NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

INFORMED CONSENT FORM

I_____(full names of the patient) voluntarily agree to be treated with a medication, namely_____which is not registered in Namibia, by_____ (name of medical doctor) for_____ (name of the disease).

I confirm that I have been fully informed and my questions answered by _____(name of applicant, i.e. prescribing doctor) about my disease (for which a section 27 application is being made), its cause, severity, prognosis, available registered treatment options (in Namibia) and the reasons for the current state of my illness and the unregistered medication and application to use a medication that is not registered in Namibia and that:

a) the medication is not registered in Namibia and that this implies that the quality, effectiveness and safety of this medication has not been verified by the Namibia Medicines Regulatory Council (NMRC);
b) the medication will only be supplied to, and used by and on me once specific approval has been obtained from the NMRC;
c) the medication_____ (generic and trade names) is approved for the treatment of _____(name of disease) in _____(name of the country from which the medication is to be imported), or (the medication is in an advanced stage of development[at least phase III trial] in Namibia and/or_____(name of country) and that its quality, effectiveness and safety are well documented and within legally and scientifically acceptable levels);
d) appropriate measures will be taken to prevent, monitor and manage the unwanted effects on me of the unregistered medication;
e) _____(name of medical doctor) will comply with all regulations of the NMRC, laws (Namibia and foreign) and conditions of

approval of use of this unregistered medication and accordingly ensure continued availability and supply of the medication;

f) use of the unregistered medication on and by me is for managing my disease and not for medical research
g) any information collected by_____(name of applicant), his/her employer, successor or any other person, the NMRC or its legal representative, may be used for research purposes upon receipt of specific written separate informed consent from me, my guardian or person responsible for my affairs after my death;
h) I am free to stop using the medication at any time and that I will inform my (treating) medical doctor accordingly.

Full Names of patient/guardian:_____

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Signature of patient/guardian Date

Name of medical Doctor:_____

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Signature of medical doctor Date

Name of Witness:_____

…… ……

Signature of witness Date