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**Certification scheme for medicinal plant produce — Part 5: Minimum requirements for registration of traditional medicines**



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## **Foreword**

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**Introduction**



## Certification scheme for medicinal plant produce — Part 5: Minimum requirements for registration of traditional medicines

### 1 Scope

### 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AEM PR 03:2013, *Procedures for conflict resolution*

EMA PR 05:2013, *Procedures for conformity assessment*

EMA PR 06:2013, *Procedures for accreditation of certification bodies*

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/PAS 17001, *Conformity assessment — Impartiality — Principles and requirements*

ISO/PAS 17002, *Conformity assessment — Confidentiality — Principles and requirements*

ISO/PAS 17003, *Conformity assessment — Complaints and appeals — Principles and requirements*

ISO/PAS 17004, *Conformity assessment — Disclosure of information — Principles and requirements*

ISO/PAS 17005, *Conformity assessment — Use of management systems — Principles and requirements*

ISO/IEC 17007, *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment*

ISO/IEC 17011, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 9001, *Quality management systems — Requirements*

ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*

ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC 17030, *Conformity assessment — General requirements for third-party marks of conformity*

ISO/IEC 17065, *Conformity assessment — Requirements for bodies certifying products, processes and*

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*services*

ISO/IEC 17067, *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

ISO 19011, *Guidelines for auditing management systems*

## **3 Terms and definitions**

For the purpose of this document the following definitions apply.

## **4 Sustainable agriculture**

### **4.1 Introducing the African Standard for Sustainable Agriculture**

### **4.2 The Principles of African Sustainable Agriculture Standard**

### **4.3 Format of the African Sustainable Agriculture Standard**

## **5 Conditions for certification**

### **5.1 General conditions**



**Table 1 — Checklist for self-assessment for minimum requirements for registration of traditional medicines**

No.	Control criteria	Level of compliance			
		Bronze	Silver	Gold	Platinum
<b>1</b>	<b>General Technical Information</b>				
1.1	<b>Particulars of the applicant</b> Is the application for the registration of traditional medicine made only by the License/patent holder, the manufacturer or any authorized Local Technical Representative (LTR)	R	R	R	R
	Is the name, physical address, telephone number, fax number, and e-mail address of the applicant shall be provided.	R	R	R	R
	The name, physical address, telephone number, fax number, and e-mail address of the applicant shall be provided.				
1.2	<b>Particulars of the product</b>				
1.2.1	<b>Product Name:</b> the trade or brand name which is unique to a particular drug and by which it is generally identified (and by which it is registered in the country of manufacture) shall be indicated.	R	R	R	R
1.2.2	<b>Dosage form of the product:</b> the form in which the drug is presented — a macerate, infusions, ashes, decoctions, tablet, capsule, solution, suspension, emulsion, ointment, suppository etc shall be indicated.	R	R	R	R
1.2.3	<b>Strength of the product</b> shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/ml, mg per 5ml spoonful, mg per g, etc.	R	R	R	R
1.2.4	<b>Therapeutic use(s):</b> the intended use should be only the major indication(s). The product may be multi-component with other pharmacological properties but the application should be restricted to the intended use.	R	R	R	R
1.2.5	<b>Visual description of the product:</b> a full description/appearance of the traditional medicine including colour, size, shape and other relevant features, e.g. green powder, brown liquid, pink film-coated tablets etc. <b>shall be provided.</b>	R	R	R	R
1.2.6	<b>Type of container:</b> state the type of the primary package in which the traditional medicine is presented e.g. in HDPE bottles, aluminium sachets, etc.	R	R	R	R
1.2.7	<b>Pack size(s):</b> the presentation of the product to be registered i.e. list all pack sizes intended for marketing.	R	R	R	R
1.2.8	<b>Proposed Shelf life (in months):</b> the specified length of time prior to use for which a traditional medicine is deemed to remain fit for use under prescribed conditions supported by stability studies should be indicated	R	R	R	R
1.2.9	<b>Storage conditions:</b> The proposed storage conditions should be indicated on the label and supported by stability studies	R	R	R	R
1.2.10	<b>Status of registration of the product in the country of origin, authorization/registration number</b> requires the applicant to provide the regulatory situation of the traditional medicine to be registered in the country of origin and other countries.	R	R	R	R
1.3	<b>Composition of the product</b>				
1.3.1	<b>List all active ingredient(s) and all non-active ingredient(s) used</b>				
1.3.2	<b>Scientific or Botanical Name of the plant(s):</b> Name in Latin (genus and species) of the plant species and family e.g. <i>Catharanthus roseus</i> (Apocynaceae), <i>Azadirachta indica</i> (Meliaceae) should be indicated.	O	O	O	O

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1.3.3	<b>The common name or synonym is the English name.</b> Where not known the local vernacular name may be used e.g. Madagascar periwinkle ( <i>Catharanthus roseus</i> ), Neem Tree ("Muarubaini" - <i>Azadirachta indica</i> )	O	O	O	O
1.3.4	<b>Part of Plant used:</b> The part used should be specified e.g. leaf, root, bark, etc.	R	R	R	R
1.3.5	<b>Quantity per dosage unit:</b> The strength of the product shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/ml, mg per 5ml spoonful, mg per g, etc.	R	R	R	R
1.3.6	<b>Chemical Constituent(s):</b> For each of the active constituent(s) listed (e.g. <i>Catharanthus roseus</i> ), indicate the major chemical compounds where known e.g. vincristine, or where not known major group of compounds e.g. indole alkaloids.	O	O	O	O
1.3.7	<b>Reason for inclusion:</b> Where a material is included and is not the active ingredient indicate the purpose of its inclusion such as sugar as sweetener, honey as preservative.	R	R	R	R
2	<b>Classification of African Traditional Medicines</b>				
2.1	Are traditional medicines categorised based on their mode of preparation and extent of the development of the traditional medicine relative to the traditional remedy used? Possible are distinguished as Category 1: Home remedies; Category 2: Established traditional medicines; Category 3: Research-based traditional medicines and Category 4: Imported traditional medicines	O	O	R	R
3	<b>Regulatory Requirements for Safety and Efficacy</b>				
3.1	<b>Safety</b>				
3.1.1	<b>Botanical name</b> — The Latin (genus and species) of the plant species and family e.g. <i>Catharanthus roseus</i> (Apocynaceae), <i>Azadirachta indica</i> (Meliaceae) shall be provided. The local name of the plant should be supplied in addition to a herbarium specimen (Voucher number) verified by a recognized herbarium should be provided.	R	R	R	R
3.1.2	<b>Ethno-medical information (Literature search):</b> The applicant should provide proof of long period use by different communities including folklore, anthropological studies etc.	R	R	R	R
3.1.3	<b>Brief description of the living plant</b> — A brief description of the living plant, this may include photographs and/or drawings, general appearance and organoleptic properties	R	R	R	R
3.1.4	If the product has a long history of use without demonstrated harm, specific restrictive regulatory action is not necessary, unless new evidence indicates a need for a revised risk–benefit assessment	O	O	O	O
3.1.5	If there is a known toxicological risk, standard toxicological studies are mandatory. Data derived from such studies should be appropriately documented and submitted to the regulatory authorities. Toxicity data should be submitted if long-term traditional use cannot be documented or if there are doubts about safety.	R	R	R	R
4	<b>Evaluation of efficacy</b>				
4.1	If the use of a traditional medicine has not been documented, or in cases where a new medicine consists of traditionally-used plants for a new indication, appropriate clinical evidence of efficacy is required.	R	R	R	R

R = Required; G = General; O = Optional

**Annex A**  
(informative)

**Applicable international laws**

**Bibliography**

Scialabba, Nadia, Pacini, Cesare and Moller, Soren (2014), *Smallholder Ecologies*. Rome, Italy: Food and Agriculture Organization of the United Nations (FAO). available at <http://www.fao.org/3/a-i4196e.pdf> [18 February 2017].

