

COMPULSORY LICENCE no. 01/MIC/04

The Government of Mozambique, conscious that the HIV/AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, under-development and misery and,

taking into consideration that.

high rates of morbidity and mortality have put Mozambique among the ten countries in Africa worst hit by this disease. Current estimates are that at the end of 2002 over 1,5 million Mozambicans were infected by HIV, of whom more than 100.000 are suffering from full-blown AIDS. The AIDS death toll is so far well over 200.000 and about 360.000 children have been orphaned by the pandemic,

and that,

In spite of multiplication and diversification of vigorous prevention campaigns the spread of the virus is still on a climbing trend as shown by the high number of infections,

considering further that,

Anti-retroviral drugs are already available, which prolong lives of those infected with HIV/AIDS, and that until now, at this day, the international patent owners have failed to make such drugs accessible at affordable prices to most of the Mozambican people,

and for such reason

on 14 November 2001 the World Trade Organization declared the right of each Member State to protect public health and in particular to promote access for medicines for all, by granting compulsory licenses in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria or other epidemics can represent a national emergency or other circumstances of extreme urgency.

Considering further that

a triple compound of lamivudine, stavudine and nevirapine has proved, in the last few years, to be one of the most effective and economical anti-retroviral treatment, but the three different international owners of such single drugs failed to reach an agreement to produce this combination,

therefore,

The Ministry of Commerce and Industry of the Republic of Mozambique, making use of the provision of article 70 no.1 point b), of Decree no. 18/99 of 4 May, has decided to grant the compulsory license no. 1/MIC/04 to the company **Pharco Moçambique Lda**, which has already presented a project for local manufacture of the mentioned triple compound under the names of PHARCOVIR 30 and PHARCOVIR 40.

Communication of this decision will be given to the applicant and to the patent owners.

In consideration that the mentioned product, a triple combination of drugs, is not marketed in Mozambique by the international patent owners and that it is in the national interest to keep the final price as lowest as possible, the total amount of royalties due to the patent owners shall not exceed 2% of the total turnover of the mentioned products, at the end of each financial year of Pharco Moçambique Lda.

This Ministry of Industry and Commerce, in accordance to provisions of Art. 70 point 6 of Decree no. 18/99 will notify the concerned parties of the expiration of the present compulsory license as soon as conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic will come to an end.

The Government of the Republic of Mozambique reserves the right to review this compulsory license, in case the conditions in which it was issued are changed.

signed by

Salvador Namburete
Deputy Minister