STATE OF KUWAIT
MINISTRY OF HEALTH

Medicines & Medical Products Registration &
Regulatory Administration

MINISTERIAL DECREE FOR REGISTRATION OF HERBAL MEDICINES AND HERBAL PRODUCTS

ملحق القرار الوزاري رقم (389) لسنة 2025 بشأن تسجيل وتداول الأدوية النباتية والمستحضرات العشبية

M.D. (389 / 2025)

Version 1.0

December 2025

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TABLE OF CONTENTS

Abbreviations *4*

Glossary of Terms *6*

Introduction *9*

1. Section I: Local agent, Marketing Authorization Holder (MAH) and Manufacturing Company Registration Requirements *10*

1.1 Authorized Representative Requirements **10**

1.2 Marketing Authorization Holder (MAH) registration requirements **10**

1 Legalized letter of appointment from the MAH stating that the local agent or the scientific office is the authorized representative in the State of Kuwait. 10

2 Original legalized manufacturing license from the country of origin for each manufacturing site issued by the health authority or the concerned authorized authority in the country of origin. 10

3 Original legalized Good Manufacturing Practice (GMP) certificate \ relavent International Organization for Standardization such as (ISO) 22716 or 2200 from the country of origin. . 10

4 Site master file (for herbal products only) which contain the following: 10

1.3 Manufacturing site registration requirements (If the manufacturer is different than the MAH) **11**

1. A letter issued from the MAH explaining the relationship between the MAH and the manufacturer. 11

2. GMP certificate of the manufacturer / ISO. 11

3. Manufacturing license of the manufacturer. 11

1.4 Document Legalization and Certification **11**

1. Legalization of Certificates issued by Health Authorities such as the CPP, GMP Certificate, Manufacturing License, and any other certificates issued by the Health Authority in the country of origin must be Original, legalized by the Embassy or Consulate of the State of Kuwait in the country of origin. 11

2. In cases where this is not possible, legalization may be done by an authorized GCC Embassy or Consulate in the country of origin. 12

3. Other Official Documents such as the Letter of Appointment, Pricing Certificate, and similar administrative documents must be legalized by the Embassy or Consulate of the State of Kuwait in the country of origin (or an authorized GCC Embassy/Consulate if not available), and The Chamber of Commerce in the country of origin. 12

1.5 Electronic Certificates and Verification 12

1. Valid Electronic certifictaes are acceptable provided that an approved verification tool is available for the authentication and verification of the electroic certificates. 12

2. For Electronic certificates legalisation is not required. 12

3. Eletronic legalization is acceptable provide that an approved verification tool is available for the authenticity of legalisation. 12

2. Section II: Herbal Products 13

2.1 Scope of a herbal product 13

2.2 Classification of herbal products 14

2.2.1 Herbal Medicine (HM) 15

2.2.2 Traditional Herbal Medicine (THM) 15

2.2.3 Herbal Natural Supplements 16

2.3. Requirements for the registration of a herbal product 16

2.3.1 Administrative registration requirements 16

2.3.2 Technical quality registration requirements 18

2.3.3 Technical safety and efficacy registration requirements 22

2.4 Requirements for the renewal of a registered herbal product 25

Section III: Herbal Teas 26

3.1 Definition of a herbal tea 26

3.2 Requirements for the registration of a herbal tea 26

3.2.1 Regional administrative registration requirements for a herbal tea 26

3.2.2 Technical quality registration requirements for a herbal tea 27

3.2.3 Technical safety and efficacy registration requirements for a herbal tea 28

3.3 Requirements for the renewal of a registered herbal tea 28

Section IV: Variation, Transfer of Agency and Cancellation of a 30

Herbal Product/ Herbal Tea 30

4.1 Variation requirements for a registered herbal product/ herbal tea 30

4.2 Transfer of Agency 30

4.3 Herbal product/ herbal tea suspension 31

4.4 Herbal product/ herbal tea cancellation 32

LIST OF ANNEXES 33

Annex I: Lists of banned and restricted herbs 33

Table 1: List of banned herbs in herbal products/ herbal teas 34

Table 2: Restricted herbal ingredients in herbal products/ herbal teas..... 37

References 43

ABBREVIATIONS

BP	British Pharmacopeia
BSE	Bovine Spongiform Encephalopathy
CIF	Cost Insurance and Freight
CPP	Certificate of Pharmaceutical Product
EMA	European Medicines Agency
FSC	Free Sale Certificate
GCC	Gulf Cooperation Council
GMP	Good Manufacturing Practice
HM	Herbal medicine
HNS	Herbal natural supplement
M.D.	Ministerial Decree
MAH	Marketing Authorization Holder

MHRA	Medicines and Healthcare products Regulatory Agency
PIL	Patient Information Leaflet
RH	Relative Humidity
TCM	Traditional Chinese Medicine
THM	Traditional Herbal Medicine
TSE	Transmissible Spongiform Encephalopathy
USFDA	United States Food and Drug Administration
USP	Unites States Pharmacopeia
COA	Certificate of Analysis
WHO	World Health Organization

GLOSSARY OF TERMS

Adverse effect: any unfavorable and unintended sign in a patient or clinical investigation of a subject administered including a symptom or disease associated with the use of a product with a therapeutic affect and which does not necessarily have a causal relationship with this treatment.

Authorized representative: also referred to as the Local Agent or scientific office or local approved affiliates, is a legal entity established in the State of Kuwait, officially appointed by the Marketing Authorization Holder (MAH) to act on their behalf before the Medicine and Medical Products Registration and Regulatory Administration in all matters related to the registration, importation, pricing, post-marketing surveillance, and communication of medicinal products

Ayurvedic medicine: is a traditional practice based on ancient writings that rely on a "natural" and holistic approach to physical and mental health. Ayurvedic medicine is one of the world's oldest medical systems and remains one of India's traditional healthcare systems. Ayurvedic treatment combines products mainly derived from plants but may also include animal or mineral components.

Certificate of Pharmaceutical Product (CPP): is an internationally recognized certificate by drug regulatory authorities for establishing the status of a pharmaceutical product registration elsewhere. This document provides evidence that the medicinal product was produced under a comprehensive system of quality assurance, conforming to Good Manufacturing Practice (GMP) standards as mandated by the World Health Organization (WHO). It contains specific information such as the name of the product, the formulation, the manufacturer, packager, product license

holder, and whether the product is marketed in the country where the CPP was issued.

Clinical trial: any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product, and/or to identify any adverse reactions to an investigational product, and/or to study the absorption, distribution, metabolism and excretion of an investigational product, with the objective of ascertaining its safety and/or efficacy.

Compatibility study: Herbal product compatibility refers to the documented evaluation of interactions between a herbal medicinal product and its reconstitution diluent(s), container-closure system, or dosage/administration device(s) to ensure that such interactions do not adversely affect the product's quality, safety, stability, or performance throughout its shelf life and in-use period

Country of origin: The country where the product is manufactured or the country of the product marketing authorization holder (MAH) .

Finished product: a medicinal product, which has undergone all stages of production, including packaging in its final container.

Free Sale Certificate (FSC): is a certificate that indicates a particular product is marketed in the country of origin or is eligible for export. It contains specific information such as the name of the product, the formulation, the manufacturer, packager, and whether the product is marketed in the country where the FSC was issued.

Good Manufacturing Practice (GMP) certificate: this certificate states that the manufacturer is periodically inspected by the relevant authorized health authority and that it follows strict current Good Manufacturing

Practice (cGMP**)** guidelines to ensure the production of products with the desired quality standard.

Marketing Authorization Holder (MAH): the pharmaceutical company that legally holds the right and responsibility of marketing the product in Kuwait.

Patient information leaflet (PIL): the leaflet is the product's information provided in the pack. It should be drawn up in accordance with the summary of the product characteristics.

Specification: is a list of tests, references to analytical procedures, appropriate acceptance criteria and reference of each tested parameter (e.g. United States Pharmacopeia, British Pharmacopeia, in-house... etc.).

Stability study: is a study that contains information on storage conditions, batch number, batch size, container closure system and completed (and proposed) test intervals, results and conclusions with respect to storage conditions and retest date or shelf-life, as appropriate.

Summary of product characteristics: the definitive description of the product.

Traditional Chinese medicine (TCM): is a combination of practices and remedies that were originated in ancient China, and has evolved over thousands of years. TCM practitioners uses herbal preparations and various mind and body practices, such as acupuncture and tai chai, to treat or prevent health problems.

INTRODUCTION

In compliance with to the Pharmacy Law of the State of Kuwait, pharmaceutical products, including herbal products and herbal teas, may not be marketed locally unless they are registered with the **Medicines and Medical Products Registration and Regulatory Administration**.

This Ministerial Decree (M.D.) is issued to clarify the regulatory framework and requirements established by the Medicines and Medical Products Registration and Regulatory Administration. All herbal products and herbal teas must be represented by a **locally registered entity**, referred to as the **Authorized Representative**. The Authorized Representative shall be responsible for submitting all documentation required under this Ministerial Decree in order to complete the registration of the herbal product or herbal tea, as well as the registration of its manufacturing company.

This Ministerial Decree is structured into four sections:

- **Section I** defines the registration requirements for Authorized Representatives, local agents, Marketing Authorization Holders (MAHs), and manufacturing companies.
- **Section II** sets out the definitions, classifications, and registration requirements applicable to herbal products.
- **Section III** defines herbal teas and outlines their registration requirements.
- **Section IV** establishes the requirements governing variations, transfer of agency, and cancellation of registered herbal products and herbal teas.

This Ministerial Decree shall be applied in a manner that is transparent, consistent, and effective.

Where necessary, the Administration may issue official memos specifying additional or product-specific requirements that must be fulfilled by the Authorized Representative or agent

1. SECTION I: LOCAL AGENT, MARKETING AUTHORIZATION HOLDER (MAH) AND MANUFACTURING COMPANY REGISTRATION REQUIREMENTS

1.1 Authorized Representative Requirements

1. Copy of valid license from the Ministry of Commerce in which the company activity includes the sale of medicines.

2. Copy of valid store license issued from the Pharmaceutical Inspection and licensing Administration.

3. Copy of valid agency license issued from Pharmaceutical Inspection and licensing Administration

4. Copy of authorized personal signatures.

1.2 MARKETING AUTHORIZATION HOLDER (MAH) REGISTRATION REQUIREMENTS

1 Legalized letter of appointment from the MAH stating that the local agent or the scientific office is the authorized representative in the State of Kuwait.

2 Original legalized manufacturing license from the country of origin for each manufacturing site issued by the health authority or the concerned authorized authority in the country of origin.

3 Original legalized Good Manufacturing Practice (GMP) certificate \ relavent International Organization for Standardization such as (ISO) 22716 or 2200 from the country of origin.

4 Site master file (for herbal products only) which contain the following:

a) General information and history of the company.
b) Capital and turnover for the past three years

c) Layout and diagrams of manufacturing sites.
d) Quality control unit and quality management.
e) Personnel information including number of employees in each department and their qualification.
f) Premises and equipment, including manufacturing sites owned by the company, manufacturing lines, and manufacturing machines.
g) List of products manufactured by the company and exporting countries.
h) Distribution problems, complaints, product defects and recalls from any authorities worldwide.
i) Contract manufacturing information.
j) Pharmacovigilance Master File.
k) Recognized global approvals for the company such as the United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Authority (MHRA) or a drug regulatory authority in one of the Gulf Cooperation Council (GCC) countries.

1.3 MANUFACTURING SITE REGISTRATION REQUIREMENTS (IF THE MANUFACTURER IS DIFFERENT THAN THE MAH)

1. A letter issued from the MAH explaining the relationship between the MAH and the manufacturer.

2. GMP certificate of the manufacturer / ISO.

3. Manufacturing license of the manufacturer.

1.4 DOCUMENT LEGALIZATION AND CERTIFICATION

1. **Legalization of Certificates issued by Health Authorities such as the CPP, GMP Certificate, Manufacturing License, and any other certificates issued by the Health Authority in the country of origin must be Original, legalized by the Embassy or Consulate of the State of Kuwait in the country of origin.**

2. **In cases where this is not possible, legalization may be done by an authorized GCC Embassy or Consulate in the country of origin.**

3. **Other Official Documents such as the Letter of Appointment, Pricing Certificate, and similar administrative documents must be legalized by the Embassy or Consulate of the State of Kuwait in the country of origin (or an authorized GCC Embassy/Consulate if not available), and The Chamber of Commerce in the country of origin.**

1.5 ELECTRONIC CERTIFICATES AND VERIFICATION

1. **Valid Electronic certifictaes are acceptable provided that an approved verification tool is available for the authentication and verification of the electroic certificates.**

2. **For Electronic certificates legalisation is not required.**

3. **Eletronic legalization is acceptable provide that an approved verification tool is available for the authenticity of legalisation.**

- **N.B** The Administration may request a GMP inspection visit for any manufacturing site.

2. SECTION II: HERBAL PRODUCTS

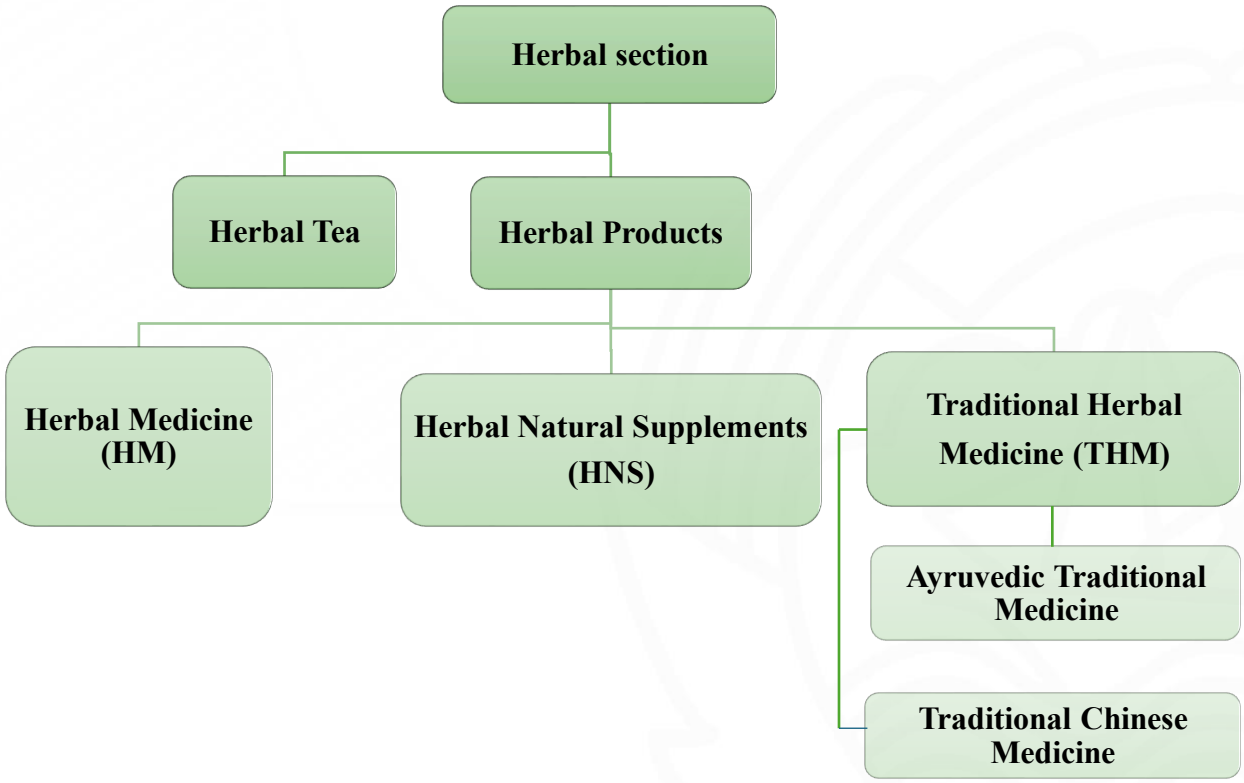
2.1 SCOPE OF A HERBAL PRODUCT

• Any medicinal product, exclusively containing active ingredients consisting of one or more herbal substances or herbal preparations, or such herbal substances in combination with such herbal preparations that are intended for prophylactic, therapeutic, or other human health benefits.

- Herbal substances consist of fragmented or cut plants, plant parts, algae, fungi, lichen in unprocessed, usually dried form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author). Herbal active substances that has been chemically altered, including synthetic compounds from herbal material, are not considered herbal.
- Herbal preparations are preparations that are obtained by subjecting herbal substances to treatments such as extractions, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juice and processed exudates.

2.2 CLASSIFICATION OF HERBAL PRODUCTS

- Herbal Medicines (HMS)
- Traditional Herbal Medicines (THMs)
- Herbal Natural Supplements (HNS)
- Herbal Tea with medical claims



2.2.1 Herbal Medicine (HM)

The classification of a herbal product as a HM suggests that the product is assessed as a herbal medicine with well-established use. This means that herbal products under this classification require their safety and efficacy to be demonstrated through data obtained from clinical trials.

1. A Herbal Medicine must be limited to 5 herbal active ingredients, in case more than 5 active herbs a compatibility study is needed.
2. A herbal product cannot be sterile or be administered by injection.
3. The presence of normal flora in the herbal product will prevent the product from being eligible for registration as a herbal product; e.g. Probiotics.
4. The presence of vitamins or minerals in the herbal product will not prevent the product from being eligible for registration under the Herbal category, provided that the action of vitamins or minerals is supplementary to that of the herbal active ingredients regarding the specified claimed indication.
5. Herbal products containing Honey presented in pharmaceutical dosage form is eligible for registration under the herbal section.
6. Raw medicinal herbs and extracts used in pharmaceutical manufacturing or scientific research does not require registration and is granted approval by the release department.

2.2.2 Traditional Herbal Medicine (THM)

Traditional medicine refers to the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures (e.g. Traditional Chinese Medicine, Ayurvedic Medicine, etc.). The traditional herbal registration is to provide a simplified registration option for herbal products.

Therefore, no clinical tests and trials on efficacy are required as long as sufficient safety and efficacy data are demonstrated based on evidence of long-standing use (i.e. a period of at least 30 consecutive years of traditional use. The dose and method of preparation must be the same as those traditionally used). THMS must only contain claims or therapeutic indications based on long-standing traditional use. Any indications or a claim added to the product that is not supported by long- standing traditional use evidence requires the product to be registered as a HM, requiring the submission of clinical studies for the presented indication.

2.2.3 Herbal Natural Supplements

This refers to a supplement of one or more herbs or a herbal preparation derived from herbal plants (or plant parts), presented in a dosage form such as capsules, tablets or liquids that is not intended to diagnose, treat, cure or prevent disease and it can be used to maintain normal overall health.

2.3. REQUIREMENTS FOR THE REGISTRATION OF A HERBAL PRODUCT

2.3.1 Administrative registration requirements

1. Covering letter: the applicant should include a covering letter for each submission with local agent letterhead, including the herbal product trade name, concentration, MAH, manufacturing company, and a complete list of documents submitted for registration.

2. Application form: should be submitted filled, signed and stamped by the applicant.

3. Original legalized free sale certificate (FSC) or Certificate of Pharmaceutical Product (CPP) issued from the regulatory authority at the country of origin for each herbal product showing that it is registered and marketed in the country of origin. The certificate should be legalized from

Kuwait Embassy The FSC/CPP should include the following:

a) The date and registration number of the product in the country of

origin.

b) The herbal product submitted for registration should be with the same composition and strength as the one registered in the country of origin.

4. Original legalized price certificate as per pricing decree regulation.

5. Product information:

- Include summary of product characteristics if available.
- Label.
- Patient information leaflet (PIL) in English or (English and Arabic).
- The leaflet must include the following details:

a) Composition
b) Indication
c) Dosage
d) Side effects
e) Warnings
f) Contraindications
g) Major drug-drug interactions should be mentioned in the leaflet.

6. Declaration of alcohol content: a declaration letter from the pharmaceutical company stating the alcohol content of the product. If the product does not contain any alcohol content, a letter from the pharmaceutical company stating that the product is free from alcohol.

- **N.B** The maximum alcohol concentrations should be aligned with the concerned M.D. for importing and handling ethyl alcohol and any material that is manufactured with it.

7. Pork- free declaration: A declaration letter from the pharmaceutical company stating that the product is free from any materials of pork/porcine source.

8. Artwork of the outer pack:

- Allergens and warnings should be mentioned on the outer pack
- Storage conditions
- Manufacturing date and expiry date
- Batch number
- Indication
- Trade name
- Composition
- In-use shelf life (whenever applicable)

9. Finished product sample.

10. List of countries where the product is registered with registration dates and numbers.

2.3.2 Technical quality registration requirements

1. Free from certificate: an evidence that the product is free from any radioactive materials, pathological microorganisms and parts of insects, and potentially artificial or chemical active pharmacological substances.

2. Certificate of Analysis (COA) and specifications of the active herbal substances stating the percentage of heavy metals (e.g. lead, mercury, cadmium, arsenic, etc.) according to approved reference international standards (e.g. European Pharmacopeia (Eur. Ph.), British Pharmacopeia (BP), etc.).

3. Summary of the risk assessment covering the risk evaluation for elemental impurities.

4. Evidence to show that the levels of elemental impurities are controlled during the manufacturing process.

5. Complete stability studies batches (preferably commercial or pilot scale). The studies must include all the tests that are mentioned in the finished product specification including:

- Long-term stability studies as per ICH guidelines over the SHELF LIFE of the product at 30°C ±2 & 65% relative humidity (RH) ±5. (Long-term stability study performed at storage condition 25°C ±2 & 60 % (RH) ±5 can be accepted).
- Accelerated stability studies at 40°C+2 & 75%RH ±5 over a period of 6 months.

6. In use stability studies

- In used stability study (post container opening) if applicable

7. Stability Summary and Conclusions for shelf life for :

The manufacturer should define the period of time during which, after being packaged for sale, the product will maintain its purity and physical characteristics and its medicinal ingredients will maintain their quantity per dosage unit and their potency. Therefore, the MAH is responsible for the determined shelf life based on scientific data.

8. Finished Product Specifications must include following parameters and their limits:

- Description
- weight content
- Weight variation
- Solubility in water
- Identification of the active ingredients of the finished products
- Assay of the active ingredients
- Microbiological tests and impurities should be mentioned

❖ **N.B** In case the herbal active is mention in a referenced pharmacopeia the applicant are expected to follow pharmacopeial specifications. Otherwise, the same specifications mentioned above should be submitted from a non-pharmacopoeial approved references for herbal product with their limits and validation .

9. Certificate of analysis of finished product of at least one batch that should be the same batch number as the sample submitted. The certificate should include all following parameters with the limits and results:

- In case of solid dosage forms: -

a) Description

b) Weight content / Weight variation

c) Identification of the active ingredients of the finished products

d) Assay in full details of the active ingredients (as the parameters stated by references)

e) Impurities

f) Microbiological tests

g) Dissolution

- In case of liquid dosage forms: -

a) Description
b) Desintigration
c) Identification of the active ingredients of the finished products
d) Assay in full details of the active ingredients (as the parameters stated by references)
e) Impurities
f) Microbiological tests

- In case of suppositories: -

a) Description

b) Disintegration

c) Identification of the active ingredients of the finished products

d) Assay in full details of the active ingredients (as the parameters stated by references)

e) Impurities

f) Microbiological tests

- In case of ointments and creams:

a) Description

b) Identification of the active ingredients of the finished products

c) Assay in full details of the active ingredients (as the parameters stated by references)

d) Impurities

e) Viscosity

f) PH

g) Water content

h) Uniformity of dosage unit

i) Microbiological tests

j) Particle size

9. For products containing substances extracted from an animal source, certificate of suitability for Transmissible Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE) should be submitted.

10. Manufacturing process should be mentioned with a flow chart/diagram.

2.3.3 Technical safety and efficacy registration requirements

Applicants must submit studies from all relevant sources to support the safety and efficacy of the product. The required evidence will vary depending on the type of claim as well as the type of the product.

2.3.3.1 TECHNICAL SAFETY AND EFFICACY REGISTRATION REQUIREMENTS FOR HMS

1. Toxicological and safety studies, precautions and side effects (if any) for the product should be submitted. Clinical studies should be submitted.

2. A scientific reference supporting the pharmacological claim (e.g.

Pharmacopeia, scientific book or scientific journal).

3. A study showing the pharmacological action of the product including its action and effects on the major organ systems of the human body.

4. When available, information based on previous marketing experience of a finished product may be provided to supplement the evidence supporting the safety of the product.

2.3.3.2 TECHNICAL SAFETY AND EFFICACY REGISTRATION REQUIREMENTS FOR THMS

For a herbal product to be eligible for a THM registration, the product should meet the following criteria:

- Have a period of at least 30 consecutive years of traditional use.
- The dose and method of preparation must be same as those traditionally used.
- Evidence of safety.
- Adherence to appropriate manufacturing standards.
- Provision of appropriate product information to users.

❖ **N.B** The supporting evidence for a THM must show that the product has been used in practice for at least 30 consecutive years. Reference to a source published 30 years ago is not sufficient, as this simply demonstrates that the product was in used 30 years ago. There must be a connection between the duration of use and the claimed use.

THMs are divided into two sub categories according to the evidence provided:

A) Pharmacopeial evidence for traditional products.

B) Non-Pharmacopeial evidence for traditional products.

- Pharmacopeial evidence for THMS

Product meeting this criterion only require one Pharmacopeial reference. The applicant must show that the following items in the dossier are identical to the Pharmacopeial references in the following aspects:

- Medicinal ingredients.
- Quantity of crude material equivalent.
- Recommended dose.
- Recommended route of administration.
- Recommended duration of use.
- Dosage form.
- Directions of use.
- Risk information.
- Method of preparation.
- Applicant should submit copies of the relevant pages from a recognized Pharmacopeia as supporting evidence.

❖ **N.B.** Official expert committee reports or monographs from learned societies (e.g. Commission E, European Herbal Substances Community List, European Herbal Substances Community Monographs, European Scientific Cooperative on Phytotherapy (ESCOP), etc.) are accepted.

- Non-Pharmacopeial evidence for THMS

Applicants who submit a product claiming that it is a THM, but is unable to provide a Pharmacopeial evidence must provide at least two independent references. The references must be reliable and from reputable sources. For example:

- Scientific book or/and scientific journal (e.g. published peer-reviewed scientific literature, Martindale, Potter's New Cyclopaedia of Botanical Drugs and Preparations etc.).

❖ **N.B** For both HMs and THMS, the applicant has the responsibility to report to the Administration any up-to-date post-marketing surveillance and adverse effect monitoring of the herbal product that occurred locally or/and internationally.

2.4 REQUIREMENTS FOR THE RENEWAL OF A REGISTERED HERBAL PRODUCT

The registration of a herbal product must be renewed every 5 years from the date of issuing the registration certificate. The agent must submit the renewal file 6 months prior to pharmaceutical registration expiration.

1. **Covering letter:** The applicant shall include a covering letter with each submission, titled **"Request for Renewal of Registration"** including:
   - Trade name, Generic name, Strength, Dosage form
   - Manufacturer, Marketing Authorization Holder (MAH)
2. **Application Form:** Either the standard application form or the electronic application form available through theregistration portal is acceptable.
3. **Letter from Marketing Authorization Holder:** Confirming continuation of Agent authorization in Kuwait.
4. **Valid Certificate of Pharmaceutical Product** (CPP).
5. **Original Legalized Price Certificate:** As per pricing department requirements.
6. **Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), and labeling**, with approved revision date.
7. **Proof of ongoing/ post approval stability studies.**
8. **Confirmation of al API &Finished Product ManufacturerS):** Including Primary, Secondary, and Batch Release sites ot Kuwait with corresponding valid Kuwait manufacturing site registration certificate(s).
9. **Confirmation of primary packaging material:** Intended for Kuwait.
10. **Updated clinical overview:** Including a summary of safety data and abenefit-risk evaluation, confirming that theproduct's benefit-risk balance remains favourable.
11. **Samples for analysis** might be requested by the Administration, during registration process or at any time after registration.

3. SECTION III: HERBAL TEAS

3.1 DEFINITION OF A HERBAL TEA

Herbal tea is a herbal product (refer to **2.1 Definition of a herbal product).** Herbal tea is used in many traditional medicine systems as a dosage form. Herbal materials (for example, dried roots, leaves or flowers) are packed into paper or cloth bags or sachets, each containing ground herbal materials (a single herb or a mixture of different herbs) sufficient for one dose for making into an infusion. Herbal tea bags should be free from bleach, gluten and dioxin. Herbal tea that is not packed in a tea bag or sachet (i.e. loose), should specify an exact dose and instruction for use. Herbal tea should include a clear medical/therapeutic indication explaining its purpose.

3.2 REQUIREMENTS FOR THE REGISTRATION OF A HERBAL TEA

3.2.1 Regional administrative registration requirements for a herbal tea

1. **Covering letter:** The applicant shall include a covering letter with each submission, titled **"Registration of a Herbal tea"** including:

- the herbal tea trade name
- concentration
- MAH
- manufacturing company (if different than MAH)
- a complete list of documents submitted for registration

2. **Original FSC** issued from the Ministry of Health or from the concerned authorized authority at the country of origin, legalized by Kuwait Embassy. The FSC must include the following information:

- Trade name
- Scientific name
- Indications
- Detailed composition for the active and inactive ingredients

3. **Status of registration** of the product in the country of origin.

4. **List of countries** where the product is registered with registration dates and numbers.

5. **Finished product sample**. Information of the product on the outer and inner pack sample must be in English or (English and Arabic) and satisfy the requirements of Ministry of Commerce of State of Kuwait. Information should include:

- Name
- Composition
- Uses
- Batch No.
- Manufacturing date
- Expiry Date
- Storage Conditions
- Indication

3.2.2 Technical quality registration requirements for a herbal tea

1. Finished product specifications and CoA of the finished product (with the same batch number as the one(s) submitted as sample(s). The CoA should include all the tests (total Ash, Acid insoluble Ash, moisture content and microbiology) mentioned in the finished product specifications, including the limits and results (if applicable).

2. CoA and specifications of the active herbal substances stating the percentage of heavy metals (e.g. lead, mercury, cadmium, arsenic, etc.) according to approved reference international standards (e.g. European Pharmacopeia (Eur. Ph.), British Pharmacopeia (BP), etc.).

3. Evidence to show that the levels of elemental impurities are controlled during the manufacturing process.

3.2.3 Technical safety and efficacy registration requirements for a herbal tea

1. Safety and efficacy studies from competent international authorities (Annex II) (and/or evidence of traditional use (refer to section **2.3.3.2)** or clinical studies (refer to section **2.3.3.1)** if applicable).

3.3 REQUIREMENTS FOR THE RENEWAL OF A REGISTERED HERBAL TEA

The registration of a herbal tea must be renewed every 5 years from the date of issuing the registration certificate. The agent must submit the renewal file 6 months prior to the herbal tea registration expiration. The following requirements are considered minimum at the time of submission and are subject to change. The Herbal Department at the Administration reserves the right to request additional documents on a case-by-case basis:

1. **Covering letter:** The applicant shall include a covering letter with each submission, titled **"Request for Renewal of Registration"** including:

2. **Original legalized FSC** issued from the Ministry of Health or from the concerned authorized health authority at the country of origin for each herbal tea, and should include the following:

- The date and registration number in the country of origin.
- The herbal product submitted for registration should be with the same composition and strength as the one registered in the country of origin.

3. **Declaration letter** stating that there is no change in the registered product submitted for registration renewal.

4. **One sample of the product should be submitted.** Information of the product on the outer and inner pack sample must be in English or (English and Arabic) and satisfy the requirements of Ministry of Commerce of State of Kuwait. Information should include:

- Name
- Composition
- Uses
- Batch No.
- Manufacturing date
- Expiry Date
- Storage Conditions
- Indication

9. Samples for analysis might be requested by the Administration, during registration process or at any time after registration.

4. SECTION IV: VARIATION, TRANSFER OF AGENCY AND CANCELLATION OF A HERBAL PRODUCT/ HERBAL TEA

4.1 VARIATION REQUIREMENTS FOR A REGISTERED HERBAL PRODUCT/ HERBAL TEA

• Any changes/ additions made to a registered herbal product/ herbal tea must be submitted to the administration for review and approval.

• Such changes/ additions cannot be implemented without prior approval from the administration.

• Covering letter: the applicant should include a covering letter indicating the requested changes.

• Specific requirements will be set for each type of change/ addition as a memo.

4.2 TRANSFER OF AGENCY

- **Covering letter** requesting transfer of agency of a product/products
- **Application form** printed out from the MOH system
- **Valid Store license** issued from Pharmaceutical Inspection & Licensing Administration for the new agent.
- **Valid Agency license** issued from Pharmaceutical Inspection & Licensing Administration for the new agent.
- Copy of **product's valid registration certificate**.
- **A valid Letter of appointment (LOA)** for new local agent issued from the MAH or regional distributer in case the legal relation is already mentioned in the original letter of appointment. The LOA should be original and legalized by the Chamber of Commerce or the Ministry & Kuwait embassy in the country of origin.
- **Termination letter** for the previous local agent in Kuwait issued from the MAH or regional distributer in case the legal relation is already mentioned

in the original letter of appointment, with confirmation that this termination is legally compatible to the previous signed agreement and including termination date. The termination letter should be original and legalized by the Chamber of Commerce & Kuwait embassy in the country of origin.

4.3 HERBAL PRODUCT/ HERBAL TEA SUSPENSION

Medicine and Medical products Registration and Regulatory Administration reserve the right to suspend the registration of a herbal product/ herbal tea or company in the following circumstances:

- If the product or the manufacturing company is suspended in country of origin. Lack of safety or efficacy of the product. If the company does not comply with
- the current GMP standards.
- If the product does not comply with the specification issued by the manufacturer or by the pharmacopoeial specification, upon repeated analysis.
- If discrepancy in the documents submitted were observed.
- Non compliance to Medicine and Medical products Registration and Regulatory Administration laws and regulations.
- If the Medicine and Medical products registration and Regulatory administration come to know by any circumstances other than agent about any warning issued for a specific drug or manufacturing site by FDA, EMA, WHO, GCC or any other International Health Forums.

4.4 HERBAL PRODUCT/ HERBAL TEA CANCELLATION

Medicine and Medical products Registration and Regulatory Administration reserve the right to Cancel the registration of a herbal product/ herbal tea or company in the following circumstances:

- Two years passed without importing the registered product.
- The herbal product/ herbal tea is banned or suspended in the country of origin or in any country due to safety, quality, issue or lack of efficacy, or if the product is proved to have toxic or serious adverse effects.
- Submitted documents are false or if it is proven to have different data from those submitted for registration.
- If there is any chemical active ingredient(s) in the herbal product/ herbal tea that was not declared.
- If the herbal product/ herbal tea does not comply with the specifications submitted by the manufacturer.
- As per the instruction from the manufacturer to cancel the product, the product will be cancelled.
- A product is liable to cancellation if the agent fails to renew the product registration within 6 months of the expiry of the registration certificate.
- The Medicine and Medical products Registration and Regulatory Administration reserves the right to cancel the registration of the product if it fails to comply with this M.D.

LIST OF ANNEXES

ANNEX I: LIST OF BANNED AND RESTRICTED HERBS

Manufacturers and Authorized representatives must ensure any herbal products/ herbal teas they place on the market do not contain banned ingredients. They must also ensure that restricted ingredients are used legally. The following tables includes banned and restricted lists that has been extracted from various competent regulatory authorities, and others based on Kuwait Ministry of Health M.D.

Table 1 consists of banned herbs that cannot be included in herbal products/ herbal teas submitted for registration.

Table 2 consists of herbal ingredients that are subject to specific restrictions (i.e. precautions for their use, indications, maximum acceptable limits etc.).

Some herbal ingredients are subject to more than one set of restrictions.

Restrictions may be added or removed at any time.

TABLE 1: LIST OF BANNED HERBS IN HERBAL PRODUCTS/ HERBAL TEAS
1-Aristolochia species ❖ Aristolochia Clematis ❖ Aristolochia Contorta ❖ Aristolochia Debelis ❖ Aristolochia Fang-chi ❖ Aristolochia Manshuriensis ❖ Aristolochia Serpentaria
2-Amygdalin
3-Cantharides, Cantharis Vesicatoria, dried insect
4-Curare or South American arrow poison, Strychnos Castelnaei, S.Toxifera, S.Crevauxii
5-Cicuta Spp. (Water Hemlock), C. Maculata
6-Chinaberry tree, Melia Azedarach, White Cedar
7-Canada Moon seed, Menispermum canadense
8-Colocynth, Citrullus Colocynth
9- English Holly Ilex Aquifolium
10-Euphorbia species; Asthmaplant, Chamaesyce hirta, Euforbia, Euphorbe, Euphorbia hirta, Euphorbia capitulata, Euphorbia pilulifera, Euphorbium Officinarum, Pillbearing Spurge, Snakeweed.

11-Jequirity (Abrus Precatorius)
12-Lilly of the vally, Covallaria Majalis
13-Lanata, Lanata Camara
14-Mandragora species, Mandagora officinarum, Atropa Mandagora, Mandagora autumnalis, M.Acaulis, M.Foemina, M.Hispanica, M.Hausskenchtii, M.Vernalis, M.neglecta, M.praecox
15-Metopium Toxiferum (Poison Wood Tree)
16-Narcissus species (Narcissus, Daffodil, Jonquil)
17-Nerium Oleander (Oleander)
18-Nux Vomica, Strychnous Nux Vomica
19-Peganum Harmala
20-Physic Nut, Jatropha Curcas, Poison Nut, Barbados Nut
21-Phystigma, Calabar Beam or Ordeal Beam, Phyostigma Venensosum
22-Red yeast rice (Poisionous dye Sudan Red G)
23-Red squill or V.Maritama or squil bulb
24-South American arrow Poison or Curare, Strychnous Castelnaui, S.Toxifera, S.Cervauxii

25-Solanum Nigrum, Solanum Dulcamara
26-white Hellebore or European Hellebore, Veratrum Album
27-White Snake root or Rich Weed, Eupatorium Rugosum
28- Senecio (Pyrrolizidine Alkaloids)
29- Atropa Belladonna or Deadly Nightshade, Belladonna Herb
30-Areca Catchu

TABLE 2: RESTRICTED HERBAL INGREDIENTS IN HERBAL PRODUCTS/ HERBAL TEAS

1-Aconitum spp. (Aconite, Monkshood): all Aconitum species including: Aconitum napellus, Aconitum stoerkianum, Aconitum uncinatum var japonicum, Aconitum deinorrhizum, Aconitum balfourii, Aconitum chasmanthum, Aconitum spicatum, Aconitum lycoctonum

Restrictions:

Internal use: no permitted dose unless made available by a prescription from a registered doctor or dentist (POM).

External use: max. dose 1.3%.

2- Adhatoda Vasica

Restrictions:

The following precaution should be added on the outer pack and leaflet: "Do not take if you are pregnant or breast-feeding".

3- Egyptian Henbane, Hyoscyamus niger, Hyoscyamus albus, Hyoscyamus muticus

Restrictions:

Internal use: 100 mg (maximum dose), 300 mg (maximum daily dose).

Can only be sold in a pharmacy

5-Gelsemium sempervirens, Yellow Jessamine, Gelsemium

Restrictions:

Internal use: maximum dose 25 mg, maximum daily dose 75 mg.

can only be sold in a pharmacy

6-Ipecac, Caphaelus Ipecacuanhua, Carapichea ipecacuanha (Rio or Brazilian Ipecac), C.Acuminata (Cartagena ipecac)

Restrictions:

The USFDA recommends that it is in the interest of the public health for ipecac syrup to be available for sale without prescription, provided that it is packaged in a quantity of 1 fluid ounce (30 milliliters), and its label bears, in addition to other required label information, the following, in a prominent and conspicuous manner:

(1) A statement conspicuously boxed and in red letters, to the effect: "For emergency use to cause vomiting in poisoning. Before using, call physician, or hospital emergency room immediately for advice."

(2) A warning to the effect: "Warning--Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosine, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested."

(3) Usual dosage: 1 tablespoon (15 milliliters) in persons over 1 year of age. UNSAFE when used in high doses or in children under the age of one year.

• Registered in the UK with minimal ingredient as a combination product syrup under the traditional herbal medicine registration, indicated for the relief of sore throats and chesty coughs only.

7- Lobelia or Indian Tobacco, Lobelia Inflata

Restrictions:

Internal use: max. dose 200 mg, max. daily dose 600.

Can only be sold in pharmacy

8- Poison Hemlock (Conium Maculatum)

Restrictions:

For external use only: max. 7.0 %.

9- Piper Methysticum (Kava Kava)

Restrictions:

For external use only.

10- Adonis Vernalis (pheasant's eye)

Restrictions:

For internal use only: max. dose 100 mg, max. daily dose 300 mg.

11- Cinchona officinalis, Cinchona bark, Peruvian bark, Cinchona Succirubra, (Red Cinchona), C. Calisaya (Calisaya bark), Cinchona Micrantha

Restrictions:

Internal use: max. dose 250 mg, max. daily dose 750 mg.

Pharmacy only.

12- Colchicum Autumnale, Colchicum corm

Restrictions:

Internal use: max. dose 100 mg, max. daily dose 300 mg.

Pharmacy only.

13-Cascara sagarda or Rhamanus purchiana Bark

Restrictions:

Internal use: max. daily dose 30 mg to be taken once daily at night. If presented as a herbal tea, amount of comminuted herbal substance (equivalent to not more than 30 mg hydroxyanthracene derivatives) in 150 ml of boiling water as herbal infusion.

- The use in children under 12 years of age is contraindicated.
- Contraindicated during pregnancy.
- Not to be used for more than 1 week.

14-English Ivy, Hedra Helix

Restrictions:

Adolescents, adults and elderly

a) Single dose: 15-65 mg, one to three times daily

Daily dose: 45-105 mg

(Note: maximum daily dose for ethanol containing finished products :67 mg; corresponding to 420 mg herbal substance)

b) Single dose: 14-18 mg three times daily

Daily dose: 42-54 mg

c) Single dose: 33 mg two times daily

Daily dose: 66 mg

d) Single dose: 100 mg three times daily

Daily dose: 300 mg

e) Single dose: 40 mg three times daily

Daily dose: 120 mg Children between 6-11 years of age

a) Single dose: 11-35 mg, two to three times daily

Daily dose: 33-70 mg.

(Note: maximum daily dose for ethanol containing finished products: 34 mg; corresponding to 210 mg herbal substance)

b) Single dose: 9-18 mg, one to three times daily

Daily dose: 15-40 mg

c) Single dose: 25 mg, two times daily

Daily dose: 50mg

d) Single dose: 75 mg, three times daily

Daily dose: 225 mg

e) Single dose: 20-26 mg, three to four times Daily

Daily dose: maximum of 80 mg

Children between 2-5 years of age

a) Single dose: 8-18 mg, two to three times daily

Daily dose: 24-36 mg

(Note: maximum daily dose for ethanol containing finished products: 24 mg;

corresponding to 150 mg herbal substance)

b) Single dose: 7-9 mg, two to three times daily

Daily dose: 14-27 mg

c) Single dose: 17 mg, two times daily

Daily dose 34 mg

e) Single dose: 20 mg, three times daily

Daily dose: 60 mg

The use in children under 2 years of age is contraindicated.

15- Nutmeg Myrestica fragrance

Restrictions:

Maximum dose 1mg/kg body weight

16- Rhamnus Frangula

Restrictions:

Internal use: max. daily dose 30 mg, to be taken once daily at night. If presented as a herbal tea: amount of comminuted herbal substance equivalent to not more than 30 mg hydroxyanthracene derivatives in 150 ml of boiling water as herbal infusion.

- The use in children under 12 years of age is contraindicated.
- Not to be used for more than 1 week.
- Not suitable during pregnancy.

17- Hyoscymus Muticus (Egyptian Henbane), Hyoscymus Niger (Black Henbane), Hyoscymus Albus

Restrictions:

Internal use: max. dose 100 mg, max. daily dose 300 mg.

Pharmacy only

Note:In addition to the herbs and plants listed above in Tables 1 and 2, the Ministry of Health has the right to ban/restrict any herb or plant if proven harmful for human use in any way, or if there is any warning for its use released by a health organization or a national health regulatory authority or stated in an established scientific reference.

REFERENCES

1. Ema, As Described In The "Guideline On The Use Of The Ctd Format In The Preparation Of A Registration Application For Traditional Herbal Medicinal Products (2008)"

2. Official Journal Of The European Union Directive 2001/**83**/Ec On The Community Code Relating To Medicinal Products For Human Use" L 136/86, L 136/87, L 136/88 "

3. House Of Commons Library "Regulations Of Herbal Medicine Standard

4. Note Sn/Sc/6002 (12 Feb 2014)"

5. Mhra, Traditional Herbal Medicines Registration Scheme: Key Requirements.

6. Medicines& Health Products Regulatory Agency,Banned And Restricted Herbal Ingredients Published 18th Of December 2014

7. Saudi Food And Drug Authority "Guidance For Products

8. Classification"

9. Saudi Food And Drug Authority "Data Requirements For Herbal &

10. Health Products Submission"

11. Sultanate Of Oman Ministry Of Health Directorate

12. General Of Pharmaceutical Affairs And Drug Control Muscat Circular No. 28/2008 (01-03-1429) (07-4-2008).

13. Health Sciences Authority Regulatory Guidance Revised

14. August 2017 (Health Supplements Guidelines).

15. Food And Drug Administration. Part 328- Over The Counter Drug Products Intended For Oral Ingestion That Contain Ethanol. Title 21- Food And Drugs. Rockville, Md: Department Of Health And Human Services (Us), Food And Drug Administration; 006.

16. World Health Organization, Swiatowa Organizacja Zdrowia. Who Guidelines On Good Agricultural And Collection Practices [Gacp] For Medicinal Plants. World Health Organization; 2003 Dec 16.