

**PERFORMANCE AUDIT OF
DEPARTMENT OF AYURVEDA,
YOGA AND NATUROPATHY, UNANI,
SIDDHA AND HOMOEOPATHY**

**MINISTRY OF HEALTH AND
FAMILY WELFARE
(DEPARTMENT OF AYUSH)**

**PUBLIC ACCOUNTS
COMMITTEE
2007-2008**

SIXTY-FOUR REPORT

FOURTEENTH LOK SABHA



**LOK SABHA SECRETARIAT
NEW DELHI**

SIXTY-FOURTH REPORT
PUBLIC ACCOUNTS COMMITTEE
(2007-2008)
(FOURTEENTH LOK SABHA)
PERFORMANCE AUDIT OF DEPARTMENT OF
AYURVEDA, YOGA AND NATUROPATHY,
UNANI, SIDDHA AND
HOMOEOPATHY
MINISTRY OF HEALTH AND FAMILY WELFARE
(DEPARTMENT OF AYUSH)

[Action taken on 38th Report of Public Accounts Committee (14th Lok Sabha)]

Presented to Lok Sabha on 13.3.2008
Laid in Rajya Sabha on 13.3.2008



LOK SABHA SECRETARIAT
NEW DELHI

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COMPOSITION OF PUBLIC ACCOUNTS COMMITTEE
(2007-2008)

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* Resigned from membership of Rajya Sabha w.e.f. 9th January, 2008.

INTRODUCTION

I, the Chairman, Public Accounts Committee, as authorised by the Committee, do present this Sixty-fourth Report on action taken by Government on the recommendations of the Public Accounts Committee contained in their 38th report (14th Lok Sabha) on "Performance Audit of Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy".

2. This Report was considered and adopted by the Public Accounts Committee at their sitting held on 9th January, 2008. Minutes of the sitting form Part II of the Report.

3. For facility of reference and convenience, the Recommendations and Observations of the Committee have been printed in thick type in the body of the Report.

4. The Committee place on record their appreciation of the assistance rendered to them in the matter by the Office of the Comptroller and Auditor General of India.

5. The Committee also place on record their appreciation for the invaluable assistance rendered to them by the officials of Lok Sabha Secretariat attached with the Committee.

NEW DELHI;
17 January, 2008

27 Pausa, 1929 (Saka)

PROF. VIJAY KUMAR MALHOTRA,
Chairman,
Public Accounts Committee.

CHAPTER I

REPORT

This Report of the Committee deals with the action taken by the Government on the Recommendations/Observations contained in their 38th Report (14th Lok Sabha) on the Report of the Comptroller and Auditor General of India for the year ended 31 March, 2004 (No. 16 of 2005), Union Government (Civil) relating to "Performance Audit of Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy".

2. In their 38th Report which was presented to Lok Sabha on 18th December, 2006, the Committee had dealt with various issues concerning the functioning of Department of AYUSH such as — efficacy of planning for implementation of various programmes; budgetary allocation and utilisation of funds; results of the efforts of the Union Government/State Governments to strengthen medical education, efficiency and extent of achievement of research activities and dissemination of research findings for the benefit of educationists, researchers, manufacturers and common man; extent of achievement of drug standardisation and availability of authentic AYUSH drugs; regulation, enforcement and adherence to Good Manufacturing Practices (GMPs); formulations and publication of pharmacopoeia standards of AYUSH drugs; extent of conservation and sustainable supply of medicinal plants for research work; development of agro-techniques, promotional and contractual farming schemes for developing marketing mechanism; extent of expansion of the outreach of health care under AYUSH and integration of AYUSH with modern medicines, Health Care Delivery System and National Health Programmes.

3. The Action Taken Notes in respect of all the 26 Recommendations/Observations have been received from the Ministry of Health and Family Welfare (Department of AYUSH) and these have been categorized as follows:

- (i) Recommendations/Observations which have been accepted by Government:

Sl. Nos. 1, 2, 3, 4, 7, 11, 12, 14, 15, 16, 18, 21, 22, 23 and 26.

Total : 15

Chapter-II

- (ii) Recommendations/Observations which the Committee do not desire to pursue in view of the replies received from Government:

Sl. Nos. 5 and 24.

Total : 2

Chapter-III

- (iii) Recommendations/Observations in respect of which replies of Government have not been accepted by the Committee and which requires reiteration:
Sl. Nos. 6, 8, 17, 20 and 25.

Total : 5
Chapter-IV

- (iv) Recommendations/Observations in respect of which Government have furnished interim replies:
Sl. Nos. 9, 10, 13 and 19.

Total : 4
Chapter-V

IMPORTANT RECOMMENDATIONS/OBSERVATIONS MADE BY PAC IN THE 38TH REPORT (14TH LOK SABHA)

4. The gist of important Recommendations/Observations made by the Committee in their 38th Report on the subject is given below:

- The Committee had emphasized the need for increasing the budgetary allocation for Department of AYUSH to the target level of 10 per cent of the total Health Budget as envisaged in National Policy on Indian Systems of Medicine and Homoeopathy.
- Government should ensure that permission for opening new AYUSH colleges are given only when the colleges possess requisite infrastructure and recognized courses as per the norms prescribed by the Regulatory Councils.
- The Committee had desired that the Ministry should take urgent steps for setting up the State-of-the Art All India Institute of Ayurveda.
- To ensure availability of abundant and quality raw materials to the AYUSH Drug Industries, the Ministry had been asked to take concerted steps for cultivation of medicinal plants on a commercial scale.
- Ministry should put in place an effective enforcement mechanism in co-operation and co-ordination with respective State Governments to ensure that drugs sold in the market maintain the stipulated quality/standards.
- Appropriate guidelines should be framed for taking up research activities under fixed parameters in a time bound manner so as to ensure that research findings relating to all components of each scheme are finalized, patented and disseminated among the stakeholders
- With a view to taking suitable necessary remedial action, the Committee had desired for immediate and prompt investigation into the allegations regarding containing of toxic substances in the Ayurvedic medicines/drugs.
- Deterrent punishment recommended for violating of Drug and Magic Remedies (Objectionable Advertisement) Act, 1954 by fraudulent drug practitioners.
- A Perspective Plan/roadmap for the next 20 years may be formulated for setting up of AYUSH hospitals/dispensaries in every nook and corner of the country with adequate infrastructural facilities

5. The Action Taken Notes furnished by the Ministry of Health and Family Welfare (Department of AYUSH) have been reproduced in the relevant Chapters of this Report. In the succeeding paragraphs, the Committee will now deal with the action taken by the Government on some of their Recommendations/Observations, made in the Original Report, which need reiteration or merit comments.

6. The Committee desire that Government should furnish final/conclusive action taken replies to the recommendations for which interim replies have been furnished.

A. Effective Utilisation of the Released Funds by various State Governments/Implementing Agencies

Recommendation (Sl. No. 6, Para No. 139)

7. Examination of the subject by the Committee had revealed that the Ministry had not only failed to provide the envisaged or targeted funds for the schemes under AYUSH till 2005-06 but could not ensure complete utilization of funds released. The State Governments in turn delayed release of funds to implementing agencies and it was noticed that substantial funds were released only in March, which would appear to have been a ploy to prevent lapse of funds. The Committee, therefore, had observed that the achievement of objectives of the Scheme that depended on prompt and complete disbursement of allocated funds thus became, *ab initio*, doubtful and difficult.

8. The Ministry of Health and Family Welfare in their Action Taken Notes on the aforementioned recommendations *inter-alia* stated as under:—

"Proposals from States for release of funds under AYUSH Schemes are processed expeditiously for ensuring timely release of funds. Lack/non-receipt of eligible and complete proposals during first two quarters of the year from States and consequential rush of proposals during remaining part of the year are the reasons responsible for release of comparatively higher amount during last quarter of the year. The Department is closely and continuously monitoring the release of funds by the States to the executing/implementing agencies and actual utilization therein. Monitoring of the transfer of funds and utilization therein will be further strengthened with operationalisation of the software being developed by the NIC for online monitoring. However, due to budget constraints of the States and poor administrative structure of the implementing agencies in the States, there have been delays in placing the funds at the disposal of the executing agencies for utilization for the intended purpose. The matter of delay in transfer of funds has been taken up with State Health Secretaries/Chief Secretaries on a regular basis. Most of the States have set up an umbrella States Health Society under National Rural Health Mission (NRHM) and others are in the process of setting up such societies. The Department has also taken concurrence of Planning Commission and Ministry of Finance for release of Department of AYUSH's centrally Sponsored Schemes funds to States through the State Health Societies for onward release of funds to implementing agencies from 2007-08 onwards. State Health Societies will be held responsible for monitoring of implementation of Schemes. These

arrangements are expected to reduce the delay in transfer of funds to the grantees."

9. The Committee are perturbed to note that no concrete steps have been taken by Ministry to remedy the situation arising out of non-furnishing of the complete proposals by the State Governments as well as rush of proposal at the end of the financial year. The action taken note is also conspicuously silent with regard to the reasons for non-utilization of funds of Rs. 36.52 crore State Government as well as the inordinate delay in release of Rs. 16.94 crore by the State Governments to the implementing agencies. However, the Committee note that from 2007-08 onwards funds would be released to State Health Societies for onward release of the same to the implementing agencies and that State Health Societies would be held responsible for monitoring of implementation of the schemes. The Committee trust that this arrangement would facilitate in quick disbursement of funds and effective utilization of funds by the implementing agencies. The Committee also expressed the hope that the software developed by NIC would help in strengthening the monitoring of transfer and utilization of funds by the States. The Committee would like to be apprised about the status of improvement brought about as a result of implementation of the new measures, within three months from the presentation of this Report.

B. Permission for Opening of new colleges as per the norms prescribed by Regulatory Councils

Recommendation (Sl. No. 8, Para No. 141)

10. In their 38th Report, the Committee had deprecated the Regulatory Councils for having permitted as many as 69 colleges to run courses without recognition, and as a result of which careers of 6830 students who had already passed out from these unrecognized colleges were put into jeopardy. In this backdrop, the Committee had recommended that Government should set up a High Level Committee to investigate into the reasons and circumstances under which these colleges were allowed to run courses without recognition by the Regulatory Councils. The Committee also strongly felt that the permission to open new colleges as well as starting Post Graduate courses and increasing admission capacity are accorded only after it is ensured that the minimum standards of infrastructure prescribed by the Regulatory Councils are achieved.

11. Apprising the Committee about the steps taken by the Ministry on the aforementioned recommendation, the Ministry, in their Action Taken Notes stated as under:—

"The concern of the Committee has been conveyed to Central Council of Indian Medicine/Central Council of Homoeopathy (CCIM/CCH). The CCIM has been requested to furnish the details of 69 colleges, which were allowed to run courses without recognition so as to take a view on the careers of the students, who have passed out from these colleges. After the amendment of the Indian Medicine Central Council (IMCC) and Homoeopathy Central Council (HCC) Acts in 2002-03, now the Ministry is granting permission to open new colleges, starting PG Courses and increasing admission capacity. Hence, the minimum standards of infrastructure prescribed under the rules are now been ensured prior to grant of recognition."

12. The Committee are not satisfied with the reply of the Ministry as no conclusive action has been taken on their recommendation. The Ministry were just content with seeking details of 69 colleges which were allowed to run courses without recognition from Central Council of Indian Medicine (CCIM) and have not bothered to follow up the matter with CCIM so as to take the matter to its logical conclusion even after lapse of more than 6 months from the date of presentation of their Report. This shows the callous attitude and utter disregard on the part of the Government for the careers of 6830 students that were put into serious jeopardy. Further, the Ministry's reply is silent with regard to their recommendation for setting up of High Level Committee to investigate into the episode which is anything but regrettable. The Committee reiterate their recommendation that the Ministry should take up the matter with CCIM with all seriousness so as to salvage the careers of the students. A High Level Committee should be set up to investigate into the matter without further delay. The Committee would like to be apprised of the conclusive action taken by the Ministry in this regard within three month from presentation of the Report.

C. Infrastructural Inadequacies and Deficiencies in Inspections Conducted by Regulatory Councils

Recommendation (Sl. No. 9, Para No. 142)

13. The Committee had observed that records of 142 colleges including 35 new colleges, which were inspected by the representatives of Regulatory Councils during 2000-2005, revealed that none of these colleges met the minimum requirement of infrastructural and teaching facility standards prescribed by the Councils. The deficiencies noticed were non-availability of enough class rooms, operation of Ayurvedic colleges without laboratory and pharmacy facilities, non-availability of own college building, inadequate books or staff in Library. In this regard, the Ministry had acknowledged various infrastructural inadequacies in the colleges and the deficiencies in the inspections made by the Regulatory Bodies. Although the Ministry had ensured that they would take necessary steps in this regard, the Committee felt that they should have noticed these deficiencies earlier and corrective remedial measures taken timely. The Committee had therefore, expected that the Ministry should ensure that adequate and identifiable measures are taken in a time bound manner to bring in parity in Medical education across the country and strengthen the infrastructure in the apex level institutes so as to enable them to function as centers of excellence.

14. Apprising the Committee about the action taken on the afore mentioned recommendation, the Ministry, in their Action Taken Reply have stated as under:—

"After the amendment in IMCC/HCC Acts the Ministry is granting permission to open new colleges starting PG Courses and increasing admission capacity and the minimum standards of infrastructure prescribed and ensured before grant of permissions. Infrastructure in apex level national institutions is being constantly upgraded to develop them as Centers of Excellence. The Process of review of infrastructural deficiencies of existing Ayurveda, Unani and Siddha colleges is on. The existing ASU colleges who have applied under Section 13(c) have been given 3 months time to fulfill the shortcoming related to teachers as per the regulations

before admitting the students for the session 2007-08. Other deficiencies will have to be fulfilled before 31st March, 2008. In order to bring parity in medical education across the country and strengthen the infrastructure of Ayush college and the apex level institutes, the Department proposes to provide grants-in-aid to AYUSH institutions in the 11th Five Year Plan on a much higher scale as compared to the assistance given in the 10th Five Year Plan. However, the statutory regulatory bodies *viz.* CCIM and CCH have to play their legitimate role in ensuring that college managements fill up vacancies of teachers and fulfil other infrastructural deficiencies by rigorous inspections by experts of integrity and repute. As the IMCC and HCC Acts do not at present enable the Central Government to give directions to these autonomous bodies and supersede them if they do not function in a transparent and affective manner, there are limitation of what the Central Government can do."

15. The Committee take note of the measures taken by the Government with regard to granting permission to open new colleges and improvement of the infrastructure of the colleges/institutions. However, the Committee would like to be apprised of the outcome of these measures and to furnish the details of those Apex National Institutions in respect of which the infrastructure upgradation has been undertaken so as to develop them as Centres of Excellence. They would also like to be apprised about the status of progress made with regard to rectifying the infrastructural and other deficiencies by the existing ASU colleges.

D. Inspection of AYUSH Colleges

Recommendation (Sl. No. 10, Para No. 143)

16. In their 38th Report, the Committee had expressed their serious concern over the utter disregard shown by the Regulatory Councils to the advice/direction given by the Ministry in the matter of selection and composition of expert panels for inspections of AYUSH colleges. The Committee had expected that the Ministry would take advocacy and other procedural measures for expeditious passing the Bills for amending the Central Council of Indian medicine and Central Council of Homoeopathy Acts by the Parliament so as to put an end to this despicable practice.

17. The Ministry of Health and Family Welfare in their Action Taken Note have stated as under:—

"The Government is taking steps to bring the bills for amending the CCIM/ CCH Acts passed from Parliament expeditiously. In the meantime the regulatory councils have been advised once again to constitute panel of experts for inspection of AYUSH Colleges from the panel already forwarded to them. Until the above Acts are suitably amended to enable the Central Government to give mandatory directions to the regulatory bodies and supersede them if they feel to function effectively in a transparent manner the problems noticed by the Committee are likely to persist."

18. The Committee regret to note that despite the introduction of the CCIM and CCH (Amendment) Bills, in the Parliament way back in 2005, no efforts have been

made by the Ministry for getting these Bills enacted by the Parliament, even after lapse of more than two and half years. The Committee expected the Government to show requisite urgency in the matter and Bills enacted at the earliest so that the Acts can empower the Government to issue necessary directions to the Regulatory Bodies for their effective functioning in a transparent manner.

E. Setting up of an Institutional mechanism for Monitoring the Progress of the National/State Medicinal Plant Boards

Recommendation (Sl. No. 17, Para No. 150)

19. In their 38th Report, the Committee had noted that there was avoidable delay in completion of the Projects relating to promotional and contractual farming schemes as only 21 per cent of them could be completed. The Committee recommended that the Ministry should set up an institutional mechanism in the Department of AYUSH so as to erotically monitor the progress made by the National Medicinal Plant Board and State Medicinal Plant Boards in respect of the projects that were sanctioned and are still pending under the Scheme. Further, the Ministry should ensure that the State Governments/State Medicinal Plant Boards submit the utilization certificates on time with respect to the funds sanctioned and spent on the various projects under the Scheme. The Committee also recommended that Ministry should also prepare an Action Plan in consultation with State Governments and Voluntary Organisations/Non-Governmental Organisations for exploitation of the rich store house of aromatic and medicinal plants indifferent vegetation zones of the country so that gainful employment can be provided to the people living in the rural and interior areas of the country.

20. The Ministry of Health and Family Welfare in their Action Taken Notes states as under:—

"The National Medicinal Plant Board (NMPB) has been set up for overall development of medicinal plants. The State Medicinal Plant Boards (SMPBs) have also been set up in 35 States/Union Territories. The Board is guided by an apex body constituted under Union Minister for Health and Family Welfare for formulation, implementation and monitoring of programmes and the achievements. NMPB is taking actions regularly for monitoring of implemented schemes in association with SMPBs and State Governments. There has been substantial improvement in implementation of the programmes. It is seen that the total projects sanctioned under promotional scheme were 499, out of which 7 projects have been cancelled. Therefore, the number of implemented projects would be 492 out of which 209 projects have been completed. Out of 2308 projects sanctioned under Contractual Farming Scheme, 532 projects have been cancelled and 780 projects have been completed. Therefore the number of implemented projects would be 1776 out of which 780 projects have been completed. The projects sanctioned during 2004-05 are expected to be completed by March 2007. It is also informed that there were pending Utilisation Certificates (UCs) of grants amounting to about 85 crores. The Board has taken required steps, and UCs for Rs. 57 crore have already been procured, liquidated and reconciled. However, there was a felt need for strengthening

the coordination mechanism further. The SMPB were not adequately strengthened for monitoring of the Programmes of NMPB. Therefore, multi-pronged strategy has been adopted. State/U.T. governments are being regularly asked to properly structure/strengthen the SMPBs, on the other hand financial support is being provided by NMPB for this purpose. As a separate institutional mechanism, it is proposed to involve specialized organizations in Government/Non-Government sector for regular monitoring of all ongoing sanctioned projects as well as the new projects that may be sanctioned. Regarding the recommendation of the Committee for preparing an action plan for exploitation of the rich store house of aromatic plants in different vegetation zones of the country, it is mentioned the promotion and development of aromatic plants come under the purview of National Horticulture Board."

21. The Committee are constrained to note that the implementation of the promotional and contractual farming Schemes has been far from satisfactory. Out of 492 projects that were taken up for implementation under Promotional Scheme since inception, only 209 projects constituting around 40 per cent have been completed so far. Similarly under Contractual Farming Scheme less than 50 per cent projects have been completed. With the past track records of the Ministry, the Committee are not very sure of the Ministry's enhanced confidence for completing all the projects within the revised schedule. The Committee, therefore, urge upon the Ministry to show the requisite urgency in the matter and render all possible help to the national/ State Medicinal Plant Boards for ensuring the completion of projects within the stipulated date so as to avoid time and cost overruns. The Committee would like to be apprised about the status of the progress made in this regard, within three months from the presentation of this Report.

The Committee are unhappy to note that Utilization Certificates for Rs. 28 crore are yet to be obtained from the various State Governments/State Medicinal Plant Boards. The Committee reiterate that Ministry should take concerted efforts for obtaining the pending Utilisation Certificates from the concerned State Governments/State Medicinal Plant Boards without any further delay. The Committee would like to be apprised of the latest position in this regard.

F. Expeditious compliance of Good Manufacturing Practices by all Drug Manufacturing Units asked for

Recommendation (Sl. No. 20, Para No. 153)

22. The Committee had observed that despite the measures taken by the Ministry for making Ayurveda, Siddha, Unani drug manufacturing units good manufacturing Practices (GMP) compliant, still around 1569 units were yet to get GMP certification as of September, 2006. The Committee had therefore, recommended that Ministry should take all possible steps including the feasibility of increasing the level of subsidy to the Ayurveda, Siddha, Unani drug units so that they are motivated to upgrade their manufacturing facilities and become GMP compliant. They had also emphasized that the Department of AYUSH should fix a time-table

within which all the drug units become GMP complaint failing which their drug licenses should be cancelled. They had also recommended that if necessary, Drug and Cosmetics Act, 1940 should be suitably amended with a view to take stringent penal measures against the drug companies which failed to adhere Good Manufacturing Practices standards.

23. The Ministry of Health and Family Welfare in their Action Taken Note have stated as under:—

"Good manufacturing Practices have been implemented since June, 2003 so far GMP complaint ASU units till March, 2007 are 4451. State Drug Controller have been asked to taken action against the non-GMP complying units and cancel their licenses immediately."

24. The Committee are unhappy to note that the Ministry's reply is incomplete in as much as it does not mention about the number of licenced drug manufactures operating in the Country *vis-à-vis*, number of drug manufacturers that had obtained GMP certification as on 31st March, 2007. Further the Ministry's Action Taken Note does not give the details of number of non-GMP units against which action has been taken by the respective State Governments for cancellation of the licences. The Committee expect that the Ministry's replies are complete. They accordingly would like to be apprised of the specific action taken by the Ministry in the matter.

G. Need for proper implementation of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

Recommendation (Sl. No. 25, Para No. 158)

25. Examination of the subject by the Committee had revealed that the Ministry had remained content with only issuing of directives to various State Governments and other agencies for implementation of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and did not monitor the continued publicity campaigns of the delinquent parties with a view to taking deterrent action against them. In this regard, the Committee had recommended that while formulating norms for electronic and print media, the World Health Organisation's ethical criteria for medicinal drug promotion which specify that "promotion of drugs must be accurate, fair and objective" and that "promotional claims should not be stronger than valid, up-to-date scientific evidence warrants", should be given due consideration and Government should also evolve a code of conduct governing the advertisements relating to promotion of magic drugs so as to protect the interests of consumers.

26. The Ministry of Health and Family Welfare in their Action Notes stated as under:—

"The Department of AYUSH is equally cautious to restrict the misuse of the provisions of Drugs and Magic Remedies (Objectionable advertisement) Act, 1954. The following steps have been taken to curb publishing of misleading advertisements in media:

- (i) Ministry of I&B has been requested to caution the publishers of newspapers and magazines not to carry misleading advertisements.

- (ii) The Advertising Standard Council of India (ASCI) has been requested to register complaints and take necessary action against the print and electronic agencies for violation of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954. A number of cases of violation of the Act have also been brought to the notice of the ASCI for necessary action from time-to-time.
- (iii) The State/UT Governments have been requested to ensure compliance of the provisions of the Act to prevent publication of misleading claims in the media.
- (iv) A public Notice has been published in national newspapers informing the public and manufacturers that publication of any advertisement claiming treatment of cancer, HIV/AIDS etc. is banned under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

The Department of AYUSH have also been emphasizing on the State Drug Controllers/Director AYUSH for strict enforcement of the provisions of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 during review meeting taken by the department, State Chief Secretary, Health Secretaries have also been requested for monitoring of enforcement machinery. The suggestion for evolving norms for electronic and print media on the lines of WHO's ethical criteria for medicinal drug promotion has been noted for further action."

27. The Committee are surprised to note that while the Ministry in their written reply furnished to them during the course of examination had proposed to amend Drugs and Magic Remedies (Objectionable Advertisement) Act, so as to make it more stringent and comprehensive, the Action Taken Note, however, is conspicuously silent in this regard which is but intriguing. The Committee are of the considered opinion that the amendments as suggested by the Ministry to the said Act would give more teeth and powers to the enforcement agencies in reigning/controlling the activities the of unscrupulous persons. The Committee expect that the Government would take necessary action for amending the Act, on the suggested lines at the earliest and the Committee be apprised accordingly.

CHAPTER II

RECOMMENDATIONS/OBSERVATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation

In spite of the spectacular advances made by the system of modern/allopathic medicines, the alternative or traditional systems of medicine currently serve the health care needs of a large population in the world. In India, this indigenous medicinal system comprises of different components namely Ayurveda, Yoga and Naturopathy, Unani and Siddha systems. These ancient systems of medicine which are a treasure house of knowledge for both preventive and curative health care are embedded in Indian culture well before the advent of Allopathic System of medicines and have continued to be an integral and significant part of our society. They are officially recognized, codified and well documented. However, its growth and development has not been as encouraging as it should be. Various problems/constraints affecting the growth of Indian systems of medicines are: neglect by Government, individualized and inhibitive behaviours, lesser adaptability, lack of quality parameters, abuse of system by unscrupulous practitioners, ad-hoc growth, poor resources and allocation and neglect of basic research.

[Sl. No. 1 of Appendix II, Para 134 of 38th Report of PAC (Lok Sabha)]

Action Taken

For promotion and development in AYUSH following thrust areas have been identified by the Department of AYUSH:

- Improvement and up-gradation of standards of education
- Quality Control and Standardization
- Sustained availability of raw materials
- Research & Development on the efficacy of the systems
- Mainstreaming of AYUSH in the National Health Care Delivery System
- Awareness and Information

After creation of separate Department of AYUSH in 1995, a series of efforts have been made to give boost to the growth and development of the indigenous medicinal system comprising of Ayurveda, Yoga & Naturopathy, Unani and Siddha systems. The initial period of the 9th plan was utilized to identify the gaps, developing strategies to fill up these gaps, appointing/recruitment of suitable staff, etc. The efforts of launching and implementation of relevant schemes for improving the quality of education, evolving quality drugs, promoting research and mainstreaming of the AYUSH systems are reflected in steep increase in the expenditure under the AYUSH plan schemes during Tenth Plan, particularly during the period from 2004-05 onwards. The Plan expenditure increased from Rs. 89.78 crores in 2002-03 to Rs. 290.96 crore in 2005-06. Expenditure during 2006-07 is anticipated to further increase to Rs. 320 crore. For further continuing

these efforts, National Policy on Indian Systems of Medicine & Homoeopathy-2002 has envisaged increase in allocation for plan schemes for the growth and development of Indian Systems of Medicine and Homoeopathy to raise the share of plan outlay for Department of AYUSH in total plan budget for health to 10% (from 2.5% of the total health outlay during 10th Plan). Accordingly, to increase the share of outlay for the plan schemes for Indian Systems of Medicine and Homoeopathy in the total health outlay, additional/new schemes have been proposed for the Eleventh Plan for developing accredited AYUSH Centers of Excellence in non-governmental/private sector, providing common facilities for AYUSH industries clusters, strengthening of international cooperation and promoting public private partnership for setting up speciality clinics in AYUSH hospitals. Besides, existing Centrally Sponsored Schemes are proposed to be modified in the light of the experience gained through their implementation during the 10th Plan to make implementation more focused and effective. Schemes for conservation and cultivation of medicinal plants for ensuring adequate availability of raw material to meet requirement of raw material in domestic and international market have received desired attention among Eleventh Plan proposals with their allocation proposed to be increased from Rs. 134.21 crores during 10th Plan to more than Rs. 1000 crores during Eleventh Plan. With these initiatives/Changes, outlay for the schemes of the Department is proposed to be substantially increased during the Eleventh Plan. Further, with a view to reduce delay in transfer of Central assistance to the gurantees, starting from the year 2007-08 funds under Centrally Sponsored Schemes of the Department of AYUSH would be released through State Health and Family Welfare Societies.

Through Area Officers appointed for close interaction with the States, organization of the meetings of the State Health Secretaries/Commissioners and Directors in charge of AYUSH and other measures, the Department is constantly monitoring the problems/constraints affecting the growth of AYUSH with a view to take timely remedial measures. With a view to address the issues related to the development of AYUSH in States, Union Minister for Health & Family Welfare has written to all Chief Ministers in December 2006 emphasizing the need for mainstreaming of AYUSH and improving utilization of funds by increasing absorption capacity for productive utilization of funds and strengthening/streamlining the administrative set up of the implementing machinery for AYUSH schemes.

Department of AYUSH has set up a permanent Technical Committee in the name of Ayurvedic Pharmacopoeia Committee having expert of Ayurveda, Botany, Chemistry, Pharmacy etc. This Committee has formulated guidelines for developing Standard Operating Procedures (SOPs) of manufacturing process and evolving pharmacopoeia standards for the identity, purity and strength of the Ayurvedic formulations. The standard format has also been designed to carry out scientific work on Ayurvedic formulations.

Department of AYUSH has published official formularies of Ayurveda, Siddha & Unani systems of medicines. These books give clear cut details of the quantity of individual ingredient drugs and method of preparation. The method of purifying the toxic ingredient is also given. It is mandatory to follow the manufacturing process as described in the text to ensure the safety of these formulations.

Pharmacopoeial standards have already been laid down for 418 most widely used single Ayurvedic drugs and standards for most widely used compound drugs are under preparation.

National Medicinal Plants Board is implementing Promotional and Contractual Farming Scheme for providing encouragement to the cultivation of medicinal plants. Under the Promotional scheme the Board gives financial assistance for conservation and regeneration of medicinal plants occurring in forest areas and their sustainable harvest. These projects are largely implemented through the forest departments who are in charge of most of the forest areas. Additionally, financial assistance is provided for creating herbal gardens outside the forest areas on public land, community lands as *ex-situ* conservation measure thereby reducing pressure of exploitation on forest areas and making available raw material for use by AYUSH industry. Under the Contractual Farming Scheme financial assistance by way of subsidy is provided to farmers, cultivators NGOs and Co-operative Societies for cultivation of public about the efficacy and cost effectiveness of the ISM&H drugs and easy availability of herbs and plants commonly available at home like Tulsi, Haldi, Neem etc. and growing techniques of medicinal plants etc. Community awareness meetings in cooperation with Mahila Mandals, Yuvak Sanghs, farmers cooperatives etc. already existing at the village level are also organized through NGOs. Yoga classes are conducted in schools under the Scheme. The Department also helps to organize Seminars and Workshops in AYUSH systems. The Seminars/workshops cover various subjects under AYUSH including medicinal plants.

The Department has also been publishing Calendar since 2003 conveying information about all the six recognized systems propagated by the department. The Department has produced short films on Ayurveda, Yoga, Siddha, Unani, Homoeopathy and Naturopathy. The schemes of the department have also been published and its copies distributed. Seven Audio spots on various systems under the Department are broadcast over of All India Radio. For dissemination of material in vernacular languages media units of Ministry of Information & Broadcasting were collaborated with.

The Department also organizes/participates in Presentation-cum-Exhibitions in various countries to increase awareness about the Indian Systems of Medicine in those countries.

The Department with the objective to encourage AYUSH drug manufacturers to participate in fairs organized to create awareness among the masses about AYUSH sector in India and abroad provides reimbursement of participation charges limited to 25% of the cost of participation subject to a limit of Rs. 1 lakh in case of International fair and Rs. 50,000 for national fair to the GMP certified industry. Under another scheme funds are given to prepare and publish good quality text books written by highly experienced teachers of Ayurveda, Siddha and Unani colleges and also support acquiring, preserving and publishing of manuscripts.

The Department has been implementing a scheme since the Ninth Plan known as "Scheme for Exchange Programme/Seminars/Workshops" with the objective to promote and develop Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH); increased involvement of professional/researchers for dissemination of the

proven results of Research and Development in the field of AYUSH and thereby promoting the culture of R&D in the Indian Systems of Medicine beside propagating the systems by establishing their efficacy abroad.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated 20th June, 07]

Recommendation

With a view to have a focussed development of the Indian System of Medicine and Homoeopathy and to address the health care delivery services through these systems the Government of India (GOI) in 1995 established an independent department of Indian Systems of Medicine and Homoeopathy (ISM&H) under the Ministry of Health and Family Welfare. Government have also formulated and approved a National Policy on ISM&H in 2002 which, *inter-alia*, reiterated that Ayurveda, Unani, Homoeopathy and Yoga offered a wide range of preventive, promotive and curative treatments and renamed the Department of ISM&H as the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November, 2003. The major objectives of Department of AYUSH were to promote good health and expand the outreach of health care; to improve the quality of teachers and clinicians; to ensure affordable AYUSH services & drugs which are safe and efficacious; to facilitate availability of raw drugs which are authentic and contain essential components; to integrate AYUSH in health care delivery system and National Programmes; to re-orient and prioritize research in AYUSH; to create awareness about the strengths of these systems in India and abroad and sensitize other stakeholders and providers of health; and to provide full opportunity for the growth and development of these systems.

[Sl. No. 2 of Appendix II, Para 135 of 38th Report of PAC (Lok Sabha)]

Action Taken

The Para mentions about the objectives of the Department of AYUSH. Activities and efforts of the Department in pursuance of these objectives have been mentioned in Action Taken Note to the recommendation at Sl. No. 134.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

The Performance review conducted by the Audit of the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy during the period 2000-01 to 2004-05 form the basis of this Report. This review has included its subordinate offices and implementing agencies in 29 States and Union Territories. The principal objectives of this review was to assess the efficacy of planning for implementation of various programmes, budgetary allocation and utilisation of funds, results of the efforts of the Union Government/States to strengthen medical education, efficiency and extent of achievement of research activities and dissemination of research findings for the benefit of educationists, researchers, manufacturers and common man, extent of achievement of drug standardisation and availability of authentic AYUSH drugs, regulation, enforcement, adherence to Good Manufacturing Practices (GMPs) and publication of formulations and pharmacopoeial standards of AYUSH drugs, extent of conservation and sustainable supply of medicinal plants and research work, development of agro-techniques, contractual farming for developing marketing mechanism, and extent of expansion of the outreach of health care under AYUSH and integration of AYUSH with modern medicines, health Care Delivery System and National Health Programmes.

[Sl. No. 3 of Appendix II, Para 136 of 38th Report of PAC (Lok Sabha)]

Action Taken

The para mentions about the objectives of Performance review of the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy conducted by the Audit during the period 2000-01 to 2004-05, which has formed the basis of the present Report. Thus, this is a matter of record.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

The Committee regret to observe that the Department of AYUSH had achieved very little success in achieving the objectives of growth and development, propagation and promotion of AYUSH health care in the country. Policy pronouncements contained in the National Policy on AYUSH-2002 could not be effectively implemented due to poor budgetary support, inadequate monitoring, evaluation and lack of coordination between various implementing agencies and the Ministry. The share of AYUSH in the total health Plan at the Central level was static at 2 per cent during 2000-05 though the policy envisaged raising of AYUSH share to 10 per cent with designed growth of 5 per cent in every Five Year Plan. The programme also suffered from absence of an effective system of transfer of funds to the implementing agencies. Out of Rs. 30.98 crore

released to 12 State Governments under Centrally Sponsored Schemes during 2002-05, Rs. 16.94 crore were not released to the implementing agencies with delays even upto 36 months. Out of total 444 colleges, 142 colleges whose records Audit test checked, did not possess adequate infrastructural facilities, faculty, attached hospitals with requisite bed strength and Out Patient Department/In Patient Department (OPD/IPD) facilities in accordance with the norms laid down by the Regulatory Councils. Five Apex level Institutes set up by the Ministry as centres of excellence for imparting high quality education and research also lacked infrastructural facilities. Ministry did not ensure that the database of practitioners of AYUSH was updated and revised promptly and regularly. Delays in upgradation ranged between 3 and 22 years in 20 States. There was neither correlation between the drugs standardised, drugs proved and drugs clinically verified nor any systematic approach to standardisation of drugs as 44 Homoeopathic drugs were taken up for proving and 47 for clinical verification without having been standardised. Pharmacopoeia Committees on which expenditure of Rs. 7.85 crore was incurred between 2000 to 2005 failed to develop pharmacopoeial standards for formulation of compound drugs in Ayurveda and Unani even after 40 years of their inception as a result of which official pharmacopoeia under the respective system for evolving uniform standards in preparation of AYUSH drugs could not be published. Out of 7849 manufacturing units only 707 had obtained the mandatory 'Good Manufacturing Practices' certificate from Government as of December 2004. The National Medicinal Plant Board, set up as a nodal agency to oversee policies for conservation and development of medicinal plants at the National and State levels did not have an authentic database on demand and supply of medicinal plants and failed to monitor and evaluate the progress of 1077 projects funded by it at a cost of Rs. 62.16 crore during 2001-04. Ministry did not ensure evaluation of progress of demonstrative medicinal plant gardens though financial assistance of Rs. 73.85 lakh was released to 18 institutions during 2000-03. Inordinate delay in completion of 33 projects of development of agrotechniques in respect of 133 medicinal plants and failure to patent and disseminating the research findings resulted in blockage of funds to the tune of Rs. 5.05 crore. These issues have been discussed in detail in the succeeding paragraphs.

[Sl. No. 4 of Appendix II, Para 137 of 38th Report of PAC (Lok Sabha)]

Action Taken

As mentioned in the above para of the report, these issues have been discussed in detail in the succeeding paragraphs of the report. Action Taken Note against each of these paras/recommendations have been given in this Action Taken Report.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

(Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

The Ministry have clarified that they have initiated some steps to check underutilization of the funds as well as to ensure that there is no delay in the release of funds by the State Governments to the implementing agencies, Further, Department of AYUSH are also stated to have taken concurrence of Planning Commission and Ministry of Finance for release of Centrally Sponsored Schemes funds of the Department to States through the State Health Societies for onward release to the implementing agencies. The Committee hope that Department of AYUSH would completely streamline the system and procedures of transfer of funds to States and further allotment by States to implementing agencies by identifying the specific bottlenecks and monitoring the internal procedures closely. A computer based tracking system may be installed for querying the data so that utilization of released grants improves significantly. They may also insist on refund of unutilized balances retained by State Governments for over a year which would help avoid blocking of resources when competing sectors face funds crunch. At their end the Ministry should also desist from releasing of funds at the fag end of the Financial Year and take measures for timely release of funds to the States.

[S.No. 7 of Appendix II, Para 140 of 38th Report of PAC (Lok Sabha)]

Action Taken

Besides routing the funds under Centrally Sponsored Schemes of the Department through the State Health Societies for ensuring timely transfer of funds to the executing/implementing agencies, the Department is further strengthening the monitoring of the transfer of funds to the States and further release of these funds by the State Health Societies to the implementing agencies. NIC has developed computerized software for getting online Information on transfer and utilization of funds which would strengthen monitoring of flow and utilization of funds with a view to ensuring that remedial measures, if any, required to be taken are taken in time.

In the meeting of the State Health Secretaries and Secretaries in charge of Indian System of Medicine and Homoeopathy held on 14th and 15th December, 2006, the State Governments were categorically told to ensure immediate utilization of all the funds released and submit the utilization certificates therein. Failing this, the State Governments were required to refund the unutilized funds out of funds released upto 31.3.2004. The Department has also taken steps to adjust the funds lying unutilized for long with the States and other entities from their releases during the year 2006-07. These steps are expected to convey the desired message to the States regarding delayed transfer and slow utilization of funds.

The Department is complying with the ceiling on the amount that can be released during the last quarter of the year. The Department would continue to ensure that funds against eligible/complete proposals are realised with reasonable time throughout the year. Besides, through other measures like meetings with the State Health Secretaries/Directors incharge of ISM&H, visits of the officers of the

Department and area officers appointed for intensive liaison with allotted States, etc. the Department would persuade and facilitate the submission of early eligible proposals, complete with required information/documents during a financial year so that the situation of rush of releases during last quarter of the year could be avoided.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

The Committee note that the preparation and maintenance of a database of practitioners of AYUSH was one of the important functions of the Regulatory Bodies. A Central Register containing the names of persons enrolled on any State Register of Indian medicine or Homoeopathy and who possessed any of the recognized medical qualifications included in the respective schedules of the Acts was to be maintained and notified in the Gazette of India. A practitioner who did not possess a recognized medical qualification and had been practicing Indian medicine or Homoeopathy before the commencement of Central Acts was also eligible for enrollment on the State register of Indian medicine or Homoeopathy. Against 6.95 lakh AYUSH practitioners (4.93 lakh qualified and 2.02 lakh non-qualified) registered with the States, as of December, 2002, database of only 1.86 lakh practitioners had been maintained by the Councils. Out of 29 States and 7 Union Territories (UTs), the database had not been updated and revised for periods ranging between 3 and 22 years in respect of these 20 States. The delay in notification of the Central Register deprived the practitioners of the opportunity to practice in other States or throughout the country. The Committee, while expressing their concern over the inordinate delay in updation of Central Register by Central Council of Indian Medicine desire that the Ministry should immediately update and lay down a periodicity to take up the matter with the respective State Governments at the appropriate level for timely submission of the list of practitioners so that the Central Register of practitioners are kept updated by Central Council of Indian Medicine.

[Sl. No. 11 of Appendix II, Para 144 of 38th Report of PAC (Lok Sabha)]

Action Taken

The Secretary (AYUSH) has written to all Chief Secretaries of the State Governments on updating of the State registers of Indian Medicine/Homoeopathy and their future updations on yearly basis. Necessary one-time financial assistance shall be provided by the Central Govt. to the needy States. CCIM/CCH have also been

advised to assign higher priority to maintenance of registers of practitioners and regulation of their ethical conduct. The observations of the Committee have also been brought to the notice of the States to ensure proper functioning of State Boards so that State registers are regularly maintained so that Central registers and timely holding of elections to CCIM/CCH is ensured.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H.11019/1/2006-AYUSH(E-III)
dated: 20th June, 2007]

Recommendation

The Committee note that the total number of AYUSH medical colleges under Ayurveda, Unani and Homoeopathy systems has increased by 19 per cent, from 374 at the end of March 2001 to 444 at the end of March 2005. While Bihar, Karnataka, Madhya Pradesh, Maharashtra, and Uttar Pradesh accounted for 62 per cent of the total AYUSH medical education institutions, no college had been set up in Manipur, Meghalaya, Mizoram, Nagaland and Sikkim. The Committee have been informed by the Ministry that there are 2 Homoeopathy and one Ayurveda colleges in Assam and one Homoeopathic College in Arunachal Pradesh. The Government have proposed to set up a North-Eastern Institute of Ayurveda and Homoeopathy and the Government of Arunachal Pradesh and North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIMS), Shillong have identified land for development of this Institution. It has further been stated that the Central Government may set up an Ayurveda college in Arunachal Pradesh and a Homoeopathy college in NEIGRIMS, Shillong. The Committee expect that Department of AYUSH would take necessary steps so that the proposed AYUSH colleges are set up expeditiously in the North Eastern Regions. The Committee also recommend that Government should give special focus to the North Eastern Regions considering its richness in flora and fauna and availability of medicinal/herbal plants in abundance. Emphasis should be laid for commercial exploitation of medicinal plants and identification of tribal medical practices and setting up of AYUSH dispensaries in this region.

[Sl. No. 12 of Appendix II, Para 145 of 38th Report of PAC (Lok Sabha)]

Action Taken

Department of AYUSH is taking necessary steps for getting required approval for setting up North Eastern Institute of Ayurveda and Homoeopathy at Shillong and North Eastern Institute of Ayurveda and Homoeopathy at Shillong and North Eastern Institute of Folk Medicine in Arunachal Pradesh. Soon EFC meeting would be convened for getting the approval of the EFC.

Considering the richness of North-Eastern Regions for availability of flora and fauna, the National Medicinal Plants Board has already sanctioned substantial funds

to government/non-government organizations and growers/farmers for development and cultivation of medicinal plants. Total expenditure of Rs. 11.57 crore during the last 3 financial years, including the current year, has so far been incurred in North-Eastern Regions under Promotional and Contractual Farming Scheme of National Medicinal Plants Board. The schemes are proposed to be continued during the next annual plan for North-Eastern Regions with enhanced budget allocations. Normally 10% of the budget is allocated for the programmes in North-Eastern Regions. However, it is proposed to allocate Rs. 14.80 crore out of total Rs. 80 crore during the year 2007-08.

During the year 2006-07, the Department has released more than the 10% of the total plan expenditure for the North Eastern States under Centrally Sponsored Schemes and the scheme for development and cultivation of the medicinal plants.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

With a view to mainstream AYUSH system of Medicine with modern/allopathic medicine, the Ministry have introduced a Centrally Sponsored Scheme in 2002-03 for 'Promoting Development of Health Care Facilities' in AYUSH. The scheme provided financial assistance to the States for setting up specialized therapy centers with hospitalization facility in AYUSH system, speciality clinics of AYUSH *i.e.* system specific outdoor treatment centers, an AYUSH wing in district allopathic hospitals with outdoor as well indoor facility in one or two systems of AYUSH and purchase of essential drugs for identified AYUSH dispensaries in rural and backward areas. During the years 2002-03 to 2004-05, Rs. 33.74 crore were released to cover 8819 units in 24 States under the scheme. Audit scrutiny has revealed that out of Rs. 494.94 lakh released by the Ministry during 2002-05 to Andhra Pradesh, Himachal Pradesh, Jammu and Kashmir, Manipur, Tripura and West Bengal, Rs. 490.38 lakh (99 per cent) remained unutilized as the State Governments did not release the funds to the implementing agencies. The Committee are constrained to note that the scheme was a total failure, as virtually no funds were released by the States to the implementing agencies even after a lapse more than 3 years since the scheme has been introduced, which is anything but inexplicable. The Committee would like the Ministry to find out the reasons for non-implementation of the scheme by the States, sort out the same by having periodical meetings with the concerned States at an appropriate level and report progress to the Committee.

[Sl. No. 14 of Appendix II, Para 147 of 38th Report of PAC (Lok Sabha)]

Action Taken

With a view to reduce delay in transfer of Central assistance to the grantees, starting from the year 2007-08 funds under Centrally Sponsored Schemes of the

Department of AYUSH would be released through State Health and Family Welfare Societies.

Through Area Officers appointed for close interaction with the States, organization of the meetings of the State Health Secretaries/Commissioners and Directors in charge of AYUSH and other measures, the Department is constantly monitoring the problems/constraints affecting the implementation of the Centrally Sponsored Schemes including the scheme for Development of Hospitals & Dispensaries with a view to timely sorting out of the problems, if any, and take remedial measures. With a view to address the issues related to the implementation of AYUSH schemes in States, Union Minister for Health & Family Welfare has written to all Chief Ministers in December 2006 emphasizing the need for mainstreaming of AYUSH and improving utilization of funds by increasing absorption capacity for productive utilization of funds and strengthening/streamlining the administrative set up of the implementing machinery for AYUSH schemes.

A meeting of the State Health Secretaries/Commissioners and Directors in charge of AYUSH was organized on 15th and 16th December, 2006 to discuss various issues and sorting out problems relating to implementation of Centrally Sponsored Schemes.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 2007]

Recommendation

The Committee note that Central Government Health Scheme (CGHS) had a network of 78 AYUSH (CGHS) dispensaries functioning at the end of the IX Plan. During the X Plan (2002-07), 21 new AYUSH dispensaries were planned to be established in the premises of the existing allopathic dispensaries. Seven new dispensaries were approved in 2003-04 and the budget provision of Rs. 86 lakh was placed at the disposal of Director General of Health Services (DGHS). However, as of June 2004, only 2 dispensaries had been opened. During 2004-05 seven more dispensaries were sanctioned at a cost of Rs. 1.30 crore but none of these dispensaries could be set-up during 2004-05 due to shortage of doctors and paramedical staff. In view of the declining trend in the attendance of patients in Ayurveda and Homoeopathy dispensaries, the Ministry asked the Indian Council for Medical Research (ICMR) to conduct a survey to assess the acceptability/non-acceptability level of AYUSH facilities under Central Government Health Scheme, perception of Central Government Health Scheme beneficiaries about AYUSH, availability of AYUSH facilities under Central Government Health Scheme in the country and the level of availability of infrastructure and facilities in the selected teaching hospitals of AYUSH. The Report of the Indian Council for Medical Research has since been submitted to

the Ministry. The Committee hope that Government would take necessary corrective steps in the light of findings of the survey Report of Indian Council for Medical Research by streamlining and strengthening the function of AYUSH dispensaries of Central Government Health Scheme. With a view to increase the acceptability of AYUSH among the masses Government should launch special campaigns to educate and increase the awareness of the people regarding the beneficial aspects of the Indian Systems of Medicine. The Committee would like to be apprised of the main findings of the ICMR and the action taken by Government thereon.

[Sl. No. 15 of Appendix II, Para 148 of 38th Report of PAC (Lok Sabha)]

Action Taken

The findings of the survey by the ICMR regarding acceptability of AYUSH facilities under CGHS are as follows:

- The ISM&H facilities under CGHS are largely accepted by the beneficiaries for common ailments like Gastro-intestinal disorders, Arthritis, Skin disease etc. The reasons for preference for ISM&H were cheap, effective and no side-effects of ISM&H medicines. Still there is very less preference for ISM&H for serious ailments.
- Most of the teaching hospitals have their own buildings and have various facilities like X-Ray, Ultrasound, Pathology and Operation Theatre etc. About one-third of the ISM&H dispensaries were housed in rented buildings. Most of the CGHS dispensaries were reported to have sufficient medicines.
- Perception of CGHS beneficiaries towards ISM&H was found satisfactory in the survey.
- Most of the patients preferred to utilize the same system in future and were reportedly satisfied with the availability of the facilities provided in the Government as well as non-government hospitals. Majority of the patients reported the treatment as satisfactory in ISM&H dispensaries. Long time and too far distances were the reasons for not visiting the ISM&H dispensaries.
- Suggestions for improvement as reported by beneficiaries were sufficient supply of medicine, strengthening of manpower in hospitals, proper publicity about ISM&H facilities. To increase the acceptability of ISM&H systems of medicine, it was suggested to situate dispensaries belonging to ISM&H in the same building in which the allopathic dispensaries are housed.

Action taken by the Department on the findings and suggestions made in the survey report is as follows:

- (i) The Department has decided that new AYUSH dispensaries shall be established in the same premises of CGHS Allopathy Dispensaries.

- (ii) Regular supply of medicine in CGHS dispensaries is maintained by the CGHS. However the Advisers of the respective systems are involved in the purchase procedures of the CGHS Medicines.
- (iii) For enhancing the awareness of AYUSH Systems, there is an ongoing IEC Programme.

For supply of essential medicines and to provide more services of AYUSH, the Department has an ongoing Central sector scheme "Hospital and dispensaries" where by establishment of AYUSH facilities is encouraged in District Allopathy hospitals and an amount of Rs. 25,000 is provided for purchase of medicines for the State dispensaries.

Information, Education and Communication is one of the six identified thrust areas of the Department. With a view to create awareness among the general people about the efficacy and efficiency of the AYUSH systems of medicine, their cost effectiveness and the availability of the herbs used for prevention and treatment of common ailments, the Department of AYUSH has been implementing the scheme for Information, Education and Communication (IEC) by utilizing various media channels. Health Melas are also organized to create awareness among the general public about the efficacy and cost effectiveness of the ISM&H drugs and easy availability of herbs and plants. Community awareness meetings in cooperation with Mahila Mandals, Yuvak Sanghs, Farmers cooperatives etc. which already exist at the village level are also organized through NGOs. Yoga classes are conducted in primary and middle schools under the Scheme. The Department also helps to organize Seminars and Workshops in AYUSH systems covering various subjects of general interest including medicinal plants.

Ever since 2001, the Department has been organizing a comprehensive health Fair AROGYA as an awareness general exercise to promote AYUSH sector as a whole. Participation in AROGYA has been made a regular feature every year thereafter. Since 2004, the annual Delhi AROGYA had also been made into a regional feature. First AROGYA Chennai was organized in Jan., 2005. AROGYA fair was also organized at Hyderabad November, 2005 and again at Chennai in February, 2006. In 2006-07, apart from the annual Delhi AROGYA in Oct., 2006, the Department participated in various Melas organized by the Ministry of Health & Family Welfare and other organizations all over the country through its Research Councils and other institutions. Some of the major events were: Perfect Health Parade, 'SATTE OPEN WORLD', the expo during World Ayurveda Congress at Pune, etc. The Department also put up informative display and clinics during the "Health Awareness Week" for Hon'ble Parliamentarians from 7-11th August, 2006 in the Parliament House Annexe, New Delhi. The Department also participates in international Fairs organized periodically by ITPO, FICCI etc.

The Department has also produced six short films on Ayurveda, Siddha, Unani, Yoga & Naturopathy and Homoeopathy and films on Home Remedies in Ayurveda &

Unani. All these films were shown during the AROGYA fairs and telecast. VCDs were distributed to the general public on demand. AIR programmes are also regularly used to disseminate information about the systems.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

Availability and supply of drugs in all AYUSH hospitals/dispensaries as well as in the open market is a pre-requisite for expanding the out-reach of AYUSH system in the country. To ensure availability of quality drugs at affordable prices to the people, there ought to be assured supply for which it is also essential to have enough availability of authentic raw-material for production of quality drugs by AYUSH drug units in the country. This, in turn, would require cultivation of medicinal plants on a commercial scale and also setting up captive nurseries to ensure assured supply of raw-material in large quantity to the drug manufacturers. It is understood that medicinal plants constitute about 80 per cent of raw materials required for manufacture of AYUSH drugs. The Committee understands that presently there is shortage of quality raw-material in the form of medicinal plants which is affecting the growth of AYUSH industry as well as availability of quality medicines in the country. Government should therefore, take steps for cultivation of medicinal plants on a commercial scale in different parts of the country for availability of abundant quantity raw-material. The Committee note that production of some precious and rare ingredients such as 'Kasturi' are banned in India. However, their availability and production is very important in production of certain critical drugs. In this regard the Committee are given to understand that China has successfully been producing and exporting Kasturi by extracting the same from the animals without torturing or killing them. The Committee recommends that Government should devise similar ways and means to extract Kasturi, Shing etc. from the animals. The methods being adopted by China in this regard may be arranged to be studied by experts so as to replicate the same in the country. Government should also explore the possibility of import of rare precious material such as 'Praval' and 'Munga' when these are considered to be very essential in the manufacture of certain critical drugs.

[Sl. No. 16 of Appendix II, Para 149 of 38th Report of PAC (Lok Sabha)]

Action Taken

Medicinal Plants Board has implemented Promotional, Commercial and Contractual Farming Scheme for cultivation, conservation and development of medicinal plants. The Board has sanctioned projects for cultivation of prioritized medicinal plants on about 37000 hectares of land. It is proposed to increase coverage under medicinal plants to 80000 hectares during the 11th Plan.

The following issues are proposed to be addressed on priority during the 11th Plan:

- Conservation and Augmentation of Wild Gene Pool of Medicinal Plants
- Cultivation of Prioritised Medicinal Plants
- Research, Development and Extension Action
- Quality Control and Certification
- Enabling Legal and Administrative Measures
- Setting up of Medicinal Plant Processing Zones
- To undertake Pilot Study to devise ways and means to augment availability of animal products viz., Kasturi, Shing and marine products viz. Praval and Munga etc. used in AYUSH medicines.

In addition, National Horticulture Mission, Department of Agriculture and Co-operation has also been requested to earmark 10% funds under NHM for cultivation of medicinal plants.

One Musk Deer Research Centre under Central Council for Research in Ayurveda and Siddha, Dept. of AYUSH, Ministry of Health & Family Welfare is located at Meharoori (Uttaranchal). For the first time in the country, the institute has done systematic research and formulated standard operating procedures for extraction of musk from musk deer without sacrificing them. Extraction of musk was successfully done from 1987 to 1989 and further continued from 2004. Besides, the standard operating procedures for feeding and farming have also been evolved by the council. This method of collection of musk from living musk deer would prevent the extinction of this endangered species. The method developed by the Council may be adopted to fulfil the large-scale requirement of the musk for different purposes.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[(Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

In order to restore public faith in the efficacy of AYUSH system, it is imperative that quality and safe AYUSH drugs are produced and made available in the market. A Centrally Sponsored Scheme namely—'Quality Control of AYUSH Drugs' was launched by Ministry in 2000-01 for ensuring availability of quality AYUSH drugs in conformity with the Drugs and Cosmetics Act, 1940 and eliminating the possibility of production and marketing of sub-standard drugs. Grants of Rs. 51.13 crore were released to 93 units in 23 States/UTs during 2000—05. Audit examination revealed that the scheme envisaged projects for strengthening 21 Drug Testing Laboratories (DTLs) and

40 Pharmacies within 18 months of the release of the financial assistance. However, none of the Drug Testing Laboratories and Pharmacies had been able to utilise the entire grant-in-aid and make the facilities functional even after 5 years of implementation of the Scheme. This resulted in blocking of 'Plan' funds amounting to Rs. 25.31 crore. The State Governments either delayed release or did not release funds, which contributed to the slow progress of capital work and delays in completion of procedural formalities. The Committee have been informed by the Ministry that the construction work, procurement of machinery required a lot of codal formalities and on an average it takes 2-3 years to complete the utilization. Out of 21 Drug Testing Laboratories funded under the Scheme, 14 labs are stated to be functional and carrying out testing of Ayurveda, Siddha, Unani drugs and during the year 2005-06, 4 more laboratories have been supported. As regards pharmacies, Ministry has indicated that out of 40 pharmacies that were supported under the scheme, 36 pharmacies are functional and producing drugs. It has been contended that Pharmacopoeial standards of 474 drugs have been published for Ayurveda and Unani drugs. Another 250 single drugs of Ayurveda, Siddha and Unani have been finalized. The Committee recommends that Government should make all out efforts for setting up Drug Testing Laboratories in the remaining States where they have not been set up and also to ensure that they become functional within a year.

[Sl. No. 18 of Appendix II, Para 151 of 38th Report of PAC (Lok Sabha)]

Action Taken

In order to ensure safety and efficacy and quality of ASU products to the consumers a Centrally Sponsored Scheme of Quality Control of AYUSH drugs have been implemented in the year 2000-01. So far Govt. have released grant-in-aid Rs. 8813.57 lakh have been released for strengthening/establishing 26 DTLs and 46 Pharmacies of ASU&H drugs in the country. Out of the grant released upto 2006-07 Rs. 3291.50 lakh of U.Cs have been issued, Rs. 5522.10 lakh U.Cs are still pending with State Govts. under the scheme. Efforts are being made with the State Govts. for getting pending U.Cs Govt. have also recognized 26 Pvt. Drug Testing Laboratories and NABL accredited laboratories in the country. Govt. have also published Pharmacopoeial standards of 474 Ayurvedic medicines and published in the form of Ayurvedic Pharmacopoeia and 912 Unani formulations have been published in the form of Unani formulary and 148 Unani Pharmacopoeial standards have been published. The work of preparation of pharmacopoeial standards of compound drugs is being undertaken. As this work is highly research intensive AYUSH research councils/CSIR laboratories have been involved and the progress of the work is being rigorously monitored by the Department of AYUSH.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No.H.11019/1/2006-AYUSH(E-III)
dated: 20th June, 07]

Recommendation

Drug standardisation is a pre-requisite for manufacture of quality drugs. It involves evolution of standards for single and compound drugs (for both Ayurvedic and Unani medicines) and mother tinctures (for homoeopathic medicines) in order to establish various qualitative characteristics of drugs. The Committee note that only 76,68 and 16 per cent of single and compound drugs standardised under Ayurveda, Unani and Homoeopathy systems respectively had been documented in the form of monographs as of March 2005. The progress in this regard after 1999 was insignificant as 11 monographs of homoeopathic drugs had been published only in 2004-05. The Committee further note that the standards for single drugs developed by Central Council for Research in Ayurveda and Siddha were not found suitable by the Ministry for inclusion in the Ayurvedic Pharmacopoeia of India due to large variations in the data and absence of Standard Operating Procedures. The standards published by the Research Councils on the basis of research conducted from time to time did not also conform to the quality and standards prescribed by Government's Pharmacopoeia Committees. Evidently the Ministry did not effectively guide, monitor and coordinate the work of its Research Councils, which continued with their work regardless of its acceptance by Pharmacopoeia Committees. The Committee recommends that the Department of AYUSH should take necessary steps in close consultation and coordination with the Research Councils for expeditious completion of drug standardization and documentation of various single and compound drugs so that quality drugs can be manufactured.

[Sl. No. 21 of Appendix II, Para 154 of 38th Report of PAC (Lok Sabha)]

Action Taken

Department of AYUSH, Ministry of Health & Family Welfare has set up a permanent Technical Committee in the name of Ayurvedic Pharmacopoeia Committee having expert of Ayurveda, Botany, Chemistry, Pharmacy etc. This Committee has formulated guidelines for developing Standard Operating Procedures (SOPs) of manufacturing process and evolving pharmacopoeial standards for the identity, purity and strength of the Ayurvedic formulations. The standard format has also been designed to carry out scientific work on Ayurvedic formulations.

Progress under AYUSH Research Councils in drug standardization is as follows:

Central Council for Research in Ayurveda & Siddha (CCRAS)

The standardization of single & compound drugs is undertaken & executed by Ayurvedic Pharmacopoeial Committee. During post audit period monographs of 92 single drugs have been published in API Vol-V. Monographs for 100 single drugs have been completed & being published in API, Vol-VI.

Monographs on 60 compound drugs are also completed and work on 220 more compound formulations are going on;

Monographs of single drugs completed	—	192
Monographs on compound formulation completed	—	60

Work on Standardization of 220 compound formulations is in progress.

The standards developed by CCRAS on single Drugs are of primary nature and were evolved manually about 20 years ago. During that period, the Council had no facilities to develop the parameters suggested in present Ayurvedic Pharmacopoeia. For example, TLC studies, which are today's master tool in quality assessment on drugs, the laboratory facilities are not available with the Council at that period.

The large variation in data is attributable to factors *viz.* geographical variation, eco-climatic changes, time of collection and drying conditions of sample etc.

The council is upgrading its laboratories with sophisticated instruments to meet the requirements of the current period, in a phased manner, during the 11th five year plan.

CCRAS has published revised edition of pharmacopoeial Standards for Ayurvedic formulations in the year 1987 consisting of 21 dosage forms of 431 compound formulations. The data provided in the book is of primary standards. This is the only book which is being referred even today by different scientists as a reference for establishing the quality of the Ayurvedic drugs.

In modern medicine the fine crystalline chemicals are mixed with the well-standardized additives, colours, binders, preservatives, syrups, flavors etc. to get the final product, tablet, syrup, or injectables; standardization is restricted only to the specific ingredients. In Ayurveda the drugs are multi component (Poly Herbal and Herbo mineral), a certain amount of Cooking/Fermentation/Maceration/Triturating/Mixing/Washing etc. is involved in the preparation of formulation due to which it is difficult to analyze the formulation for presence/absence of particular ingredients and it will take time to evolve easy procedure for the formulations.

Central Council for Research in Homoeopathy (CCRH)

A. Completion of Drug Standardization Studies

The Council has completed Physico-chemical and Pharmacognostic studies on 18 and 17 drugs respectively in the post audit period. Since the Council does not have its own Animal house, it has assigned 08 drugs for pharmacological studies to Osmania University, Hyderabad.

Council has also approached King George Medical University, Lucknow, CDRI, Lucknow and AIIMS, New Delhi, College of Pharmacy, Delhi, National Botanical Research Institute, Lucknow for the study of pharmacological aspects of the assigned drugs of the Council. KGMU and AIIMS have responded positively.

B. Documentation of Drug Standardization Studies

- (i) A Book on "Standardization of Homoeopathy Drugs, Vol. I containing monographs of 11 drugs was published in 2006.
- (ii) Three separate monographs entitled 'Carica Papaya' 'Terminalia Chebula' and Boerrhaavia diffusa containing data on Drug Standardization Studies have been published in the post audit period.

- (iii) Drug standardization data on 12 drugs has already been compiled and approved by SAC for publication. These monographs on 10 drugs are in press for publication in the form of Book "Standardization of Homoeopathic Drugs" Vol. 2.

The inputs given by the Council on Drug Standardization studies are being considered by Homoeopathic Pharmacopoeia Committee for inclusion in Homoeopathic Pharmacopoeia of India (HPI). The Council is contributing information regarding drug standardization work for consideration of HPC regularly and the information conforms to the standards prescribed by HPI.

Central Council for Research in Unani Medicine (CCRUM)

The Council in the post audit scenario published two monographs on single drugs (each having standards for 50 drugs and one monograph on compound drugs) having standards for 50 drugs. Thus bringing publication of a total of 250 single drugs out of 277 drugs standardized and 350 compounds set forth by the respective Pharmacopoeia Committee, and in case of C.C.R.U.M., the Unani Pharmacopoeia Committee. Any Pharmacopoeia, as such is an ongoing process and standards set forth may have to be updated with the advancement of science. It so happened that with the development in the scientific field, the parameters adopted 20 years back needed some revision and consequently some new parameters had to be added, otherwise the standardization work done both in single and compound drugs by the Council right from 1972 has been on the basis of parameters set forth by the U.P.C. The need for having additional parameters was only because of the scientific/pharmacopoeial advancement.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H.11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

The clinical research facilitates assessment of therapeutic utility of a drug in specific disease conditions and was expected to aid in establishing economically cheap and effective remedies for common as well as chronic ailments. The Research Councils undertook clinical studies in Tribal Health Care, Family Welfare and Reproductive and Child Health Programmes. However, Audit Review pointed out that there was a large gap between the number of clinical trials completed and documented as well as the dissemination of the research findings for the benefit of various stakeholders such as educationists, researchers, physicians, manufacturers and the common man. The Committee have been informed by the Ministry that Central Council for Research in Ayurveda and Siddha has developed Ayush-64 an anti-malarial

formulation which is highly beneficial in the management of Plasmodium-Vivax malaria. As regards Central Council for Research in Unani Medicine the Ministry has stated that the effectiveness of Unani medicine has been proved during dengue, dropsy and plague epidemics. In so far as Central Council for Research in Homoeopathy is concerned, it has been stated that Filaria, Malaria and Japanese Encephalitis cases have been successfully managed with Homoeopathic drugs.

Though considerable work has been done by the Research Councils in clinical Research, the Committee however, note that the research work has largely been confined to communicable and non-communicable diseases such as Malaria, Filaria, Cholera, etc. and no worthwhile clinical and research has been conducted in respect of life style related diseases and other diseases like diabetes, AIDS, Cancer, Tuberculosis etc. To enable the Research Councils to conduct research in these diseases and other newly emerging diseases the Committee recommend that necessary infrastructural and financial support should be extended by Government to the Research Councils. Ministry should also involve reputed private drug companies for collaborative research in invention of drugs for various diseases. The Government may also track the research activities conducted by various research institutes in the world in Complementary System of Medicine so as to coordinate and collaborate with each other for the mutual benefit. The Committee also recommends that Ministry should draw appropriate guidelines for taking up research activities under fixed parameters in a time bound manner and ensure that research findings relating to all components of each scheme are finalized, patented and disseminated among the stakeholders. The ongoing research should be completed early and findings disseminated to stakeholders such as educationists, researchers, manufacturers and Government Institutions through internet and research journals.

[Sl. No. 22 of Appendix II, Para 155 of 38th Report of PAC (Lok Sabha)]

Action Taken

The Department of AYUSH has four Research Councils, viz. (i) Central Council for Research in Ayurveda & Siddha (CCRAS); (ii) Central Council for Research in Unani Medicine (CCRUM); (iii) Central Council for Research in Homoeopathy (CCRH); and (iv) Central Council for Research in Yoga & Naturopathy (CCRYN), as the Apex bodies for research in the concerned systems of Indian traditional medicine. Their research programmes are allotted on the recommendation of their Scientific Advisory Committees and technical experts to ensure that Councils undertake meaningful research under fixed parameters within specified period and disseminate research findings for the benefit of educationists, researchers, physicians, manufacturers and common man. The Councils are also collaborating with different research centres of repute.

In addition to intra-mural research conducted by the Central Research Councils, the Department of AYUSH has been implementing the Scheme for Extra Mural Research in AYUSH since the year 1998 with the objectives of developing evidence based support on the efficacy of AYUSH drugs and therapies; to undertake research in the preventive and promotive aspects of AYUSH practices and therapies; to generate data

on safety standardization and quality control for AYUSH products and practices; to promote research on fundamental principles of AYUSH; to facilitate the validation of relevant and promising practices and skills of traditional health practitioners for public benefit; etc. The Scheme aims at utilizing the potential of eminent research institutions in the country and supplementing the research needs under AYUSH.

As a measure of streamlining the work, the Department has drawn up guidelines. The respective Councils have been authorized to invite research proposals through open advertisement in the newspapers. Project Evaluation Committees of technical experts in each field have been constituted and these PECs then recommend only feasible projects to Department's Screening Committee headed by Secretary (AYUSH) for release of funds. Periodic monitoring/evaluation are also ensured by the technical experts of these committees. The PECs are specifically asked to check whether similar work has been done elsewhere so as to avoid duplication to the best of their knowledge.

With a view to disseminating research information and interaction with scientific community, the Councils periodically organize National seminars and scientific workshops. The research papers presented in different seminars are published in different Indian and International Scientific Journals including those of the Councils. The Councils also organize different training programmes for updating research methodology and also depute Council's Researchers to different training programmes organised by other institutions. Audio and video material containing information on diseases, medicinal plants, activities of the Council are also produced and displayed in health melas.

In addition to the EMR, a Golden Triangle Partnership Scheme has been devised as an integrated technology mission for the development of Ayurveda (in the initial phase) using the latest scientific tools and technology. Department of AYUSH, CSIR and ICMR are working together to achieve the objectives of bringing safe, effective and standardized Ayurvedic products for the identified disease conditions; to develop new Ayurvedic and plant based 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; etc.

Details relating to the clinical and collaborative research undertaken by the Research Councils of the Department and dissemination of the research information are as under:

Central Council for Research in Ayurveda & Siddha (CCRAS)

During post audit period, in the 1st phase, the pre-clinical studies *viz.* standardization (physico chemical analysis, microbial load, pesticide residue, heavy metal content etc.), and toxicity studies of **coded formulations** for various life style/other diseases have been completed. TLC, HPLC, HPTLC profiles of individual ingredients has been completed and those of finished products are in progress.

S.No.	Area	Action
1.	Life style disorders *	AYUSH Rasayan-A and AYUSH Rasayan-B for Improving QOL in elderly persons,
2.	HIV/AIDS	* AYUSH QOL-2A for improvement of quality of life in HIV/AIDS,
3.	Cancer	* AYUSH QOL-2C for improvement of quality of life in cancer,
4.	Others	* AYUSH-RP for Sickle Cell Anaemia, * AYUSH-Osto for Osteoporosis and fractures, * AYUSH-LIV for Hepatitis B & C, * AYUSH-M for Migraine, * AYUSH Manas for Mental retardation, * Annabedhichenduram and Dhatri Lauha for Anaemia.

Collaborative research with reputed private drug companies

- AMUL INDIA (GUJARAT)—The development of Nutraceuticals for improving memory and cognitive functions in school going children, as mid-day meal supplement, is under progress. This is a joint research venture of CCRAS, NIN and Amul, India
- VAIPANI HERBALS (NAGPUR)—Development of anti-inflammatory and analgesic cream from haldi leaf oil (*C. longa* leaf oil).
- RANBAXY—development of anti-obesity formulation.
- LILA IMPLEX—drug development for clinical trails as per requirement/need.

The Council has established collaboration with Centre for Study for Oriental Medicine (CSIMO) Brescia, Italy to promote co-operation in the field of Ayurveda & Siddha and related sciences. This includes clinical studies, drug development, protocol and exchange programmes.

Besides this, the reverse pharmacological studies for revalidation of classical preparations for Anaemia are focused under public health programmes. The standardization and toxicity studies of Annabedi chenduram and Dhatri Lauha, the classical Siddha and Ayurveda preparation for Anaemia have been completed and clinical trial are being launched under current programme projection.

Procedural formalities and timelines: The time taken for completion of a project depends upon various factors. In general, the period of completion of different phases of new drug development viz., literary survey, formulation of coded drug, collection of raw material, verification for authenticity, formulation of SOPs, standardization, toxicity and targeted activity studies, drafting of clinical protocols and initiation of clinical trial etc. taken about 10-15 years. However, for conducting clinical trials in the past as per the parameters prevalent in the contemporary period, took approx. 5-6 years.

Central Council for Research in Homoeopathy (CCRH)

(a) *Dissemination of Clinical Research Findings:* The Council has completed 97 clinical trials since its inception. Final reports on 24 studies have already been compiled and were approved by the SAC in December 2006. These reports will be published and disseminated for the benefit of the profession by March 2007. The compilation of reports on 25 other studies is in progress and will be put up in the next meeting. These reports will be published and sent to the Institutions and Clinicians etc. with a view to disseminate the research finding among the stakeholders.

(b) *Research on life style disorders etc.:* The Council is already carrying out clinical research in Diabetes Mellitus and AIDS etc. The Council has undertaken two multi-centric clinical studies in HIV/AIDS (one disease specific and other drug specific), and two distinct clinical studies in Diabetic peripheral neuropathy and Diabetic foot ulcer. The protocol on Comparative study on HIV/AIDS with Anti/Retroviral Therapy (ART) vis-a-vis Homoeopathic Drugs plus ART has been approved by the SAC and Ethical Committee of the Council and Ethical Committee of Safdarjung Hospital. The funding for the study has already been approved by SFC in its meeting held on 7.02.2007. The study would start at Safdarjung Hospital, soon.

The following research studies have also been taken up on Diabetes and Cancer under Extra-Mural Research Scheme:

1. Studies concluded

(a) On Diabetes Mellitus—

"Defining Scope and Clinical Approach for Homoeopathic Management on Diabetes Mellitus" at Dr. M.L. Dhawle Memorial Trust, Mumbai concluded in post-audit period.

(b) On Cancer—

"Evaluation of Homoeopathic medicines in the management of side effects of chemotherapy and radiotherapy" at Institute of Homoeopathic Medical Education & Research, Punjab is concluded.

2. On-going Studies

(a) On Diabetes Mellitus

"Randomized Double Blind Clinical Trial of some Homoeopathic medicines in the treatment of Tropic Ulcer and Neuropathy in Diabetes-leprosy and combination of the two and with additive factors like HIV infection" at Society for Welfare of the Handicapped Persons, Durgapur (W.B.) is in progress.

(b) On Cancer

There are two ongoing Extra-Mural research studies on cancer based *on Human model*—

- (i) "Homoeopathic Management of Carcinoma of Breast" at Bharati Vidyapeeth's Homoeopathic Medical College, Pune,

- (ii) "Evaluation of anti-proliferative, apoptotic and immunomodulatory activity of some Indian System and Homoeopathic anti-cancer drugs" at AIIMS.

Also two Extra-Mural Research studies are continuing on *Cancer on Animal model*—

- (i) "Search for potential anti-Cancer agent Evaluation of anti-Cancer activity of Potentized and Dynamized Carcinocin 200, Thuja 200 and Apis mel. 200 against Ehrlich Ascites Carcinoma (EAC) cells in Swiss Albino Mice" at Jadavpur University; and
- (ii) "An Investigation for testing efficacy and mechanism of action of certain potentized homoeopathic drugs in combating artificially induced hepatic carcinoma in mice and rats" at University of Kalyani.

Reputed private Companies were invited by the Council for a meeting on 08.02.2007 to discuss quality of drugs used in Homoeopathy, especially with reference to shelf-life study of Homoeopathic drugs. Since leading Drug manufacturers expressed their inability to attend the same, it was postponed and will be held sometime in April-June, 2007.

Regarding collaboration with research done elsewhere in the world:

** International Collaboration—*

- I. CCRH has undertaken another two year study 'Train the Trainer' Study- 'Delivery of Model HIV Prevention and Health Promotion Programs in India by Homoeopathy Physicians and Educators' (2005-07) in collaboration with University of California Los Angeles (UCLA). The study is currently in progress and expected to be completed in May 2007.
- II. International Scientific Committee of Homoeopathy on Influenza has also involved the Council for preparation of research protocol for taking up multi-centric trial on Influenza.
- III. Council has prepared Drug Proving Protocol and has invited comments of European Committee of Homoeopathy for international recognition and acceptance.

**Collaborations within the Country*

Council has also taken collaborative studies with Institutes of repute in India, such as, Jawahar Lal Nehru Institute of Post Graduate Medical Education and Research, Pondicherry, Dept. of Zoology, Osmania University, Hyderabad, Scientists of Bhabha Atomic Research Centre, Trombay & Defence Institute of Physiology and Allied Sciences, Delhi, Department of Medical Elementology and Toxicology, Jamia Hamdard, Delhi, Homoeopathic Research Foundation, Lucknow.

**Time-bound Research Studies:*

In 2005, the Council had concluded all ongoing clinical trials and had planned time bound clinical research studies.

- (1) It has undertaken time-bound 18 multi-centric clinical studies at its Institutes and Units in April, 2006. These studies are being conducted on Protocols which prescribe predefined sample size, fixed duration of study (2-4 years), mandatory laboratory/radiological and other investigations for objective evaluation for evidence based outcome.
- (2) The revised protocols for Drug Standardization studies, Clinical Verification and Drug Proving have been prepared in the post-audit period, in the light of the observations and recommendations of the CAG and PAC and got the approval of respective Special Committees and the SAC of the Council in 2006. These protocols are also time bound and are based on fixed scientific parameters.

Central Council for Research in Unani Medicine (CCRUM)

In Clinical Research, there is not always assured success in clinical trial of a particular drug and therefore, unsuccessful trials have to be abandoned midway. Whatever drugs showed evidence of efficacy or in the areas there are some positive leads, work was pursued for a limited sample size and it so happens that in the post-Performance Audit period, the Council has been able to publish findings in the form of monograph and also have applied for patent. For instance, the work done in the field of Vitiligo, Eczema, Psoriasis, Filariasis, Infective Hepatitis, etc., has been published. Clinical studies/therapeutics trials conducted in different diseases during the Xth Five Year Plan are being consolidated so as to publish these documents in the form of monographs/success stories in order to disseminate research findings to the scholars, academicians and practitioners. The documentation work has already been initiated. Five such publications have been brought out in the post audit period. Whereas other four monographs are in the process of compilation and will be ready by June 2007.

As already stated, the Council disseminated the findings of clinical trials through published monographs/success stories/workshops/Seminars/Conferences/Exhibitions and also by way of interactive mechanism with the practicing physicians, Research Scholars and Media. In the post audit period, the Council has launched a series of workshops as System Rejuvenation Initiative in the areas of Geriatrics, Fundamentals, Regimenal Therapy/HIV/AIDS. Such other sessions are planned for Rheumatoid Arthritis and Cosmetics, etc. During the 11th Five Year Plan period, organized Media briefings will be arranged.

Research on lifestyle disorder: The positions remains that the Council has already been seized of the problem and the clinical research programme of the Council includes *Diabetes Mellitus, Hyperlipidemia, Hypertension, Obesity* and such other conditions. *HIV/AIDS, Cancer, Leprosy, Tuberculosis* will be taken up in next Plan. Initial work on these projects has already been started and the studies will be started from April-2007. The basis for taking areas for clinical research has always been National priorities as well as the areas in which Unani System of Medicine has potential.

Collaborative Research: The Council has already been engaged in the collaborative research with the eminent institutions of modern sciences in the field. Drug industries were also approached. The Council in the Post-Audit scenario entered

in MoU with Institute, Delhi Lady Harding Medical College, RRL (CSIR) , Srinagar, Ajmal Khan Tibbia College, Aligarh in the areas of clinical research, Fundamental research and drug standardization. The drug industry is being involved in the research work programme. Three reputed drug industries viz., Hamdard Laboratories, New Delhi, Dawakhana Tibbiya College, Aligarh, Niamath Laboratory, Chennai have already been involved in the drug research programme which has to be taken up this year and in the XIth Plan.

The Council has already a mechanism of coordination and collaboration with other institutions doing the work in the area of complementary medicine. Whenever, any clinical research work is planned, the work done elsewhere is being taken into account to avoid duplication. The work done in the Council is also shared with other institutions in different countries. Also, the Council organized an International seminar/Conference to share experience with other institutions, individuals and scientists and the Council's Research workers are also allowed to participate in various International events so as to there is a coordinated and interactive mechanism. A Seminar has been organized during 20th to 22nd March, 2007 to discuss basic philosophy of the system and other advancements in different fields. Participation from abroad including Iran, Sri Lanka, Bangladesh, Pakistan, U.K., U.S.A., is expected. This will help dissemination to a larger audience.

All Clinical Research work in the Council now is target oriented and time bound. The work presently in hand is being reviewed. Work in new areas to be taken up during XIth Plan will be initiated from April, 2007 onwards.

Central Council for Research in Yoga & Naturopathy (CCRYN)

Central Council for Research in Yoga and Naturopathy has also taken up collaborative studies. 15 studies are completed while the same no. of projects is continuing.

All the four Research Councils are undertaking review of all their research projects with a view to ensure their timely completion and publication of research work and commercial utilization.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)

dated: 20th June, 07]

Recommendation

The number of medicines patented is an indicator of the overall achievement of Research Councils in Clinical Research. Audit examination revealed that position of Ayurvedic and Unani medicines patented by the councils was not encouraging as patents for only three drugs had been obtained and five were under process. The

Committee have been informed by the Ministry that the number of patents obtained by Central Council for Research in Ayurveda and Siddha is 19 and patents filed/processing for filling is 12. The patents/processes released to the Industry (commercialized) is 6. As regards Central Council for Research in Unani Medicine it has been stated that the Council has published monographs on 12 drugs, filed patents for 8 and 17 drugs (a kit of common remedies for Out Patient Department Centre (NRDC). 12 drugs are in the pipeline for filling patents. In so far as Central Council for Research in Homoeopathy, the Ministry have stated that in India, there are no homoeopathic patent medicines as before a homoeopathic medicine is made available for use it has to undergo many stages of evolution. The confidentiality of data gets breached after proving. As such no patents are allowed. The Committee hope that Ministry would extend all possible support-financial, infrastructure and logistics so that research work for patenting of drugs is carried out without any impediments. The Committee expect that the Central Council for Research in Ayurveda and Siddha and Central Council for Research in Unani Medicine would take all possible steps for patenting the drugs for which applications have already been filed, at the earliest.

[Sl. No. 23 Appendix II, Para 156 of 38th Report of PAC (Lok Sabha)]

Action taken

Central Council for Research in Ayurveda and Siddha (CCRAS)

The Patents which are filed, are granted soon after the completion of examination of the claims by the patent office. Details of the patents obtained by CCRAS are as under:

1.	Patents obtained	19
2.	Patents filed/processing for filing	12
3.	Patents/Processes released to the Industry (commercialized)	6

PROCESS PATENTS FOR FORMULATIONS: (4)

- | | | |
|-----|------------|---|
| (1) | AYUSH-64 | An anti-malarial preparation
(Patent No. 152863) |
| (2) | AYUSH-56 | An anti-epileptic preparation
(Patent No. 141170 dated 28.7.1976) |
| (3) | 777 Oil | A medicated oil for Psoriasis
(Patent No. 166740 dated 11.9.1987) |
| (4) | Ksharsutra | A medicated thread for Ano-rectal diseases
(Patent No. 186243 dated 15.2.2002) |

PATENTS OBTAINED JOINTLY (INTERNATIONAL): (1)

1. A Process for preparation of an Ayurvedic formulation for treatment of leukemia. Indian Patent No. 11708 dated 23.08.1999 and German Patent No. 6990577 dated 3.6.08

INNOVATION UNDER THE PROCESS METHODS OBTAINED: (15)

- (1) Patent No. 138350 (26.9.73) A process for the production of a Lactonic glycoside from *Nerium indicum* Mill. (syn. *N. odorum* Sol.).
- (2) Patent No. 139868 (4.4.74) A process for the production of an Extract useful in the treatment of Bronchial asthma from *Mesua ferrea* Linn. Seds.
- (3) Patent No. 140032 (4.4.74) A process for the production of a Sodium Salt of a natural 2 methy/chromone isolated from the pods of *Cassia Siamea*.
- (4) Patent No. 140321 (4.4.74) A process for the isolation of a Pongaflavone from *Pongamia pinnata* (L) Pierre (syn. *P. glabra*)
- (5) Patent No. 140367 (4.4.74) A process for the isolation of 2.3-a., a-Dimethy/chromen-1-methoxy-9-hydroxy-10y, y-demethylallyl pterocarpan, known as Gandetin, from the roots of *Desmodium gangeticum*.
- (6) Patent No. 139869 (4.4.74) A process for the production of a Benzofuran derivative form kojic acid and catechol.
- (7) Patent No. 140381 (4.4.74) A process for the production of isolation of Tomatid-5-en-3 β -ol from the leaves of *Solanum trilobatum*.
- (8) Patent No. 140382 (10.5.74) A process for the isolation of Methylangolensate and Deoxyandirobin from the bark of *Soymida febrifuga*.
- (9) Patent No. 140384 (10.5.74) A process for the production of a new triterpenoid glycoside named Entanin isolated from the seed kernals of *Entada scandens* Benth.
- (10) Patent No. 145858 (11.5.79) A process for the isolation of Liriodenine, a 7-oxo aporphine from the heartwood of *Aquilaria agallocha*.
- (11) Patent No. 147936 (14.8.78) A process for the isolation of 2-Hydroxy-3 (3-methyl-2butenyl)-1, 4-napthaquinone, known as Lapachol from the root of *Steriospermum tetragonum* DC.
- (12) Patent No. 140367 (14.8.78) A process for the preparation of 9,13-Epoxy-6 β -hydroxy-8 α -Labdana-16,15: 19, 2-diolactone known as Nepetaefolinol from the whole plant of *Leonotis nepetaefolia* Linn.
- (13) Patent No. 150019 (21.6.79) A process for the isolation of vincristine from *Vinca rosea*.
- (14) Patent No. 150024 (21.6.79) A process for the preparation of vinblastine from *Vinca rosea*.
- (15) Patent No. 545/DEL/84 Nimbatiktam—for the management of Psoriasis (Kitibha).

PROCESS PATENTS FOR FORMULATION: FILED (2)

- (1) AYUSH GHUTTI—A herbomineral preparation for Cough, Cold Fever & Diarrhoea for children. Indian Patent Application No. 1241Del/2002
- (2) BAL RASAYAN—A herbomineral formulation for general immunity and strengthening the body of children and process there of. Indian Patent Application No. 1242Del/2002

INNOVATION UNDER THE PROCESS METHODS: FILED (5)

- (3) A Process for the pre paration of Novel Composition from Swertia Chirata Buch. Ham. (Gentianaceae) having Anti-carcinogenic (Cancer Preventive) and anti-tumour (Cancer Therapeutic) Action. Indian Patent Application No. 168/Cal/02 dated 26.3.2002.
- (4) A Process for the Isolation of Amarogentin, Novel Seco-Iridoid Glycoside Possessing Anti-carcinogenic (Cancer Pregventive) and Anti-tumour (Cancer Therapeutic) Action. Indian Patent Application No. 169/Cal/02 dated 26.3.2002.
- (5) A novel Anti-Cancer composition from Plant Source with Anti-carcinogenic (Cancer Preventice) and anti-tumour (Cancer Thereapeutic) Action, Indian Patent Application No. 167/Cal/02 dated 26.3.2002.
- (6) A novel Anti-Cancer compound Amarogentin, A Seco-Iridoid Glycoside with Anti-carcinogenic (Cancer Preventice) and anti-tumour (Cancer Thereapeutic) Action, Indian Patent Application No. 166/Cal/2002 dated 26.3.2002.

PROCESS OF FILING (4)

- (7) A novel technology for in vitro propagation of *Celastrus paniculatus* Wild through leaf culture.
- (8) A novel technology for in vitro propagation of *Celastrus paniculatus* Wild through cotyledone culture.
- (9) Culture media composition useful for formation of multiple shoots from nodes of *Asparagus adscendens* Roxb.
- (10) Improved technology for enhancing rate of seed germination of *Asparagus adscendens* Roxb.

NOVEL TECHNIQUES FOR MODERNIZATION OF BIO-MEDICAL INSTRUMENTATION UNDER PROCESS OF PATENT FILING JOINTLY WITH IIT, DELHI: (1)

- (11) A novel modernized technology for the development of Pachakarma Instrumentation (Sarvanga Dhara Yantra)

Besides this, the Council is actively involved in the project TKDL (Traditional Knowledge Digital Library) being executed by Deptt. of AYUSH and NISCAIR (CSIR) which is aimed at providing the knowledge of Ayurveda and Siddha to international patent examiners there by protecting the piracy of traditional formulations/processes etc. and preventing the grant of patents globally.

Central Council for Research in Unani Medicine

The Council have so far been able to publish 12 monographs based on the drugs finalized as part of the Clinical Research Programme. Effective steps are being taken for expediting the award of patent in the drugs which have already been filed. Its Medicines have already been commercially exploited.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 07]

Recommendation

The Committee feel that AYUSH is an efficient and cost effective alternative system of medicine to the modern/allopathic system of medicine and every possible effort should be made for its growth and development, popularization and expansion of its outreach. However, the Committee regret to note that no long term perspective plan appears to have been formulated by the Government for achievement of the avowed objectives. Had such a perspective plan conceived and implemented earlier, it would have gone a long way in popularising and expansion of AYUSH in the country. The Committee are of the considered view that for popularising AYUSH Government should formulate a perspective plan/roadmap for the next 20 years under which Government hospitals/dispensaries equipped with adequate infrastructural facilities such as buildings, staff, laboratories/pharmacies etc. should be set up in every nook and corner of the country. Special emphasis should be laid for setting up of AYUSH dispensaries/hospitals in rural/semi-urban areas, where traditionally the AYUSH System have been well accepted and there is lack of enough allopathic services. The Committee would like to apprise of the steps taken/proposed to be taken in this regard.

[Sl. No. 26 Appendix II, Para 159 of 38th Report of PAC (Lok Sabha)]

Action taken

With an objective to propagate AYUSH in catering to the health care needs of the public, the Department of AYUSH administers a Centrally sponsored scheme through which creation of AYUSH facilities in allopathic hospitals is supported. Support is provided for capital works, equipment & furniture, medicines etc. States have been supported so far to establish 375 specialty clinics, 56 specialized therapy centres and 213 AYUSH wings in district hospitals. From the year 2006 this scheme has been subsumed under the NRHM for the purpose of mainstreaming of AYUSH and it is now extended to cover Primary Health Centres (PHCs), Community Health Centres (CHCs) and District Hospitals

for setting up AYUSH facilities. With such an arrangement, now the States are in a position to take Central assistance for development of basic infrastructure required for accommodating AYUSH facilities in allopathic hospitals from Department of AYUSH and for manpower and other requirements from NRHM. The Department of AYUSH intends to expand the ambit of the scheme in the 11th Plan with addition of new components aimed at strengthening and upgradation of existing AYUSH dispensaries and hospitals and to set up tertiary care AYUSH centres under public-private partnership. AYUSH medicines are included in the medicinal kit of ASHA (Accredited Social Health Activist) being appointed under the NRHM initiative for mobilization of community towards the use of public health facilities. States have been given the flexibility to include need based AYUSH medicines in the ASHA/ANM kit. Presently seven Ayurveda medicines and five unani medicines for use in maternal and child health.

As per the NRHM strategy for mainstreaming of AYUSH, States have been asked to take up relocation of AYUSH facilities to the PHCs, CHCs, wherever possible and if such relocation is not possible AYUSH doctors and paramedic may be hired on contractual basis from NRHM funds for creating AYUSH facilities in the PHCs and CHCs. Indian Public Health Standards (IPHS) have been evolved for AYUSH components in primary health network and the States are being supported under NRHM to develop AYUSH facilities accordingly in PHCs, CHSs and District Hospitals. Six AIIMS like institutions in the offing should have AYUSH Wing with specialized health care facilities. Apart from all this, the department of AYUSH also supports AYUSH teaching hospitals and the relevant scheme is being revamped to make it befitting for improving the quality of hospitalized health care through AYUSH.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III),
dated: 20th June, 2007]

CHAPTER III

RECOMMENDATIONS/OBSERVATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE REPLIES RECEIVED FROM THE GOVERNMENT

Recommendation

The Committee are surprised to note that the budget allocation for Department of AYUSH during 2000-01 to 2004-05 constituted only two per cent of the total health budget of the Union Government as against 10 per cent envisaged in the National Policy on Indian Systems of Medicine and Homoeopathy (ISM&H)-2002. As per the National Policy the share of allocation for AYUSH in the total health plan at the Central level was to be raised to 10 per cent and was to be increased at the rate of 5 per cent in every Five Year Plan. However, Government did not allocate the targeted funds till 2005-06 which meant that there was inadequate support for the achievement of envisaged objectives. The budgetary allocation to AYUSH was recently enhanced to Rs.350 crore in the Annual Budget 2005-06. Although the allocation for AYUSH had increased in the recent years from 2.34 per cent of the Health budget in 2002-03 to 3.38 per cent in 2006-07, nevertheless the fact remains that it is still way below the target level of 10 per cent of the total health budget as envisaged in National Policy. The Budget allocation is much less as compared to China which is allocating significant portion of its health budget on their indigenous systems of medicine which has not only led in providing better and adequate health services to their people but also contributed to huge export of herbal Chinese medicines across the world. The Committee emphasise the need for increasing the allocation to the targeted levels so that the objectives laid down in National Policy on Indian Systems of Medicine and Homoeopathy could be achieved and the Indian System of Medicine is able to contribute effectively in expanding the outreach of AYUSH health care through preventive, promotive, mitigating and curative interventions and ensuring affordable and efficacious AYUSH services and drugs and integrating AYUSH in health care delivery system under the National Health Programme.

[Sl.No. 5 Appendix II, Para 138 of 38th Report of PAC (Lok Sabha)]

Action Taken

By envisaging allocation of 10% of total health budget for Department of AYUSH and further increase of 5% in every plan, the National Policy on Indian Systems of Medicine & Homoeopathy, 2002 has emphasized the need for initiating corrective and promotional policy for full realization of the AYUSH potential. Initiation of these policy measures is already showing results in terms of quantum jump in allocation for AYUSH schemes during Tenth Plan and further quantum jumps in allocation proposed for Eleventh Plan. Policy measures during Eleventh Plan include proposed launching of new schemes for developing accredited AYUSH Centres of

Excellence in non-governmental/private sector, providing common facilities for AYUSH industries clusters, strengthening of international cooperation and promoting public private partnership for setting up speciality clinics in AYUSH Hospitals. Further, with a view to reducing delay in transfer of Central assistance to the grantees, starting from the year 2007-08 funds under Centrally Sponsored Schemes of the Department of AYUSH would be released through State Health and Family Welfare Societies.

Year-wise Plan allocation available and released for AYUSH scheme are indicated below:

(Rs. in crores)

Financial year	Budget available	Actual Expenditure
1997-98	35.30	33.04
1998-99	50.00	50.02
1999-2000	59.13	49.05
2000-01	100.00	79.46
2001-02	120.00	82.15
2002-03	150.00	89.78
2003-04	145.00	133.96
2004-05	200.00	198.76
2005-06	345.00	290.96
2006-07	383.00	320.00 (anticipated)

Above figures indicate that releases, which are decided by the absorption capacity or actual utilization of funds, have been significantly less than the available budget support available for the purpose. Thus, absorption capacity and not the budgetary support has been the reason for not achieving the envisaged target of 10% of total allocation for AYUSH schemes. The policy document recognized abysmally low allocation for AYUSH schemes at State level and non-release & poor utilization of funds by States as a problem in utilizing required funds for AYUSH schemes. Administrative infrastructure of the implementing machinery at State is weak, besides poor backward and forward linkages. The problems hindering and utilization of funds have to be solved in a steady manner in reasonable time by convincing States to allocate more funds for AYUSH scheme, strengthening the implementing machinery, creating awareness and establishing/strengthening the required links with raw material, market, education, research, quality control etc.

Union Minister for Health & Family Welfare has written to all Chief Ministers in December 2006 drawing attention to the issues related to the development of AYUSH in States and emphasizing the need for mainstreaming of AYUSH and improving utilization of funds by increasing absorption capacity for productive utilization of funds and strengthening/streamlining the administrative set up

and the implementing machinery for AYUSH schemes. Quantum increase in allocation and utilization of funds during later part of the Tenth Plan shows the contribution of efforts being made by the Department in increasing the absorption capacity of the States so that budget support and be increased as envisaged in the Policy.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III),
dated: 20th June, 2007]

Recommendation

Recently some of the Ayurvedic medicines manufacturing in the country have been termed as unsafe particularly by some International Research Institutes/media etc. for having allegedly containing toxic substances like lead, arsenic etc. and also human organs/parts. This has naturally created suspicion and doubts in the minds of public about the efficacy, authenticity and safety of the AYUSH drugs in general and Ayurvedic drugs in particular. In this regard the Committee heard the views of experts in the field of AYUSH as well as reputed AYUSH drug manufacturing companies, besides the representatives of Ministry of Health and Family Welfare. The Committee were informed that the Ayurvedic medicines are manufactured in the country conforming to the formulae prescribed in the ancient texts/treatise etc. and are safe and does not have any side effects. The Committee are of the opinion that whenever such allegations are made either in our country or by any foreign country/International Agency, Government should promptly investigate into these allegations and ensure that the drugs produced do not contain toxic/heavy materials etc. If the allegations are found true the licenses of these Drug units/firms manufacturing drugs and the drugs in question should be immediately withdrawn. If after the research the drugs are found safe, appropriate publicity rebutting the false allegations should be launched in National and International media informing the general public about the genuineness as well as safety of these medicines.

The Committee note that at present a bilingual Journal entitled "Journal of Research in Ayurveda and Siddha" is being brought out by the Central Council for Research in Ayurveda and Siddha and the Central Council for Research in Unani Medicine (CCRUM) have launched Hippocratic Journal of Unani Medicine on quarterly basis and also publishes a quarterly Research Journal in Urdu titled "Jehan-e Tibb". The Committee feel that these Journals have very limited circulation and are mostly confined to research institutions and academia. The outside world and the general public do not come to know about these Journals. The Committee, are therefore, of the opinion that Department of AYUSH should bring out a comprehensive Journal *inter alia* covering all the disciplines of AYUSH which can act as an effective medium for publicity campaign and to spread the news and views relating to research and development done in AYUSH as well as popularising the AYUSH systems of medicine among the general public. The Journal should be made available in all the libraries, colleges, academic institutions etc. The Journal should provide a platform for debate/

discussion on all issues relating to AYUSH by the practitioners/experts/pharmaceutical companies and also to counter the false claims/allegations made by certain foreign countries on the quality and authenticity of drugs manufactured by the Indian Drug Companies. Government should also take appropriate measures for dissemination of information regarding efficacy of the AYUSH drugs manufactured in the country through internet. For this an exclusive web site should be created.

[Sl. No. 24 Appendix II, Para 157 of 38th Report of PAC (Lok Sabha)]

Action Taken

The problem of safety/toxicity of Ayurveda, Siddha, Unani drugs is relatively a new phenomenon associated with the commercial production of these drugs on a large scale as well as possible contamination of medicinal plants cultivated along road side or in polluted soil conditions. The problem is more acute with regard to herbo-metallic compound drugs generally shown as Bhasma ausidhis. It is also a fact that some countries are using the bogey of safety of Ayurveda drugs to protect their domestic herbal drug industries. The Department of Ayush has taken the following steps in this direction:—

1. A large study undertaken by ITRC, Lucknow/other scientific institutions to estimate the presence of heavy metals in medicinal plants in the natural state.
2. Enforcement of Good Manufacturing Practices in the country. A separate GMP is being prepared for production of herbo-metallic preparations.
3. All manufacturing units whose products have been found to be contaminated to undertake chemical analysis/safety analysis of their products.
4. Exports of only purely herbal ASU drugs is permitted after batch-wise testing for heavy metals w.e.f. 1.1.2006.
5. A scheme being introduced in the 11th Plan to provide subsidy upto Rs. 50 lakhs to ASU&H units to set up in house quality control laboratories to ensure testing of all raw materials/finished products.
6. National Medicinal Plants Board is preparing Good Agricultural/collection practices to deal with contamination of plants.

2. Central Council for Research in Ayurveda & Siddha (CCRAS) has taken up some JAMA listed drugs for study of heavy metal contents and toxicity studies revealed no toxic effects in acute and sub acute studies. Chemical studies, acute, sub acute toxicity studies of 9 listed drugs and chronic toxicity of 1 drug, have been completed. The chronic toxicity studies are in progress. The findings shall be published and disseminated through national and international media for the information and use of scientific community and general public at large. The findings on "Naga Bhasma" shall be published in association with National Institute of Ayurveda(NIA), Jaipur.

Concerning the dissemination of the research findings among educationist, researchers, manufacturers etc., the finding of the studies are published by the CCRAS in scientific journals viz. Journal of Research Ayurveda and Siddha (JRAS), Bulletin of Medico Ethno Botanical Research (BMEBR) and Bulletin of Indian Institute of History of Medicine and Scientific Monographs. The findings are also disseminated through I.E.C. materials in seminars, workshops, Health meals and distributing to visiting delegates also.

To improve the circulation of the journals among scientific/academic organizations the CCRAS has circulated information to all Medical and Ayurvedic and Pharmacy colleges in the country to enroll them as subscribers. Other steps by CCRAS in this regard are as under:

- IEC material including soft (CD) and hard copies of 16 life style disorders have been provided to the Health Secretaries of all the States for dissemination of same among concerned officials and masses.
- For the use of laboratories and AYUSH pharmaceutical companies, the council has published a Manual on "Parameters for quality assessment of Ayurveda and Siddha Drugs" and provided complimentary copies to major pharmaceutical companies in the country.
- Data Base on Medicinal Plants used in Ayurveda (seven volumes) are provided to selected scientific Research institutes.
- The complimentary copies of selected/choice publication are provided as complimentary copies to Hon'ble Members of Parliament on their request.
- Copies of important publications are provided to Parliament Library.
- Some medicinal plants for other posters are provided to the institutes who desired for the same.

3. The council has been publishing its Research Journal entitled 'CCRH Quarterly Bulletin' which are sent to the Homoeopathic Medical Colleges, Directorates, Industries and some of the reputed clinicians, for their benefit. However, this publication will continue with a new title "Indian Journal of Research in Homoeopathy" from 2007 as decided by the SAC of the Council.

4. The Council have also initiated steps for undertaking safety evaluation on various products developed. Toxicological studies of 92 drugs have already been undertaken so far. The scientific journal has now been streamlined and it is proposed to increase the periodicity of the journal with a view to make the dissemination of research findings more frequent.

As mentioned above, the Councils under the Department have revamped their research journals and taken steps to increase their circulation. Since the Councils have trained Research Officers as also exclusive Publications Officers and the fact that the Department of AYUSH has no exclusive dedicated IEC team, the journals are best brought out by Councils only. Directors of the Councils have been informed to expand the circulation of their journals.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III),
dated: 20th June, 07]

CHAPTER IV

RECOMMENDATION/OBSERVATION IN RESPECT OF WHICH REPLIES OF GOVERNMENT HAS NOT BEEN ACCEPTED BY THE COMMITTEE AND WHICH REQUIRE REITERATION

Recommendation

Whereas substantial funds are required under AYUSH with a view to achieve the avowed objectives, it is a matter of concern that not only there was under utilization of funds by the various States but there was delay also in release of funds by the State Governments to the implementing agencies. This is evident from the fact that out of the total outlay of Rs. 50.87 crore that was released to 12 States during 2000-01 to 2004-05, Rs. 30.98 crore (61 percent) was routed through the States and Rs. 19.89 crore (39 per cent) was released directly to the implementing agencies, Surprisingly, out of these Rs. 50.87 crore, an amount of Rs. 36.52 crore (72 per cent) remained unutilised. Further the State Government failed to release Rs. 16.94 crore (55 percent of the total amount released) in time to the implementing agencies leading to delays ranging upto 36 months. It was also noticed that out of the total amount of Rs. 62.63 crore that the Ministry had released to all the States during 2002-03 and 2003-04, as much as Rs. 14.82 crore (24 per cent) were released only in March in the two years, only to prevent lapse of the funds. The Ministry have explained that substantial amount remaining unutilised related to the scheme for strengthening Drug Testing Laboratories and Pharmacies and that the construction of buildings and procurement of equipment for which funds were provided under the scheme to the States were a time consuming activity and that the Government was pursuing the matter with the State Governments. It was further stated that monitoring and evaluation of projects sanctioned under various Centrally Sponsored Schemes was being done by Secretary (AYUSH). The Committee conclude that the Ministry not only failed to provide the envisaged or targeted funds for the schemes under AYUSH till 2005-06 but could also not ensure complete utilization of funds released. State Governments, in turn, delayed release of funds to implementing agencies and also released substantial funds only in March which would appear to have been a ploy to prevent lapse of funds. Achievement of objectives of the scheme that depended on prompt and complete disbursement of allocated funds thus became, *ab initio*, doubtful and difficult.

[Sl. No. 6 of Appendix II, Para 139 of 38th Report of PAC (Lok Sabha)]

Action Taken

Proposals from States for release under AYUSH schemes are processed expeditiously for ensuring timely release of funds. Lack/non-receipt of eligible and complete proposals during first two quarters of the year from States and consequential rush of proposals during remaining part of the year are the reasons responsible for release of comparatively higher amount during last quarter of the year. The Department

is closely and continuously monitoring the release of funds by the States to the executing/implementing agencies and actual utilization therein. Monitoring of the transfer of funds and utilization therein will be further strengthened with operationalisation of the software being developed by the NIC for online monitoring. However, due to budget constraints of the States and poor administrative structure of the implementing agencies in the States, there have been delays in placing the funds at the disposal of the executing agencies for utilization for the intended purpose.

The matter of delay in transfer of funds has been taken up with State Health Secretaries/Chief Secretaries on a regular basis. Most of the States have set up an umbrella State Health Society under NRHM and others are in the process of setting up such societies. The Department has also taken concurrence of Planning Commission and Ministry of Finance for release of Department of AYUSH's Centrally Sponsored Schemes funds to States through the State Health Societies for onward release of funds to implementing agencies from 2007-08 onwards. State Health Societies will be held responsible for monitoring of implementation of schemes. These arrangements are expected to reduce the delay in transfer of funds to the grantees.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH, O.M. No. H. 11019/1/2006-AYUSH (E-III),
dated: 20th June, 07]

Recommendation

With a view to strengthen and regulate medical education the Ministry had set-up two Regulatory Councils namely, the Central Council of Indian Medicine (CCIM) and the Central Council of Homoeopathy (CCH) as autonomous bodies under the Indian Medicine Central Council (IMCC) Act, 1970 and the Homoeopathy Central Council (HCC) Act, 1973, for advising the Government in matters relating to recognition and withdrawal of medical qualification, prescribing minimum standards of infrastructure and manpower to be maintained by medical institutions, undertaking regular inspection to ensure adherence to the standards, and maintaining Central Registers of Practitioners and update them from time to time. As per amendments brought about in 2002-2003 to the Indian Medicine Central Council (IMCC) Act, 1970 and the Homoeopathy Central Council (HCC) Act, 1973, prior permission of the Ministry had to be obtained for opening new colleges, starting new courses and increasing intake of students. However, the Committee are constrained to note from the records of Central Council of Indian Medicine and Central Council of Homoeopathy that as of March 2005, medical qualification awarded by 69 out of 444 colleges was yet to be recognised. Further, the Councils allowed these colleges to run various courses from time to time without recognition. Though the courses of the concerned universities were not recognised, 6830 students had already passed out from various colleges of Ayurveda and Unani

systems during 1997—2005. The Ministry had also granted permission to two Homoeopathy colleges in Chhattisgarh and Orissa for continuance of courses in new sessions during 2003-04 and 2004-05 respectively against the specific advice of the Regulatory Council, though these colleges lacked adequate infrastructural facilities.

The Committee cannot but deprecate the casual manner in which the Regulatory Councils permitted as many as 69 colleges to run courses without recognition, and due to which careers of 6830 students who have already passed out from these unrecognised colleges were put into jeopardy. The Committee recommend that the Government should set up a High Level Committee to investigate into the reasons and circumstances under which these colleges were allowed to run courses without recognition by the Regulatory Councils. The Government ought to devise ways and means to ensure that the careers of those students who have passed out from the unrecognized colleges are protected and they are allowed to conduct their own practice/take up jobs. The Committee while expecting that a harmonious relationship between the Government and the Regulatory Councils would be developed, recommend that permission to open new colleges, starting Post Graduate Courses and increasing admission capacity are accorded only after it is ensured that the minimum standards of infrastructure prescribed by the Regulatory Councils are achieved.

[Sl. No. 8 of Appendix II, Para 141 of 38th Report of PAC (Lok Sabha)]

Action Taken

The concern of the Committee has been conveyed to CCIM/CCH.

The CCIM has been requested to furnish the details of 69 colleges, which were allowed to run courses without recognition so as to take a view on the careers of the students, who have passed out from these colleges.

After the amendment of the IMCC and HCC Acts in 2002-03, now the Ministry is granting permission to open new colleges, starting PG Courses and increasing admission capacity. Hence, the minimum standards of infrastructure prescribed under the rules are now been ensured prior to grant of recognition.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH, O.M. No. H. 11019/2/2006-AYUSH(E-III),
dated: 20th June, 07]

Recommendation

Most of the medicinal plants grow in the wild as natural components of vegetation of a particular region. With a view to streamlining the medicinal plants sector and developing an appropriate mechanism for initiating and implementing the policies for conservation and development of medicinal plants at the National and State levels, a National Medicinal Plant Board (NMPB) was set up by the Ministry in November 2000

for ensuring coordination of all matters relating to medicinal plants including drawing up of policies and strategies for conservation, proper harvesting, marketing of raw material and protecting, sustaining and developing this sector. At the initiative of the National Medicinal Plant Board, State Medicinal Plant Board (SMPB) was set up in all the States/UTs (except Delhi and Meghalaya) between 2001 and 2004. During the period from 2000-01 to 2004-05, 472 promotional schemes and 1389 contractual farming schemes were sanctioned by the Board and an expenditure of Rs. 59.37 crore and Rs. 34.02 crore respectively was incurred and only 368 (21 per cent) of the projects have been completed so far. The Ministry have explained in this regard by saying that out of 1861 projects sanctioned during the period under report, 41 per cent (753 projects) pertained to the year 2003-04 and 42 per cent (779 projects) to the year 2004-05. Since the project period is usually three years, only those projects which were sanctioned during 2003-04 or earlier could have been completed by March 2006. The project sanctioned during 2004-05 would be completed by March 2007.

It is evident from the above that there is avoidable delay in completion of the projects as only 21 per cent of them could be completed whereas according to the Ministry themselves 58 per cent of the projects should have been completed by March, 2006. The Committee, therefore, recommend that the Ministry should set up an institutional mechanism in the Department of AYUSH so as to periodically monitor the progress made by the National Medicinal Plant Board and State Medicinal Plant Boards in respect of the projects that were sanctioned and are still pending under the scheme. The Ministry should also ensure that the State Governments/State Medicinal Plant Boards submit the utilization certificates on time with respect to the funds sanctioned and spent on the various projects under the scheme. The Committee, are of the opinion that Ministry should also prepare an action plan in consultation with State Governments and voluntary organisations/Non-Governmental Organisations for exploitation of the rich store house of aromatic and medicinal plants in different vegetation zones of the country so that gainful employment can be provided to the people living in the rural and interior areas of the country by encouraging them to grow these plants which can provide in abundance the raw material for the manufacturing of AYUSH drugs.

[Sl. No. 17 of Appendix II, Para 150 of 38th Report of PAC (Lok Sabha)]

Action Taken

The NMPB has been set up for overall development of medicinal plants. The SAPBs have also been set up in 35 States/U.Ts. The Board is guided by an apex body constituted under Union Minister for Health and F.W. for formulation, implementation and monitoring of programmes and the achievements. The NMPB is taking actions regularly for monitoring of implemented schemes in association with SMPBs and State Govts. There has been substantial improvement in implementation of the programmes. It is seen that the total projects sanctioned under promotional scheme were 499, out of which 7 projects have been cancelled. Therefore, the number of implemented projects would be 492 out of which 209 projects have been completed.

Out of 2308 projects sanctioned under Contractual Farming Scheme, 532 projects have been cancelled and 780 projects have been completed. Therefore, the number of implemented projects would be 1776 out of which 780 projects have been completed.

The projects sanctioned during 2004-05 are expected to be completed by March 2007. It is also informed that there were pending UCs of grants amounting to about 85 crores. The Board has taken required steps, and UCs for Rs. 57 crore have already been procured, liquidated and reconciled. However, there was a felt need for strengthening the coordination mechanism further. The SMPB were not adequately strengthened for monitoring of the programmes of NMPB. Therefore, multi-pronged strategy has been adopted. State/U.T. Governments are being regularly asked to properly structure/strengthen the SMPBs, on the other hand financial support is being provided by NMPB for this purpose.

As a separate institutional mechanism, it is proposed to involve specialized organizations in Govt./Non-Government sector for regular monitoring of all ongoing sanctioned projects as well as the new projects that may be sanctioned.

Regarding the recommendation of the Committee for preparing an action plan for exploitation of the rich store house of aromatic plants in different vegetation zones of the country, it is mentioned that promotion and development of aromatic plants come under the purview of National Horticulture Board.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH, O.M. No. H. 11019/2/2006-AYUSH(E-III),
dated: 20th June, 07]

Recommendation

In June, 2000 the Department of AYUSH had issued a notification directing the drug manufactures to mandatorily adhere to Good Manufacturing Practices (GMP) standards as laid down in the Drugs and Cosmetics Rules, 1945. The time limit for adherence was extended up to June 2003 with a view to enabling the drug manufacturers to improve their infrastructure, comply with statutory requirements and obtain Good Manufacturing Practices certificates from the concerned State Drug Control authorities. The Committee regret to note that out of 7849 manufacturing units, only 707 pharmacies possessed Good Manufacturing Practices certification. Nineteen State Governments/UTs namely Gujarat, Rajasthan, Karnataka, Pondicherry, Daman & Diu, Himachal Pradesh, Kerala, Uttaranchal, Haryana, Delhi, Chandigarh, Andhra Pradesh, Uttar Pradesh, Chhattisgarh, West Bengal, Orissa, Punjab, Madhya Pradesh and Tamil Nadu did not cancel the licences of non-Good Manufacturing Practices manufacturers for not adhering to Good Manufacturing Practices norms. Further, thirteen State Governments did not carry out annual inspection of AYUSH manufacturing units and regular testing of drug samples for ensuring quality control under the Drugs and Cosmetics Act, 1940 due to shortage of manpower and non-availability of specified standards for testing AYUSH drugs. Thus, funds amounting to Rs. 51.13 crore earmarked by the Ministry for quality control during 2000-05 proved largely unfruitful as funds were blocked in incomplete projects or the State Governments released funds in unplanned and injudicious manner. The Ministry have informed the Committee that

in October, 2005, Department of AYUSH had issued orders to the State Secretaries under Section 33(P) of Drugs and Cosmetic Act to cancel the manufacturing licenses of non-Good Manufacturing Practices complying units.

The Committee note that despite the various measures taken by the Ministry for making Ayurveda, Siddha, Unani drug manufacturing units Good Manufacturing Practices compliant still around 1569 units are yet to get Good Manufacturing Practices certification as of September, 2006. The Committee recommend that Ministry should take all possible steps including the feasibility of increasing the level of subsidy to the Ayurveda, Siddha, Unani drug units so that they are motivated to upgrade their manufacturing facilities and become Good Manufacturing Practices (GMP) complaint. They further recommend that the Department of AYUSH should fix a time-table within which all the drug units become Good Manufacturing Practices compliant failing which their drug licenses should be cancelled. The Committee also recommend that Drug and Cosmetics Act, 1940 should be suitably amended with a view to take stringent penal measures against drug companies which fail to adhere Good Manufacturing Practices standards.

[Sl. No. 20 of Appendix II, Para 153 of 38th Report of PAC (Lok Sabha)]

Action Taken

Good Manufacturing Practices have been implemented since June, 2003 so far GMP complaint ASU units till March, 2007 are 4451. State Drug Controller have been asked take action against the non-GMP complying units and cancel their licenses immediately.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH, O.M. No. H. 11019/1/2006-AYUSH (E-III),
dated: 20th June, 07]

Recommendation

With a view to control the advertisement of drugs in certain cases and to prohibit the advertisements for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith, the Drugs and Magic Remedies (Objectionable Advertisement) Act was enacted in 1954. Under this Act the definition "Magic Remedy" includes alismans, mantras, kavachas and any other charm or any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease of human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals. Several advertisements relating to AYUSH Drugs often appear in print media and are also beamed in electronic media making claims for the

cure of various chronic ailments such as epilepsy, migraine, etc. and rejuvenation of sex powers. Explaining the measures taken for implementation of the Act, and rules framed thereunder, the Ministry have stated that State Drug Licensing Authorities and Directors of Indian Systems of Medicine of the State were directed to take action including setting up a monitoring cell at State level for checking the misleading advertisements and exaggerated claim of Ayurvedic Siddha/Unani drugs made by individuals companies that are objectionable under the Act. Department of AYUSH are also stated to have issued general guidelines on action proposed to be taken under the Act on 30.9.1999, whereunder all the licensing authorities were required to draw the attention of the provisions of the Act, to the manufacturers of Indian Systems of Medicine drugs under their jurisdiction as also the leading publishers of newspapers for strict compliance. It has also been state that Ministry have also written to the Secretary, Ministry of Information and Broadcasting and press Information Bureau for compliance of the Act, by the print and electronic media. AYUSH Research Councils have also been asked to set up surveillance units for monitoring such advertisements. Obviously, such measures have proved ineffective so far. It is a matter of concern that several misleading advertisements regarding AYUSH Drugs continue to appear in print media. The Committee regret to point out that the Ministry have remained content with issue of directives and did not monitor the continued publicity campaigns of the delinquent parties with a view to take deterrent action against them.

The Government now propose to amend the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 with a view— (i) to bring treatment within the scope of the Act to prevent luring of patients through advertisements offering cure or treatment, (ii) to increase penalties so as to make the law more deterrent. (iii) to bring electronic media under its scope to prevent exaggerated advertisements of drugs and (iv) to delete the Schedule to the Act containing list of diseases and disorders for bringing it under the Rules to facilitate its timely revision. The Committee however, would expect that the Government would show urgency in bringing forward the legislation for amending the Act, so that the gullible public is not taken for a ride. The Committee are of the considered view that merely amending the Act would not achieve the objectives unless its provisions are strictly enforced both in letter and spirit. Steps should be taken to ensure strict implementation of the Act both by the Central and State Governments. The Committee recommend that while formulating norms for electronic and print media, the World Health Organisation's ethical criteria for medicinal drug promotion which specify that "promotion of drugs must be accurate, fair and objective" and that "promotional claims should not be stronger than valid, up-to-date scientific evidence warrants", should be given due consideration. Government should also evolve a code of conduct governing the advertisement relating to promotion of magic drugs so as to protect the interests of consumers.

[Sl. No.25 of Appendix II, Para 158 of 38th Report of PAC (Lok Sabha)]

Action Taken

The Department of AYUSH is equally cautious to restrict the misuse of the provisions of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

The following steps have been taken to curb publishing of misleading advertisements in media:

- (i) Ministry of I&B has been requested to caution the publishers of newspapers and magazines not to carry misleading advertisements.
- (ii) The Advertising Standard Council of India (ASCI) has been requested to register complaints and take necessary action against the print and electronic agencies for violation of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954. A number of cases of violation of the Act have also been brought to the notice of the ASCI for necessary action from time-to-time.
- (iii) The State/UT Government have been requested to ensure compliance of the provisions of the Act to prevent publication of misleading claims in the media.
- (iv) A public Notice has been published in national newspapers informing the public and manufacturers that publication of any advertisement claiming treatment of cancer, HIV/AIDS etc. is banned under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

The Department of AYUSH have also been emphasizing on the State Drug Controllers/Director, AYUSH for strict enforcement of the provisions of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 during review meetings taken by the department, State Chief Secretary, Health Secretaries have also been requested for monitoring of enforcement machinery. The suggestion for evolving norms for electronic and print media on the lines of WHO's ethical criteria for medicinal drug promotion has been noted for further action.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH, O.M. No. H. 11019/1/2006-AYUSH(E-III), dated: 20th June, 07]

CHAPTER V

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH GOVERNMENT HAVE FURNISHED INTERIM REPLIES

Recommendation

Test-check of records of 142 colleges including 35 new colleges, which were inspected by the representatives of Regulatory Councils during 2000—2005, revealed that none of these colleges met the minimum requirement of infrastructural and teaching facility standards prescribed by the Councils. The deficiencies noticed were non-availability of enough class rooms, operation of Ayurvedic colleges without laboratory and pharmacy facilities, non-availability of own college building, inadequate books of staff in Library. The test-check of records of educational institutes in Andhra Pradesh, Chhattisgarh, Delhi, Haryana, Madhya Pradesh, Maharashtra, Rajasthan, Uttar Pradesh and West Bengal revealed shortage of teaching staff ranging between 19 and 72 per cent, of para-medical and other staff ranging between 13 and 78 per cent while bed occupancy ranged between 1 and 71 per cent.

The Committee note that Central Council of Indian Medicine and Central Council of Homoeopathy (CCIM and CCH) granted permission or recognition to new as well as existing colleges for admission of a specified number of students on session-to-session basis on the recommendations of a Committee of experts nominated by the councils for inspection of each colleges. The Committee are, however, concerned to note that 32 to 59 per cent of the Ayurvedic colleges and 23 to 71 per cent of the Homoeopathy colleges were inspected every year by Regulatory Councils during 2000—2005. 61 to 62 per cent colleges of Ayurveda and Homoeopathy were inspected only once or twice in the last five years. What is the surprising is the fact that no systematic or rational system for inspecting the colleges had been devised or followed and visits were generally carried out randomly.

The Ministry have acknowledged various infrastructural inadequacies in the colleges and the deficiencies in the inspections made by the Regulatory Bodies. Although the Ministry have ensured that they would take necessary steps in this regard, the Committee feel that they should have noticed these deficiencies earlier and corrective remedial measures taken timely. That this was not done is regrettable. The Committee would, therefore, like the Ministry to ensure that adequate and identifiable measures are taken in a time bound manner to bring in parity in medical education across the country and strengthen the infrastructure in the apex level institutes so as to enable them to function as centers of excellence.

[Sl. No. 9 of Appendix II, Para 142 of 38th Report of PAC (Lok Sabha)]

Action Taken

After the amendment in IMCC/HCC Acts the Ministry is granting permission to open new colleges, starting PG Courses and increasing admission capacity and the

minimum standards of infrastructure prescribed are ensured before grant of permissions. Infrastructure in apex level national institutions is being constantly upgraded to develop them as Centres of Excellence.

The Process of review of infrastructural deficiencies of existing Ayurveda, Unani and Siddha Colleges is on. The existing ASU colleges who have applied under Section 13 (c) have been given 3 months time to fulfil the shortcoming related to teachers as per the regulations before admitting the students for the session 2007-08. Other deficiencies will have to be fulfilled before 31st March, 2008.

In order to bring parity in medical education across the country and strengthen the infrastructure of AYUSH colleges and the apex level institutes, the Department proposes to provide grants-in-aid to AYUSH institutions in the 11th Five Year Plan on a much higher scale as compared to the assistance given in the 10th Five Year Plan. However, the statutory regulatory bodies viz. CCIM and CCH have to play their legitimate role in ensuring that college managements fill up vacancies of teachers and fulfil other infrastructural deficiencies by rigorous inspections by experts of integrity and repute. As the IMCC and HCC Acts do not at present enable the Central Government to give directions to these autonomous bodies and supercede them if they do not function in a transparent and effective manner, there are limitations of what the Central Government can do.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH, O.M. No. H. 11019/1/2006-AYUSH (E-III),
dated: 20th June, 2007]

Recommendation

Another area of concern is the fact that the teams of experts constituted by the Councils for inspection of colleges included members of the Executive Committee of these Councils. As these members also took part in the Executive Committee's meetings in which inspection reports were considered, there could be a conflict of interest diluting the regulatory mechanism. The Ministry have informed the Committee that a panel of experts prepared by them for inspection for Ayurveda, Unani and Siddha and Homoeopathy colleges and forwarded to the respective Councils were largely disregarded by the Councils. Central Government have no powers under the Central Council of Indian medicine/Central Council of Homoeopathy Acts to enforce directions given to them. As Central Government has no powers under the Acts to enforce its directions the Central Council of Indian Medicine and Central Council of Homoeopathy (Amendment) Bill 2005 have been introduced in the Parliament to address this anomaly. The Committee express their serious concern over the utter disregard shown by the Regulatory Councils to the advice/direction given by the Ministry in the matter of selection and composition of expert panels for inspections of AYUSH colleges, which is nothing but inexplicable. This only reinforces the belief that the Regulatory Councils

want to promote the Interest of some of the errant colleges by showing favours in recognition of colleges. The Committee expect that the Ministry would take advocacy and other procedural measures for expeditious passing of the Bills for amending the Central Council of Indian Medicine and Central Council of Homoeopathy Acts by the Parliament so as to put an end to this despicable practice.

[Sl. No. 10 of Appendix II, Para 143 of 38th Report of PAC (Lok Sabha)]

Action Taken

The Govt. is taking steps to bring the bills for amending the CCIM/CCH Acts passed from Parliament expeditiously. In the meantime the regulatory councils have been advised once again to constitute panel of experts for inspection of AYUSH Colleges from the panel already forwarded to them.

Until the above Acts are suitably amended to enable the Central Government to give mandatory directions to the regulatory bodies and supercede them if they fail to function effectively in a transparent manner the problems noticed by the Committee are likely to persist.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH, O.M. No. H. 11019/1/2006-AYUSH (E-III),
dated: 20th June, 2007]

Recommendation

The Committee notes that a State-of-the-Art All India Institute of Ayurveda is proposed to be set up at New Delhi. For this, an Expenditure Finance Commission Memo was prepared in the light of the observations made by the Planning Commission as well as Investment for Development (IFD). The Estimated project cost was Rs. 325.00 crore. In September, 2004, the Delhi Development Authority allotted approximately 6.00 acres of land near Apollo Hospital at Sarita Vihar, New Delhi at a cost of Rs. 13.62 crore. The proposal for setting up of such an Institute was stated to have been considered by the Expenditure Finance Commission in October, 2005 and recommended the proposal 'in-principle' subject to certain observations. The Committee are informed that in pursuance of the observations of the Expenditure Finance Commission a detailed project report is being reformulated. The Committee regrets to observe that the proposal is yet to be approved by Expenditure Finance Commission even though two years have elapsed since land was allotted to the institute by the Delhi Development Authority. This clearly indicates that the Ministry has not accorded the urgency that this project deserved. At the tardy pace with which the Ministry is proceeding, it would take years for the completion of the prestigious institute. The Committee strongly urge

the Ministry to take urgent steps for getting the project approved/cleared by the concerned agencies so that the project is completed expeditiously within a time bound period. The Committee would like to be apprised of the progress made by the Ministry so far in this regard and the precise date by which the project would be completed and made functional.

[Sl. N. 13 of Appendix II, Para 146 of 38th Report of PAC (Lok Sabha)]

Action Taken

Expenditure Finance Committee chaired by Secretary (Expenditure), Ministry of Finance has approved the revised project proposal with certain conditions in its meeting held on 9.5.07 and the proposal is being resubmitted for approval of CCEA.

Sd/-

(SHIV BASANT)
Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 2007]

Recommendation

The Committee have noticed that quite often the price of a drug product is cheaper as compared to the ingredients that go into its manufacturing. This gives rise to the suspicion about the quality and quality of ingredients used in the composition of the medicine. In this regard, the Ministry have explained that Department of AYUSH have been supporting establishment and functioning of Drug Testing Laboratories in the States, and the Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad have been asked to test 50 samples every month. Good Manufacturing Practices have been notified and labelling provision has been made mandatory. Further the Department have written to all States to get Ayurveda, Siddha, Unani drugs tested from National Accreditation Board for Testing and Calibration Laboratory (NABL) accredited labs for which Rs. 500 per sample will be reimbursed. The Committee note that notwithstanding these measures several sub-standard drugs are still available in the market without any Good Manufacturing Practices certification. The Committee feel that Ministry should not just remain content with issue of instructions but should put in place an effective enforcement mechanism in co-operation and co-ordination with respective State Governments so that drugs sold in the market maintain the stipulated quality standards. Further, Government should also conduct frequent surprise checks at the chemist shops and get the samples tested to ensure that the drugs sold in the market conforms to the quality standard.

[Sl. No. 19 of Appendix II, Para 152 of 38th Report of PAC (Lok Sabha)]

Action Taken

Department of AYUSH has approved 26 Pvt. Drug Testing Laboratory and all NABL accredited laboratories for testing of ASU drugs. Pharmacopoeial Laboratory of

Indian Medicine, Ghaziabad has started testing of ASU drug samples every months as per the allotted target. During the year 2006-07, 373 drug samples have been tested out of which 19 drug samples are failed. Similarly Homoeopathic Pharmacopoeial Laboratory, Ghaziabad has tested 1085 drug samples out of which 29 samples were failed. Good Manufacturing Practices have been implemented through out the country. So far till March, 2007, 4451 ASU units are GMP complaint units. State Drug Controllers of AYUSH have been asked to take stringent action against ASU units who are selling sub-standard drugs. Labelling provision on each ASU drug should be stipulated therein either on label or in leaflet. Batch-wise testing have been made compulsory to all ASU manufacturing units before drug sold in market. Director, PLIM, Ghaziabad have been asked to conduct tests of drug samples from any chemist shops/market samples of ASU drugs and send report to the Government. In spite of several measures taken by the Department of Ayush the fact remains that the enforcement of the provisions of Drugs and Cosmetics Act and rules by States varies from State to State. The Central Government has proposed to set up the Central Drug Authority of India to bring about improvements in the enforcement of Drugs and Cosmetic Act and Rules throughout the country. Enforcement of provisions of the above Act and Rules with respect to Ayush Drugs would also be the responsibility of the proposed Central Drug Authority of India.

Sd/-

(SHIV BASANT)

Joint Secretary (AYUSH)

[Department of AYUSH O.M. No. H. 11019/1/2006-AYUSH (E-III)
dated: 20th June, 2007]

NEW DELHI;
17 January, 2008
27 Pausa 1929 (Saka)

PROF. VIJAY KUMAR MALHOTRA,
Chairman,
Public Accounts Committee.

PART II

MINUTES OF THE SIXTEENTH SITTING OF THE PUBLIC ACCOUNTS COMMITTEE (2007-2008) HELD ON 9TH JANUARY, 2008

The Committee sat from 1600 hrs. to 1630 hrs. in Committee Room "D", Parliament House Annexe, New Delhi.

PRESENT

Prof. Vijay Kumar Malhotra — *Chairman*

Lok Sabha

2. Shri Kirip Chaliha
3. Shri Khagen Das
4. Shri K.S. Rao
5. Shri Mohan Singh
6. Shri Rajiv Ranjan Singh 'Lalan'
7. Shri Kharabela Swain
8. Shri Tarit Baran Topdar

Rajya Sabha

9. Prof. P. J. Kurien
10. Shri Janardhana Poojary
11. Dr. K. Malaisamy
12. Shri Ravula Chandra Sekar Reddy

SECRETARIAT

- | | | |
|--------------------------|---|-----------------------------|
| 1. Shri S.K. Sharma | — | <i>Additional Secretary</i> |
| 2. Shri A. Mukhopadhyay | — | <i>Joint Secretary</i> |
| 3. Shri Brahm Dutt | — | <i>Director</i> |
| 4. Shri M.K. Madhusudhan | — | <i>Deputy Secretary-II</i> |

Representatives of the Office of the Comptroller and Auditor General of India

Shri A.N. Chatterji — *Director General (PA)*

2. At the outset, the Chairman, PAC welcomed the Members to the sitting of the Committee. Thereafter, the Committee took up for consideration of the following draft Reports:—

- (i) Action Taken Report on 19th Report of PAC (14th Lok Sabha) relating to **"National AIDS Control Programme"**;
- (ii) Action Taken Report on 38th Report of PAC (14th Lok Sabha) relating to **"Performance Audit of Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)"**;

- (iii) Action Taken Report on 40th Report of PAC (14th Lok Sabha) relating to **"Management of Projects relating to Utilisation & Conservation of Soil and Water Undertaken by Institutes of ICAR"**; and
- (iv) Action Taken Report on 43rd Report of PAC (14th Lok Sabha) relating to **"Performance Audit of Sarva Shiksha Abhiyan (SSA)"**.

3. After taking up the Draft Reports one by one, the Committee adopted these draft Reports with some verbal changes and authorised the Chairman to finalise and present the same to Parliament in the light of factual verification by the Audit.

The Committee then adjourned.