INFORMAL TRANSLATION

MINISTERIAL DIPLOMA No. 10/2004
of September 22nd

LICENSING FEES FOR PHARMACEUTICAL ACTIVITIES

Decree Law No. 12/2004, of June 16, approved the legal regime for pharmaceutical activities, providing in paragraph 5 of article 3 and in paragraph 1 of Article 21, for the fixing of fees due for the licensing of activities of import, storage, export and sale of medicines for human use and for the granting of authorizations for the commercialization of medicines, which, as provided in article 32 of the same law, are intended to cover the operating costs of the Regulatory Commission of Pharmaceutical Activities in favor of public health.

Thus:

The Government, by the Ministers of Planning and Finance and of Health, orders, under the provisions of no. 5 of article 3 and of no. 1 of article 21 of Decree-Law no. 12/2004, of June 16, to publish the following legal diploma:

Article 1

The fees due for the licensing of pharmaceutical activities included in Tables I, II and III, annexed to this statute, are hereby approved.

Article 2

The fees shown in Tables I and II shall enter into force on September 17, 2004.

Article 3

The rates shown in Table III shall enter into force on March 17, 2005.

The Minister of Planning and Finance,

(Maria Madalena Brites Boavida)

The Minister of Health,

(Rui Maria de Araújo)

Dili, August 17, 2004

TABLE I

License for import, storage, wholesale and export activities of medicines

a) For each license - Fee of US$ 1000

b) For each license renewal - Fee of US$ 500

TABLE II

License for the activity of retail sale of medicines

a) For each license granted to a pharmacy or private clinic in accordance with subparagraph b) of paragraph 1 of article 80 of Decree-Law no. 12/2004, for the sale of:

- of medicines in general - Fee of US$ 500
- of medicines in general, including narcotics or psychotropic drugs - Fee of US$ 1000

[Note: There is no paragraph b)]

c) For each license renewal - Fee of US$ 300

TABLE III

Authorization for commercialization of medicines

a) For marketing authorization of each drug, including only one pharmaceutical form, and one dosage - Fee of US$ 100

NOTE: For the purposes of commercialization authorization, "different drug products" are considered to be those that, even if they have the same active substance or the same international non-proprietary name or the same generic or commercial name, are produced by different entities.

b) For each individual authorization provided for in article 190 of Decree-Law no. 12 /2004, of June 16, including a single pharmaceutical form and dosage - Fee of US$ 100

NOTE: The individual authorization is exceptional and may only be requested when there are no essentially similar medicines approved in Timor-Leste or, when they exist, they are not being commercialized, and when they are intended to solve clinical problems with no proven alternative therapeutic, or when they are exclusively intended for research and clinical trials. These authorizations must be requested only by the highest management body of the duly licensed private clinics or practices, and on a reasoned proposal from the clinical director, and must indicate, in addition to the items listed in article 170, number 2 of Decree-Law No. 12/2004, the following:

a) Therapeutic indication for which the drug is intended;

b) Indication of the existing therapies on the market and proof of their inadequacy to the situation in question;

c) Indication of the clinical condition or clinical trial justifying the application, the number of patients and the period of treatment.

These authorizations shall be limited to the quantities and time period necessary, duly proven. Any extension sought must again be duly requested and shown to be necessary.