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AYUSH MARK(S): INITIATIVE FOR ENHANCING CONSUMER CONFIDENCE AND EXPORT POTENTIAL OF AYUSH PRODUCTS

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ABSTRACT

Ayush Standard Mark and Ayush Premium Mark are the certification marks for the products of Indian System of Medicine called AYUSH products. AYUSH marks are awarded under the scheme of Voluntary Certification Scheme For Ayush Products (VCSAP) after quality evaluation according to Quality Council of India (QCI) norms by an approved certification body (CB). The CB is accredited to appropriate international standards by the National Accreditation Board For Certification Bodies (NABCB). The criteria for Ayush Standard Mark is compliance to the domestic regulatory requirements where as for Ayush Premium Mark is compliance to WHO-GMP requirements with flexibility to certify against any overseas regulation provided these are stricter than the former criteria. The aim of this certification scheme is to enhance consumer confidence and export potential of AYUSH products. AYUSH marks on the product gives visual assessment tool regarding quality of product. The scheme is recognized by various sates governments.

Keywords: Ayush Premium Mark, Ayush Standard Mark, AYUSH, Certification Body, QCI.

INTRODUCTION

The interest for traditional medicines is increasing throughout the world. India has the unique distinction of having six recognized systems under this category namely Ayurveda, Siddha, Unani and Yoga, Naturopathy and Homoeopathy. However, India is unable to take full advantage of these at international platform due to qualitative competition. Ayush Mark is an initiative undertaken by AYUSH Ministry to voluntarily certify the quality of Indian Traditional Medicines to enhance the consumer confidence and to improve the export potential. AYUSH marks are awarded under scheme named Voluntary Certification Scheme For Ayush Products (VCSAP).

VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS (VCSAP)

The matter of VCSAP was discussed in a series of meetings taken by the secretary (AYUSH) beginning 24 Dec 2008. Department of AYUSH signed an agreement with the QCI (Quality Council of India) on 27 July 2009 to design the scheme. The draft scheme was given to the Department of AYUSH on 3 Aug 2009 and simultaneously placed on the websites of Department of AYUSH and QCI for public consulta-

tion. The scheme will be overseen by a Multistakeholder Steering Committee (MSC) chaired by the secretary (AYUSH) with secretariat in QCI. The MSC will be supported by a Technical Committee and a Certification Committee constituted by QCI. The scheme is based on criteria for certification. The Department of AYUSH (now Ministry of AYUSH) itself is not involved in the certification process. AYUSH is the owner of the certification scheme, certification criteria and the certification mark(s), QCI is responsible for managing the scheme. Certification is operated by independent body called product Certification Bodies (CB).

CERTIFICATION BODY (CB)

Under VCSAP scheme, each manufacturing unit would obtain a certification from an approved certification body (CB) accredited to appropriate international standards by the National Accreditation Board For Certification Bodies (NABCB) and will be under regular surveillance of the certification body. The Certification Body shall be registered as a legal entity in India, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its certification activities. The certification body shall be responsible for and shall retain authority for its decisions relating to certification. The certification body shall have top management commitment to impartiality. The certification body and any group within its control or personnel employed or contracted, in an organization within its control shall not offer or provide training on the product that it certifies. The certification body is allowed to explain its findings and/or clarify the requirements of the normative documents but shall not give prescriptive advice or consultancy as part of an evaluation. The CB shall document how they manage their certification business and any other activities so as to eliminate actual conflict of interest and minimize any identified risk to impartiality.

Any certification body interested in the accreditation of NABCB for the purpose of AYUSH products certification may apply to NABCB. New certification body shall send an application using NABCB format BCB:F (PCB) 001. Already accredited CB for product certification shall send a request for scope extension on its letterhead.

PROCESS FOR OBTAINING AYUSH MARK(S)

Planning, Preparation and Self-Assessment by Organization

The Scheme of VCSAP is based on criteria for certification. It has two levels: Ayush Standard Mark and Ayush Premium Mark. The former is based on compliance to the domestic regulatory requirements where as the later is based on GMP requirements based on WHO Guidelines and product requirements with flexibility to certify against any overseas regulation provided these are stricter than the former criteria. Obtaining certification against the certification criteria represents a challenge to manufacturers of Ayush products. It is therefore essential that the organizations interested in obtaining this certification consider carefully- what Ayush Certification they wish to achieve and identify the criteria for that. Review your current systems and practices against the requirements of the latest relevant certification criteria. Identify areas which need to be addressed and ascertain compliance prior to applying for product certification. Confirm that your production facility has been in production for at least one year. Verify that five commercial batches of the products of dosage form for which certification is being planned to be sought, have been manufactured during the current licensed period. In addition to physiochemical parameters, the product should comply limit tests for heavy metals, aflatoxins, heavy metals and microbial contaminations. The elements of the certification process are evaluation of the manufacturing facility for manufacturing and hygiene processes, and capability to manufacture Ayush products of a desired quality on a continuous basis, as well as evaluation of the quality of the Ayush product(s) for compliance to relevant certification criteria through testing of products sampled from the manufacturing facility and the market or any other source.

Application and Registration

Select an approved CB, by considering the range of products covered under the scope of accreditation of the CB. The CB will require details of your site, operations, products and relevant certification criteria on

a prescribed Application form. Information are required such as the name and address of applicant with contact details, proof of legal entity, location of manufacturing unit, products being manufactured, products and dosage form for which certification is being sought, relevant certification criteria against which certification is being sought, description of production processes, own installed/existing manufacturing and testing facilities, number of shifts of operation, number and competence of manpower, and accessibility to external testing facilities, if required. Once the application is found to be complete, it shall be registered by the CB. Registration shall be done within seven days of receipt of application or deficiencies communicated.

Evaluation by CB

The CB will carry out the evaluation in one stage for Ayush Standard Mark and in two stages for Ayush Premium Mark. It is important that the facility is in production at the time of the evaluation. During the stage 1 evaluation, state of preparedness, status of GMPs and availability of competent personnel and equipment for production and testing will be assessed for their adequacy. At the end of stage 1 evaluation the CB will inform the applicant in writing about the deficiencies observed, if any, with respect to the certification criteria. Take necessary actions and inform the CB as soon as possible but not later than 3 months of the stage 1 evaluation. Delays beyond this will lead to another stage 1 evaluation. The CB will undertake the stage 2 evaluation only after you have confirmed that necessary actions on the identified shortfalls have been taken. For the stage 2 evaluation the CB will visit the facility and evaluate the process and controls being implemented, the prevailing hygienic conditions, the testing facilities and the competence of the personnel for compliance to the certification criteria. The CB will draw samples of products from stocks that are representative of normal production capacities of the facility, and have the same tested in an independent laboratory accredited by NABL, for compliance to the certification criteria.

Follow up and Corrective actions

At the end of stage 2 evaluation, the CB will inform the applicant in writing of the deviations observed, if any, with respect to the certification criteria. Take necessary actions and inform the CB as soon as possible. If you do not show progress towards completion of corrective actions within three months of Initial Evaluation your application shall be closed. The corrective actions can be verified through documented evidence, site visit or fresh sampling as required.

Decision and Issue of Certificate

The certification process should be completed within 12 months of the registration of the application. The CB will review the onsite stage 1 (if applicable) and stage 2 evaluation reports, corrective action documentation provided by the applicant and verified if so required by the evaluation team, and the independent test report(s) in order to make a certification decision. The decision for certification will be taken only when all requirements of the scheme have been complied with. The certificate should be issued within 7 days of the certification decision. The CB immediately informs the QCI about the grant of product certification. The certificate shall be awarded for fixed time tenure of 3 years, during which your operations and the products will be subjected to surveillance evaluations and testing, and beyond the 3 years period of validity the certificate will be renewed subject to ongoing compliance. The CB issues a certificate to the manufacturer indicating that the requirements of the certification scheme have been met with and that the products conform to the relevant certification criteria. The name of the manufacturer with address of site, names of products, and the relevant certification criteria are clearly mentioned on the certificate, along with effective date of certificate, validity of the certificate, name and address of the CB and applicable logos.

Agreement, Maintaining and usage of Ayush Certification Mark(s)

The Ayush Certification Mark(s) is owned by the Department of Ayush and provided on its behalf to the certified unit. Enter into a legally enforceable agreement with QCI authorizing you to affix the certification mark on the products for which you have been certified. The Ayush Certification Mark(s) is for use

only by organisations that have achieved product certification. The labelling of product is to be done as per regulatory requirements. The Ayush Certification Mark(s) is to be affixed on the product and its packaging to depict product conformity to requirements of the Ayush certification criteria. The Ayush Certification Mark(s) shall be affixed only on products conforming to relevant certification criteria, and non conforming products shall not to be marked with Ayush Certification Mark(s). The Ayush Certification Mark(s) can be used on all the manufacturing unit's communication tools such as company vehicles, letterheads, compliment slips, business cards, marketing collateral, advertising, exhibition graphics, and electronic media. Misuse of the Ayush Certification Mark(s) would invite actions including rejection of application or suspension/cancellation of certification.

ADVANTAGES AND RECOGNISATION OF AYUSH MARKS

AYUSH marks on the product gives a visual assessment tool regarding quality of product and is helpful to guide consumers to your product. The presence AYUSH mark on the product is a symbol of trust nationally and internationally. The quality marks enhances the reputation and name of the establishment locally, regionally and internationally. It provides a base for COPP (certificate of Pharmaceutical Products) for Ayurveda, Siddha, Unani and Homoeopathy Products issued by DCI (Drug Controller General). Ayush Mark is meant in-lined with the international norms such as those set by WHO, or Regulations of EC (European Commission), USA & other Countries. For AYUSH marks, certification is operated by independent Certification Bodies duly accredited by NABCB and/or recommended by QCI. The quality indirectly is controlled & measured by QCI (Quality Council of India). It's a product approval & it certifies the quality and performance of the product. The Scheme has been recognized by Ministry of AYUSH, Governments of Haryana, Gujarat, Uttar Pradesh, Orrisa and Rajasthan in different schemes.

DISCUSSION

Regardless of why an individual uses it, traditional and alternative medicine provides an important health care service to persons. India has the unique distinction of having six recognized systems (AYUSH) under this category namely Ayurveda, Yoga, Unani, Siddha, Homoeopathy, and Naturopathy. The Ayush products are regulated under the Drugs and Cosmetics Act, 1940 by the Drugs Controller General of India through the State Governments. However, India is unable to take full advantage of these at international platform due to qualitative competition. The Department of AYUSH has been exploring the possibility of introducing a voluntary product certification scheme for selected AYUSH products to enhance consumer confidence. For this, the Quality Council of India (QCI) drafted scheme called Voluntary Certification Scheme for Ayush Products (VCSAP). The Scheme is based on criteria for certification. It has two levels: Ayush Standard Mark which is based on compliance to the domestic regulatory requirements and Ayush Premium Mark which is based on GMP requirements based on WHO Guidelines and product requirements with flexibility to certify against any overseas regulation provided these are stricter than the former criteria. Under this scheme, each manufacturing unit would obtain a certification from a approved certification body (CB) which is accredited to appropriate international standards by the National Accreditation Board For Certification Bodies (NABCB) and will be under regular surveillance of the certification body. AYUSH is the owner of the Certification Scheme, Certification Criteria and the Certification Mark(s) QCI is responsible for managing the scheme. Certification is operated by product Certification Bodies (CB). The elements of the certification process are compliance to the certification criteria, onsite evaluation of the manufacturing facility, processes, and capability, analysis of samples from the manufacturing facility and the market or any other source by independent laboratory accredited by NABL. The Ayush Certification Mark(s) is owned by the AYUSH and provided on its behalf to the certified unit. Enter into a legally enforceable agreement with QCI authorizing you to affix the Certification Mark on the products for which

you have been certified. AYUSH marks on the product gives a visual assessment tool regarding quality of product, a symbol of trust nationally and internationally, reputation and name of the establishment locally, regionally and internationally and finally a base for COPP (certificate of Pharmaceutical Products) for Ayurveda, Siddha, Unani and Homoeopathy Products issued by DCI (Drug Controller General). The certification mark(s) have gained recognition in government of various states. As discussed the scheme is actually an initiative taken by AYUSH for enhancing the consumer confidence and to improve the export potential. The turn is manufacturer how they benefit from the scheme. Ayurvedic Manufactures have benefited for this voluntary scheme, but the response from other system Indian medicine is not enhancing.

CONCLUSIONS

AYUSH Marks are certification marks for products of Indian System of Medicine. Like other quality marks, they are the visual indication for additional quality standards. AYUSH Mark (s) are awarded after quality evaluation according to QCI norms. Ultimately AYUSH Mark(s) are meant to enhance consumer confidence. Currently there are two levels of Ayush Mark (s) i.e. Ayush Standard Mark – for products of domestic market & Ayush Premium Mark – for products of international market. AYUSH marks are awarded under scheme named Voluntary Certification Scheme for Ayush Products (VCSAP). AYUSH is the owner of the Certification Scheme, Certification Criteria and the Certification Mark (s), QCI is responsible for managing the scheme and certification is operated by independent body called product Certification Bodies (CB).

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