

JOINT SUBMISSION BY
SOUTH AFRICAN PHARMACEUTICAL TRADE
ASSOCIATIONS

TO THE DEPARTMENT OF TRADE AND INDUSTRY

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Introduction

South Africa has, as a country, taken a different approach to address the challenges facing it, the most prominent that of transition to democracy, of macro-economic development and of addressing its main social challenges. To this end South Africa has learnt the lessons of constructive engagement and taking a non-confrontational stance that has made it perhaps one of the leaders in finding solutions and preventing a downward spiraling of conflict.

It is perhaps this unique history and the continuation of the same approach and attitude to engagement with government and other stakeholders that underpins this submission and has led to South Africa adopting creative and pragmatic solutions to those situations that risk conflict.

This submission is made jointly by the following collective SA pharmaceutical manufacturers, importers and industry organizations, representing in excess of 95% of the South African market in value terms:

- Innovative Medicines SA (IMSA)
- National Pharmaceutical Manufacturers Association (NAPM)
- Pharmaceutical Manufacturers Association (PMA)

The parties have recently demonstrated this positive attitude to constructive engagement with the Department of Health, by participating in key activities and supporting the achievement of key Departmental objectives, such as the medicines pricing regulations and the draft Health Charter.

In the interests of optimal patient access to medicines, this submission seeks to strike a balance between unique challenges of national public health, a sustainable supply of medicines and the protection of the rights associated with intellectual property.

Principles

The industry associations that make this joint submission endorse the following:

- Intellectual property rights in general and upholding the South African intellectual property system in particular.
- Striking a balance in cases of national public health emergencies, between access to healthcare and rights associated with intellectual property.
- Ensuring that patient safety and quality are never compromised.

- By using this approach SA could provide a more positive climate for fostering and strengthening foreign direct investment¹ and increased exports.
- The substance and principles that underpin the Motta decision and Menon Statement.

Alternative approaches to address access in national public health emergencies have worked in South Africa

The parties to this submission regard voluntary licensing as a preferred route to that of compulsory licensing in order to address access to medicines in national public health emergencies. Voluntary licences, as opposed to compulsory licences, have proved more pragmatic and have achieved the desired objectives of enhancing access and significantly reducing the cost of patented medicines required in such national public health emergencies. The system has been used to ensure that there is more than one supplier, thus assuring continuity of supplies particularly where continuity of treatment is essential.

The voluntary licensing approach ameliorates the risk of increased tension and the likelihood of conflict in the investment sector and its health-subsector in particular.

South Africa has already achieved significant price decreases on an ex manufacturer level for the private market (21%²). Apart from the medicines pricing system, South Africa has various other domestic mechanisms, ranging from the constitutional mandate to progressively realize access to healthcare, to measures flowing from the 1997-amendments to the Medicines Act and the Broad-based Black Economic Empowerment Act to address issues of access.

The government's rollout of ARV's together with the implementation of various models of voluntary licensing in the field of HIV, are two factors that have increased access to medicines. It is estimated that some 110 000 – 115 000 SA patients can now access ARV's through products using both the original- and voluntary licenced products. This effect is further enhanced by the introduction of a transparent price system and the full implementation of a Single Exit Price on a manufacturer level. A combination of patented and voluntary licensed products can currently service all the patients in this country. IP protection does not present a barrier to access. Other

¹ South Africa is currently not among the top 10 African investment destinations – UNCTAD 2005 World Investment Report, on FDI outflows South Africa is nr 1.

² The data used in the calculation was extracted from the following sources:

- Units: The audits of the global company IMS, Total Pharmaceutical Market January 2004
- Prices: Pharmaceutical Computer Data supplied the medicine prices (SEP or pharmacy purchase price) The SEP is the ex manufacturer selling price that includes wholesale and distribution fees, i.e. does not account for retail sector.

barriers, such as stigmatization of people living with HIV, still affect the uptake of ARV treatment thereby hampering effective access.

In national public health emergencies, voluntary licences and IP sharing agreements increase access to medicines without the negative impact that compulsory licensing may have on investment and growth. The parties agree that there can be grave repercussions to using compulsory licensing as a mechanism to address such emergencies, leading to a negative spiral whereby compulsory licensing leads to tension between stakeholders,³ and possible subsequent threats and litigation. It can also lead to passive investors that causes negative investment and, may eventually, lead to disinvestment and loss of skills and technology to the country. This, in turn, can lead to patients having less, instead of increased, access to healthcare and to negative growth, with a loss in both up – and downstream benefits brought by the pharmaceutical industry. In Brazil, for example, the threat of using compulsory licensing may lead to the potential for access to 2nd line drug-resistant HIV treatment being significantly affected.

Voluntary licencing provides a win-win for all the stakeholders in therapeutic areas that constitute national public health emergencies, i.e. patients, the state, South African business and the investor community, clinicians, the pharmaceutical industry, and above all can achieve all of this by upholding international IPR treaties and South Africa's multilateral trade obligations.

Voluntary licenses also allow the parties to maintain the standards of pharmacovigilance reporting that is necessary in the interest of all patients.

However, it is important to state that such voluntary licences should be truly voluntary on the basis of each party being a willing participant, with a variety of options to be available to suit the specific nature of the parties and particularities of the national public emergency.

South African case studies

Agreements representing various forms of sharing of intellectual property, to the benefit of public health emergencies, exist. These range from full technology transfer and empowerment, to licensing to manufacture, and use of patents.

Examples of successful IP sharing includes -

- Lilly & Aspen (fully licenced technology transfer agreement)

³ Within the broader manufacturing, and investment sector and with government departments, most notably DoH and DTI.

- BMS not enforcing their patent and Cipla Medpro manufacturing generic of stavudine
- Aspen patent use agreement with BMS
- MSD & Aspen
- Gilead Sciences & Aspen (full technology transfer agreement)

Agreements may cover a large number of companies throughout Africa if this has been negotiated as part of the voluntary licensing agreement. There is an ongoing interest in these types of arrangements as an option to deal with national public health emergencies.

Conclusion

The parties that make this submission believe there are creative ways of addressing access to healthcare that could go beyond the current international legal wrangles and supersede conflict in order to address the healthcare needs, and transformational needs of South Africa.

We would recommend that the use of voluntary licensing as a first step where ever possible in cases of national public health emergencies. We also regard the inclusion of the Motta text and Menon statement in the TRIPS Agreement as providing the required balance between access to health care and protection of the rights associated with intellectual property in cases of national public health emergencies, were no other mechanisms are available domestically.
