



REPÚBLICA DEMOCRÁTICA DE TIMOR LESTE
MINISTÉRIO DA SAÚDE
Ministry of Health

National Drugs and Medicines Policy



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Introduction

The National Drug Policy (synonyms also used; National Medicine, or; National Pharmaceutical policy for Timor Leste) deals with the development, provision and use of medicines within both the public and the private sector. The overarching goal is to secure safety and protect the individual patient and the public. The National Drugs and Medicines pharmaceuticals Policy aims to contribute to improved health and wellbeing of all people in Timor Leste.

This National Medicine Policy document aims for uninterrupted supply of safe, effective and good quality Essential Medicines, and promoting the rational and safe use of medicines both in public and private sectors throughout the country. For the National Medicine Policy to have impact, it must be owned by all stake holders and implemented through updated legislation and regulations, through a National Drug Administration as central Authority in line with WHO recommendations.

The National Drug Policy embraces all aspects of supply, quality, use and management of pharmaceuticals/medicines/drugs. The Policy addresses all drugs, both branded and generic, as well as biological products derived from living sources such as blood, blood products and vaccines as well as medicines of chemical composition, and products which are classified as so called traditional medicines or traditional health products.

A Drug, a Pharmaceutical or Medicine/Medicinal product is defined by its intended use, if it is intended for diagnostic, preventive, curative or palliative care for human use. Also products used for diagnostic, preventive or curative use in animals are classified as medicines.

This is addressed by development of legislative norms and acts, action plans, guidelines and programs that improves

the health status of the people and prevents and reduce drug-related harm. This is achieved through optimal availability and use of essential pharmaceuticals in prevention, diagnosis and treatment of illness and disease. An important objective is to strive towards equity and efficiency in access to medicines of reliable quality for all citizens and/or visiting people in country, regardless of social vulnerability, poverty or any form of social marginalization.

The Pharmaceutical policy thus promotes both efficiency and efficacy of healthcare service delivery.

The National Drug Policy recognizes that medicines constitute an integral and vital part of healthcare, in diagnosis, prevention, curative treatment, palliative care and control of disease.

Medicines are defined in the Law of Timor Leste, in line with international praxis; A Medicine or Pharmaceutical product is any product or substance(s) which is used for the purpose to prevent, diagnose or treat conditions and diseases in humans. The same definition also applies, when products are used with the purpose to prevent, diagnose and/or treat conditions in animals.

All medicines fall under the requirement of formal requirement of registration approval, before they can be allowed to be imported or allowed to be sold or used in Timor Leste. The objective with this requirement is to protect the population from harm, and to secure that only medicines with reliable quality are made available in Timor Leste.

Timor Leste is therefore updating and implementing a new Law for the Pharmaceutical sector. This new Law also includes rules for the storage, prescribing, dispensing and use of medicines in all sectors of medical practice, private and public, and this Law also defines clear requirements for import, export, production, stock holding, wholesale and retail, prescribing, use and handling of all medicines (Synonyme

terminology also used, Drugs, Pharmaceuticals or Medicinal products).

The Government is committed to a vision of ensuring safe, effective, reliable quality, essential medicines to be available at affordable cost at all times to the entire population of Timor Leste. This commitment is emphasized in this Drug Policy as amendment to the National Health Policy and Strategy. Moreover access to essential medicines is also formulated in line with the national commitments to reach the Millennium Development Goals.

While assessing challenges and problems, the National Drug Policy also recognizes that many practical factors still hamper availability of medicines at various levels of health care. The situation of limited resources is always present in all national healthcare systems, and Timor Leste is no exception in this regard.

The National Drug Policy therefore recognizes that Priorities must be made in terms of selecting drugs for supply, to meet the most important needs of the healthcare system, solving the most important health problems of the population.

The National Drug Policy therefore promotes the Essential Drugs concept and mechanism, and also promotes Standard Treatment Guidelines. Priority is given to supply of vital Essential drugs, as an important mechanism to reach key Goals of the National Drug Policy.

An important goal in the National Drug Policy is therefore also, to build good public sector including work with defining needs specifications for supply of Essential Drugs for hospitals and primary care.

The National Drug Policy also require Government Licensing to private and public sector healthcare providers and institutions, before they are allowed to deliver healthcare services and/or to import, sale, distribute or prescribe and

dispense Medicines and Pharmaceuticals.

The benefit to a private sector in healthcare and pharmaceutical service delivery has been established. However the establishment of private pharmacies and private clinics has not yet been matched with adequate regulatory control. The National Drug Policy therefore addresses this gap. The new Drug Policy and new Drug Law is aiming to address the needs to control both the public and the private sector, with the overarching aim to safeguard peoples health.

Legal and regulatory demands are defined with the aim to protect the people against the risk of unsafe and poor quality medicines and pharmaceutical products, a risk which has been reported to occur in many other countries World-wide and in the region.

New clear standards, guidelines and technical regulations are launched, to set requirements for registration of medicines, setting requirements for Good Pharmaceutical Practices, Good Distribution Practices, Good in-hospital Pharmaceutical Management, and Good Pharmaceutical Management in Primary Care.

The National Drug Policy therefore launch new standards, guidelines and technical regulations for the control of the private and public sectors alike, as defined in a new Pharmaceutical Law.

Specific new guidelines are defined to ensure compliance with retail only of medicines registered and approved by the National Drug Regulatory Authority, and to ensure that unsafe sale of medicines without prescription is reduced. Professional performance benchmarks are also launched for both private and public pharmacy practice, including to ensure necessary education and information to patients, always ensuring that patients are well informed about dosages and how to safely use the prescribed medicines.

The new Pharmacy Law also set clear regulatory requirements about the importation of medicines.

The legal requirements connect closely to the WHO Certification scheme to combat and prevent unsafe, counterfeit and substandard quality drugs from being imported into Timor Leste.

The Drug Policy and legislation recognizes that the present number of qualified pharmaceutical personnel, both in the public and private sector is inadequate. This shortage must be met to develop pharmaceutical services.

The National Drug Policy recognizes that there is a need to strengthen the quality assurance and quality control mechanisms for medicines.

This entails both in-country adherence to Good Distribution Practices, Good Pharmacy Practices and requirements in regard to procurement and importation. Formal requirements are therefore set in the Law for Quality Assurance and Quality Control during procurement and importation of medicines, only allowing medicines produced under certified Good Manufacturing Practice (GMP) and controlled under the umbrella of WHO Certification scheme. The Quality assurance requirement also addresses the need to set-up collaboration with an internationally certified drug quality control laboratory for quality-testing of samples taken during inspections of Pharmacies in Timor Leste.

The National Drug Policy is clearly stating the objective to promote the essential medicine concept and promote adherence to standard treatment guidelines to guide rational and safe clinical drug use in Timor Leste. The National Drug Policy recognizes that a Code of Quality of Care is needed along with establishment of hospital Therapy committees, to promote adherence to rational use of drugs, as well as to establish safe prescribing and safe medicine dispensing practices.

The Government of Timor Leste has established a national wholesaler, the "SAMÉS" as a centralized procurement, wholesale and supply system. The Public Health objectives for the operation of the SAMÉS need to be further defined, with clearly objectives, goals Guidelines and Standard Operating Procedures.

This is essential both to optimize public health protection and to economize and minimize cost expenditure on medicines and thereby ensuring availability and supply of medicines to all levels of health care in a predictable manner. A well functioning mechanism for quantification of drug quantity requirements shall be established, based on patient case load and case mix statistics, and based on Standard treatment guidelines, to present a reliable estimate of needs as base for budget planning and allocation of adequate financial resources for drug procurement and supply.

In order to fill the gaps between needs and current practice, there is an urgent need to establish a National Drug Regulatory Authority in Timor Leste, matching WHO recommendations many policies and functions which need to be established at national level.

The organization, authority and responsibilities and organization set-up of the National Drug Regulatory Authority (National Drug Administration) is outlined in the updated Drug Law.

Goals set in the National Drug- and Medicine Policy

Three main Goals are defined in the Policy;

- (i) To ensure that all medicines which are imported or locally manufactured, distributed, sold and used in the Timor Leste are effective, safe and of good reliable quality. This objective shall be ensured

through the effective function and operation of a National Drug Regulatory system, spearheaded by the key institution, the National Drug Regulatory Authority (synonymous terms: National Drug Administration, currently the Pharmacy department of the Ministry of Health).

- (ii) To ensure that adequate quantities of quality Essential Medicines are determined correctly, based on the needs of the population and based on the patient case load and case mix in primary care and hospitals. Needed essential drugs shall be made available at affordable costs at all times, to meet the need of the entire population, and especially protecting the needs of the most poor and vulnerable.
- (iii) To promote rational, safe and cost-effective use of medicines: The use of medicines shall be guided and controlled, both to reduce risk for harm, and to optimize the curative effect of used medicines, while also reducing cost, thereby optimizing the ability to reach and cover the whole population with effective and safe treatment, within available budget frame. Key mechanisms shall be established, including active implementation of standard treatment guidelines, in-hospital therapeutic committees, active provision of consumer independent drug-information and activities to raise awareness and prevent avoidable adverse and side effects of drugs.

Objectives

In order to achieve set Goals and to reduce and solve problems in the pharmaceutical sector, the following objectives are set:

To ensure reliable supply of essential drugs of good and reliable quality and quantity

To ensure rational selection, procurement, and storage and distribution of medicines according to procedures to maintain quality, in both public and private sectors to ensure availability of Essential Medicines throughout the country.

To establish key functions and services of a National Drug Administration (National Drug Regulatory Authority), and within this institution establish key functions, including a well functioning medicine registration system, and a system for Licensing and Pharmaceutical Market surveillance and control.

To establish a range of quality assurance mechanisms including efficient inspection system, with which to monitor wholesalers, retail pharmacies and other distribution outlets including public and private hospitals and clinics with pharmacies throughout the country. This quality assurance system shall both function as a regulatory control and enforcement mechanism, to ensure compliance with laws and regulations, and; provide supportive services to strengthen Good Pharmacy Practices in private and public sector pharmaceutical sector operators alike.

To optimize the curative and preventive result of drug treatment by promoting rational and safe use of drugs, and reduce the risk for harm caused by unsafe and irrational drug-use; Healthcare professionals shall be provided with updated standard treatment guidelines matching the reality in Timor Leste, and matching in-service supervision and training. A drug-use audit and survey system shall be established along with the establishment and set-up of Drug and Therapy Committees in all hospitals.

To promote safe prescribing and safe procedures in dispensing, thereby preventing medication mistakes and errors.

To strengthen the prescribing and monitoring of narcotic and psychotropic drugs and substances, while also promoting the needed availability and appropriate and rational use of pain control and mental health drugs for all patients in need.

To establish a national repository depot of key antidotes and emergency drugs, and a poisoning information service.

To Establish mechanisms for advertising control and provision of producer-independent drug information to prescribers and pharmacists in Timor Leste.

To establish a consensus and participatory mechanism and organization for revision, development and implementation of standard treatment guidelines, matching evidence based medicine and matching the reality situation in Timor Leste.

For Special pharmaceutical products, blood, serum, vaccines, special requirements shall be defined and implemented for quality and safety, especially for blood-products, any products containing biological materials and especially materials from human origin, vaccines and other biological products to ensure safety from perspective of viral and bacterial contamination.

To develop and strengthen adequate technical, human resources in the field of pharmacy and medicine management by appropriate training and continuing education,

To establish a prospective planning and budgeting mechanism, with which to allocate adequate resources, especially for implementing and monitoring the National Medicines Policy, print and disseminate Standard Treatment Guidelines, Essential Drug Lists and the updated Pharmacy Law, to be available widely in all facilities and institutions.

To establish a prospective planning and budgeting mechanism, with which to calculate needed budget resources for the procurement of drugs, matching the patient case-mix

and case-load in hospitals and primary care of the public health system in Timor Leste.

To establish twinning and exchange with other National Drug Regulatory Authorities / Drug Administrations in the ASEAN region and in wider International cooperation with international and regional agencies, in areas such as training of staff, exchange of information and exchange of technical methods.

To establish a partnership between the government of Timor Leste and its National Drug Administration and the private providers in the pharmaceutical sector.

To establish collaboration with the Ministry of Agriculture, regarding the regulatory issues pertaining to veterinary drugs.

Priority areas to be strengthened, as defined by the Policy.

The National Drug Policy aim gives priority to key outputs and aim to strengthen the following areas:

Set-up and establish a National Drug Administration (synonym terminology: National Drug Regulatory Authority), in line with WHO recommendations for National Drug Regulatory Authorities in small countries with limited resources. Including key functions such as Drug registration, market regulation, surveillance and control, and control of drug use in all segments of healthcare, public and private.

Updating of Laws, Legislation and Regulations for the Pharmaceutical sector and for the control of prescribing and use of medicines in all sectors of healthcare, both public and private.

Implementation of Regulatory, administrative and quality standards in the Pharmaceutical sector and for handling and

use of medicines in all segments of healthcare, public and private.

Establishment of Medicine registration services, as a key function of National Drug Regulatory Authority, with the establishment of a national Drug registration database, and establishment of well-functional drug registration mechanism. This drug registration mechanism shall ensure that only reliable medicines with available documentation about efficacy, available documentation about safe/risk profile and with reliable quality are allowed into Timor Leste.

Pharmaceutical inspection and enforcement services for implementing and ensuring adherence to regulations and procedures in practical pharmacy work, strengthened

Quality assurance and quality control services established, through collaboration with internationally certified QC laboratory and market surveillance.

Supply of essential medicines to all levels of health care.

Medicine and poison information services established

Advertising control mechanisms established

License database for pharmacies and clinics using and storing, prescribing and dispensing medicines, established

Licensing database for all pharmaceutical personnel, and database over all authorized personnel with prescribing rights established

Monitoring and supervision to promote rational use of medicines, by updating and implementation of Standard Treatment Guidelines and Essential Drugs

Antibiotic resistance surveillance and measures to prevent, stop further spread and limit the negative health and cost impact of antibiotic resistance infections.

Supervision of pharmaceutical practices and supervision of safe prescribing and dispensing practices in hospitals, and in clinics, public and private

A comprehensive National Medicine Policy has hereby been formulated addressing a set of listed priorities. National Strategies shall be drawn up, with specific action plans as needed to address each component of the National Drug Policy.

Specific objective

1. Updated Law and Regulations

An updated Law of the Republic of Timor-Leste shall form the legal basis and framework for regulatory control of the pharmaceutical sector, matching set goals, objectives and priorities defined in the National Drug Policy.

The updated Law shall incorporate elements of existing rules and regulations which are in line with this policy. The updated Law shall also harmonize requirements in Timor Leste with international praxis, paving the way for safe trade and safe importation of reliable pharmaceutical products of good quality and ensuring best possible safety for patients and people in Timor Leste.

For enactment of the Law by the relevant bodies, detailed regulations governing standards and key procedures shall be defined in Guidelines to carry out the provisions of the Law. A set of necessary Guidelines, for Good Pharmacy Practice, Good Distribution practice and guidelines for drug management in healthcare facilities and institutions shall therefore be formulated and issued.

The updated Law and updated regulatory framework shall include solutions and norms to enable:

The updated Law shall pave the way for the establishment of a National Drug Administration syn. National Drug Regulatory Authority, in the organization of the Ministry of Health.

Enforcement of the Drug Law, with technical regulations for authority and authority.

The operation of the National Drug Administration as focal point for implementation of the National Drug Policy.

The National Drug Administration support with help of a Advisory body. (hereinafter called Advisory Board)

2. Medicine / Drug Registration

A functional Drug Registration shall be established. Approval by Drug Registration shall be required with definition of approved purpose(s) (indications) for any pharmaceutical, drug or medicine, before any pharmaceutical, drug or medicine can be imported, sold or used in Timor Leste. Only products with adequate and documentation about its efficacy and its safety/risk profile in use for the suggested indication(s) can be approved by registration. Import license and marketing authorization from the Drug Administration shall also be required before any pharmaceutical product (medicine, drug) is allowed on the market in Timor Leste. Regulations for issuing or denying marketing authorizations shall be clearly defined in the updated Pharmacy Law, and shall be based on evaluation of safety, efficacy, quality and medically defined need.

Marketing Authorization shall be valid for a specified period of time as defined in the updated Pharmacy Law. A review shall be required for renewal of all Drug registrations.

A registration fee shall be charged for registration, marketing authorization and for import License for all pharmaceutical products and Medicines and other products as determined by the Ministry of Health.

A database for registration and monitoring imports of pharmaceutical products shall be developed and established.

3. Importer, Wholesaler, Pharmacy Licenses

The Ministry of Trade and Development is responsible for issuing a general trade license for any corporation. Once such a License has been obtained, the corporation must also apply to the Drug Administration of the Ministry of Health for License to operate as medicine importer, wholesaler or as retail pharmacy.

Legislation requirements shall be defined in the updated Pharmacy Law, for all importers, wholesalers, pharmacies and other retail outlets. Basic requirements shall include the demands:

To be Licensed by the National Drug Regulatory Authority in Ministry of Health (syn Drug Administration), and

Before License can be issued, the applying institution or corporation must fulfill a defined set of quality requirements defined by the Ministry of Health. These requirements includes both the demand to keep and maintain suitable premises and quality procedures, appropriate storage conditions for medicines to preserve quality in line with Good Distribution Practices. Requirements also include demands for available personnel with pharmaceutical competence, to endure good pharmacy practices.

Licenses shall be issued to all Pharmaceutical personnel, and to all Healthcare personnel with the right to dispense and prescribe. All such personnel shall be licensed by the National Drug Regulatory Authority (Drug Administration).

Data about all personnel with License shall be kept in an annually updated License-database in the National Drug Regulatory Authority (Drug Administration). Updated printed records over licensed prescribers, shall be provided to all pharmacies 2 times per year.

4. Standards, Monitoring and Supervision

It shall be the responsibility of the National Drug Administration to monitor, supervise and enforce that the medicine / pharmaceutical regulatory requirements and quality standards are properly followed by importers, wholesalers and pharmacies during procurement, distribution storage, sale and prescribing and dispensing of all pharmaceuticals in the country.

National Drug Administration will conduct regular Supervision and Monitoring, of stock holding and procedures in all public hospitals and clinics, and in all private pharmacies, wholesalers and all private clinics with sale and dispensing of medicines.

5. Control of pharmaceutical advertisement

Advertisement and medicine promotion through the mass media shall require prior approval.

The content and distribution of medicine information provided by pharmaceutical companies and/or their representatives to health care professionals and the public shall be subject to monitoring and control and conform to the WHO Ethical criteria for promotion of Medicinal products.

6. post-marketing surveillance.

All marketed medicines shall be under vigilance to ensure constant conformity with the conditions and terms of the marketing authorization and safety

7. Antibiotic resistance

The National Drug Administration shall lead and establish a national surveillance of antibiotic resistance, in collaboration with the National Laboratory. Data from antibiotic resistance surveillance shall be shared with the WHO regional collaboration, and data from surveillance in Timor, and data from the regional collaboration, shall be used to revise national standard treatment guidelines, as well as to design and implement activities to reduce irrational and unsafe prescribing, use and irrational and unsafe sale of antibiotics in Timor Leste.

Every effort shall be made through appropriate regulations, to reduce the further spread of drug resistant infections, including the problem of drug resistant Tuberculosis, drug resistant Malaria and drug resistant infections such as occur in primary care and hospitals in Timor Leste.

8. Safe Prescribing Practices.

Prescribing authority will be limited to registered and licensed health professionals, as defined in annually updated database over licensed personnel. A Database shall be established in the National Drug Administration, annually updating all healthcare personnel who are licensed and authorized to prescribe medicine.

Regulations will define clearly which medicines require prescription and which can be sold without prescription, as Over-the-Counter OTC medicines.

Clear regulations and legal requirements shall be available about which medicines are controlled substances, (Narcotic and psychotropic drugs), with clear instructions and guidelines about prescribing, dispensing and record keeping requirements. National Drug Administration and Ministry of Health Inspectorate will conduct special Monitoring, supervision and audits to all institutions, to control compliance with the specific legal requirements.

In addition, the national Drug Law defined which medicines are Controlled substances, narcotics and psychotropic medicines, for which extra stringent prescribing and recording practices are required.

9. Access To Medicines

A centralized procurement and supply system has been established, the SAMES with the aim to ensure availability and supply of medicines to all levels of health care in a predictable manner. The Public Health objectives of the SAMES system shall be defined in the new Drug Law of Timor Leste.

10. Selection of Medicines

Medicines for procurement and importation shall only be selected from the list of products which have a valid Registration approval and a valid marketing authorization.

Medicines for procurement shall also only be selected from a list of medicines supplied from pre-qualified sources, based on quality performance, based on the WHO Certification scheme, and based on international exchange of information about reliable product supply.

Selection of medicines shall be done by the National Drug Administration, defining Essential Medicines List and through international tender procedures managed by the wholesaler,

under control of the regulatory requirements set by the National Drug Administration and national Drug Law.

11. *Essential Medicines*

A National Essential Medicine List that shall be reviewed annually, to be based on medical needs defined by morbidity, mortality and evidence based medicine and to be used as a guide for procurement and prescribing at all levels of health care.

Adequate stock level of Essential Medicines must be maintained at all levels of health care.

Quantity needed shall be calculated, based on Case-load and case-mix in primary care and hospitals, matching drug selection defined in standard treatment guidelines and matching the Essential drug list.

Provisions shall be made for supply of medicines for exceptional needs, which are not registered or not on the National Essential Medicines List

12. *Generic Medicine (Multisource products)*

The government encourages import and use of generic medicine nomenclature in all aspects, ensuring multisource products of assured quality and safety.

13. *Procurement of medicines.*

The National Medicine Policy promotes the purchase of essential medicines through the SAMES governmental wholesaler. The position of SAMES as Governmental Wholesaler, includes Public Health objectives, basing drug procurement on medical priorities, and not only on commercial

objectives of meeting high volume requests for “popular medicines”. This means, that the budget allocated to drug procurement by SAMES shall give first priority to essential medicines of vital importance for treating serious and important medical conditions.

A mechanism shall also be provided for procurement of additional medicine supply from private importers.

Under both cases, importation is controlled under the regulations of the National Drug Law and National Drug Administration guidelines.

14. *Distribution of medicines*

The government will organize sufficient and appropriate logistic facilities to ensure a systematic and reliable distribution. Hereby, adequate supplies of Essential Medicines shall be made available at all times to the all levels of health care, even in remote locations.

District warehouses shall be established, with staff, logistic support resources and warehouse management IT systems in place.

The organization of distribution system and its management shall match the wider healthcare system organization, if per district or per future regional organization.

Supply depots shall be established both at central and district levels, with buffer stock and with task to reduce overstock and stock-out differences between primary care facilities within a district or region.

Hospital and health center pharmacies are required to promote the concept of Essential Medicines and rational and safe prescribing and rational and safe dispensing.

Community participation to set-up and operate pharmacies on self sustainable basis shall be encouraged and supported.

Regulations shall be revised to allow for clinicians and nurse practitioners to dispense in locations with low population.

All parties involved in procurement import, and distribution of medicines shall follow WHO Certification scheme and WHO based guidelines on good distribution and storage practices and good pharmacy practice procedures.

15. *Stakeholder involvement*

Activities of all sectors should complement each other and aim towards effective medicines distribution, availability and rational medicine use throughout the country.

Every effort shall be made to minimize wastage of medicines at all levels.

The role of the active players in the pharmaceutical sector in the emergency response and preparedness to national disasters shall be stipulated.

All agencies donating medicines must ensure compliance to WHO Medicine Donation Guidelines and with the national Essential Medicines List and with the National Drug Law.

16. *Quality Assurance and Quality Control*

Quality assurance of medicines shall be achieved through a comprehensive medicine registration system, testing of marketed medicines, inspection at ports of entry and at points of distribution and retail

As part of the product registration system, the WHO Certification Scheme¹ and Prequalification Scheme shall continue to be adopted as a means of ensuring quality of medicines imported in to the country

Medicines storage facilities and outlets at both public and private institutions shall be inspected regularly.

Regulations and practices shall be put in place to ensure that quality is maintained during transport and handling

The government National Drug Administration will take action and confiscate and destroy any medicines found with unacceptable quality, or any medicine found imported without valid importation license, without valid registration or without valid marketing approval or without valid quality certificate.

17. *Rational and Safe Use of Medicines*

The National Medicine Policy aims at promoting rational use of medicines in all aspects and areas of prescribing, dispensing, and also in private pharmacy operation and self-medication.

A system for promotion of rational and safe use of drugs will be based on standard treatment guidelines (STGs), developed with a strong base in international best practice, and connected to the reality of currently available resources in Timor Leste.

Standard treatment guidelines define the place in diagnosis, therapy, prevention and palliative care for pharmaceutical products. The STGs will be developed with active involvement of the prescribers who later also shall use the guidelines, building consensus with support from a Clinical Pharmacology Adviser. Development and revision of standard treatment guidelines shall also build up a panel of national reference committees for STG revision in key therapeutic areas.

¹ WHO Certification Scheme for Quality of Pharmaceuticals Moving in International Commerce

These committees shall involve both specialists and non-specialist prescribers, and link with drug and therapy committees in district and national referral hospitals.

The standard treatment guidelines will be used as base for assessing drug needs, and also for clinical audits and for training to promote Quality of Care.

Standard treatment guidelines will also be used as base for Continuous Medical Education and Continuous Professional Development. A national system for development and revision of treatment guidelines will be formed with strong national and international collaboration as fundament. In addition to the Standard Treatment Guidelines, Timor Leste will also distribute the WHO Model Formulary, as an objective and producer independent handbook for rational use of drugs for prescribers.

To promote the rational use of medicines at all levels, the government shall:

Provide and up-date the National Essential Medicine List to be used as a guide for procurement, prescribing and dispensing.

Encourage prescribing medicines in their generic (non-proprietary) names.

Update and regularly make available to the prescribers, pharmacists, public, and the pharmaceutical sector the list of marketed medicines.

Develop and revise standard treatment guidelines for primary care and hospital care.

Provide continuing education programs and refresher courses for health care professionals on rational use of medicines, matching standard treatment guidelines.

Develop, implement and monitor adherence to national Standard Treatment Guidelines and Formularies.

Create public awareness on the rational use of medicinal medicines using mass media and other means of communication in local language.

Strengthen prescription monitoring system to improve prescribing habits.

Ensure correct dispensing, labeling and patient counseling procedures.

Ensure disposal of expired and banned medicines environment friendly in accordance with regulations.

18. *Drug and Medicine Information*

Mechanisms shall be developed to provide current and objective information on medicines for health care professionals and prescribers to promote rational use of medicines.

A medicine and poison information unit shall be established at central level for health professionals and consumers

All medicines approved for importation, sale and use in Timor Leste, must include written information about dosage and risks, written in the language of Tetun, Portuguese, Bahasa or English.

Information dissemination mechanisms shall be developed.

Reliable and producer-independent information about all medicines registered in Timor Leste, shall be made widely available to all prescribers and all pharmacists.

This information shall include information about documented risks, including risk for adverse reactions and side effects, risks

associated with use of drugs during pregnancy and breast feeding, and risks associated with pathological conditions such as allergy, or risks due to reduced kidney or liver function of the patients.

Objective information about the correct use and correct dosage shall be available to all prescribers.

A clear system shall be set-up, with database recording import license for all medicines which have been given approval and which have been imported. The database shall include information about each imported batch registration. This shall allow the National Drug Administration to launch recalls in the event that information is made available about substandard quality or any aspect of defective medicine products.

Health care professionals and, the public shall be informed about risks and safety problems that are observed on marketed medicines. Awareness shall be raised especially about the risk of self-medication, specifically targeting unsafe self-medication and irrational sale of antibiotics, aiming to reduce risks for adverse effects as well as to reduce the risks for further spread of antibiotic resistance in Timor Leste.

A procedure for product recall, shall be in place for all marketed products

19. *Human Resources Development*

For effective implementation of various elements of the National Medicine Policy:

Training of technical, administrative and health care personnel who are required for organizing and operating at different levels of implementing the National Medicine Policy shall be facilitated.

Pharmacists and other professionals needed for inspection, enforcement, and regulatory activities shall be trained.

Pharmacy education shall be up-graded to a diploma level.

Funds and loans shall be allocated for pharmacy education

Regulatory incentives shall be provided to encourage more locals to enter into the pharmacy profession.

More students shall be sent for training abroad in the field of pharmacy, to meet the country's need for pharmacists in the areas of hospital pharmacy, regulatory activities, as well as medicine supply and management.

Pharmaceutical and health care professionals shall be provided regular education and training on Essential Medicines concept, Rational Medicine Use and Management of Supplies.

The National Drug Administration shall establish a collaboration network with pharmaceutical and medical advisers, to assist in setting up and delivering / providing postgraduate and Continuous education for medical and pharmaceutical professionals, promoting rational and safe use of drugs.

20. Calculation of drug quantity needs

The National Drug Administration shall provide estimates of needed drug requirements, based on case-mix and case-load, and based on standard treatment guidelines for major diseases, to be used to calculate adequate annual financial resources to procure and supply availability of essential medicines throughout the country by the public health services.

The National Health Information system shall provide monthly updates to the National Drug Administration, about the case-load and case mix and bed days, for main diseases treated in hospitals and primary care throughout the country.

Reliable drug quantity estimates shall be provided as base to calculate adequate financial resources to procure medicines.

Special funding provisions shall be made for the low-income and especially vulnerable groups of the population who are unable to pay for their treatment.

Special funding provisions must also be made for providing treatment priority diseases and conditions, including Tuberculosis, Malaria, Antenatal care and as defined in amendment to the National Drug Law by annual decree by Ministry of Health. These diseases and conditions shall be decided at national level based on prevalence, mortality and chronic nature.

21. *Production of medicines*

For domestic production of medicines, standards, technology and personnel required for pharmaceutical production shall confirm to international standards of Good Manufacturing Practice (GMP). ASEAN level GMP is the first required level tier in the quality requirements for medicine GMP.

For non-pharmaceutical “traditional medicines” local standards and best practices shall be developed. ASEAN level GMP is the first tier, in the quality requirements in all production.

22. *Research*

Human rights of the patients shall always be safeguarded and protected, following WHO – WMA Guidelines and the Helsinki declaration of human rights of the patient.

Research shall be carried out to find practical solutions and solve operational problems such as medicine selection, procurement and distribution. The aim is to enable to achieve the goals and objectives of the National Drug Policy. It will focus particularly on the following areas:

Health systems research to measure the impact of the National Medicines Policy.

Point prevalence prescribing studied, in hospitals and primary care to assess adherence to Essential medicines and standard treatment guidelines at different levels of the health systems.

Medicine stock-out survey and supply utilisation.
Practice survey, on record keeping, record writing, prescribing records and safe dispensing procedures
Social and cultural aspects of medicines use.

Self medication, and attitudes of medicine consumers.
Antibiotic use and assessment of the spread of antibiotic resistance and planning and assessment of impact of interventions to limit and contain antibiotic resistance

Assessment of adverse drug reactions and side effects, aiming to identify how to limit the extent of drug-related harm and iatrogenicity

Surveys shall be conducted to ensure that no research is conducted without compliance to international standards, for human rights of the patient, as defined in the Helsinki declaration and in the WHA Ethical guidelines for clinical research (No clinical research is allowed, without appropriate approval of research ethical committee in Timor Leste and in the country of origin of the donor, in line with provisions of the WMA and Helsinki declaration)

23. Control of Traditional Medicine

For all Traditional medicine, the Government shall:

Develop clear regulations within the frame of an updated Drug Law.

Standardization and quality control requirements shall be enforced for all components, products and raw materials.

Any traditional medicines sold, with claimed therapeutic, diagnostic or preventive effect, is breaking the rules, since it then in fact meets the definitions of a Medicine or Pharmaceutical product.

It can therefore only be allowed if it is evaluated and given a full registration approval as Medicine / Pharmaceutical product.

As an example; Consequently, herbals claiming effect against Malaria can not be allowed as traditional medicine. Such products, claiming a therapeutic effect defines the product as a medicine.

As stated, all medicines must undergo a full registration assessment before they can be issued or rejected approval. Only medicines which get registration approval can be allowed to be imported and to be allowed to be prescribed, used and sold in Timor Leste.

A key requirement is, that a pharmaceutical product (medicine, drug) can only be approved for registration, if there is full documentation available, proving both clinical efficacy and documenting clinical safety/risk profile.

Any traditional medicine sold with claimed preventive, diagnostic or curative effect, and any pharmaceutical product lacking such documentation, is forbidden. The reason for this, is

to match international praxis, in protecting patients and protecting the people from unjustified dangers, risks and harm.

Only traditional medicines with PROVEN safety and harmless ability can be allowed in Timor Leste, in line with international standard procedures and international praxis.

Develop a system to provide marketing authorization for traditional medicine prescribers and launch of an audit system to monitor their practices.

Protect the community from danger and consequences of using unknown ingredient products or which are fraudulent or do not meet required quality and standards.

24. Monitoring and Evaluation

The Ministry of Health in close collaboration with relevant national bodies will form a committee and set indicators for monitoring and evaluating the implementation of the National Medicine Policy and achievement of its objectives.

The implementation status of the national medicine policy shall be reviewed every five years.

Problems and constraints encountered in the process of implementation shall be discussed and appropriate solutions shall be sought.

25. Regional / International Collaboration

Coordination mechanisms for collaboration between Ministries and the Pharmaceutical sector shall be strengthened.

Links with Medicine Regulatory Authorities of countries within and outside the region shall be strengthened, with

priority given to collaboration and exchange of information within ASEAN.

All opportunities to transfer technology, to build national capacity shall be explored
International assistance shall be sought to train more Pharmacists abroad and up-grade the pharmacy curricula at Timor Leste College of Higher Education, Faculty of Health Sciences.

Collaborate in the implementation of international conventions on narcotics and psychotropic substances, which the country is signatory to.

The Ministry of Health will co-ordinate with Ministry of Trade and Development and other government sectors, to ensure that public health interests are taken into account in negotiations and implementation of international and regional trade agreements by Timor Leste. The government recognizes the potential impact of TRIPS and other international trade agreements on access to medicines and will exercise maximum rights including enacting relevant legislation to offset any adverse impact

26. Policy Implementation, Enforcement

Following approval of the proposed policy by the Government, relevant laws, rules and regulations shall be instituted to enforce this policy. An operational plan (Strategy) for implementing the National Drug Policy shall be developed.

Definitions

Medicine; A "medicine" is defined as any substance which is used with intent to prevent, diagnose, cure or modify or explore the physiological state or conditions in a human or animal.

Synonymous terms used includes "pharmaceutical" or "pharmaceutical product", or the term "drug" for human or veterinary use. The definition is based on intended use: Intention to use with the aim to prevent, diagnose or treat conditions or disease, modify or explore physiological systems or pathological states.

(Note that this definition is broad and includes blood products, vaccines, diagnostic materials, essential consumables and devices)

National Drug Administration synonyme: National Drug-or Medicines Regulatory Authority

A national body that administers the full spectrum of medicine regulatory activities, including at least all of the following functions:

Registration, marketing authorisation of new products and variation of existing products;
Revision and development of standard treatment guidelines

Development and implementation of practice guidelines and standards for drug management and drug-use in all sectors of healthcare, public and private.

Quality assurance and Quality Control. Collaboration with international licensed QC Laboratory for quality control laboratory testing of samples of medicines taken from the market (taken at point of import or from retail or healthcare facility pharmacy).

Drug information to healthcare providers and adverse medicine events monitoring.

Provision of medicine information and promotion of rational medicine use;

Setting standards for Good Distribution Practice, Good Manufacturing Practice (GMP), Good Pharmacy Practice and standards for Inspections and Licensing of prescribers, licensing of pharmacists, Licensing of manufacturers, wholesalers, pharmacies.

Monitoring of medicine utilisation.

Essential Medicines

"Essential Medicines" are medicines with available documentation about efficacy and safety/risk profile, which are needed based on evidence based medicine for health care of the disease occurring in the population

Registered Approved Medicines

These are Pharmaceutical products (medicines) which have been granted formal Registration approval and marketing authorization, for a specified medical purpose, e.g for defined indication(s).

Marketing Authorization

An official document issued by the national medicine regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.

It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Non-proprietary Names or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics.

It specifies the information on which authorization is based. It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

Once a product has been given marketing authorization, it is included on a list of authorized products - the register - and is often said to be registered or to have registration. Marketing authorization may occasionally also be referred to as product license.