Submission by Innovative Medicines SA on compulsory licensing in national health emergencies to the South African Department of Trade and Industry October 2005

Background information on Innovative Medicines SA (IMSA)

We provide some important background information on IMSA in Annexure A.

Innovative Medicines SA regards access to healthcare as a priority

IMSA is actively involved in addressing issues of access to healthcare, as we believe that SA health care and the health system is a collective responsibility that demands joint solutions. IMSA has illustrated this commitment by, inter alia -

- Proactive work on the Health Charter, both on the issues of broad-based black economic empowerment and options to increase access to healthcare within a Charter context. The IMSA chairperson at that time, John Fagan, was appointed to the Ministerial Charter Task Team (MTT) – the only person from the pharmaceutical industry to serve on the MTT. In this process IMSA has also succeeded in drawing together the private healthcare sector in making a single, agreed upon and generally supportive submission to the MTT.
- Active involvement in finding solutions in the medical schemes environment for low-income groups (LIMS). These households should also be able to benefit from risk-pooling and access to enhanced care. IMSA does not support poor healthcare for poor people.
- IMSA supported the medicines pricing regulations as far as it pertains to manufacturer pricing, by taking the lead in the consultative processes that lead to the promulgation of the regulations. Moreover, it stood by its principles, at grave commercial risk to member companies, by approaching the Constitutional Court as *amicus curiae* in order to ensure that the single-exit pricing system is maintained and that ex-manufacturer savings already affected (at some 21%) were not lost.
- IMSA members companies have taken important steps in addressing access to treatment for diseases that burden the developing world. These range from voluntary licensing agreements to programmes relating to the donation of drugs for opportunistic infections.
    - The Pfizer Diflucan Partnership Programme couples the donation of drugs (for life-threatening opportunistic infections to countries with a prevalence of higher than 1%) with the

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training of healthcare providers to enhance the quality of diagnosis and delivery of healthcare service for the critical medical condition.

- Eli Lilly partnered Aspen Pharmacare in 2004 to transfer Lilly technology to them for the manufacture and distribution of the essential antibiotics capreomycin and cycloserine needed to treat the growing cases of multi-drug resistant tuberculosis (MDR-TB) in the region.
- charge to patients in the public sector.
- In TB, sanofi -aventis developed fixed dose combination products based on the requirements of the South African Department of Health and the WHO. The programme includes the creation of patient friendly packs to enhance compliance and a possible public-private partnership to assist in DOTS training. The TB SA specific designed medicines are manufactured in a local facility in Mamelodi and a 100% BEE partner will commercialise the TB range.
- n doses) of the antiviral Tamiflu (oseltamivir) to the WHO to be used at sites for new and potentially pandemic outbreaks of human influenza in order to reduce morbidity and mortality and to contain or delay the spread of an outbreak.
- MSD expanded its manufacturing activity in Midrand for stocrin (Efavirenz) in order to meet growing demand both in SA as well as in the export markets in the sub-region. MSD also granted a voluntary patent license to Aspen for Efavirenz. All MSD's ARVs are made available to all sub-Saharan African countries (incl. SA) at prices at which it makes no profit.

IMSA supports the approach of finding solutions that address the need of populations in cases of health emergencies in a non-confrontational manner that takes account off the complexities of each case and its stakeholders.

IMSA's view on compulsory licensing and the current mechanisms to address access to healthcare

IMSA believes that access to healthcare in South Africa should be expanded and enhanced. This includes access to medicines. As stated above, IMSA is actively involved in finding solutions in this field. IMSA also believes that the barriers to access to healthcare are complex and varied, ranging from issues of affordability, human capacity, infrastructure, regulatory complexities to economic inequities in society at large. IMSA's experience has been that even where medicines are made available for free, other challenges limit availability.

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IMSA supports drives by the SA government to address access by various means and mechanisms, some of which are found in the current domestic regulatory frameworks, including, but not limited to the fast-tracking of medicines registration in cases where [1] and the provisions contained in section 15C of the Medicines Act of 1965, as amended.

IMSA member companies support the provisions relating to access in national, public health emergencies where countries have no local manufacturing capacity, and where attempts to address the access needs by means of domestic provisions and negotiations have failed. IMSA interprets these national public health emergency situations as inclusive of HIV/AIDS, TB, malaria and other diseases of similar gravity and scope. It is common cause that, in international human rights law, national emergencies warrant violations to human rights (such as property rights as is the case with instances of compulsory licensing), within certain parameters. The derogations are to be applied narrowly and "strictly [as] required by the exigencies of the situation". Any such measure also has to be "proportional" and "necessary".[2]

IMSA supports the formalization of the August 30, 2003 Agreement into a TRIPS amendment and believes that the meaning and integrity of this Agreement must be preserved in any such amendment. IMSA also confirms its support for measures intended to avoid the diversion of medicines intended for emergency situations. It also supports assurances that the provisions relating to compulsory licences will not be used for commercial policy purposes. In its view, compulsory licensing should be used as a last resort and only in the contexts originally envisaged by the Agreement, and where domestic mechanisms have failed.

It is not well understood that the pharmaceutical industry discovers and develops more t
medicines – not governments or universities. This ongoing development of medicines is only possible with constant investment by this sector. Support for the system of competition incentivises this financial risk taken in searching for new medicines to deal with the ever changing health demands of populations. IMSA recognises that research-based companies require stability and certainty as to the protection of their intellectual property. Increased and continued investment in countries depends on the level of protection afforded to their core businesses. This in turn, translates into access to innovative medicines by the country at large and the existence of a vibrant generics market.

[1] S15(2)(b) Medicines Act of 1965, as amended.
[2] See Davis et al *Fundamental Rights in the Constitution* 1997: 327.

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In Summary, in respect of the issue at hand, we support the following provisions to increase access to medicines:

- Fast-tracking of medicines registration in cases where it is essential for public health.
- Voluntary- and competitive mechanisms, such as negotiation and consultation to address access to healthcare in a holistic manner.
- The provisions relating to access in national, public health emergencies where countries have no local manufacturing capacity, provided that -
    - The definition of public health emergencies is not interpreted expansively.
    - The provision is used as a last resort where all other existing domestic measures have failed.
    - Measures are implemented to prevent the diversion of medicines.
    - Compulsory licensing is not used for commercial policy purposes.

ANNEXURE A

Innovative IMSA was established in direct response to the so-called “Act 90” court case in 1997. Companies who later formed IMSA realised that the approach and methodology of the pharmaceutical sector have to change in a transforming South Africa.

The approach to stakeholders and government in particular has to be constructive, open and consultative, rather than confrontational. IMSA believes that the challenges facing South African healthcare may be solved to succeed in a changing environment. Therefore IMSA tackles all healthcare challenges in a solution-oriented manner.

IMSA is founded on the following core values:

- Ethics in the healthcare environment
- Engagement and consultation
- Belief in the inevitability of- and need for healthcare transformation

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	MSD	Lilly	Roche	Pfizer	sanofi-aventis	Novartis
# Employee	280	150	280	936	625	180
# Pharma Products	36	20	44	73	210	59
Value of R&D in S.A. per annum	R35mio	R40mio	R50mio	R50mio	R32mio	R25mio
Local Manufacturing Plants	Yes	No	Yes	Yes	Yes	Yes
Community Partnership Programmes	7mio	15mio	7mio	110mio	150mio	15mio

IMSA companies jointly employ some 2 451 employees.

systems. IMSA companies contribute 442 products to the South African healthcare market and invest some R232million in research and development in South Africa per annum. Five of the six IMSA companies have manufacturing plants, of which some manufacture for the export market.

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