

Telephone : 260 - 1- 226727
 Telefax : 260 - 1- 226727
 Telex : ZA 45630
 Telegrams : COMIND
 E-mail : cabmin@zamnet.zm
 Website : www.mcti.gov.zm



REPUBLIC OF ZAMBIA
MINISTRY OF COMMERCE, TRADE AND INDUSTRY

OFFICE OF THE MINISTER
 P.O. BOX 31
 LUSAKA

In reply please quote

No.

COMPULSORY LICENCE No. CL 01/2004

The Government of Zambia, 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 Zambia among the ten countries in Africa most hit by this disease. Current estimates are that, at the end of 2003, over **917,718** Zambians were infected by HIV, of whom unestimated number are suffering from full-blown AIDS. The AIDS death toll is so far in excess of **835,904** and about **750,504** children have been orphaned by this pandemic, creating a situation where 75% of households below 14 years headed more than 130,000 poverty stricken households and that children aged a total of 1,905,000, and that;

In spite of the multiplicity and diversity of vigorous prevention campaigns, the spread of the virus is still on an upward trend as shown by the high number of infections;

Taking into account the gravity of the situation being faced by most African Countries, including Zambia, the need to ensure access to drugs at affordable prices, while respecting the protection of intellectual property, is well recognised. For this reason;

On 14 November, 2001 the World Trade Organisation, while recognising Members' commitment to the TRIPS Agreement, declared the right of each Member State to take measures aimed at protecting public health and in particular to promote access to medicines for all, by utilising to the full, the flexibilities in the TRIPS Agreement relating to among others, the granting of compulsory licences, 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 which can represent a national emergency or other circumstances of extreme urgency.

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PHARCO LTD ZAM

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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 that the three different international owners of such single drugs failed to reach an agreement to produce this combination, and therefore;

The Ministry of Commerce, Trade and Industry of the Republic of Zambia, making use of the provisions of Section forty of the Patent Act, Chapter 400 of the Laws of Zambia, and Statutory Instrument No 83 of 2004 titled 'The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004' Regulation 3, has decided to grant a Compulsory Licence No. CL 01/2004 to PHARCO LTD, a company incorporated in Zambia, which has already presented a project proposal for the local manufacture of the mentioned triple compound under the names of Normavir 30 and Normavir 40.

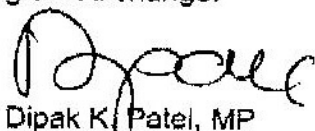
It is further understood that the use or vending of the above mentioned drugs is subject to Regulation 4 of Statutory Instrument No 83 of 2004, titled 'The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004' and therefore cannot be exported to any place outside Zambia.

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

In consideration that the mentioned product a triple combination of drugs, is not marketed in Zambia by the International Patent owners and that it is in the national interest to keep the final price as low as possible, the total amount of royalties due to the patent right owners shall not exceed 2.5% of the total turnover of the mentioned products at the end of each financial year of PHARCO LTD.

The Ministry of Commerce, Trade and Industry, shall in accordance with Section forty one of the Patent Act notify the concerned parties of the expiration of the present Compulsory Licence as soon as conditions of national emergency and extreme urgency created by the HIV / AIDS pandemic will come to an end, or upon expiry of the period of emergency stipulated in Statutory Instrument No 83 of 2004 titled 'The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations 2004'.

The Government of the Republic of Zambia reserves the right to review this Compulsory Licence should the conditions and circumstances under which it is granted change.


 Dipak K. Patel, MP
 MINISTER

Ref: MCTI/104/1/1c
 Date: 21/09/04