This short case study is based on an Oxfam GB briefing paper entitled “Assessing the Impact of TRIPs-Plus Patent Rules in the Proposed US-SACU Free Trade Agreement” (2005) by Jonathan Berger and Achal Prabhala. A draft version of the paper is attached is for your reference. Participants are expected to use the MSF pricing guide in answering the questions posed.

Summary:

In South Africa, the state is in the process of rolling out a comprehensive HIV/AIDS treatment package. Crucial to the success and sustainability of this program is the procurement price of antiretroviral medicines (ARVs). We examine different price scenarios, underpinning a key determinant of price – Market Structure – especially in relation to intellectual property rules and national laws. The context of the case study is a real life situation where (as of presenting this exercise in April 2005), the Southern African Customs Union (SACU) of which South Africa is a key member, is negotiating a Free Trade Agreement (FTA) with the United States that includes potential changes to national intellectual property laws.

The Case Study:

Background

On 19 November 2003, the South African National Department of Health announced an ‘Operational Plan’ for the rollout of ARV medicines in the public health system. The DoH was responding to an urgent domestic concern: UNAIDS/WHO statistics from 2004 suggested that of the approximately 5.3 million people living with HIV/AIDS in the country, 750,000 were in need of ARV treatment.

The operational plan was announced at a time when the price of ARVs had seen significant decline. Indeed, the operational plan noted that: “Two years ago, this programme for comprehensive care and treatment would have been impossible amongst other things due to the cost of the medicines and laboratory tests required.”

ARV pricing

Current ARV procurement prices (annual cost per patient) are –

Regimen 1a (lamivudine/stavudine/efavirenz): ZAR 4212 or US$ 702
Regimen 1b (lamivudine/stavudine/nevirapine) ZAR 1473 or US$ 300
Regimen 2 (zidovudine/didanosine/lopinavir): ZAR 10334 or US$ 1722

1 Figures used in the case study are indicative, and are for the purposes of analysis only: for actual figures, please consult the briefing paper referred to above.
Of these medicines, the SA government is currently buying two products (lopinavir/ritonavir and efavirenz) from the patent holders (innovative drug companies). The other medicines are being currently procured from generic manufacturers.

**Question 1:** Could the government effect cost savings if it were to buy efavirenz from a generic manufacturer? What would the cost saving be? What are the possible reasons why the government is not procuring efavirenz from a generic supplier? What are the possible reasons why government is not procuring lopinavir/ritonavir from a generic manufacturer? There are only two suppliers producing lopinavir/ritonavir: what does the price difference between the companies indicate?

At the current time, the best world prices for the medicines being procured under the SA government ARV rollout are as follows:

Regimen 1a: ZAR 2592 or US$ 432  
Regimen 1b: ZAR 995 or US$ 150  
Regimen 2: ZAR 5375 or US$ 895

**Question 2:** Imagine that for Year 1 of the ARV rollout, government has limited the budget for ARV procurement to US$ 3,000,000 - and also, that everyone needs only be treated with Regimen 1b. All other things being equal (i.e., assuming that support and health infrastructure remain constant and can support additional capacity without any extra cost) how many additional people could be treated with ARV medicines if government was to procure at best world prices instead of at the prices reported on the previous page? Next, assuming that ARV price information is easily available and that the SA government is aware of the suppliers quoting the lowest prices reported in this case study, what are the possible reasons why it is unable to buy from the lowest-quote suppliers as mentioned in the MSF pricing guide?

**Competition in the SA pharmaceutical industry**

The generic medicines being procured by the government (didanosine, stavudine, lamivudine, zidovudine and nevirapine) are all under patent in South Africa. A generic alternative can be sold – and therefore legally procured by the government – because in each case, the patent holders have either licensed generic manufacturers or have decided not to enforce exclusive rights on the relevant patents. In each case, civil society action was taken to correct market imbalances in the original market price of the medicine. In the case of BMS, civil society protests at Yale University and in South Africa resulted in BMS deciding not to enforce its exclusive rights to patents on didanosine and stavudine. With GSK and BI, the holders of the other three patents, a lawsuit filed by the AIDS Law Project on behalf of several complainants in the South African Competition Commission resulted in a settlement that saw ‘voluntary licensing’ of generic manufacturers by the rights-holders.
Question 3: What options does a government have with regards to correcting market anomalies in the pricing of an essential medicine? Of these options, which would you classify as being amongst the most important? In your opinion, would the availability of legal options to correct market anomalies have played a role in the patent-owning pharmaceutical companies (BMS, GSK and BI) having decided not to enforce patent exclusivity and/or voluntarily license generic manufacturers?

Potential implications of trade agreements

A certain “Country X” has just concluded trade agreements with a number of countries around the world – most recently – Morocco, Singapore, Chile, Australia and Central America. In those trade agreements, Country X has managed to make the following changes to the policies and laws of the aforementioned countries:

- The scope of compulsory licensing has been limited.
- Parallel trade has been banned or severely restricted.

Country X is now engaged in negotiating a trade agreement with South Africa. It is assumed that Country X will seek the same policy changes as before in its negotiations with South Africa.

Question 4: Based on your answers to Question 3, and from the sole perspective of access to ARV medicines, what advice would you give the government of South Africa? In your answer, there is no need to detail specific policy measures: instead, simply list the steps in the process you would advise policymakers in South Africa to undertake to ensure that access to ARV medicines is increased, and to ensure the sustainability of the state’s ARV treatment programme.

Some rough guidelines to answering the questions posed:

- The point of these exercises is to discuss the process: therefore, the ‘right’ answers are less important than the right thought process!
- For Question 1, use the MSF pricing guide: it might be helpful to recall the first few slides in the handouts to this session, relating to market structures
- For the mathematical component of Question 2, you should not need a calculator, a pen and paper will suffice
- For parts of Questions 1 & 2, it will be useful to recall processes discussed in earlier modules of this training programme, particularly registration and quality assurance
- For Question 3, the handouts from this module, included in your course packet, will be useful, particularly the section on “Additional Strategies”
- For Question 4, it will be useful to recall the session on Intellectual Property Rights, and consider (a) what international trade rules relate to intellectual property, and, in general, (b) what country governments are entitled to do under this trade rule.