

DEMOCRATIC REPUBLIC OF TIMOR-LESTE

GOVERNMENT

DECREE-LAW NO. 12/2004

OF 26 MAY 2004

PHARMACEUTICAL ACTIVITIES

Under the National Health Policy, pharmaceutical activities relating to production, import, commercialisation and export of medicines and medicinal products shall be subject to a special legislation in order to ensure their quality, safety and effectiveness.

The Government has already established a public company for the import and commercialisation of medicines. Such a measure, however, does not prevent the import and commercialisation of medicines by private entities.

It is therefore important to establish the necessary conditions for the exercise of pharmaceutical activities so as to guarantee the defence and protection of health, meet the needs of the population, and rationalize the consumption of medicines.

Thus, pursuant to sub-paragraph (e), item 1, of Section 115, and sub-paragraph (d) of Section 116, of the Constitution of the Republic of Timor-Leste, the Government decrees the following, to have the force of law:

CHAPTER I
General Provisions

Article 1
Object

1. The present statute regulates the conditions for the exercise of pharmaceutical activities relating to import, storage, export, and sale, in bulk or

in retail, of medicines for human use, and establishes the entities that regulate such activities.

2. The activity of manufacturing medicines shall be subject to special legislation.

Article 2 **Definitions**

For the purposes of the present statute the following terms shall have the following meanings:

- a) “*Medicine*” means every substance or composition presenting curative or preventive properties of human diseases and its symptoms and with a view to establishing a medical diagnosis or to restoring, correcting or modifying its functions.

- b) “*International common denomination*” means a designation adopted or proposed by the World Health Organisation for medicine active substances, in accordance with defined rules, which cannot be the object of trademark or brand name registration, and which is contained in a list published periodically by the World Health Organisation.

- c) “*Essentially similar medicines*” means all medicines with the same qualitative and quantitative composition in active substances, under the same pharmaceutical form, and for which, whenever required, the bio-equivalence with the original branded medicine has been demonstrated on the basis of bio-availability studies.

- d) “*Branded medicine*” means the medicine the active substance of which has been authorized and commercialised for the first time in the market on the basis of complete documentation, including the results of chemical, biological, pharmaceutical, pharmacological, toxicological, and clinical experiments.

- e) “*Generic medicine*” means medicine essentially similar to a branded medicine, generally produced after expiration or renunciation of patent rights of the branded medicine, and in relation to which no different therapeutic indications are invoked.

- f) ***“Stupeficients and psychotropic substances”*** means the substances considered as such by the United Nations in accordance with the rules laid down in the Conventions on the matter.
- g) ***“Pharmacist”*** means a person holding a bachelor’s degree in pharmacy.
- h) ***“Pharmacy Technician”*** means a person holding an associate degree in pharmacy.
- i) ***“Pharmacy Assistant”*** means a person holding a diploma of a technical-professional course in pharmacy.
- j) ***“Pharmacy Helper”*** means a person holding at least a diploma of secondary education and having experience in the pharmaceutical area.
- l) ***“Fee”*** means the amount payable for the licensing of the pharmaceutical activity or for obtaining the authorization to enter the pharmaceutical market.

CHAPTER II

Licensing of the Activities

Section I General Rules

Article 3 Licensing

1. Activities of import, storage, sales in bulk, sales in retail, and export of medicines for human use may only be exercised by entities duly registered in accordance with the applicable law for registration of businesses and duly licensed by the Regulating Commission of Pharmaceutical Activities pursuant to the present statute, after consultation with the Board of Management pursuant to sub-paragraph (d), item 1, of Article 22 of the Organic Statute of the Minister of Health.
2. Licenses shall be granted upon application to that effect containing the following details:

- a) Civil as well as fiscal identification, including residence or head office address;
 - b) Certificate of registration of business;
 - c) Proof of contractual relation with a duly qualified technical manager;
 - d) Localisation map, map and descriptive memory of the facilities for storing and commercialising medicines;
 - e) Indication of the means for transporting the medicines, where this is the case.
3. The following are conditions for licensing:
- a) Verification of the validity of the registration;
 - b) Verification of the validity of the contract with the technical manager;
 - c) Verification of the qualifications of the technical manager and of his/her registration with the respective professional association;
 - d) Verification, through inspection, of the health conditions and technical adequacy of the facilities and the means of transport as contained in a statute of the Minister of Health.
4. The technical manager shall be either a pharmacist, a pharmacy technician, or a pharmacy assistant who shall be responsible for complying with the technical norms relating to medicines as contained in the law and in the regulations issued by the Ministry of Health but whose permanent presence in the pharmacy, without prejudice to the provisions of Article 9 of this Decree-Law relating to pharmacies, shall not be required.
5. The fees to be paid for the licensing of pharmaceutical activities shall be fixed by a joint statute of the Minister of Planning and Finance and the Minister of Health.

Article 4

Validity and Time Limits

1. The decision to grant a license shall take place within a maximum period of 90 days counting from the date of submission of the application duly completed, and the license shall be valid for three years.

2. Licenses shall be renewable for equal periods whenever the initial conditions are maintained, and the requests for renewals shall be submitted within a minimum period of 30 days before their expiration dates.

3. Licenses shall be personal and non-transferable, and any act of alienation, trespass, or cessation of activities of the companies or commercial establishments covered by the present statute shall be communicated in advance to the Regulating Commission of Pharmaceutical Activities to enable it verify and ensure that the new entity holds a license for the respective activity.

Article 5 Dismissal

Applications shall be dismissed whenever the requirements laid down in Article 3 are not complied with, and the applicants shall be notified of the grounds for dismissal for purposes of appealing to the Minister of Health within a period of 20 days.

Article 6 Suspension and Revocation

1. Licenses may be suspended for a maximum period of 90 days, or revoked, whenever the requirements laid down in Article 3 cease to be complied with and whenever the conditions established in the present statute for protecting public health are repeatedly or seriously violated.

2. Pursuant to Chapter V, definitive decisions to suspend or revoke licenses shall always be anticipated by an administrative offence proceeding.

Article 7 Communications

Every decision to grant, refuse, renew, not renew, suspend, or revoke licenses shall be communicated to the Business Registration Unit of the Secretariat of State for Commerce and Industry for registration in the respective file.

Section II

Retail Commercialisation

Article 8

General Rule

1. Only duly licensed pharmacies shall undertake retail commercialisation of medicines, except for:
 - a) Free sale medicines, which may be commercialised in any retail commercial establishment provided hygienic and storing conditions are appropriate;
 - b) Free sale medicines and medicines contained in the list of essential medicines, which may be commercialised in duly licensed private clinics where no local pharmacies exist.

2. The provisions of this Section and of the Articles relating to pharmacies shall not apply to hospital pharmacies and to medicine distribution centres existing in public hospitals, health centres and private clinics for supplying medicines to their own patients, which shall be subject to a special legislation.

Article 9

Pharmacies

1. In addition to the generic requirements laid down in Article 3 for licensing, pharmacies shall be specifically required to have the assistance of a technical manager for the entire working period of the commercial establishment and to be located in an area considered to be adequate for the needs of the respective population.

2. Technical managers may not be absent for more than 30 days per year, and the technical assistance provided by them shall in any case be ensured by a substitute technical manager or, where this is not possible, by a pharmacy helper authorized by the technical manager, who shall expressly recognize the appropriateness of the respective professional experience.

Article 10

Exercise of the Activity

A statute of the Minister of Health shall lay down the technical rules for the functioning of pharmacies, namely on:

- a) Goods and products liable to be sold, in addition to the medicines;
- b) Minimum stock of medicines;
- c) Records of stocks and of sales of medicines;
- d) Records of stocks and of sale of medicines under special control;
- e) Codes of conduct;
- f) Norms relating to work organisation, working hours and shifts;
- g) Health conditions and quality of facilities and medicines.

Article 11

Suspension and Revocation of Licenses

In addition to the provisions of Article 6 above, pharmacies licenses may be suspended or revoked in the following cases:

- a) Lack of adequate assistance by the technical manager;
- b) Serious deficiencies in the health conditions of the commercial establishment;
- c) Serious deficiencies in the facilities for conservation and preparation of the medicines;
- d) Sale of incompatible goods or products;
- e) Repeated non-compliance with the technical operating rules;
- f) Closure of the pharmacy without prior communication to the Regulating Commission of Pharmaceutical Activities, or failure to open the pharmacy within three months after the date of its licensing;
- g) Serious non-compliance with the conditions for sale of medicines as contained in Article 12.

Article 12

Sale of Medicines

1. Pharmacies may only sell medicines that are within the period of validity indicated in the package and that are in perfect conditions of conservation.
2. Except for over-the-counter medicines, pharmacies may only sell medicines prescribed by competent health professionals, pursuant to the statute referred to in Article 14.
3. After verifying the compliance with the rules relating to medical prescriptions, pharmacies shall respect the respective prescriptions and, where

the user so requests, they may only substitute prescribed medicines by other essentially similar medicines if the prescription does not contain a clear indication of the prescriber to the contrary.

4. Pharmacies and their professionals have the duty to advise users about the adequate mode to apply the medicines.

CHAPTER III Medicines and Respective Prescription

Article 13 Prescription

1. Prescriptions shall be signed by the prescriber and contain the following details:

- a) Name and address of the prescriber and respective number of registration with the Ministry of Health;
- b) Name and address of the user;
- c) Date of the prescription;
- d) International Common Denomination of the medicine;
- e) Where necessary, commercial name of the medicine;
- f) Where necessary, indication that the branded medicine cannot be replaced with an essentially similar medicine;
- g) Dosage of the pharmaceutical form and of the posology;
- h) Number of packages or of medicine units;
- i) Indication of the prescription conditions.

2. When attending, prescriptions must be sealed, dated and signed by the pharmacy professional and returned to users, except in cases of medicines subject to special control measures, where prescriptions must be filed in the pharmacy and a copy thereof given to the user.

Article 14
Prescription

Except for over-the-counter medicines, the prescription of the various types of medicines may only be issued by health professionals contained in a statute issued by the Minister of Health.

Article 15
Classification of medicines

The regime for classification of medicines and respective lists shall be approved following a statute to be issued by the Minister of Health to that effect.

Article 16
Advertisement of medicines

Advertisement of medicines subject to medical subscription shall be prohibited, except in technical publications designed for physicians and other health professionals, in terms to be established in a joint statute by the Minister of Health and the Secretary of State for Commerce and Industry.

CHAPTER IV
Authorisation to commercialise medicines

Article 17
Application

1. No medicine may be imported, stored, sold, or exported without prior authorisation of commercialisation granted by the Ministry of Health.
2. Authorisation to commercialise medicines may be applied for by duly licensed importers through an application to be submitted to the Regulating Commission of Pharmaceutical Activities with the following details:
 - a) Civil, fiscal and commercial identification, as well as respective residence or head office;
 - b) Number of the license of the activity;
 - c) Name of the medicine;

- d) Pharmaceutical form and composition insofar as active substances, excipients, dosage, presentation, and administration way are concerned;
 - e) Therapeutic indication;
 - f) Summary of the characteristics of the medicine;
 - g) Project for labelling and informative leaflet in one of the official languages of Timor-Leste or, provisionally, in English or Indonesian;
 - h) Sample of the medicine;
 - i) Official document, accompanied by a translation into one of the official languages of Timor-Leste, certifying the existence of authorisation to commercialise the medicine in the country of its production and in the country from where it is exported.
3. The Autonomous Service of Medicines and Health Equipment, a public company, shall be the sole public entity with competence to apply for authorisations to commercialise and import medicines.
4. Other requirements may be demanded following a statute of the Minister of Health.

Article 18 **Authorisation**

1. The Regulating Commission of Pharmaceutical Activities shall analyse the details submitted and shall grant the authorisation to commercialise medicines if it concludes that the medicine is safe and effective for the use it has been designed for and possesses the necessary identity, activity, quality, purity and inoquity.
2. To this effect, where the Regulating Commission of Pharmaceutical Activities has doubts about the characteristics of the medicine, it may require the applicant to submit samples of the medicine for control by an authorised laboratory.

3. Requests for authorisations shall be the object of a decision within a maximum period of 30 days to be counted from the date of submission of the application and priority shall be given to applications relating to generic medicines.

Article 19 Individual Authorisation

1. The Regulating Commission of Pharmaceutical Activities may authorise the import by private clinics or physicians of medicines that have not yet been the object of commercial authorisation whenever:

- a) For reasons of urgency and through a clinic justification, the medicines are considered to be indispensable for the treatment or the diagnosis of certain pathologies;
- b) The medicines are exclusively designed for research and clinical experiments.

2. Medicines donated to public or private institutions shall be notified to the Regulating Commission of Pharmaceutical Activities which shall ensure that the rules about donation of medicines contained in a statute of the Minister of Health are complied with.

Article 20 Labelling

The label of the medicines and the informative leaflet must contain the details laid down in a statute of the Minister of Health in one of the official languages or, provisionally, in English or Indonesian languages.

Article 21 Granting

1. The Regulating Commission of Pharmaceutical Activities shall notify the applicant of the granting of the authorisation and, against the payment of fees as fixed by statute of the Minister of Health, shall issue the respective certificate containing the summary of the characteristics of the medicine as well as of the labelling and the information leaflet, including the special conditions of the authorisation, in accordance with applicable regulations.

2. Authorisations shall be valid for three years, renewable for equal periods of time, in accordance with applicable regulations.

Article 22 Dismissal

1. The application shall be dismissed whenever:
 - a) The process is not duly completed and no correcting steps are taken within the period of time indicated by the Regulating Commission;
 - b) The medicine is considered to be harmful;
 - c) The therapeutic effect has been insufficiently proved;
 - d) The medicine is susceptible to pose risks to public health;
 - e) The medicine does not contain the declared qualitative and quantitative composition.
2. Applicants shall be notified of the dismissal and the respective justification for purposes of appealing to the Minister of Health, to be filed within a period of 20 days.

Article 23 Suspension and revocation

1. Authorisations to commercialise medicines may be suspended or revoked whenever the premises supporting them cease to exist and, specifically, whenever any of the cases provided for in sub-paragraphs b) to e) of Article 22 above are detected.
2. Suspensions and revocations shall imply prohibition of commercialisation or utilisation of the medicines up until such suspensions or revocations are lifted.
3. Revocations shall always imply the removal of all or part of the batches of medicines at stake from the market, which shall be the responsibility of the holder of the authorisation.

4. Definitive decisions to suspend or revoke authorisations for commercialisation shall be communicated to their holders, with the indication of the respective grounds to enable them appeal to the Minister of Health within a maximum period of 20 days, and to the National Directorate of Customs of the Ministry of Planning and Finance.

Article 24
Medicines Deriving from Blood

Applications for authorisations to commercialise medicines deriving from blood shall be accompanied by a declaration of the manufacturer certifying that the plasma and blood-relating measures as recommended by the World Health Organisation have been complied with, namely in terms of selection and control of donors, and indicating the methods to reduce or eliminate the pathogenic details susceptible of being transmitted.

Article 25
Narcotics or Psychotropic Substances

1. Medicines the composition of which contains narcotics or psychotropic substances shall be subject to the provisions of the present statute and of other special legislation, as well as to the provisions of the existing United Nations Conventions on the matter.

2. Up until the entry into force of the special legislation provided for in paragraph 1, only the Autonomous Service of Medicines and Health Equipment, a public company, may import narcotics or psychotropic substances.

CHAPTER V

Monitoring

Article 26
Competence

It is incumbent upon the Office of Health Inspection, in collaboration with the Regulating Commission of Pharmaceutical Activities and the Department of Pharmaceutical Services, to monitor the activities of import, storage, export

and commercialisation of medicines and, to that end and for the safety of public health, it may:

- a) Have free access to all commercial establishments undertaking the above-mentioned activities;
- b) Have free access to all documents referring to them;
- c) Collect samples of medicines for analysis.
- d) Apprehend, on a provisional basis, non-authorized medicines or medicines in poor conditions the conservation of which may endanger public health;
- e) Close, on a provisional basis, non-authorized commercial establishments or commercial establishments operating in violation of the regulating norms of the respective activity and endangering public health.

Article 27

Offences and Sanctions

1. Offences to provisions provided for in the present statute and complementary legislation shall be considered administrative offences punishable under the general law with the adaptations contained in the following articles, save where they constitute crimes, in which cases they shall be punishable under the penal code.

2. Negligence and attempt of negligence shall always be punishable.

3. Penalties shall be fixed between a maximum and a minimum amount, and their application shall be graded depending on the seriousness of the offence and the danger posed to public health, the degree of fault and the economic status of the offender.

4. When applied to individuals, the maximum and minimum limits of the penalties shall be reduced to their half.

5. Concomitantly with the penalty, the application of the following sanctions may be determined depending on the degree of fault of the offender, the seriousness of the offence and the danger posed to public health:

- a) Loss of objects belonging to the offenders;
- b) Closure of the commercial establishment;
- c) Suspension or revocation of the licenses and authorisations provided for in the present statute;
- d) Inhibition, in a maximum of two years, of the exercise of activities or professions carried out pursuant to the present statute.

Article 28

Procedures

1. A record shall be prepared for each and every detected infraction reflecting the facts until they are proved to the contrary, and such record shall constitute the basis for the administrative offence procedure to be filed.
2. The record shall be submitted to the Health Inspection Office, the competent authority to file the respective proceeding in collaboration with the Pharmaceutical Services and the Regulating Commission of Pharmaceutical Activities.
3. The offender must be notified of the facts constituting the offence, of the legislation violated, of the applicable sanctions and the period of time granted, of the place for presenting his or her defence, of the possibility for his or her voluntary payment of the fine, as well as of the consequences for non-paying the fine.
4. The offender may, within 20 days, submit his or her defence in writing or voluntarily effect the payment, and may also submit his or her defence confined to the seriousness of the offence and to the accessory sanctions after having effected the voluntary payment of the fine.
5. The competence for applying fines and accessory sanctions rests with the Minister of Health, whose final decision may be the object of contentious appeal to be filed within 30 days.

Article 29
Destination of the Fines

75% of the proceedings resulting from the fines shall revert to the coffers of the State and 25% shall revert to the entities of the Ministry of Health which monitored and prepared the respective administrative offences.

Article 30
Administrative Offences and Fines

1. The following shall constitute administrative offences, punishable with the following fines:

- a) The exercise of the activities of import, storage, sales in bulk or in retail, and export of medicines for human use by somebody who does not hold the respective valid license, thus in violation of the provisions of articles 3 and 8, attracting a minimum fine of US\$ 1,000 and a maximum fine of US\$ 3,000;
- b) The lack of communication as provided for in item 3 of Article 4, attracting a minimum fine of US\$ 100 and a maximum fine of US\$ 300;
- c) The occurrence of situations as contained in the sub-paragraphs of Article 11, attracting a minimum fine of US\$ 100 and a maximum fine of US\$ 2,000;
- d) The import, manufacturing, storage, sale in bulk or in retail, and export of medicines not authorised for commercialisation in violation of Article 17, attracting a minimum fine of US\$ 1,500 and a maximum fine of S\$ 5,000.

CHAPTER VI
Regulating Entities of Pharmaceutical Activities

Article 31
Establishment

The Regulating Commission of Pharmaceutical Activities and the Commission for Selection of Medicines, Medical Products, and Medical Equipment are

hereby established within the Ministry of Health with the composition and the competencies contained in the following articles.

Article 32
Regulating Commission of Pharmaceutical Activities

1. The Regulating Commission of Pharmaceutical Activities shall be composed of the following entities:

- a) The Permanent Secretary, who presides it over;
- b) One representative of the Secretary of State for Commerce and Industry;
- c) The head of department of the Pharmaceutical Services of the National Directorate of Health Delivery Services;
- d) One representative of the Autonomous Service of Medicines and Health Equipment, a public company;
- e) One representative of the Association of Pharmaceuticals;
- f) One representative of the Association of Physicians.

2. It is incumbent upon the Regulating Commission of Pharmaceutical Activities to:

- a) License the pharmacies as well as the companies dealing with import, storage, bulk sale, retail sale, and export of medicines;
- b) Authorise the commercialisation of medicines, as well as suspend or revoke the respective authorisations;
- c) Collaborate with the Office of Health Inspection and with the Pharmaceutical Services on the licensed activities and the respective commercial establishments and products;
- d) Undertake the verifications and analyses that are necessary for granting licenses and authorisations and ensure that the respective legal and regulatory norms applicable to the exercise of such activities are complied with;

- e) Check the quality of the medicines as well as the conditions for storage, distribution and granting, in accordance with the legal and regulatory norms of quality and good practice;
 - f) Propose to the Minister of Health the technical regulations deemed necessary for regulating pharmaceutical activities.
3. The Regulating Commission of Pharmaceutical Activities may operate by sections, and the respective operating norms shall be the object of a specific regulation to be approved by the Minister of Health.
4. The technical and administrative support necessary for the exercise of the competencies of the Regulating Commission of Pharmaceutical Activities shall be ensured by the Pharmaceutical Services of the National Directorate of Health Delivery Services.

Article 33 Charges

The proceedings from the fees provided for in the present statute shall be designed to cover the operating costs of the Regulating Commission of Pharmaceutical Activities.

Article 34 Commission for the Selection of Medicines, Medical Products and Medical Equipment

1. The Commission for the Selection of Medicines, Medical Products and Medical Equipment shall be composed of the following entities:
- a) The head of department of the Pharmaceutical Services of the National Directorate of Health Delivery Services, who shall preside it over;
 - b) One representative of the Guido Valadares National Hospital;
 - c) One representative of the Autonomous Service of Medicines and Health Equipment, a public company;
 - d) One representative of the District Health Services;

- e) An individual appointed by the Minister of Health from among the non-profit institutions with a manifest public interest in the area of health.
2. It is incumbent upon the Commission for the Selection of Medicines, Medical Products and Medical Equipment to prepare the proposal of classification of medicines, medical and equipment products, including the respective lists.
3. The operating norms shall be the object of a specific regulation to be approved by the Minister of Health.
4. The technical and administrative support necessary for the exercise of the competencies of the Commission for the Selection of Medicines and Medical Products and Equipment shall be ensured by the Autonomous Service of Medicines and Health Equipment, a public company.

CHAPTER VII

Final and Transitional Provisions

The regulation provided for in Articles 3, 10, 14, 15, 19, 20, and 21 of the present statute must be approved and published within a maximum period of two months from the date of its publication, and the Commissions provided for in Articles 32 and 34 shall be constituted and regulated in the same period of time.

Article 36

Transitional Norm

Entities which, at the time of the entry into force of the present statute, are exercising activities of import, storage, export, and sale in bulk or in retail of medicines must, within a period of six months from the date of publication of the present statute, apply for the respective licenses provided for in the same statute, under pain of closing of the commercial establishment and of prohibition of the exercise of the respective activity for a period of two years.

Article 37
Entry into Force

The present statute shall enter into force three months after its publication, except:

- a) The norms contained in Chapter IV, which shall enter into force within nine months from the date of its publication;
- b) The norms contained in Chapter VI, which shall enter into force on the day immediately after its publication.

Approved by the Council of Ministers on 30 April 2004.

The Prime-Minister
[Signed]

Mari Bin Amude Alkatiri

The Minister of Health
[Signed]
Rui Maria de Araujo

Promulgated on 17 May 2004

To be Published.

The President of the Republic

[Signed]

Kay Rala Xanana Gusmao