

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:1493
ANSWERED ON:05.03.2010
AYURVEDIC DRUGS
Reddy Shri K. Jayasurya Prakash

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government has set up industrial clusters with the common testing facilities for the manufacturing of ayurvedic drugs more scientifically;
- (b) if so, the details thereof;
- (c) the amount allocated for each cluster and the details of the guidelines issued in this regard;
- (d) whether the Government has also launched Golden Triangle Partnership Scheme for the scientific validation of ayurvedic products; and
- (e) if so, the details and the objectives of this scheme and the benefits accrued therefrom?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI S. GANDHISELVAN)

(a) to (c) Yes. So far 6 clusters have been set up:

S.No Name of the Clusters Amount Allocated Amount Released so far.

1. CARE Keralam Ltd., Rs. 10.00 Crore 2.00 Crore
Thrissur, Kerala

2. Herbal Health Rs. 10.00 Crore Rs. 2.00 Crore
Research Consortium
Pvt Ltd., Amritsar,
Punjab

3. Konkan Ayur Pharma Rs. 7.48 Crore Rs. 1.50 Crore
Ltd., Sangameshwar,
Maharashtra

4. Maharashtra AYUSH Rs. 9.49 Crore Rs. 2.00 Crore
Cluster Pvt. Ltd.,
Pune, Maharashtra

5. Ayurvpark Healthcare Rs. 10.00 Crore Rs. 2.00 Crore
Ltd., Bangalore,

6. Traditional AYUSH Rs. 9.65 Crore Rs. 2.00 Crore
Cluster of Tamilnadu
Pvt Ltd., Chennai

The detailed guidelines issued in this regard is annexed.

(d) Yes.

(e) The Golden Triangle Partnership(GTP) scheme is being implemented through research councils i.e. Central Council for Research in Ayurveda Siddha (CCRAS), Central Council for Research in Unani medicine, (CCRUM), Central Council for Research in Homoeopathy (CCRH), Council of Scientific and Industrial Research (CSIR) and Indian Council of Medical Research (ICMR) for scientific validation of Ayurveda, Siddha and Unani products. Following are the objectives of GTP:-

1. To bring safe, effective and standardized ASHU (Ayurveda, Siddha, Homoeopathy & Unani) products for the identified disease conditions;
2. To develop new Ayurvedic/Siddha/Unani/ Homeopathic products effective in the disease conditions of national/global importance. Products should be better than the available products in the market for such disease conditions;
3. The criteria will be to have best quality, safe and effective products. Mechanism will be evolved to make products affordable for the domestic market;
4. To utilize appropriate technologies for development of single and poly-herbal products to make it globally acceptable;
5. To promote collaborative research on AYUSH with modern medicine/modern science institutions.

Under the GTP scheme the following 9 disease conditions have been identified for further research on priority basis:

- i) Mutra vikara
- ii) Sleep disorders
- iii) Rasayana
- iv) Joint disorders
- v) Cardiac disorders
- vi) HIV/AIDS
- vii) Malaria
- viii) Menopausal syndrome
- ix) Ayurveda & Genomics

CCRAS has also identified 38 formulations for the above disease conditions. Further, scientific research is in progress in collaboration with CSIR & ICMR.

SCHEME FOR DEVELOPMENT OF AYUSH CLUSTERS

(1) Background

(a) The Ayurveda, Yoga and Naturopathy, Unani, Sidha & Homeopathy (AYUSH) industry represents the traditional form of Indian medicine, and has been part of India's socio- cultural heritage. The industry, that has approximate annual turnover of Rs. 5000 Crore is essentially dominated by micro, small and medium enterprises (MSMEs) which account for more than 80% of the enterprises that are located in identifiable geographical clusters

(b) The market for traditional health medicine has been increasing steadily, the world over. Although AYUSH industry has been one of the most traditional form of medicine, it has not been able to exploit the emerging market opportunities, primarily due to constraints such as: fragmentation of the industry, lack of standardization of raw material and the finished products, inadequate R&D, slow pace of modernization of production processes and technology, absence of focused marketing and branding, inadequate emphasis on HRD and others due to which AYUSH Sciences are not recognized as Medical & Health Care Sciences

(c) AYUSH industry has the potential to contribute positively to national health programme by providing traditionally and historically proven healthcare solutions

(d) Cluster based approach is increasingly being recognized as an effective and sustainable strategy for competitiveness enhancement of MSMEs. Such an approach, which leverages the geographical proximity of the enterprises on 'collaborating while competing' principle is participatory, cost effective and provides critical mass for customization of interventions

(e) It is in this context that this scheme for AYUSH clusters' development is being implemented during the XI Five Year Plan

(2) The Scheme

(a) The Scheme termed as 'Scheme for Development of AYUSH Clusters', is a Central Sector Scheme and would be co-terminus with the 11th Five year plan

(b) Department of AYUSH would allocate Rs 100 Crores in the 11th five year plan to fund the pilot projects under the scheme

(c) The Scheme would be implemented on a Public Private Partnership (PPP) format. Support from Department of AYUSH would be by the way of grant to the Special Purpose Vehicle (SPV), formed by group of entrepreneurs from AYUSH sector

(d) The assistance would be restricted to 60 % of the Project Cost subject to a maximum of Rs 10.00 crores. The remaining 40% would be required to be arranged by the SPV through equity, borrowings from Banks / Financial Institutions and other sources

(3) Objectives of the scheme:

(a) To fill in the critical gaps in the sector especially related to standardization, quality assurance and control, productivity, marketing, infrastructure and capacity building through a cluster based approach

(b) To encourage the level of organisation in the sector thereby creating social capital for sustainability of collective initiatives

(4) Eligibility, Scope and Coverage

(a) The assistance under the scheme would be available to units operating in the following sectors; located in existing clusters:

(i) Ayurveda

(ii) Sidha

(iii) Unani

(iv) Homeopathy

(v) Yoga and naturopathy

(b) SPV formed by at least 15 enterprises located in an existing cluster shall be eligible for funding under the scheme

(c) The assistance under scheme would be available for a project, prepared for development of a cluster in general, covering the following two sets of interventions:

(i) Core Interventions such as those related to setting up of common facilities for testing, certification, standardization, quality control and other capacity building measures

(ii) Add On Interventions such as those related to marketing/ branding, provision of general infrastructure to support production units etc.

(d) The project proposed for funding under the scheme shall necessarily have at least one testing laboratory as part of core interventions that is useful to the cluster in general, in addition to the other interventions

(e) These interventions are indicative in nature and the project may cover any of the other felt needs of the cluster (as approved by SMC), that will enable the cluster enterprises in improving their competitiveness

(f) The interventions proposed to be taken up under the project shall benefit a significant number of enterprises in the cluster

(g) The SMC may consider relaxing the above conditions depending upon the merit of the project on case to case basis

(5) List of eligible interventions under the scheme

(a) Core Interventions

a. First Level Processing facilities such as cleaning, drying, sorting, storing, extracting, packaging etc

b. Testing facilities such as Analytical Lab, Toxicology Centre, Process & Product Validation Laboratory, Raw Material Testing, Standardisation laboratory etc which will enable better Quality Assurance & Control

- c. Facilities for Tableting, Capsulation, Packaging and Labeling
- d. Product Display Centre
- e. Quality and productivity improvement
- f. Standardisation of raw materials and finished products
- g. Development of references and standards
- h. Adoption of new technologies and processes
- i. Application of ERP and other IT tools
- j. Assistance for ISO, WHO cGMP, GLP, US FDA, EU GMP, Australian TGA and other standards and Compliances
- k. Development of Drug Master File for the purpose of registration with regulatory bodies overseas
- l. Studies/ surveys
- m. Preparation of DPRs
- n. Sensitisation/ Awareness creation/ Skill development

Entrepreneurial Level

Managerial Level

Worker Level

- o. Setting up subcontracting exchange
 - p. Hiring of Cluster Development Executives (CDEs)
- (b) Add On Interventions
- a. Common Marketing Brochure
 - b. Common Website
 - c. Joint Participation in National and International Exhibitions
 - d. Business Delegations Abroad
 - e. Brand development and promotion
 - f. Infrastructure to support the production units such as water supply, roads, sewerage, effluent treatment, power supply, boundary wall etc
- (i) Any proposal prepared under the scheme should necessarily have a testing laboratory while other interventions are optional and need based
- (ii) The project cost of the components of a common facility (such as those mentioned under core interventions), for the purpose of this Scheme, shall include Land, Building, Plant and machinery, Support infrastructure such as water supply, electricity supply, roads etc subject to the condition that it shall be the responsibility of the SPV to bring in land as its contribution
- (iii) While the funding under the scheme is generally for development of Greenfield facilities, SMC may also consider the proposal of SPV for upgrading/ strengthening of any existing facility into a common facility based on the merit of such proposal
- (iv) The cost of professional experts engaged by SPV to avail of the services as listed above will become part of the project cost eligible for funding under the scheme
- (v) The cost incurred by SPV in hiring professional experts/ agencies for providing above services, expenses incurred on trainers fee, logistics of trainers, training material, exposure visits, IT support for SPV, salary of CDE (Cluster development executive), Resource centre, designing and printing of brochure, stall space rent, design and hosting of website, cost of hiring PR Agency, advertising and promotion etc are the components eligible for funding under the scheme
- (vi) The interventions listed above are indicative in nature, any other need based intervention subject to approval by the SMC is eligible to be funded under the scheme. Nature of such an intervention, whether core or add on would be decided by the SMC

(6) Financial Assistance

- (a) Each of the cluster development projects proposed to be implemented by a Special Purpose Vehicle (SPV) representing at least

15 AYUSH manufacturing enterprises in a cluster shall be eligible for grant funding under the scheme upto 60% of cost of the core interventions, 25 % of the cost of add on interventions, within overall ambit of 60% of the project cost subject to maximum of Rs.10.00 crore per cluster. The assistance is further subject to the following:

- (i) Assistance for engagement of CDEs and other management support of SPV shall not exceed 5% of the overall project cost
 - (ii) Assistance for engaging engineers/ architects/ construction management/ other experts for execution of civil works shall not exceed 5% of the overall project cost
- (b) Project cost for the purpose of the scheme shall mean the total cost of proposed interventions as mentioned in Section 5
- (c) The scheme would be modular in nature with a provision to add interventions to the approved project DPR while implementation is on. The addition however should be in conformity to the over all project and the scheme objectives and subject to approval by SMC
- (d) SPVs may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. However, in cases of such dovetailing, it shall be ensured that the contribution of the participating units of SPV is atleast 10% of the overall project cost

(7) Time Frame

- (a) The timeframe for implementation of the project is 3 years from the date of approval

(8) Implementation framework

(a) Scheme Monitoring Committee (SMC)

(i) The Department of AYUSH will be the coordinating department providing overall policy, coordination and management support to the Scheme. A Scheme Monitoring Committee (SMC) will be constituted under the Chairmanship of Secretary (Department of AYUSH). The constitution of the committee is detailed in Annexure I

(ii) The SMC may induct representatives of industry associations, R&D institutions and other private sector expert organisations as members or special invitees

(iii) The SMC without affecting the basic objectives and structure of the Scheme may make intrasectoral adjustments of activities and corresponding allocation of funds

(iv) The SMC, to the extent possible would facilitate synergies of this Scheme with other schemes of the Department in general and proposed herbal medicinal processing zones initiative of National Medicinal and Plant Board in particular

(b) Project Management Consultant (PMC)

(i) Recognizing the fact that the projects of the proposed nature would require very extensive project development efforts, Department of AYUSH would engage the services of an agency that has experience in developing, financing and executing the cluster development projects and as Advisor in implementation of similar PPP based Schemes, from the stage of conceptualization to commissioning. PMC would act as a link between the Department and the industry and would help in speedy implementation of the projects in a transparent manner

(ii) The PMC will report directly to Department of AYUSH and shall have the following responsibilities:

- a. Assist Department in formulating a suitable strategy for implementation of the scheme
- b. Need assessment through diagnostic studies in the clusters identified by SMC based on growth potential of such clusters
- c. Identification of potential entrepreneurs and projects
- d. Assist industry associations/ groups of entrepreneurs in preparation of Preliminary Proposals (PP) to be put up before SMC while seeking In-principle approval
- e. Assisting the identified entrepreneurs in establishment and structuring the project specific SPV
- f. Assist SPVs in preparing Detailed Project Reports (DPR) establishing the contours of the projects covering the components detailed in the scheme
- g. Assisting the SPVs in mobilizing the balance funds to complete the project
- h. Assisting the SPVs in obtaining all necessary statutory clearances/approvals
- i. Appraisal of the DPRs
- j. Submission of the financially viable projects/DPRs to the Department of AYUSH for final approval of the project and sanction of its share of grant funding

k. Assisting the SPVs in liaisoning with the State Government agencies for land, external infrastructure like water supply, effluent disposal, connecting roads, power supply etc

l. Assisting the SPVs in selection of agencies/ experts for various services: capacity building, business development, technical, engineering, CDEs etc

m. Assisting the Department of AYUSH in periodical monitoring of the progress of the projects, and disbursement of funds to the SPVs and their utilisation

n. Assisting the SPV in developing suitable O&M framework

o. Providing other need based advisory services to the Department of AYUSH in effective implementation of the scheme

(iii) The fee payable to PMC by AYUSH will be separate from the grant-in-aid being given to the SPVs

(c) Special Purpose Vehicle

(i) The scheme would be implemented on a PPP basis through project specific Special Purpose Vehicles (SPV) formed, owned and managed by the user Industry. An SPV shall ordinarily be a Company registered under Companies act 1956. Any other structure of SPV would require prior approval of SMC

(ii) SPV should represent the cluster as a whole and should have a minimum of 15 manufacturer enterprises of AYUSH products as its shareholders, of them at least 75% should have been license holders for manufacturing of AYUSH products under Drugs & Cosmetics Act 1940 with license valid for 3 years preceding to incorporation of SPV

(iii) AYUSH enterprises shall hold at least 51 % equity of the SPV and remaining may be held by any Government agency, Financial Institution/Bank, strategic partners like buyers, ASU colleges etc as the case may be

(iv) The shareholding/member enterprises taking/holding stake in the SPV shall be legally independent entities without any related party relationship with each other as described under Accounting Standard (AS) 18 of the Companies (Accounting Standard) Rules, 2006

(v) There shall be one nominee of the Department of AYUSH and one nominee of PMC on the Board of Directors of the SPV till completion of the project

(vi) The SPV as the Project Implementing Agency would play the following role:

a. Prepare the Detailed Project Report covering the technical, financial, institutional and O&M aspects of the projects. Broad areas to be covered under the DPR are given in Annexure II

b. Raise rest of Project cost (balance of Department of AYUSH contribution) through debt/equity

c. Obtaining any statutory approvals/ clearances including release of funds

d. Recruit suitable functional professionals in order to ensure that the project is executed smoothly

e. Implement various interventions as outlined and approved in DPR

f. O&M of assets created under the project by way of user services

g. Responsible for furnishing regular progress reports to Department of AYUSH in the prescribed formats

(d) Role of State Governments

(i) The Scheme envisages pro-active involvement of the State Governments in the following areas:

a. Providing requisite land to the project, wherever needed, in appropriate mode, to the project

b. Providing necessary external infrastructure to the such as power, water supply, roads, effluent disposal etc, wherever needed

c. Providing necessary project related clearances on expeditious basis

d. Dovetailing assistance available under related schemes for overall effectiveness and viability of the projects

e. Extending incentives available under related industrial promotional policies

(ii) The process of implementation of the projects under the scheme is outlined in Annexure III

(9) Project Approval and Funding

(a) Project Approval

(i) The SMC shall be responsible for approval of the projects and monitoring of their implementation. There would be two-stage process for approval of the projects: In-principle approval and final approval

(ii) In-principle approval: In-principle approval for a project will be accorded by the SMC based on Preliminary Proposal submitted by PMC/ Industry Association/ groups of entrepreneurs covering the major features of the proposed project and availability of land. Such In-principle approval will be valid for a period of 6 months from the date of approval, and before that it is expected that the project would be ready for final approval. In case final approval is not accorded to the project, within 6 months, the in-principle approval will automatically lapse, unless it is specifically extended by the SMC.

(iii) Final Approval: A project will be accorded final approval by the SMC if the following conditions are fulfilled

1. Establishment of project specific SPV
2. Execution of shareholders agreement and other related agreements between the SPV and the members
3. Procurement of requisite land by the SPV
4. Preparation of DPR by SPV and its appraisal by PMC
5. Establishment of project specific Trust and Retention Account (TRA), with Schedule A Commercial Banks, by the SPV, into which funds could be released by Department of AYUSH
6. Tying up of sources of funds

(b) Release of Funds by Department of AYUSH

(i) The following schedule will be adopted for release of Department of AYUSH share to the SPV:

- a. 20% as mobilization advance, on Final Approval of the project by SMC
- b. 40% as IInd installment
- c. 40% as IIIrd installment

(ii) IInd Installment would be released after the utilisation of at least 60% of the 1st installment and after the proportionate expenditure has been incurred by the SPV

(iii) IIIrd and final installment would be released after the utilisation of at least 60% of 1st and 2nd installments and after the proportionate expenditure has been incurred by the SPV

(iv) The SPVs shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format in accordance to GFR 19A is provided in Annexure IV

(v) Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India

(10) O&M of Assets

(a) SPV shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/ users

(b) SPV shall ensure that the services of the facilities created under the scheme are extended to the cluster in general, in addition to the member enterprises

(c) In case of dissolution of SPV within 7 years from the date of sanction of assistance by the Government under the Scheme, the assets created with such assistance shall be vested with the Government. The Memorandum of Association & Articles of Association of the SPV shall incorporate this condition.