****

**TRADITIONAL MEDICINAL PRODUCTS MANUFACTURING CERTIFICATE OF COMPETENCE AND MARKETING AUTHORIZATION DIRECTIVE**

**February 2021**

**ADDIS ABABA**

# PREAMBLE

**WHERE AS,** it is necessary to ensure the efficacy, safety and quality of Traditional medicine so as to protect and promote public health;

**WHERE AS,** it is necessary to ensure that traditional medicine meet Good manufacturing practices requirements

**WHEREAS,** it is found necessary to enforce and provide detail requirements entailing what documents shall be submitted for marketing authorization of Traditional medicinal products;

**WHERE AS,** it is necessary to put adequate regulatory mechanisms in place; considering the need to take action against products that pose "a significant or unreasonable risk of illness or injury to the users;

**WHERE AS,** it is necessary to bring about a regulation of traditional medicine with a specific legislation in order to address the gap of existing legal requirements;

**WHERE AS,**To Protect or deter misleading practices and risks emerging out of unsafe and poor quality in traditional medicinal products;

**NOW, THEREFOR,** this directive is issued in accordance with Article 71 (2) and (5) ofFood and Medicine Administration Proclamation No. 1112/2019.

# PART-1

# GENERAL

## Short title

This directive may be cited as **“Traditional medicinal products manufacturing certificate of competence and marketing authorization Directive No.….../2021.”**

## Definitions

Without prejudice to the definitions provided under Proclamation No. 1112/2019, unless the context requires otherwise, for the purposes of this directive:

* 1. **“Authority”** means Food and Drug Control Administration Authority.
	2. **"Traditional medicinal products"** means any finished, labeled Traditional medicinal products, herbal cosmetics and herbal medicinal supplements containing active ingredients from natural sources (plant, animal or mineral) applicable for the human health use and includes herbal cosmetics and herbal medicinal supplements;
	3. "**Good Manufacturing Practice (GMP)"** means measures or practices undertaken to ensure that the process by which the traditional medicinal or herbal medicinal products manufactured or processed is in good quality and safety;
	4. **“Distributor”** means a person who distributes traditional medicinal products across more than one regional state.
	5. **“Ingredient”** means any substance which is used in the manufacture or preparation of the herbal medicinal supplement;
	6. **“Marketing authorization”** means an official confirmatory document issued by the Authority used for the distribution of the product in Ethiopia;
	7. **“Product"** means traditional medicinal products and herbal medicinal products regulated as per the provisions of this directive;
	8. **"Revocation"** is the cancellation of a license of certificate competence and withdrawal of the authorization to perform regulated activities/manufacturing Traditional medicinal products under the Directives;
	9. **"Suspension"** means an administrative measure taken against regulated person or product when the Authority has a reason to believe that any of the grounds for suspension exist;

10) **"Proclamation"** means Food and Drug Administration Proclamation No. 1112/2019.

11) **"Person"** means a natural person or a legal entity.**7)**12) Any expression of the masculine gender also includes the feminine.

## Scope of Application

This directive shall be applicable for the registration of locally manufactured and distributed Traditional medicinal products

# PART -2

# Traditional medicine products Manufacturing Certificate of Competence

## General

1. Any manufacturer of traditional medicine products manufacturer shall get a certificate of competence from the Authority.
2. The application and necessary information shall be submitted electronically through electronic regulatory information system of the authority available on the website

## Application to get Certificate of Competence

1. An application to get Certificate of Competence of the traditional and herbal medicinal shall be addressed to authority, the following documents:
	* 1. Details of the production facility;
		2. A copy of the memorandum of understanding, or other form of partnership agreement between the manufacturer and the research institution.;
		3. Proof of payment of the Certificate of Competence fee as fixed by the national drug regulatory authority;
		4. Layout and design of the manufacturing plant/ accompanied with a sketch design of the proposed premiseshall be required
		5. Quality control and laboratory testing results;
		6. Waste management and treatment systemdocuments;
		7. Material and personnel flow direction including controlled areas; Clean area classification; Equipment design and location documents;
		8. Source and quality of water including its design, treatment, storage, distribution and monitoring documents;
		9. Full dossier submission of a proposed Traditional Medicinal Products to national regulatory authority.
2. Any manufacturer of traditional medicine products before engaging in construction of the intended premises shall fulfill the requirement of this directive.

##  Pre-approval inspection

1. Prior to the conduct of official pre-approval inspection, the applicant shall be required to fill the checklist;
2. The actual conduct of the site audit shall depend on the assessment of the outcome of the checklist completed by the applicant;
3. While pre-approval inspections shall be considered to be an important part of the application review and approval process, inspections might be carried out only in specific cases where noncompliance is possible;
4. An inspection team shall conduct the audit in accordance with the GMP Guidelines of Traditional Medicinal Products;

##  Requirement for certificate of competence

1. The Authority through authorized inspection team shall verify if the sketch suits for the intended purpose and may approve, reject or propose an alternative to the submitted sketch design.
2. Upon satisfactory assessment of the completed application form and when the sketch is accepted, the applicant will be notified to continue with process of construction or renovation of the premises and upon completion shall inform the Authority for inspection.
3. A pre-registration inspection of the proposed manufacturing facility shall be conducted by a team of experts.
4. Where the sketch is rejected or need to be modified the applicant shall be informed accordingly.
5. The authorized person of the Authority shall evaluate and, as the case may be, recommend or decide after receiving duly filled application, premises inspection report and all other necessary documents from the inspectors.
6. Where the premises requirements have not been met, the applicant shall be informed to address the deficiencies.
7. An applicant shall receive an official letter informing them on the status of their application within five working days from the day the decision was made.
8. Applicants who are required to take corrective action shall carry out remedial/corrective measures.
9. Approved applicants will be required to procure raw materials from approved/recognized supplier and other reference materials related to the type of product and production line before starting manufacturing.
10. The Authority shall issue approval to conduct manufacturing activity
11. Samples for laboratory analysis shall be collected during the pre-registration inspection.
12. Upon satisfactory evaluation of the laboratory reports, the brief for the registration of the product is presented to the national expert committee on traditional medicine for consideration.
13. After approval by the committee, the applicant may be required to pay a fixed amount per product for a registration certificate that would be renewable after expiry.

## Manufacturing Premises

1. The premise shall be located, constructed, and maintained to suit the operation to be carried out.
2. Premises shall be situated in an environment to suit to protect the manufacturing process and, presents minimum risk of causing any contamination of materials or products
3. Premises shall be carefully maintained, and shall be ensured that repair and maintenance operations do not present any hazard to the quality of medicine.
4. Electrical supply, lighting, temperature, humidity and ventilation shall be appropriate such that they do not adversely affect, directly or indirectly, either the products during their manufacture and storage or the accurate functioning of equipment or safety and comfort of the operators.
5. The premise shall be designed and equipped so as to afford maximum protection against the entry of insects, vermin’s, rodents, birds or other animal and shall have sign board conspicuously displayed at the main entrance.
6. The layout and design of premises shall aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross contamination, build-up of dust or dirt and in general any adverse effect on the quality of the product.

## Manufacturing plant Water system

1. The water system, storage and distribution for traditional medicinal products manufacturing shall be designed, to ensure the reliable production of water of an appropriate quality and shall be produced, stored and distributed in a manner that prevents unacceptable microbial, chemical or physical contamination.
2. Water used in the manufacture of Traditional Medicinal shall be suitable for its intended use.
3. Where appropriate, purified water shall be used and the purification method, or sequence of purification steps, shall be appropriate to the intended purpose

## Manufacturing Materials

1. The materials used for operations such as cleaning, lubrication of equipment and pest control, shall not come into direct contact with the products, and such materials shall be of a suitable grade to minimize health risks.
2. All materials and products shall be stored under the appropriate conditions established by the manufacturer and in an orderly manner to permit batch segregation and stock rotation by First Expiry First Out and/or First in First out manner.
3. Appropriate stock management system and procedures shall be established with the use of bin cards and stock cards or any fully validated electronic record system.
4. Materials shall not be kept directly in contact with floors, nearer to walls and ceilings in order to allow appropriate space for cleaning and inspection.

## Complaints

1. There shall be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.
2. Special attention shall be given to a complaint whether it was caused by counterfeiting or by any other reason.
3. Any complaint concerning a product defect shall be recorded with all the original details and thoroughly investigated. The person responsible for quality control should be normally involved in the review of such investigations, and where necessary, appropriate follow-up action, possibly including product recall, shall be taken after investigation and evaluation of the complaint.
4. The authority shall be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, or any other serious quality problems with a product.

## Product recalls

1. There shall be a system to recall from the market, promptly and effectively, traditional medicine products known or suspected to be defective.
2. The authorized person shall be responsible for the execution and coordination of recalls.
3. There shall be established written procedures, which are regularly reviewed and updated, for the organization of any recall activity.
4. Recall operations should be capable of being initiated promptly down to the required level in the distribution chain.
5. Regulatory authority shall be promptly informed of any intention to recall the product because it is defective or is suspected of being defective.
6. The distribution records shall be readily available to the authorized person, and they should contain sufficient information on wholesalers and directly supplied customers to permit an effective recall.
7. The progress of the recall process shall be monitored and recorded.

## Manufacturing Documentation

1. Documents shall be designed, prepared, reviewed and distributed with care and signed and dated by the appropriate responsible persons.
2. Documents shall have unambiguous contents: the title, nature and purpose shall be clearly stated and regularly reviewed and kept up to date.
3. Where documents require the entry of data, these entries shall be the reading of the original information.

# PART -3

# REGISTRATION AND, MARKET AUTHORIZATION OF TRADITIONAL MEDICINE

## Application for registration of traditional medicinal

1. Any traditional medicine manufacturer and distributer shall have COC and GMP certificate from the authority.
2. An application for the registration traditional medicinal product shall be made in written in Amharic or English language and shall be legibly printed and not hand written, dated, signed and stamped by the applicant/license holder.
3. The appropriate application form is duly completed and submitted to authority along with the common technical document format and accompanied by Administrative requirements:
	1. A covering letter addressed to the Respective Directorate of the Authority, Table of content, Application form (ANNEX 1)
	2. Dossier Overall summery
	3. Quality data
	4. Non clinical study reports
	5. Clinical study reports, if required

## General application requirements

1. The application requirement for registration of traditional medicinal products shall not have any resemblance in spelling and pronunciation of name, or packaging to another product, that has been previously registered by the Authority.
2. All samples submitted should conform to existing labeling regulations as specified in the Authority’s guidelines for product labeling.
3. Scientific and/or botanical names of the plants used, as well as the parts of plants used and the quantity of active ingredients in the preparation, shall be submitted.
4. The list of all recipients used and their quantities per dosage units used in the preparation shall be submitted.
5. The indications for which the products are being presented for registration shall be unambiguously stated.
6. Brand (trade name) generally the first and last three letters of any trade name shall not be identical with a registered product in Ethiopia.
7. The authority may ask the applicant to supply other information as may be required to enable it reach a decision on the application.
8. Where the Authority is satisfied that there is the need to register products, and all requirements for its registration have been satisfied, it shall issue to the applicant a certificate of registration.
9. The registration of a product under this Directive, unless otherwise revoked, shall be valid for a period of 4 (four) years and may be renewed.
10. No person shall disclose any information supplied to the Authority in pursuance of this Directive, except with the written consent of the person who supplied the information.

## Product Variation

1. An application for the variation of registration of traditional medicinal products prior to re-registration shall be made to the Authority.
2. The application shall be accompanied by supporting documentation for the variation and based on the type of variation actual sample will be requested for quality control test.

## Re-registration

1. An application for the re-registration of traditional and herbal medicinal products shall be made four months before the expiration of the registration.
2. The applicant shall notify the authority for any change to the product since the previous market Authorization certificate of the product.
3. Confirmatory letter that indicates the absence of any change on the manufacturing process, specification, primary and secondary package, formulation and composition to the previous registered products.
4. Re-registration requirements shall include valid manufacturing license or current GMP Notification of variation and re-registration

## Product information

1. Traditional and herbal medicinal products information include package insert, labeling, and summary of product characteristics shall be provided, and all information label statements are required to be in English or Amharic.
2. Any information appearing in the traditional medicinal products shall be based on scientific justification.
3. Recommended format shall be used by the applicant to provide the content of the Summary of Product Characteristics.

## Packaging and Labeling

* 1. The labeling for traditional and herbal medicinal shall be original labels or computer-ready color-printed labels shall be accepted for final approval.
	2. The titles for batch number, manufacturing, and expiry dates shall be part of the printing (type written materials, stickers, etc., are not acceptable).
	3. The contents of the label shall at least contain:
1. The name of the product- Brand and Generic;
2. Traditional Medicinal product form and route of administration;
3. Qualitative and quantitative composition of each part;
4. The volume of the contents, and/or the number of doses or quantity in container;
5. Direction for use
6. Handling and storage conditions;
7. License number of the manufacturer;
8. Batch number
9. Manufacture date;
10. Expire date;
11. Name and address of manufacturer;
12. Patient information leaflet (PIL)/ Package Insert shall be required

## Ethno botanical and Toxicological research data

Acute, chronic and sub-chronic toxicity test reports of the finished product, relevant ethno botanical data of herbal products, preclinical and clinical (if applicable) data shall be submitted from a recognized national research institute.

##  Quality testing data

* + - 1. Physical identification tests shall be done on the final dosage form and should be documented as per the finished product specifications.
			2. Tests for physical identification of the finished product shall include tests such as organo-leptic evaluation
			3. Microbial testing of the under listed parameters shall be done according to Pharmacopoeia (USP, Ph. Eur. etc.), WHO methods or any other internationally recognized methods: Total viable aerobic plate count, Contaminating fungus (yeast and mould), *Salmonella* spp, *Escherichia coli, Staphylococcus aureus)*
			4. Heavy Metals (i.e., arsenic (inorganic), cadmium, lead and mercury) shall be tested individually or as total heavy metals expressed as lead at the finished product stage or at the raw material stage if all medicinal and non-medicinal ingredients are tested. Testing should be done according to Pharmacopoeia or any other internationally accepted methods.
			5. Testing for pesticides in plant or plant materials, algae, fungi, shall be done according to WHO methods for pesticide screening.
			6. Foreign matter Testing shall be done according to internationally recognized methods.

## Authorization of the product

* + - 1. Authority shall grant or renew authorization upon receipt of the application and verifying the statements made in the application form; or inspecting the Manufacturing site in accordance with the provisions of this Directive.
			2. Herbal Cosmetics and Herbal medicinal supplements are only requiring quality testing, acute toxicity tests, skin irritation testing, with no health claim and ingredient listing on the product label.

## Clinical trials

1. Clinical trial shall be undertaken by authorization issued after a decision by a technical review committee for applications for clinical trial authorization.
2. The promoter or (sponsor) is legally recognized and undertakes to initiate, organize and/or finance a clinical trial.
3. The maximum period of 90 days shall be required for the notification of the approval, adjournment or rejection of the clinical trial application. Beyond this period, authorization shall be deemed to have been granted.
4. The promoter and chief investigator must ensure that the clinical trial is conducted in accordance with the clinical good practices guidelines defined by proclamation.
5. The promoter shall inform to the authority if there is any unexpected event in the course of the study or other studies involving the same product, in accordance with the procedures in force.
6. A mid-term report, where it exists and a final report of the trial results, in line with the framework described in the clinical trial protocol should be submitted to authority.
7. Any duly mandated clinical trial may be subjected to inspection by the authority to ensure compliance with the protocol.
8. All ethical matters for clinical and non-clinical trials shall be made in accordance with the requirements provided for in the Ethical Regulations in force.
9. The granting of an authorization shall be subject to the payment of an application fee.

# PART -4

# POST APPROVAL INSPECTION, STORAGE, TRANSPORTATION AND DISTRIBUTION

## Post approval inspection

1. The Authority shall monitor and evaluate Premises for manufacturing and storage of Traditional medicinal products, or appropriate responsible professionals approved by the inspector even after the granting of the certificate of competence.

Unless found to be necessary to perform incidental inspection, every premises for manufacturing and storage of Traditional medicinal products, shall be inspected as required as part of renewal of the certificate of certificate.

##  Notification for change of premises

* + - * 1. Any change of location (shift of premises), trade name of the premises, ownership or any other change of registered premises, needs prior notification and approval by the Authority.
				2. An intention to change location of registered premises shall be made in writings to the Authority before the change is made and the Authority shall notify the applicant on the procedure to be followed.

## Packaging and labeling

Packaging and labeling of imported products shall be in accordance with the registration specification for finished products.

## Export

Depending on requirements of the country of destination and mandate of the Authority, the

Authority may issue required regulatory documents to exporters.

##  Storage, transportation and distribution

1. All Traditional medicinal products shall be stored in an appropriate condition according to instructions placed on its label.
2. All Traditional medicinal products shall be stored separately from chemicals and other potential sources of contamination.
3. The responsible person shall observe applicable safety requirements during storage, handling and transportation oftraditional medicine.
4. Deteriorated, expired, and damaged products shall be stored separately from other Traditional medicinal products until disposal.

# PART-5

# ADMINISTRATIVE MEASURES

##  General

1. In accordance with the Directive/regulation on Administrative Measure Taking and Complaint Handling, the Authority, depending on the severity of the violation, shall take one or more administrative measures on non-complying Traditional medicinal products manufacturer.
2. The Authority shall take appropriate administrative measure on the product or regulated person if a manufacturer of Traditional medicinal product is found to be non-complying with the requirement of market registration of a product introduced in the market and with the provisions regarding packaging and labeling, and content and disclosure information supplied or declared to the Authority at the time of initial licensing.
3. The Authority, when it has sufficient reason to support administrative measure-taking, may seize and cause the disposal of non-complying TM held by manufactures.

## Suspension of license

* + - * 1. Without prejudice to grounds of suspension provided under relevant laws/ Directive on Administrative Measure Taking and Complaint Handling, this Directives and based on the severity of the violation, the Authority shall suspend manufacturer’s certificate of competence if, but not limited to
1. the manufacturer allows a professional who is not duly licensed or who has been suspended from practicing by a competent person from practicing his/her profession/knowledge
2. If the license holder fails to allow inspection pursuant to applicable laws and requirements.
3. the manufacturer fails to submit, accurately or on time, or provides falsifyed information requested by the Authority;
4. the manufacturer fails to notify the Authority of any change to professionals or premises design and/or place without approval; and
5. Any of the permanent professional the manufacture is found registered or employed as a permanent staff in any other facility except where dual appointment is permitted by law.

## Revocation of license

1. Without prejudice to grounds of revocation provided under relevant laws, and based on the severity of the violation, the Authority shall revoke manufacturer’s certificate of competence if, but not limited to:
2. engage in any act which constitutes a serious violation in accordance with the directive on Administrative Measure Taking and Complaint Handling and the violation is subject to revocation measure;
3. engages in manufacturing products other than permitted by the Authority;
4. The manufacturing permit is not annually renewed within three months from the start of the Ethiopian budget year.
5. Its certificate of competence is proved to have been obtained by submitting false information intended to deceive the Authority or it is obtained in other illegal manner.

## Termination of manufacturing

* + - * 1. If the certificate of competence is revoked, suspended and not renewed by the authority permanently, the licenses granted to manufacture Traditional medicinal products shall be terminated.
				2. If the authority believes the service is dangerous for the society and orders to return, the certificate of competence will be terminated.

##  Criminal responsibilities

Where violation of any provision of this directive by any regulated person constitutes Criminal offence in accordance with the Ethiopian criminal code, the Food and Drug and Authority Proclamation No.1112/2011 or any other appropriate laws, the violating person shall be held criminally responsible

# PART-6

# MISCELLANEOUS

##  Advertising, Promotion and Sponsorship of Traditional medicinal products

* + - * 1. All kind of registered Traditional medicinal products advertising, promotion, and sponsorship activities shall be prohibited.
				2. Without prejudice to the complete prohibitions on Traditional medicinal products advertising, promotion and sponsorship of traditional medicine products the following acts and related activities shall also be prohibited:
1. Communication through broadcasts or other social Medias;
2. Flyer and related promotional activities in different public places;
3. Supply of free samples of Traditional medicinal products,
4. Promotion by discounting the price;
5. Connecting a brand name, symbol, trademark, logo or trade sign or any other Distinctive feature of a Traditional medicinal products brand with essential /modern medicines in such a way that two are likely to be associated or used for the same purpose;

## Service fee

Any person who is provided with regulatory service under this directive may be required to

Pay an applicable service fee as determined by Councils of ministers’ service fee regulation No.370/2008.

##  Duty to cooperate

Any concerned Traditional medicinal products manufacturers, government and private institutions and individuals shall have the duty to cooperate to assist all appropriate organs to effectively execute their responsibilities given in accordance with this directive.

##  Inapplicable laws

Any directive, circular or customary practice which is inconsistent with this directive may

Not be applicable with respect to those matters provided for in this directive.

##  Effective Date

This directive shall enter into force on the date of……... 2020.

**Heran Gerba**

**Director General**

**The Ethiopian Food and Drug Authority**

# Annex 1: Application Form for Registration of Product

The applicant is required to provide completed application form by summarizing the registration dossiers in the format below. Annexes and addendum shall always be cross referenced in the application form.

|  |
| --- |
| ***Application Form for Registration of Product******Product Registration and Licensing Directorate******Ethiopian Food, Medicine and Health Care Administration and Control Authority*** |
| **S/N** | **Title** | **To be completed by the applicant** | **Page number and/or annexes** |
| ***1*** | *Applicant* |  |
|  | * 1. *Name*
 |  |  |
| * 1. *Physical address including street number, Telephone, e-mail etc*
 |  |  |
| * 1. *Contac person in a company*
 |  |  |
| ***2*** | *Type of application**New Or Re-Registration Or Variation* |  |  |
| ***3*** | *Manufacturer of the Product* |  |
|  | *4.1. Name* |  |  |
| *4.2. Physical address including street number, Telephone, e-mail etc* |  |  |
| *4.3. Contact person in a company* |  |  |
| ***4*** | *Details of the Product* |  |  |
|  | *5.1. Name of the Product (common name and trade name)* |  |  |
| *5.2. Botanical Scientific Name* |  |  |
| *5.3. Part of the plant used (leaf, root etc)* |  |  |
| *5.2. Physical appearance* |  |  |
| *5.3. Presentation* |  |  |
| *5.4. Container closure type* |  |  |
| *5.5. Use of the product* |  |  |
| *5.6. Shelf life and storage condition* |  |  |
| ***6*** | *Formulation* |  |  |
|  | *6.1. Dosage form* |  |  |
|  | *6.2. Unit composition of medicinal and non-medicinal ingredient in mg (eg Per ml) and function* |  |  |
|  | *Example; Ingredient 1, 3mg* |  |  |
|  | *{Insert as much row as needed}* |  |  |
| ***7*** | *Regulatory Situation in other Country* |  |  |
|  | *List of the countries in which this product has been registered, restrictions on sale or distribution, withdrawn from the market etc* |  |  |
| ***8*** | *List of Documents attached with this application* *(indicate page number and annexes as applicable)* |  |  |
|  | *8.1. Agency Agreement* |  |  |
|  | *8.2. Certificate of TMP* |  |  |
|  | *8.3. GMP certificate if applicable* |  |  |
|  | *8.4. Summary of Product development and formulation* |  |  |
|  | *8.5. Manufacturing and Formulation* |  |  |
|  | *8.6. Finished Product specification* |  |  |
|  | *8.7. Analytical Procedure* |  |  |
|  | *8.8. Stability Study* |  |  |
|  | *8.9. Labelling* |  |  |
|  | *8.10. Others (please indicate the type of document other than those mentioned above)* |  |  |
| ***9*** | *Declaration by Applicant* |  |  |
|  | *I the undersigned certify that all the information in the accompanying documentation concerning an application for registration of Traditional medicinal products product**Traditional Medicine name (trade name, common name)­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Dosage form \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_duly authorized to represent (Applicant company) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**is correct and true, and reflects the total information available. I further certify that I have examined the following statements and I attest to their accuracy.**I further confirm that the information referred to in my application file is available for verification. I also agree that I am obliged to comply with the requirements of the Authority related to the Traditional Medicinal Product at any time point in future.**Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Position in company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| ***10*** | *To be completed by Authority designated person* |
|  | *Date of Application* |  |  |
|  | *Remark* |  |