures and patent revocation
    - Medicines Act and the MCC
        - Deal with problematic institutional overlap between the DoH and the MCC
        - Need to ensure that MCC is sufficiently resourced to enable it to develop sufficient internal capacity
        - Need to amend or repeal section 34 dealing with secrecy – the Promotion of Access to Information Act may suffice
    - Competition Act
        - Insert an express compulsory licensing remedy for abuse of dominance cases dealing with intellectual property
        - Clarify the definition of excessive pricing
        - Clarify broadly under what circumstances a refusal to license an unjustifiable exclusionary act
    - Access to Essential Products for Health Act

- Could provide the legislative form for relevant access to medicines amendments to each of the three key statues
- Would allow for amendments to apply only to essential products for health

- Review of procurement framework, policies and practices
  - Focus on specific ARV tender to develop a guideline on how to use the tender system efficiently:
    - Time duration – three years may be too long as prices drop, new forms and combinations arise and new drugs become available
    - Ensure that where potential suppliers are limited, the quotation system is largely used.
  - Review to establish whether legal framework remains appropriate

c. Long-term

- Development of sufficient local API manufacturing capacity
  - Implementation of the pharmaceutical sector strategy insofar as it deals with APIs
  - Ongoing monitoring and evaluation (including five-yearly reviews of the amended National Drug Policy)
- Developing and implementing an appropriate research agenda
  - ATM research
  - Drugs for neglected diseases
  - Appropriate formulations and dosages of existing medicines