

VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS

Section II

GOVERNING STRUCTURE

1. SCOPE OF THIS DOCUMENT

This document explains the governing structure of the Voluntary Certification Scheme for AYUSH Products (also referred to as 'the Scheme') and the roles and responsibilities of various organizations and committees involved in operating the Scheme.

2. OBJECTIVE

The objective of this document is to clearly define the roles of various organizations/committees involved in the operation of the Scheme.

3. GOVERNING STRUCTURE

3.1 The governing structure of the Voluntary Certification Scheme for AYUSH Products shall have a Multi-Stakeholder Steering Committee (MSC) at the apex level supported by a Technical and a Certification Committee each with its secretariat in the Quality Council of India (referred to as QCI hereinafter)

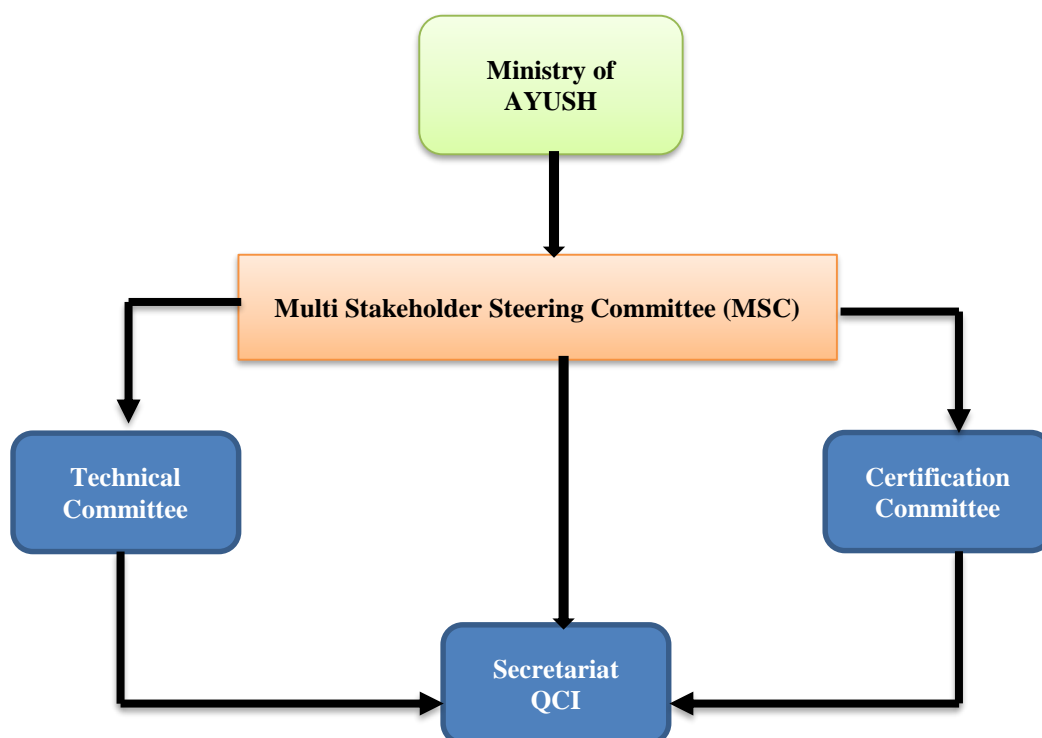
3.2 The governing structure is depicted schematically in Fig 1.

4. APPOINTMENT OF COMMITTEES – GENERAL RULES

In the appointment of various committees, the following general principles shall be kept in mind:

- a) representation of a balance of interests such that no single interest predominates.
- b) key interests to include: representatives of AYUSH industry associations, Certification Bodies, Testing Laboratories, Accreditation bodies, representatives of regulatory bodies or other governmental agencies, Academic / Research Bodies and representatives of non-governmental organizations.
- c) offer of membership to individual experts shall be made with great caution and only when a suitable person is not forthcoming as a representative of an organization
- d) except when a member is appointed in his capacity, a person vacates his membership on leaving his organization and a fresh nomination is sought from the member organization.
- e) the member organizations shall nominate a principal and an alternate representative on the committee(s).
- f) all committees shall be reconstituted every 2 years to provide representation to organizations like State Governments, Certification Bodies etc. by rotation, where necessary.

SECTION II: PADD: AYUSH MARK: GOVERNING STRUCTURE



5. MULTISTAKEHOLDER STEERING COMMITTEE (MSC)

5.1 Membership - The MSC shall comprise of the following;

- a) Secretary, Ministry of AYUSH - Chairperson;
- b) Central Government Ministries - One Representative each from the concerned Ministries – Ministry of Commerce, Ministry of Consumer Affairs, Ministry of Health, Ministry of Forests, MoEF & CC, and Ministry of AYUSH;
- c) Regulatory Bodies - Drugs Controller General of India
- d) Accreditation Bodies – One Representative each from NABCB and NABL;
- e) Industry Bodies – One industry body of each stream of AYUSH – Ayurveda, Unani, Siddha and Homeopathy
- f) State Governments – 3 (by rotation for 2 years);
- g) Testing Laboratories – 3 – One representative each from PLIM, HPL, and IIM, Jammu
- h) Certification Bodies – One representative from QCI accredited bodies (2 years by rotation)
- i) Research bodies – 2 (2 years by rotation)
- j) Chairman APC
- k) NMPB (2 years by rotation)
- l) Professional Bodies of practitioners of each discipline – One representative from each stream of AYUSH Practitioners
- m) Representative of the Drug Retail Trade Association
- n) Secretary General, QCI
- o) Any other Technical expert(s) as invitees for specific meetings, as identified by the Secretariat.

p) Secretariat – Quality Council of India

5.1.1 MSC may co-opt any other members.

5.2 Terms of reference - The MSC is responsible for ;

- a) Overall development, modification and supervision of the Scheme
- b) Receiving recommendations from the Technical/Certification Committees and deciding on them
- c) Constituting any committees, as needed

5.3 Meetings - The MSC shall meet at least once every year.

6 TECHNICAL COMMITTEE (TC)

6.1 Membership – The Technical Committee shall comprise of the following;

- a) Chairperson
- b) Central Council for Research in Ayurveda and Siddha
- c) Certification Body - One from those represented on the MSC
- d) Pharmacopeial Laboratory for Indian Medicines (PLIM)
- e) Industry Bodies - One of each stream of AYUSH
- f) Pharmexcil Export Promotion Council - One Representative
- g) Ministry of AYUSH - One Representative
- h) DCGI - One Representative
- i) Accreditation Bodies – One Representative each from NABCB and NABL
- j) Research body from MSC - One
- k) Secretariat – Quality Council of India

6.1.1 TC may coopt more members.

6.2 Terms of reference - The Technical Committee is responsible for

- a) Defining the certification criteria and resolving any related issues;
- b) Assisting the Certification Committee in finalizing the Internal Quality Assurance Protocol, for controlling the processes and production of AYUSH products.

6.3 Meetings - The TC shall meet at least once every year

7 CERTIFICATION COMMITTEE (CC)

7.1 Membership - The Certification Committee shall comprise of the following:

- a) Chairperson
- b) Ministry of AYUSH - One Representative
- c) Certification Body – 2 CBs by rotation
- d) Accreditation Boards – One Representative each from NABCB and NABL
- e) DCGI
- f) EIC
- g) Industry - One of each stream of AYUSH
- h) Pharmexcil
- i) PLIM

j) Secretariat – Quality Council of India

7.1.1 CC may coopt more members.

7.2 Terms of reference - The Certification Committee is responsible for

- a) Developing, maintaining and revising as appropriate the certification scheme
- b) Developing a guidance document to assist manufacturers in applying for Voluntary Certification for AYUSH Products.
- c) Developing, maintaining and revising as appropriate the requirements for certification bodies for the operation of the Voluntary Certification for AYUSH Products.
- d) Developing, maintaining and revising as appropriate the generic Internal Quality Assurance Protocol for controlling the processes and production of AYUSH products.
- e) Developing, maintaining and revising as appropriate the process for permitting certified units for use of Certification mark.
- f) Any other issue relating to certification

7.3 Meetings - The Certification Committee shall meet at least once every year.

8. ROLES OF ORGANIZATIONS

Ministry of AYUSH shall be the Scheme Owner and own the Certification Mark(s). It shall establish the MSC while the management of the Scheme shall be the responsibility of QCI.

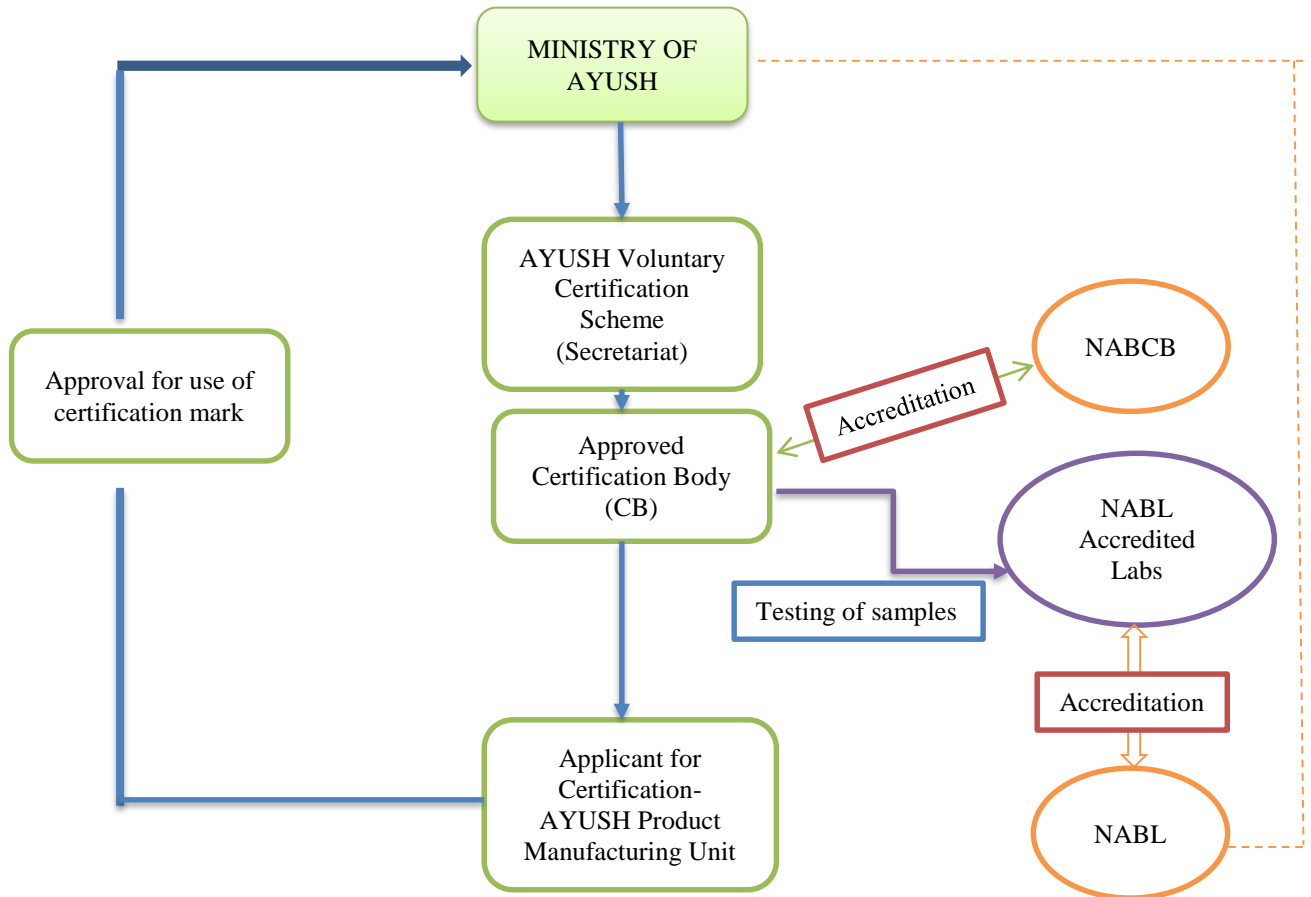
Quality Council of India (QCI) shall provide the secretariat to the Scheme and the MSC. It shall set up the Technical and Certification Committees and provide a secretariat to them. It shall also manage the Scheme on behalf of the Ministry of AYUSH.

National Accreditation Board for Certification Bodies (NABCB) shall be responsible for accrediting certification bodies desirous of participating in the Scheme to appropriate international standards

National Accreditation Board for Testing and Calibration Laboratories (NABL) shall be responsible for accrediting testing and calibration laboratories to appropriate international standards to support the Scheme.

9. The arrangements for the operation of the Voluntary certification for AYUSH Products are as outlined in Fig 2;

SECTION II: PADD: AYUSH MARK: GOVERNING STRUCTURE



10. COMPLAINTS

- 10.1** The system has provisions for entertaining complaints from any stakeholder against any component of the Scheme, the manufacturing units certified under the Scheme, the Certification Bodies approved under the Scheme, the laboratories utilized under the Scheme, and the accreditation bodies, NABCB/NABL, are all required to have a complaints system in place as per standards applicable to them. Anyone having a complaint is encouraged to utilize the available mechanisms.
- 10.2** Any complaint received directly by the Ministry of AYUSH shall be referred to QCI who in turn will reference to the appropriate body against which the complaint is made and monitor it till it is decided upon.
- 10.3** Any complaint received by QCI shall be similarly handled.
- 10.4** A statement on complaints as received above with their status shall be reported to the MSC in each meeting.

11. APPEALS

- 11.1** There are provisions for entertaining appeals from the manufacturing units certified/desirous of certification under the Scheme, the Certification Bodies approved under the Scheme, and the laboratories utilized under the Scheme, which can be utilized.
- 11.2** In case anyone aggrieved by the decision of the TC/CC appeals, it shall be handled by the MSC.
- 11.3** In case anyone is aggrieved by the decision of MSC appeals, the Chairperson, MSC shall appoint an independent appeals panel to look into the appeal and recommend action to him/her
- 11.4** In handling appeals, the broad principle that the appeal is handled independently of the personnel involved in the decision appealed against shall be maintained.
- 11.5** A statement of appeals received by the Ministry of AYUSH/QCI shall be placed before the MSC in each meeting.