

ACCREDITATION AND CERTIFICATION FOR AYURVEDIC MEDICINES IN INDIA

ANIL JAUHRI
DIRECTOR

**NATIONAL ACCREDITATION BOARD FOR
CERTIFICATION BODIES (NABCB)
QUALITY COUNCIL OF INDIA**

AYURVEDA - ORIGIN

- ✘ Ancient scriptures called Vedas
- ✘ RIGVEDA - First and oldest Veda
- ✘ SAMAVEDA - Rigveda contents put to a more musical chant.
- ✘ YAJURVEDA - Deals with yogic rituals and methods for purifying the mind and awakening consciousness.
- ✘ ATHARVAVEDA - Last and latest of Vedas from which developed the AYURVEDA – Upaveda of Atharvaveda - Ancient Knowledge - 5,000 years old - Charak and Susruta tradition of Ayurvedic medicine and surgery

AYURVEDA

Ayurveda = Ayus + Veda

meaning

‘Knowledge concerning maintenance of Life’

Emphasis on:

- ✘ Promotion and protection of health in healthy individuals
- ✘ Treatment of diseases in afflicted

SYSTEMIZATION OF AYURVEDA

- ✘ Beginning of the 20th century lead to:
 - Efforts to develop the teachings and research in Ayurveda
 - Surviving the test of the time, Ayurveda has emerged as the first integrated holistic complementary health system

AYURVEDA IN INDIA

- ✘ 250 universities teaching ayurveda
- ✘ Approx. 350,000 registered ayurvedic practitioners
- ✘ About 1000 Ayurvedic hospitals and research centres
- ✘ About 9,000 ayurvedic manufacturing and pharmaceutical units

REGULATORY SCENE

- ✘ Drugs governed by regulations – Drugs and Cosmetics Act, 1940
- ✘ Ayurvedic and other Indian systems of medicine added in 1964
- ✘ Authoritative texts listed in Schedule 1
- ✘ Standards including permissible level of contaminants as per Ayurvedic Pharmacopoeia of India
- ✘ GMP as per Schedule T for manufacturing

WHY VOLUNTARY CERTIFICATION

- ✘ Meeting in Dec, 2008 in the Ministry of Health, Govt of India for consultation with Quality Council of India (QCI) (parent of NABCB) and BIS, national standards body
 - Enhance consumer confidence
 - Promote regulatory compliance
 - International acceptance

DEVELOPMENT OF SCHEME

- ✘ QCI offer to develop Scheme - Concept Paper submitted Apr 2009
- ✘ Formal MoU signed July 2009 – one time grant by Govt.
- ✘ Department of AYUSH and QCI to be Joint Scheme Owners – QCI to provide secretariat and manage the Scheme
- ✘ Draft Scheme designed – Aug 2009 – public consultation
- ✘ Industry consultation –Aug 2009 - Mumbai

GOVERNING STRUCTURE

- ✘ Multistakeholder steering committee (MSC) in line with international practice – set up by Deptt of AYUSH - Secretary (AYUSH) Chair
- ✘ Technical and Certification Committees set up by QCI
- ✘ Meetings of TC & CC to consider comments – 25 Sept 2009
- ✘ MSC meeting – 14 Oct 2009

ELEMENTS OF SCHEME

- ✘ Certification Criteria or Standards
- ✘ Certification Process
- ✘ Internal Quality Assurance Protocol for units to follow – self certification
- ✘ Requirements for Certification Bodies (CBs)
- ✘ Approval of CBs
- ✘ Rules for use of Certification Mark

CERTIFICATION CRITERIA

- ✘ Domestic regulation - regulatory requirements prescribed under the Drugs and Cosmetics Act, 1940 for AYUSH products
- ✘ GMP Requirements based on WHO Guidelines for Ayush Products
- ✘ Permissible levels of contaminants
- ✘ Regulations of importing countries – to be identified by the organization seeking certification and provided to the Certification Body

LEVELS OF CERTIFICATION

- × Certification at two levels
 - + **Ayush Standard Mark** compliance to the domestic regulatory requirements
 - + **Ayush Premium Mark**
 - + **Option A:** Compliance to the GMP Requirements based on WHO Guidelines and Levels of contaminants as given in Certification Criteria document .
 - + **Option B:** Compliance to regulatory requirements of any importing country provided these are more stringent than Option A above.

CERTIFICATION PROCESS

- ✘ Registration of Application – separate certification for each premises – any number of products
- ✘ Initial Evaluation
 - + Single stage evaluation for Std Mark - two stage evaluation for Premium mark
 - + Testing of samples
 - + Factory and independent testing
 - + Use of NABL accredited laboratories
- ✘ Internal quality assurance protocol – to be followed by each certified unit – self certification
- ✘ Grant of certificate valid for 3 years
 - + NABCB accredited certification bodies
- ✘ Surveillance
 - + Evaluation every 6 months – flexibility to increase or decrease based on performance in each certification cycle
 - + Market samples

CERTIFICATION BODIES

- ✘ Accredited as per international standards – ISO Guide 65 - by NABCB
- ✘ Requirements under the Scheme — beyond international standards
- ✘ E.g. publicly available information, mandays to be spent, competence of evaluators
- ✘ Approval under the scheme – simple process – formal agreement with QCI
- ✘ 2 CBS approved – Foodcert India, BVCI

MEDICINAL PLANTS

- ✘ National Medicinal Plants Board (NMPB) initiative – MoU with QCI
- ✘ Steering Committee under Secretary AYUSH
- ✘ Technical Committee
- ✘ GAP and GCP standards finalized and available
- ✘ Certification Process
- ✘ Scheme announced Apr 2011

INTERNATIONAL ACCEPTABILITY

- ✘ Design of Scheme to promote international acceptability
- ✘ Multistakeholder oversight
- ✘ Certification criteria – development process follows international best practice – public comment period – multistakeholder – requirements aligned with international norms
- ✘ Certification bodies – to meet applicable international standard – ISO Guide 65
- ✘ Labs – to meet ISO 17025
- ✘ National accreditation bodies – NABCB and NABL

GOALS

- ✘ Enhance consumer confidence – quality mark on products
- ✘ Improve compliance to regulations – considered low currently especially to Schedule T GMP
- ✘ Product differentiation – claim world class – choice to consumer
- ✘ International acceptance – Premium mark – G-2-G dialogue and agreements

CHALLENGES

- ✘ Incentivization – industry to feel it provides tangible benefits
- ✘ Consumer pressure – demand for the Marks
- ✘ Capacity building
- ✘ International recognition – dialogues with overseas regulators

CONTACT

Quality Council of India
2nd Floor, Institution of Engineers Building
2, Bahadur Shah Zafar Marg
New Delhi - 110002
INDIA

Tel : +91-11-23379321/9260/8057

Fax : +91-11-23378678

Email : info@qcin.org,

Website : www.qcin.org

.

THANK YOU