ESTADO PLURINACIONAL DE BOLIVIA
MINISTERIO DE SALUD Y DEPORTES

MEDICINE REGULATION AND REGISTRATION POLICY FOR PHARMACEUTICAL PRODUCTS IN BOLIVIA

AGEMED
AGENCIA ESTATAL DE MEDICAMENTOS Y TECNOLOGÍAS EN SALUD

Dr. Yuri Werner Quisbert Aruquipa **EXECUTIVE GENERAL DIRECTOR AGEMED**

ESTADO PLURINACIONAL DE BOLIVIA
MINISTERIO DE SALUD Y DEPORTES

AGEMED

AGEMED AT THE SERVICE OF SOCIETY

HEALTH TECHNOLOGIES AND RATIONAL USE

CONCAMYT

FARMACOVIGILANCIA
TECNOVIGILANCIA
ESTUDIOS CLINICOS

CONTROL FISICOQUIMICO
CONTROL MICROBIOLOGICO
DISEÑO Y DESARROLLO
ASEGURAMIENTO DE CALIDAD

BPM/ BPA AUDITS
MARKET SURVEILLANCE
CUSTOMS CLEARANCES
CONTROL OF OPERATING LICENSE

MEDICAMENTOS
DISPOSITIVOS MEDICOS
COSMETICOS
PRODUCTOS NATURALES, ANCESTRALES Y TRADICIONALES

ESTADO PLURINACIONAL DE BOLIVIA
MINISTERIO DE SALUD Y DEPORTES

AGEMED

The State Agency for Medicines and Health Technologies AGEMED, created to exercise the regulatory role of the State

Responsible for regulating the activities carried out by natural and legal persons, private, community, public, mixed and cooperatives

AGEMED
AGENCIA ESTATAL DE MEDICAMENTOS
Y TECNOLOGÍAS EN SALUD

It monitors, controls and audits the production, manufacture, import, export, storage, distribution, transportation, marketing, promotion, advertising, prescription, dispensing and prices of medicines and other health technologies, to meet the health needs of the population

EXPORT TO BOLIVIA

PUBLIC ROAD

CEASS
HEALTH SUPPLY
AND CENTRAL
SUPPLY

PRIVATE ROAD

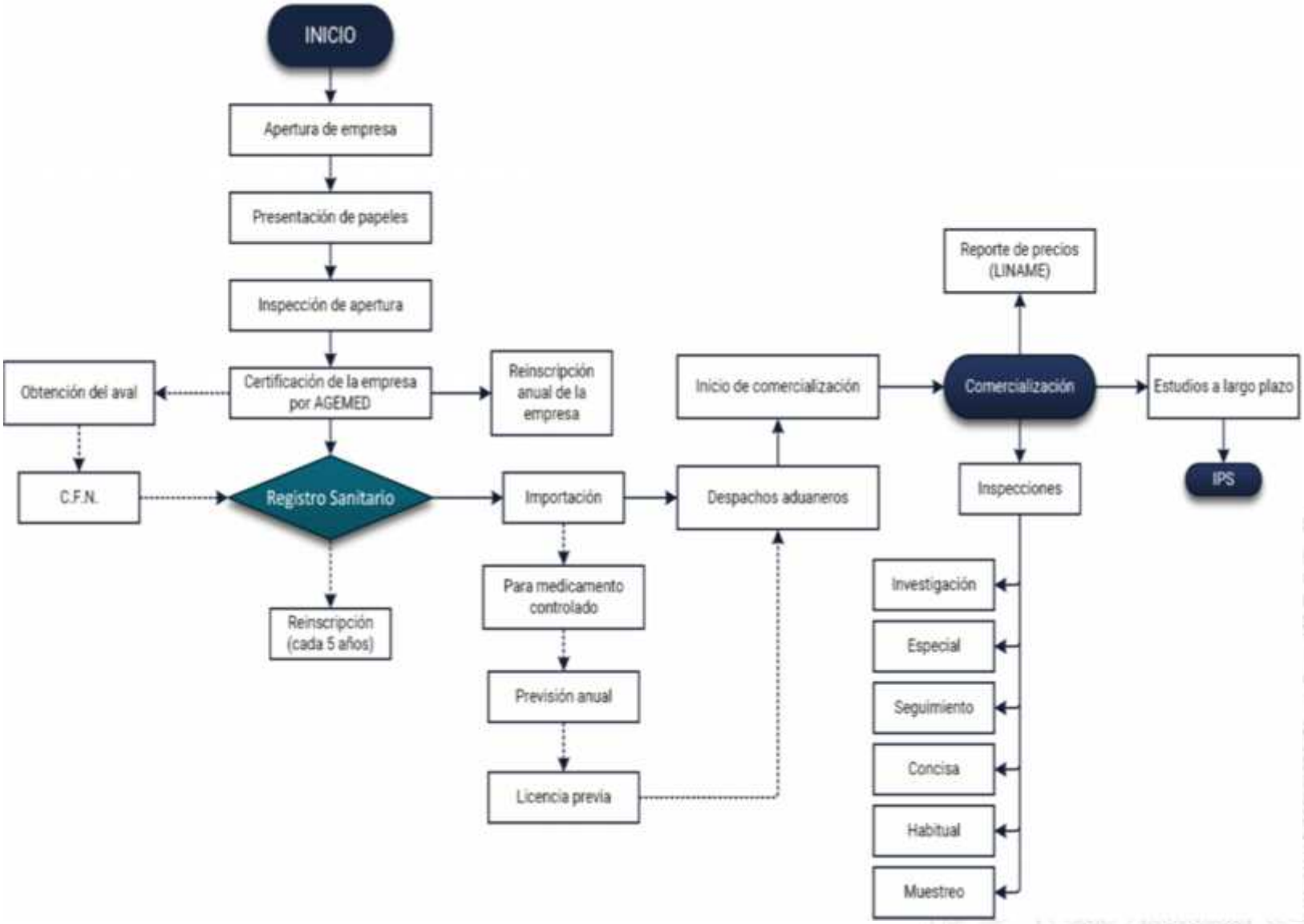
PRIVATE
IMPORTING
COMPANIE

EXPORT TO BOLIVIA

ESTADO PLURINACIONAL DE BOLIVIA
MINISTERIO DE SALUD Y DEPORTES

AGEMED

FLOW CHART FROM OPENING A COMPANY UNTIL ITS COMMERCIALIZATION



REQUIREMENTS FOR THE OPENING OF IMPORTERS

REQUIREMENTS FOR OPENING A DRUG IMPORTER RECOGNIZED BY LAW AT THE NATIONAL LEVEL

Request letter addressed to the Executive Director of AGEMED

COMPANY DOCUMENTS

1. AGEMED Form 003 (Registration of Laboratories and Importers) duly filled out by machine: 1- Names of the legal representative and the pharmaceutical regent must be registered as it appears on the identity card. 2. Write the activity as it is registered in the FUNDEMPRESA Certificate.
2. Electronic certification of the NIT (Tax Identification Number)
3. Plurinational Trade Registry Service -SEPREC
4. Legalized photocopy of the operating license
5. Legalized photocopy of the Company Constitution (if applicable)
6. Legalized photocopy of the power of Legal Representation (if applicable)
7. Photocopy of Identity Card of the Legal Representative
8. Photocopy of the AGEMED Invoice of the payment for the Registration Fee.

DOCUMENTS OF THE PHARMACEUTICAL REGENT

1. Legalized photocopy of the Title in National Provision
2. Time Compatibility Certificate issued by SEDES
3. Work contract endorsed by the Ministry of Labor
4. Photocopy of professional registration
5. Photocopy of membership card
6. Photocopy of identity card

FULL TIME

PAYMENT FOR REGISTRATION RIGHT Bs12,410.-. COLLECT THE PAYMENT ORDER FROM THE AGEMED WINDOW, THE DEPOSIT WILL BE MADE RECENTLY, WHEN THE FILE HAS THE APPROVAL OF THE RESPONSIBLE PERSONNEL.

THE APPLICANT MUST SUBMIT THE DOCUMENTATION IN A YELLOW RAPID FILE. FILED ACCORDING TO THE ORDER ESTABLISHED IN THE REQUIREMENT

ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

NATIONAL PHARMACOLOGY COMMISSION

Any medicine to proceed with the Sanitary Registry must previously have the pharmacological evaluation by the National Pharmacology Commission

ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

WHO ENTERS EVALUATION

1. New Molecules (new chemical entity) active ingredient not previously registered in the country.
2. New indications.
3. New associations.
4. Products that by recent clinical studies have alerts.

The request is made through the attached MISA platform:

1. **Payment service.**
2. **pharmacological monograph**
3. **Form 007**
4. **Form 019**

ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

PHARMACOLOGICAL MONOGRAPH

I. FIRST PART: GENERAL INFORMATION.-

1. Commercial name (when it exists)
2. International Nonproprietary Name (Generic Name)
3. Manufacturing laboratory
4. Pharmaceutical form
5. Concentration
6. Chemical structure
7. Routes of administration
8. Therapeutic action
9. Mechanism of action
10. Dosage and dosage
11. Indications
12. Contraindications
13. Precautions
14. Side effects
15. Drug interactions
16. Method of preparation, when applicable

PHARMACOLOGICAL MONOGRAPH

II. SECOND PART: PRECLINICAL INFORMATION.-

It will be presented, according to appropriate, the general information of the tests carried out, including the Next:

1. **Experimental Pharmacology**
   a) Pharmacodynamics
   b) Pharmacokinetics
      - ✓ Absorption
      - ✓ Distribution
      - ✓ Biotransformation
      - ✓ Excretion and metabolites

2. Toxicology

a) Single dose toxicity
b) Repeated dose toxicity
c) Subacute toxicity
d) Subchronic toxicity
e) Chronic toxicity
f) Carcinogenicity
g) Study of the reproductive function
   - ✓ Teratogenicity studies
   - ✓ Fertility studies and general reproductive capacity
   - ✓ Perinatal and postnatal studies
   - ✓ Excretion across the placental barrier
   - ✓ Excretion through breast milk (lactation)

PHARMACOLOGICAL MONOGRAPH

3. **Other Studies:** As appropriate, other studies will be presented such as; studies of the mutagenic potential, tumorigenicity tests, tests of carcinogenic potential, microbiological information.

III. THIRD PART: CLINICAL INFORMATION.- The general information will be presented of the tests carried out, including the following:

1. **Human Pharmacology**
   - a) Pharmacodynamics
   - b) Pharmacokinetics
     - ✓ Absorption
     - ✓ Distribution
     - ✓ Elimination
     - ✓ Metabolism
     - ✓ Availability
   - c) Interactions
2. **Clinical Studies**: Published clinical studies will be presented and not published completed and in process including any security data, considering the aspects indicated in the Evaluation Form of Efficacy and Security Form. 019. This will present, among others, studies that demonstrate efficacy, non-comparative, comparison against placebo, comparison with other drugs, studies in special populations, etc. It should be noted that clinical studies may be presented in the language English, not being necessary in this case the translation.

PHARMACOLOGICAL MONOGRAPH

3. Pharmacovigilance: During the marketing of the drug, the representative will inform the Directorate of Medicines and Technology in Health on detection, both in the country and in other countries where markets the product, of adverse effects associated with the drug and that may imply restrictions on its use. Likewise when you take carried out post-marketing studies in the country or in others, it must be presented, among others, information about them indicating the number of patients exposed, evaluation of adverse reactions and their notifications.

IV. FOURTH PART: LABEL AND PACKAGE LEAFLET.-

The model of the label and prospectus of the product will be attached, being accepted only for the case of products of national manufacture projects of the same.

V. FIFTH PART: SUPPLEMENTARY INFORMATION.-

Any information that the interested party considers important should be added to this part, indicating the corresponding references.

VI. PART SIX: BIBLIOGRAPHICAL REFERENCE.-

Attach a photocopy of the reference, which must come from a publication internationally recognized.

ESTADO PLURINACIONAL DE BOLIVIA

Estado Plurinacional de Bolivia
Ministerio de Salud

ACEMED

AGEMED

FORM. 007

QUALIFICATION REQUEST

Dr(a) _____ With Registration r* N Pharmaceutical Regent of _____ requests the National Pharmacological Commission a qualification of the product of: Registration ☐ Re-registration ☐ Reconsideration ☐ OTC ☐

Trade Name...

Name G Generic ((D.C.I.)

Productive Laboratory:

Pharmaceutical Form: Concentration:

Qualitative - Quantitative Formula:

Administration route :

Therapeutic action:...

Dose:

Prompt:...

Contra indicated clones:

Precautions:

Side effects/interactions

EXCLUSIVE USE OF THE NATIONAL PHARMACOLOGICAL COMMISSION.

Minutes of communication:

Comment...

The National Pharmacological Commission requests more information .....

Therefore, the aforementioned product is ... being able to proceed with the corresponding registration and re-registration process.

peace,

President
Adelaide Farmational Macologice

ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

HEALTH REGISTER

Table of requirements for the registration of a drug

ITEM	REQUIREMENTS
2.1	FORM
	Application Form for Registration and Quality Control of Medications (DINAMED Form. 005)
2.2.	LEGAL DOCUMENTATION - ADMINISTRATIVE OF THE COMPANIES
2.2.1.	Photocopy of Ministerial or Secretarial Resolution
2.2.2.	Photocopy of Current Company Certificate
2.2.3.	General License and Manufacturer Information
2.2.4.	Format for Clarification of Particularities
2.3.	GENERAL PRODUCT DOCUMENTATION
2.3.1.	Certification of the Technical Director-Pharmacist Regent
2.3.2.	Certificate of Good Manufacturing Practices (GMP)
2.3.3.	Contract Manufacturing or Quality Control by Third Parties
2.3.4.	Certificate of Pharmaceutical Product Subject to Consularized International Trade
2.3.5.	Photocopy of Previous Sanitary Registration
2.3.6.	Legal representation
2.3.7.	Photocopy of Customs Clearance Certificate, only for cases of (psychotropic or narcotic drugs)

ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

HEALTH REGISTER

2.4.	**TECHNICAL INFORMATION OF THE ACTIVE PRINCIPLE**
2.4.1.	Photocopy of Certificate of Analysis of Raw Material
2.4.2.	Generic Name (D.C.I.) and Anatomical Therapeutic Classification (A.T.Q.)
2.4.3.	Chemical Name, Structural Formula, Molecular Formula and Molecular Weight
2.4.4.	Physical and Chemical Characteristics of the Active Ingredient
2.4.5.	Organoleptic characteristics
2.4.6.	Routes of Synthesis or Obtaining Biological Products
2.4.7.	Impurities and Degradation Products
2.4.8.	Stability of Active Ingredients
2.4.9.	Analytical methodology
2.4.10.	Analytical Method Validation
2.5.	**TECHNICAL INFORMATION OF THE FINISHED PRODUCT**
2.5.1.	Galenic Product Development
2.5.2.	Qualitative-Quantitative Formula
2.5.3.	Photocopy of the Certificate of Analysis of the Finished Product
2.5.4.	Photocopy of the Quality Control Certificate issued by the Medicines and Toxicology Quality Control Laboratory (CONCAMYT)
2.5.5.	Physicochemical Characteristics of the Excipients
2.5.6.	Manufacturing Methods (a summary or flowchart)

ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

HEALTH REGISTER

2.5.7.	Analytical methodology
2.5.8.	Analytical Method Validation
2.5.9.	Primary or Secondary Reference Pattern(s)
2.5.10.	Finished Product Release
2.5.11.	Stability studies
2.5.12.	Storage conditions
2.5.13.	Characteristics of the Packaging Material
2.5.14.	Batch Coding
2.6.	**BIOPHARMACEUTIC TECHNICAL DOCUMENTATION**
2.6.1.	Bioavailability studies *
2.6.2.	Bioequivalence studies *
2.7.	**LABELS AND TAGS, INSERTS OR LEAFLETS**
2.7.1.	Labels, Labels and Cases
2.7.2.	Inserts or Prospects
2.8.	**PHARMACOLOGICAL EVALUATION**
2.8.1.	Request Form Qualification DINAMED form. 007
2.8.2.	Efficacy and Safety Rating Form DINAMED form. 019
2.8.3.	Summary of Pharmacological Monograph
2.9.	**SAMPLE X**
2.10.	PAYMENT FOR SERVICE CONCEPT X

Estado Plurinacional de Bolivia
Ministerio de Salud

AGEMED

FORM. 005

APPLICATION FOR REGISTRATION AND CONTROL QUALITY OF MEDICINES

I. General Information

Type of procedure: Registration: ☐ Re-registration: ☐ Change of: ☐ Other: ☐

Origin: Import: ☐ National: ☐

Product type: Medicine: ☐ Cosmetic: ☐ Homeopathic: ☐ Miscellaneous: ☐ Natural: ☐ Vaccine: ☐

II. Data of the Applicant Company

Company Name:...

R.S.N *:... Date:

Name of the Holder:

Address:... Phone...

Accredited Pharmacist:... N°Mat.

III. Laboratory Data Manufacturer

Laboratory manufacturer :

Under license from:

For:

Country of Origin:...

Address:

IV. Product Data

Trade name...

Generic name:

Pharmaceutical Form:

Concentration (p.A.)

Administration route:

Therapeutic action;... Type of sale:

Conservation:... Period of validity:

Specification of the container:

Clinical packaging:

Endorsement of the C.F.N.:

Health Registration No.:

N° of Quality Control Certification (CONCAMYT - INLASA):

ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

CUSTOMS CLEARANCE

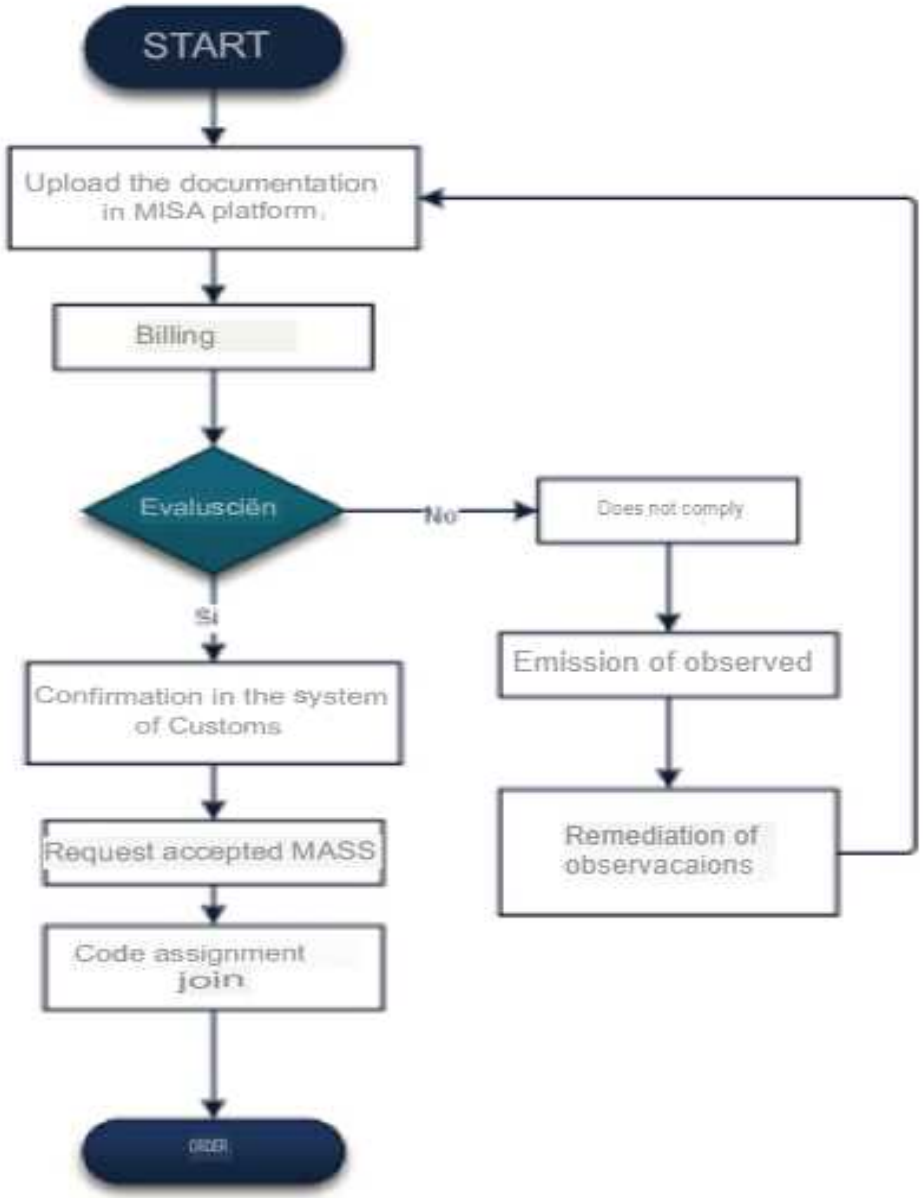
In compliance with article 84 of the General Customs Law and in application of the CODEX alimen- tariff established by the World Trade Organization, for the purposes of customs clearance, certificates shall be limited to the following goods:

* Pharmaceutical products and medicines regulated by the specific Law, require certificate of national registration and authorization for customs clearance, granted by the Ministry of Health and Sports in accordance with the Drug Law No. 1737. The certificates (Form. UNIMED-011, signed, stamped and numbered) noted above will be- they will be presented by the importer through the Customs broker as an indispensable requirement- sable for the customs clearance procedure.

The lack of presentation of the aforementioned certificates will prevent the adua clearance- nero and the customs administration, in coordination with the competent body, will arrange the destination or destruction of the goods.

Consider:

- Current legal representation
- Current health record or in re-registration procedure
- Have the Previous License



ESTADO PLURINACIONAL DE BOLIVIA MINISTERIO DE SALUD Y DEPORTES

AGEMED

OFFICE ADDRESS

Captain Ravelo N°2199 in front of Mario Mercado square 1st floor
Tel. (591) (2) 2444432-2440807;
Fax (591) (2) 2440122; PI: 2014 – 2020.

City of La Paz, Plurinational State of Bolivia

WEB PAGE:

www.agemed.gob.bo

ESTADO PLURINACIONAL DE BOLIVIA
MINISTERIO DE SALUD Y DEPORTES

AGEMED

THANKS FOR YOUR ATTENTION