VOLUNTARY CERTIFICATION SCHEME
FOR MEDICINAL PLANT PRODUCE

INTRODUCTION & GOVERNING STRUCTURE
INTRODUCTION

India is one of the richest countries in the world in terms of biodiversity, and has 15 agro-climatic zones. Out of the about 17000-18000 species of flowering plants, more than 7000 are estimated to have medicinal usage in folk and documented systems of medicine like Ayurveda, Unani, Siddha & Homoeopathy (AYUSH System of Medicine).

Medicinal plants are not only a major resource base for the traditional medicine & herbal industry but also provide livelihood and health security to a large segment of Indian population. About 1178 species of medicinal plants are estimated to be in trade of which 242 species have annual consumption levels in excess of 100 metric tons/year. The domestic demand of medicinal plants has been estimated 1,95,000 MT for the year of 2014-2015 and export demand of medicinal plants has been estimated 1,34,500 MT during 2014-2015. Total consumption of herbal raw drug in the country for the year 2014-15 has been estimated at 5,12,000 MT with corresponding trade value of ₹ 5,500 Crore. A major increase has been recorded in export value which has increased from ₹ 345.80 Crore in 2005-06 to ₹ 3211 Crore in 2014-15, registering a nine fold increase in during last decade.

In order to encourage good agricultural and field collection practices in medicinal plants (GAP and GFCP) and enhance quality and safety of these plants, the National Medicinal Plants Board (NMPB), in collaboration with the Quality Council of India (QCI), has launched a Voluntary Certification Scheme for Medicinal Plant Produce (VCSMPP). QCI will manage the day to day operation of the Scheme.

Based on international best practices, the Scheme is driven by a multi-stakeholder Steering Committee at the helm and has based its certification criteria on the WHO Guidelines for good agricultural and field collection practices. The system of certification is based on guidelines provided in the international standard, ISO 17067, which guides development of product certification schemes worldwide and the certification bodies approved under the Scheme would eventually be accredited as per international standard, ISO 17065, by the National Accreditation Board for Certification Bodies (NABCB), a constituent Board of QCI. Since NABCB has achieved international equivalence for its accreditation programme for product certification bodies by signing the multilateral mutual recognition arrangement of the International Accreditation Forum (IAF), which is increasingly forming the basis of free flow of goods among countries through bilateral or regional free trade agreements, it is expects to facilitate exports of India medicinal plants in the world market.

It is expected that the Scheme would benefit not only the cultivators or collector of herbs but also the AYUSH industry with supply of assured quality raw material, traders and other users of herbs, and ultimately the consumers of herbal based products.
SECTION II

VOLUNTARY CERTIFICATION SCHEME FOR MEDICINAL PLANT PRODUCE

GOVERNING STRUCTURE

1. SCOPE
This document explains the governing structure of the Voluntary Certification Scheme for Medicinal Plant Produce (hereinafter 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
The governing structure of Voluntary Certification Scheme for Medicinal Plant Produce shall have a multi-stakeholder Steering Committee (SC) with secretariat in the National Medicinal Plants Board (hereinafter referred to as NMPB) at the apex level supported by a Technical and a Certification Committee each with its secretariat in the Quality Council of India (hereinafter referred to as QCI).

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 medicinal plant growers' collectors' associations, ayurvedic and other user industry bodies, representatives of regulatory bodies or other governmental agencies, Academic/Research Bodies, Certification Bodies, Testing Laboratories, Accreditation 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 personal capacity, a person vacates his membership on leaving his organization and a fresh nomination is sought from the nominating authority.

e) the member organizations shall nominate a principal and an alternate representative on the committee(s) to maintain continuity. Both members can attend any meeting.
f) the tenure of a committee shall be 3 years after which it may be reconstituted especially to provide representation by rotation to interests where there may be several representative bodies like state governments, certification bodies etc.

5. STEERING COMMITTEE (SC)

5.1 Membership - The SC shall comprise of the following;

a) Secretary, Ministry of AYUSH - Chairperson
b) Representative of Department of Agriculture & Co-operation - Member
c) Representative of Ministry of Environment & Forest - Member
d) Representative of Department of Commerce- Member
e) Representative of Ministry of AYUSH - Member
f) Drugs Controller General of India or his representative
g) Representatives of state governments (state medicinal plants boards) – 3 at a time by rotation
h) Representatives of growers’/collectors’ – one each
i) Representatives of user industry bodies – ADMA, AMAM, Cosmetics manufacturers association, any others concerned
j) Representative of CSIR-Member
k) Representative of ICAR-Member
l) Representatives from NABCB/NABL-Members
m) Representative of approved Certification Bodies – 2 at a time by rotation
n) Representative of labs – PLIM, IIM
o) Representative of Quality Council of India- Member
p) Chief Executive Officer, NMPB- Member Secretary .

5.1.1 SC may coopt any other members.

5.2 Quorum - The presence in person, at a meeting of the Steering Committee (SC) of the representatives of at least 5 members shall constitute a quorum for a meeting.

5.3 Terms of reference - The MSC is responsible for;

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

5.4 Meetings - The SC shall meet at least once every year.
6 TECHNICAL COMMITTEE (TC)

6.1 Membership – The Technical Committee shall comprise of following:
   Chairman (by name – to be appointed)
   Representative of Ministry of AYUSH
   Representative of CIMAP, Lucknow
   Representatives of ADMA/AMAM
   Representative of One approved CB by rotation.
   Representatives of Medicinal Plants Growers Association – 2
   Experts in Individual capacity
   NMPB
   Member Secretary - Representative from Quality Council of India

6.1.1 TC may coopt more members.

6.2 Quorum -- The presence in person, at a meeting of the Technical Committee of at
   least 2 members other than the Chairman and Member Secretary shall constitute a
   quorum for a meeting.

6.3 Terms of reference - The Technical Committee is responsible for
   a) Defining the certification criteria for the Scheme
   b) Developing any standards or technical documents needed for certification.
   c) Resolving any technical/related issues

6.4 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) Chairman (to be appointed by name)
   b) Representative of Ministry of AYUSH
   c) Representative of NMPB
   d) Representative of Growers/Collectors’ associations – one each from the SC
   e) Representative of Certification Bodies - One from the SC
   f) Representatives of Accreditation Bodies – One Representative each from NABCB
      and NABL
   g) Representative of DCGI
   h) Representative of User Industry (ADMA/AMAM)
   i) PLIM
   j) Member Secretary – Quality Council of India

7.1.1 CC may coopt more members.
7.2 Quorum - The presence in person, at a meeting of the Certification Committee of at least 2 members other than the Chairman and Member Secretary shall constitute a quorum for a meeting.

7.3 Terms of reference - The Certification Committee shall be responsible for
a) Developing, maintaining and revising as appropriate the certification scheme
b) Designing the Certification Marks
c) Developing any guidance document to assist growers/collectors to apply for certification
d) Developing, maintaining and revising as appropriate the requirements for certification bodies for the operation of the Voluntary Certification
e) Developing, maintaining and revising as appropriate the process for permitting certified entities for use of Certification mark.
f) Any other issue relating to certification

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

8. ROLES OF ORGANIZATIONS

National Medicinal Plant Board under the Ministry of Ayush shall be the Scheme Owner jointly with QCI.

Quality Council of India (QCI) shall be the joint Scheme owner and provide the secretariat for the Scheme and own the Certification Mark(s)/logo(s)

National Accreditation Board for Certification Bodies (NABC) 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 laboratories to appropriate international standards to support the Scheme.

9. COMPLAINTS

9.1 The entire 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, NABC/NABL, are all required to have a complaints system in place as per standards applicable to them. Anyone having a complaint is encouraged to utilise the available mechanisms.

9.2 Any complaint received directly by the National Medicinal Plant Board shall be referred to QCI who in turn will make a reference to the appropriate body against which the complaint is made and monitor it till it is decided upon.

9.3 Any complaint received by QCI shall be similarly handled.

9.4 A statement on complaints as received above with their status shall be reported to the SC in each meeting
10. APPEALS

10.1 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 shall invariably be utilized.

10.2 In case any one aggrieved by the decision of the TC/CC appeals, it shall be handled by the SC.

10.3 In case any one aggrieved by the decision of SC appeals, the Chairperson, SC shall appoint an independent appeals panel to look into the appeal and recommend action to him/her.

10.4 In handling appeals, the broad principle that the appeal is handled independently of the personnel involved in the decision appealed against shall be maintained.

10.5 A statement of appeals received by the NMPB/QCI shall be placed before the SC in each meeting.