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PERFORMANCE AUDIT OF DEPARTMENT OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)

MINISTRY OF HEALTH AND FAMILY WELFARE
(DEPARTMENT OF AYUSH)

PUBLIC ACCOUNTS COMMITTEE 2006-2007

THIRTY–EIGHTH REPORT

FOURTEENTH LOK SABHA

LOK SABHA SECRETARIAT
NEW DELHI

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

Presented to Lok Sabha on 18-12-2006
Laid in Rajya Sabha on 18-12-2006

LOK SABHA SECRETARIAT
NEW DELHI

December, 2006/Agrahayana, 1928 *(Saka)*

P.A.C. No. 1823

Price: Rs. 180.00

Published under Rule 382 of the Rules of Procedure and Conduct of Business in Lok Sabha (Eleventh Edition) and Printed by the Manager, Government of India Press, Minto Road, New Delhi-110 002.

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INTRODUCTION

I, the Chairman, Public Accounts Committee, as authorised by the Committee, do present this Thirty-eighth Report relating to "Performance Audit of Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)" on the Report of C&AG of India for the year ended 31 March, 2004 (No. 16 of 2005), Union Government (Civil – Performance Audit).

2. The Report of the C&AG of India for the year ended 31 March, 2004 (No. 16 of 2005), Union Government (Civil - Performance Audit) was laid on the Table of the House on 20th December, 2005.

3. The Committee heard the views of the experts in the fields of Ayurveda, Yoga & Naturopathy, Unani and Homoeopathy and the representatives of drug companies of Ayurveda, Unani and Homoeopathy on 12th June and 5th September, 2006 respectively. The Committee took the evidence of the representatives of the Ministry of Health and Family Welfare (Department of AYUSH) on the subject at their sitting held on 6th September, 2006. The Committee considered and finalised this Report at their sitting held on 15th December, 2006. Minutes of the sittings form Part–II of the Report.

4. For facility of reference and convenience, the Observations and Recommendations of the Committee have been printed in thick type in the body of the Report and have also been reproduced in a consolidated form in the Appendix to the Report.

5. The Committee would like to express their thanks to the experts in the fields of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy and the representatives of drug manufacturers of Ayurveda, Unani and Homoeopathy for expressing their views and giving suggestions on the subject. They would also like to express their thanks to the officers of the Ministry of Health and Family Welfare (Department of AYUSH) for the cooperation extended by them in furnishing information and tendering evidence before the Committee.

6. 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.

NEW DELHI;
15 *December*, 2006
24 *Agrahayana*, 1928 *(Saka)*

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

REPORT ON PERFORMANCE AUDIT OF DEPARTMENT OF AYUSH

I. Introductory

Alternatives to allopathic medicine or traditional medical systems have always maintained their popularity worldwide. They are often part of a wider belief system in an organic unity of the body, mind and nature. They are considered integral to everyday practices for well being. It is said that these systems of medicine currently serve the health care needs of the 80 per cent of the population worldwide, despite the spectacular advances in modern medicines. India possesses an unmatched heritage represented by its ancient systems of medicine which are a treasure house of knowledge for both preventive and curative healthcare. The positive features of the Indian systems of medicine, are their diversity, flexibility; accessibility; affordability; broad acceptance by a section of the general public; comparatively low cost, low level of technological input and growing economic value.

2. In India the indigenous forms of medicine are not a single system. They comprise different components of Ayurveda, Yoga and Naturopathy, Unani and Siddha systems. These systems, being embedded in Indian culture well before the advent of allopathic system of medicines, have continued to be an integral and significant part of our society. They are officially recognized, codified and well documented. Scientists all over the world now look towards the Indian systems along with the German system of Homoeopathy (AYUSH) for possible answers to certain global health problems that are life style related, degenerative and psychosomatic in origin and generally considered incurable. However, its growth and development has been the focus of discussion in different fora. Some of the prominent contemporary issues relating to it are individualized and inhibitive behaviours, lesser adaptability, lack of quality parameters, abuse of the system by unscrupulous practitioners, ad-hoc growth, poor resources and allocation and neglect of basic research.

II. Organisational Set Up

3. To address the health care delivery services through the Indian System of Medicine and Homoeopathy, 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. Thereafter, the Government approved a separate 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 Department of AYUSH headed by the Secretary to Government in the Ministry of Health and Family Welfare is the nodal agency for overall direction, coordination, budgetary control and policy interventions for implementation of the policy. A Joint Secretary and four Directors/Deputy Secretaries and a number of Advisors assist the

Secretary. Out of the 35 States/UTs, 21 States have established a separate Directorate to coordinate and implement AYUSH related programmes. As of March 2003, an infrastructure comprising of 3845 hospitals with 65159 beds, 23630 dispensaries, 6.91 lakh registered practitioners, 439 and 96 under-graduate and post-graduate colleges with admission capacity of 23555 and 1888 students respectively and 9226 licensed pharmacies, had been created in the country

4. The major objectives of Department of AYUSH are: (i) to promote good health and expand the outreach of public health care; (ii) to improve the quality of teachers and clinicians; (iii) to ensure affordable AYUSH services & drugs which are safe and efficacious; (iv) to facilitate availability of raw drugs which are authentic and contain essential components; (v) to integrate AYUSH in health care delivery system and national programmes ; (vi) to re-orient and prioritize research in AYUSH; (vii) to create awareness about the strengths of these systems in India and abroad and sensitize other stakeholders and providers of health; and (viii) to provide full opportunity for the growth and development of these systems.

III. The National Policy on Indian Systems of Medicine and Homoeopathy, 2002

5. The Ministry of Health and Family Welfare have formulated and approved a National Policy on Indian System of Medicine and Homoeopathy in 2002. The salient features of the policy are as under:—

- Strengthening the standards of medical, nursing and pharmacy education through strong regulatory control, upgradation of course curricula, strengthening of infrastructural facilities in AYUSH educational institutes and setting up of model colleges and centres of excellence;
- Re-orientation and prioritisation of research activities and areas in 'AYUSH' covering clinical trials, pharmacology and toxicology keeping in view the strength of each system and contemporary relevance;
- Drug standardisation, regulation and enforcement including adherence to good manufacturing practices (GMPs) and publication of formulations and pharmacopoeial standards;
- Conservation and sustainable use of medicinal plants including remunerative farming for ensuring availability of authentic and quality raw drugs with essential components as required under pharmacopoeial standards;
- Integration of AYUSH with health care delivery systems for optimal use of the vast infrastructure of hospitals, dispensaries and physicians; and
- Ensuring affordable AYUSH services and safe and efficacious drugs.

IV. Audit Review

6. Audit conducted a review of the Department of AYUSH for the period 2000-01 to 2004-05 including its subordinate offices and implementing agencies in 29 States and

Union Territories. The objectives of the Audit 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 for 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.

7. Several drawbacks in the working of the Department of AYUSH have been identified by Audit which *inter-alia* includes the following—

- 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 pronouncement envisaged raising of AYUSH share to 10 per cent with designed growth of 5 per cent in every Five Year Plan;
- The Centrally Sponsored Scheme suffered from absence of an effective system of transfer of funds to the implementing agencies;
- The Regulatory Councils responsible for prescribing minimum standards had failed in checking the growth of substandard institutions;
- Most of the 444 colleges of Ayurveda, Unani and Homoeopathy in the country lacked minimum required faculty, attached hospitals and teaching facilities;
- Research activities were not undertaken under fixed parameters within specified time period and their results had not been disseminated for the benefit of educationists, researchers, manufacturers and the common man;
- During the last 25 years, the Councils had obtained patents for only three Ayurveda drugs and did not contribute concrete research findings in the core area of family planning/contraceptive measures;

- Pharmacopoeial Committees did not finalize standards in respect of any of the compound formulations in Ayurveda and Unani even after 40 years of their establishment, though the National Policy-2002 had envisaged completion of this work by 2005;
- The National Medicinal Plant Board 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 maintain any consolidated record of utilisation of grants depriving it of an effective monitoring tool;
- None of the 142 colleges whose records Audit test checked, out of total 444 colleges, possessed adequate infrastructural facilities, faculty, attached hospitals with requisite bed strength and OPD/IPD facilities in accordance with the norms laid down by the Regulatory Councils;
- There was neither correlation between the drugs standardised, drugs proved and drugs clinically verified or any systematic approach to standardisation of drugs;
- Ministry did not monitor the progress of implementation of the Centrally Sponsored Scheme of 'Development of Health Care Facilities in AYUSH' by 24 States though assistance of Rs. 33.74 crore was released during 2002-05;
- Inordinate delay in completion of 33 projects of development of agro techniques in respect of 133 medicinal plants and failure to patent and disseminating the research findings resulted in blockade of funds to the tune of Rs. 5.05 crore.

These issues have been discussed in detail in succeeding paragraphs.

8. With a view to develop a proper prospective on the subject under examination as well as to have first hand information on the various problems and constraints faced by the AYUSH System of Medicine in the country, the Committee heard the views of the experts in the fields of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy. The Committee also interacted with the representatives of drug manufacturing companies of Ayurveda, Unani and Homoeopathy to know the constraints/problems faced by the AYUSH industry. During their visit to Shimla and Jaipur in June and September 2006, respectively as a part of their Study Tour Programme, the Committee held informal discussions with the representatives of the State Governments of Himachal Pradesh and Rajasthan, National Institute of Ayurveda, Jaipur and Ministry of Health and Family Welfare (Department of AYUSH). These informal discussions helped the Committee in understanding the subject better and has enabled the Committee during detailed examination of the subject as well as of representatives of the Ministry of Health & family Welfare (Department of AYUSH) with reference to audit observations. The various shortcomings and deficiencies noted during the interactions and study visits are also discussed in the Report at the appropriate place.

V. Efficacy of Planning, Budgetary Allocation and Utilisation of Funds

9. Audit scrutiny has revealed that the budget provision for AYUSH during 2000-05 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 policy, the allocation for AYUSH in the total health plan at the Central level to 10 per cent 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, when Rs. 350 crore was provided for the scheme in the budget. This meant inadequate support for the achievement of envisaged objectives.

10. When asked about the reasons for insufficient allocation of funds to the Department of AYUSH during 2000-05, the Ministry in a written note stated as under:—

> "There has been an increase in allocation for AYUSH from 2.34 per cent of the Health budget in 2002-03 to 3.38 per cent in 2006-07. There has been a ten-fold increase in allocation to AYUSH as compared to 1997-98 and allocation has doubled in last three years. Absorption capacity of States was also a limiting factor in not allocating the targeted funds for the Department of AYUSH during 2000-05 as envisaged in the National Policy on Indian System of Medicines and Homoeopathy. Health being a State subject, responsibility devolves on States also to increase allocation for AYUSH. The department is also taking steps to increase the budget allocation in the Eleventh Five Year Plan."

11. In this regard, the Secretary, Ministry of Health and Family Welfare (Department of AYUSH) during evidence deposed as under: —

> "We do agree that two per cent is nowhere near the stated 10 per cent. Although there has been an increase in the last few years, it has gone up to about 3.3 per cent. That also is negligible. So, we do agree that this has to be stepped up. We face this constraint of absorption capacity also. That is because these AYUSH dispensaries, hospitals etc., are all in the State Government sector."

12. The witness added:—

> "In terms of our own request for the Eleventh Plan, we have made certain additional projections over and above asking for more funds for the same type of schemes or the same kind of things which we want to implement. We are also asking for new type of funding for giving recognition to all the efforts which are being made in the private sector or the Government sector from very good institutions in different parts of the country which are doing very good work in terms of dispensaries, health care, through the Indian systems of medicine. So, we are saying that let us recognize them by promoting public-private partnerships, and asking for fund to support such institutions and organizations so that they can expand their operations in their own sphere of excellence."

13. Enumerating the problems arising out of meagre allocation of funds for Department of AYUSH from the total health budget of the Ministry of Health & Family Welfare, one of the experts in the field of Ayurveda during the hearing by the Committee on the subject stated as under:—

> "Due to insufficient budget we are not able to improve the standard of our education and research work is not done. Today we find that the 25—30 crore Rupees are being spent per year on the research work started around thirty years ago. Even then neither the 'Ayurveda' nor common man or the scientific fraternity has been benefited of that. It is a big issue that such a huge amount of taxpayers is spent. The way research work should have been undertaken in Ayurveda and Unani system of medicine is not taking place."

The expert added:—

> "Today, Chinese exports have touched the Rs. 30,000 crore mark. In China, the State help in this regard is 30 per cent against two per cent in India. Our total exports are only to the tune of Rs. 15,000 crore. We can increase our exports only through enhanced State assistance, through increasing the quality of our education and through excellence in research. The variety of herbs present in India is unparalleled. We can earn a lot through its export."

14. According to Audit out of Rs. 50.87 crore released to 12 States by the Ministry during 2000-05, Rs. 30.98 crore (61 per cent) was routed through the States. An amount of Rs. 19.89 crore (39 per cent) was released directly to the implementing agencies. Out of the total funds of Rs. 50.87 crore that the Ministry released, Rs. 36.52 crore (72 per cent) had remained unutilised. Further Rs. 16.94 crore (55 percent of the total amount released) was not released timely by the State Governments to the implementing agencies and the delays ranged upto 36 months. It was noticed that out of the total amount of Rs. 62.63 crore that the Ministry had released during 2002-04 as much as Rs. 14.82 crore (24 per cent) were released only in March in the two years, to prevent lapse of funds.

15. When asked whether the Ministry have analysed the reasons for delay in release of funds to the implementing agencies by respective State Governments, the Ministry in a written note replied as under:—

> "Department of AYUSH has been giving tentative scheme wise allocation to States well before the beginning of the next Financial Year…… State Governments do not release the funds to the concerned implementing agencies in time due to lengthy procedure at their end and also some times due to their budgetary constraints".

16. On being enquired about the steps taken to impress upon the States for timely release of funds to the implementing agencies, the Ministry in a written reply submitted as under:—

> "The matter 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. State Health Societies will be held responsible for monitoring of implementation of schemes. These arrangements will be operationalized in 2007-08."

17. As regards the action taken to avoid the delay in releasing of funds to the implementing agencies, the Ministry in their written note stated as under:—

"The Department is monitoring the utilization of funds regularly and emphasizing on State Governments to release funds to implementing agency in time and furnish utilization certificates in time, failing which second installment and any other fresh grant is not released. Situation is expected to improve. Department has been organizing the meetings of Health Secretaries/ Director of ISM&H and the situation has been reviewed and it was agreed that all out efforts would be made to release the fund in time by the State Governments and utilization certificates submitted along with supporting documents."

18. The Committee enquired whether the Ministry have set up any monitoring mechanism to ensure that funds released to the implementing agencies were utilised for the purpose for which they were given. In response, the Ministry in a written note stated as under:—

"In form of prescribed physical progress reports and physical verification of selected grantees through regular field visits by the officers of the Department, the Ministry already has a mechanism for ensuring that funds released to the implementing agencies were utilised for the purpose for which they were given. The Department is also getting an independent evaluation done on the impact of the Centrally Sponsored Scheme. Further to strengthen the monitoring mechanism, the Department is computerizing the monitoring of the schemes and is in the process of developing a software for online monitoring of the schemes of the Department."

19. When the Committee desired to know whether the Ministry have investigated the reasons for slow pace of utilization of funds by the implementing agencies with a view to fixing responsibility on the concerned officials, the Ministry in a written note submitted as under:—

"Inordinate delay in utilization of funds has been mostly in the Centrally Sponsored Schemes which are implemented by the State Governments. Apart from sensitizing the concerned State Governments and their officers, and not releasing further grants, it is not feasible to fix responsibility on States which are constitutional entities."

20. During the hearing of the Committee of the experts in the field of AYUSH, one of the experts in the field of Homoeopathy have alleged that grants to Central Council of Research in Homoeopathy (CCRH) are mostly released at the fag end of the Financial

Year, resulting in non-utilization of grants by the Council. When the Committee enquired about the reasons for the release of grants at the fag end of the year, the Ministry in a written note stated as under:—

> "Vast improvement has been achieved in timely release of the funds to CCRH, other Research Councils of the Department and to States under Central Sector and Centrally Sponsored Schemes. Following details of quarter-wise releases to CCRH during 2004-05 and 2005-06 indicate that release of funds to CCRH was distributed over all quarters''.

Statement of Quarterly Grant-in-Aid released by the Department of AYUSH

(Rs. in lakh)

Year	1st Qtr.(upto June)		2nd Qtr.(upto Sept.)		3rd Qtr.(upto Dec.)		4th Qtr.(upto March)		
	PLAN	NON-PLAN	PLAN	NON-PLAN	PLAN	NON-PLAN	PLAN	NON-PLAN	Total
2005-06	200.00	160.00	102.00	80.00	251.00	120.00	166.00	160.00	**1239.00**
2004-05	183.00	30.00	367.00	163.72	275.00	148.14	85.00	158.14	**1410.00**
Total	**383.00**	**190.00**	**469.00**	**243.72**	**526.00**	**268.14**	**251.00**	**318.14**	**2649.00**

VI. Strengthening of Medical Education

21. A mechanism for strengthening of medical education was adopted by the Ministry through Regulatory Councils and National/Apex level institutions Accordingly, the Ministry 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.

22. In 2002-2003 Government brought about amendments to the aforesaid Acts requiring that prior permission of the Ministry be obtained for opening new colleges, starting new courses and increasing intake of students. However, Audit scrutiny of records of CCIM and CCH revealed that that as of March 2005, medical qualification awarded by 69 out of 444 colleges was yet to be recognised. 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. Further Audit revealed that Ministry 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, that these colleges lacked adequate infrastructural facilities.

23. When asked about the action taken against the colleges running unrecognized courses, the Ministry in a written reply stated as under:—

> "According to IMCC (Amendment) Act, 2003, prior permission of Central Government is mandatory for starting new course in Ayurveda, Unani and Siddha colleges. Similarly, according to HCC (Amendment) Act, 2002 prior permission of Central Government is mandatory for starting new course in Homoeopathy colleges. …… Further, physicians only with recognized qualifications listed in schedules 2, 3 and 4 of the relevant acts can practice Ayurveda, Unani and Siddha and Homoeopathy systems of medicine and they should also be registered with the CCIM, CCH and / or State Boards. IMCC and HCC Acts provide for punishment for practice by practitioners not registered by the Central/State Boards. These provisions have to be enforced by the State Governments/ State Boards."

24. The Ministry have added as under:—

> "With the amendment of Indian Medicine Central Council Act, 1970 and Homoeopathy Central Council Act, 1973 in 2002 and 2003, prior permission of Central Government has been made mandatory for opening new college and starting new course. The list of recognized colleges is on the websites of the Regulatory Councils and this has been brought to the notice of general public by advertisements in National/Regional newspapers. State Governments have been requested in certain cases to take legal action against organizations running unrecognized colleges."

25. When asked about the steps taken by the Ministry for ensuring that the standards envisaged by CCIM and CCH are maintained by the colleges/institutions, the Ministry in a written reply stated that regular inspections are carried out by CCIM and CCH and in case of doubt, the Central Government sends a team of experts.

26. The Committee enquired as to why the Ministry granted permission to two Homoeopathy colleges in Chhattisgarh and Orissa for continuance of courses during 2003-04 and 2004-05 despite the specific advice of the Regulatory Councils that these colleges lacked adequate infrastructural facilities. In response, the Ministry in a written reply submitted as under:—

> "Since many representations had been received for allowing the Raipur Homoeopathic College, Raipur which was established in the year 1982 for running diploma courses and which was upgraded to BHMS course in 1998, for taking admissions from 2003-04, a central team of experts, consisting of Adviser (Homoeopathy), Department of AYUSH and Principal, Nehru Homoeopathic Medical College, New Delhi were deputed to inspect and assess the infrastructure of the college. They were also advised to inspect the other college situated in Raipur which was granted permission by CCH for the year 2003-04. After making an objective assessment of the infrastructure, the team of experts had recommended to allow admission of 50 students in the Raipur Homoeopathic Medical College, Raipur and the permission was granted with the approval of the competent authority i.e. Minister of Health and Family Welfare. The Orissa Medical College of Homoeopathy and Research, Sambalpur (A State Govt. Institution) had not been given extension

of recognition by CCH for the year 2000-01 and 2000—02. However the college took the admission of the students as the decision of CCH was communicated to the college only after the admission was over. The recognition was not granted for the year under reference on the ground that the college did not fulfill the minimum prescribed norms. Further the CCH did not furnish any inspection report. As such, a Central Team of Officers consisting of Adviser (Homoeopathy) and Assistant Director, CCRH was deputed for inspection. The team recommended the grant of *ex-post-facto* permission for the year 2000-01 and 2001-02 and for making fresh admission in 2004-05 and onwards considering the assurance given by the State Government for fulfilling the deficiencies. The Department of AYUSH had also provided funds under the Centrally Sponsored Scheme of Development of institution to the institution for development of the infrastructure. Considering the recommendations of the team of experts permission was granted with the approval of Hon'ble Minister of Health and Family Welfare to the college subject to fulfilling the deficiencies pointed out in the CCH reports."

Inspection of Ayush Colleges/Institutions by regulatory Councils

27. A test check of records of 142 (Ayurveda: 58; Unani: 14 and Homoeopathy: 70) colleges including 35 new colleges, which were inspected by the representatives of Regulatory Councils during 2000—05, revealed that none of these colleges met the minimum requirement of infrastructural and teaching facility standards prescribed by the Councils. Further, 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 paramedical and other staff ranging between 13 and 78 per cent while bed occupancy ranged between 1 and 71 per cent. Audit examination of the records relating to the number of colleges inspected, colleges permitted to run courses on the basis of new inspections or on the basis of previous inspections on which the Councils disallowed permission during 2000-01 to 2004-05 revealed that only 32 to 59 per cent of the Ayurvedic colleges and 23 to 71 per cent of the Homoeopathy colleges were inspected every year by the Regulatory Councils during 2000—05. Colleges with persistent deficiencies in infrastructure that were denied permission to run courses during 2000—05 ranged between 1 and 13 during these years. 61 to 62 per cent colleges of Ayurveda and Homoeopathy were inspected only once or twice in the last five years, and no systematic or rational system for inspecting the colleges had been devised or followed and visits were generally carried out randomly.

28. The Ministry, while agreeing with the Audit observations stated (September 2005) that the Councils would consider the system of inspection of colleges at the earliest. The Ministry have acknowledged in the Exit Conference held in October 2005 that the inspections made by Regulatory Bodies had been deficient and stated that strict adherence to prescribed norms was now being ensured while granting recognition to colleges and that amendments to different laws was being actively considered to overcome various bottlenecks.

29. When enquired about the action that have been initiated by the Ministry to improve the infrastructure and teaching facilities in the 142 colleges that were found to be lacking minimum infrastructural and teaching facility standards prescribed by the Councils, the Ministry in a written reply submitted as under:—

> "There are 458 Ayurveda, Unani, Siddha & Homoeopathy, Yoga & Naturopathy (AYUSH) Colleges/ teaching institutions in the country. It has been observed that several teaching institutions do not meet the requirements of prescribed standards. The onus for creating the required infrastructure and making provision for teaching faculty etc. in accordance with the prescribed standards lies with the concerned college management. However, in order to assist the colleges to fill the critical gaps, this Department has been implementing Schemes for assisting the Government/Government aided teaching institutions. The following components of Centrally Sponsored Scheme "Development of AYUSH institutions" are being implemented during 10th Five Year Plan by this Department for upgradation of the standard of AYUSH education. They are (i) Development of AYUSH UG Colleges; (ii) assistance to PG Medical Education; (iii) re-orientation Training Programme for AYUSH personnel; (iv) renovation and strengthening of hospital wards of Govt./ Govt.-aided teaching hospitals of AYUSH; (v) establishment of Computer Laboratory in AYUSH colleges; and (vi) upgradation of academic institutes to the status of State Model Institute of Ayurved/ Siddha/ Unani/ Homeopathy…….The shortcomings of colleges inspected by the Regulatory Councils are communicated by them to the University and also to the college concerned. Further it is the responsibility of these regulatory councils to follow up rectification of the deficiencies noted by them with the concerned colleges and recommend to the Central Government for taking action against the defaulting colleges which is a continuing process."

30. When asked to explain the reasons for the deficiencies in the inspections made by Regulatory Bodies, the Ministry stated in a written note as under:—

> "Reasons for the deficiencies in the inspections made by Regulatory Bodies could be as follows:(i) instead of professionals involved in teaching members of CCIM and CCH who are mostly practitioners are sent for inspection of colleges and they in turn sit in judgment on their own Reports as members of CCIM/CCH; (ii) CCIM and CCH did not follow direction of Ministry to prepare database of teachers in AYUSH colleges so that at the time of inspection same teacher may not be produced during inspection by different colleges; and (iii) many times the inspection reports lack consistency e.g. the existing infrastructure may not justify the final recommendation."

31. On being enquired about the efforts made by the Regulatory Councils for rationalizing the inspection of various colleges, the Ministry in a written reply stated as under:—

> "The CCIM has laid down the minimum standards and requirements for education in Ayurveda/Unani/Siddha systems of medicine for under-graduate

and post-graduate courses. Besides, the Central Council had also laid down the Performa to be filled by the visitors at the time of visitation on each and every point on the minimum standards and requirement and other infrastructure facilities available at the college. Further, the Central Council had also laid down the Performa to be filled by the college and to furnish a copy of the same as well as to the visitors on each and every point to enable the visitor to do the physical verification at the time of visitation. Normally, new colleges are visited every year for five years and thereafter on every alternate year. Very old and well-established colleges are visited after a gap of every two years or so. The CCH in routine inspects Homoeopathic Medical Colleges once in three years but in respect of new college granted permission by the Central Government, inspection is carried out every year. Also the Council undertakes inspection of the college as and when a request is received as per provisions of Section 12 A of Homoeopathy Central Council Act for increase of seats, starting of new or higher course or for considering a proposal for new college. Inspection of colleges/examinations are undertaken as per provisions of Sections 17 and 18 of HCC Act and also as per Inspectors and Visitors Regulations."

32. The Committee desired to know about the steps taken by the Ministry to ensure autonomy and Independence of the Regulatory Councils for promoting transparency and accountability, the Ministry in a written note stated as under:—

"…….. that the Department had taken the following steps to ensure autonomy and Independence of the Regulatory Councils for promoting transparency and accountability : (i) Department provides all financial and administrative support to Central Council of Indian Medicine (CCIM) and Central Council of Homoeopathy (CCH), (ii) Department has repeatedly advised CCIM/CCH to depute only qualified and experienced teachers of unimpeachable integrity for visitations/inspections of AYUSH colleges but this advice has not been honoured. CCIM/CCH have been deputing its own members who do not have teaching experience for carrying out visitations/ inspections. Qualities of their reports are poor and they are unreliable. Department has also provided a list of panel of experts from eminent institutions to CCIM and CCH in February, 2006 for getting the inspections of the colleges done in a professional manner, but the same has been disregarded by CCIM and CCH, (iii) Ministry has no powers under the CCIM/HCC Acts to give directions to the regulatory councils and enforce these directions and (iv) Keeping in view these constraints IMCC and HCC Amendment Bills, 2005 have been introduced in the Parliament providing for providing fixed tenure of 5 years for members and for enabling the Central Government to give directions to the regulatory councils and to enforce these directions in public interest. The Reports of the Parliamentary Standing Committee of Health and Family Welfare Ministry on these bills have been received which are being examined by the Department of AYUSH with a view to striking the right balance between ensuring autonomy of the regulatory councils on one hand and transparency in their functioning on the other. Central Government

would move for consideration of these bills after incorporating requisite official amendments."

33. Audit scrutiny of inspections teams constituted by Regulatory Councils revealed that teams of experts 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.

34. When the Committee desired to know the action taken by the Ministry to ensure avoiding conflict of interests of the members of the Regulatory Council when they are included in the team of experts constituted by the Councils for inspection of colleges, the Ministry in a written note submitted as under:—

> "The Ministry has prepared a panel of experts for inspection for Ayurveda, Unani and Siddha and Homoeopathy colleges. The panel was forwarded to the respective Councils for constituting inspection team from the panel. These panels have been largely disregarded by the Council. Central Government has no powers under the CCIM/CCH Acts to enforce directions given to them. Inspite of repeated advice from the Department. of AYUSH not to involve CCIM/CCH members in inspections/visitations and depute only reputed teachers, the Council are not accepting the advice of the Department. Central Government has no powers under the Acts to enforce its directions. IMCC and HCC (Amendment) Bills 2005 have been introduced in the Parliament to address this anomaly."

35. When asked about the steps taken to amend the laws relating to Regulatory Bodies, the Ministry in a written note stated as under:—

> "The Central Council of Indian Medicine was constituted initially through nomination of members in the year 1971. ……..In the IMCC and CCH Acts, there is no provision for removal of the President, Vice-President, elected members of the Council and also withdrawal of the membership of a person nominated to the Council inspite of proven misconduct or failure to carry out their duties. Further, as per Section 3(2), any member can hold the Office of the President/Vice-President for any number of terms. The Department is of the opinion that the tenure of the members should not exceed five years and also there should be a provision for the removal of the President, Vice-President or the members for proven misconducts or failure to discharge their duties. Sometimes the Councils abuse/exceed their powers and in such situations, there is a need to issue appropriate directions to the Councils. Since there is no provision in the IMCC Act, 1970 and CCH Act, 1973 to give directions to the Central Councils in public interest, the Central Government is not in a position to check default or gross abuse of powers by the Councils. The proposed amendments are very much essential to make the functioning of CCIM and CCH effective and accountable and to prevent the influence of vested interests in their decision making."

36. Audit examination also revealed that the Ministry had constituted a Commission of Inquiry headed by a retired judge of Delhi High Court in January 2004 to investigate complaints made by certain individuals and institutions and 52 Parliamentarians against the functioning of CCH. The terms of reference of the Commission, *inter-alia*, included investigation into violations of Section 20(1) of the CCH Act, 1973 in granting recognition to new colleges and deputing executive Committee members of the Councils, who participated in the decision making process, for inspection of the colleges. The report of the Commission was awaited as of March 2005. Audit also noticed that though complaints had mentioned involvement of the Vice-President of CCH, he was nominated by the Council as a Member of the Inquiry Commission.

37. When asked as to how the Vice-President of Central Council of Homoeopathy (CCH) could be nominated as a member of the Inquiry Committee, when the complaints mentions of his involvement, the Ministry in a written reply explained as under:—

> "……... The Central Council of Homoeopathy had recommended the name of its Vice-President, Dr. Ramjee Singh for nomination in the Commission on behalf of the Central Council of Homoeopathy. That is why Dr. Ramjee Singh was nominated as the representative of the Central Council of Homoeopathy. The Order for appointment of the Commission was made *vide* this Ministry's letter No.R-14030/06/2002-HD dated 14th January, 2004 and next letter regarding terms and conditions of the services of Ms. Justice Usha Mehra, Retired Judge of Delhi High Court was issued *vide* this Ministry's letter of even number dated 31st March,2004. The Commission started its functioning from the next day *i.e*. 1st April, 2004 in the premises of the Central Council for Research in Homoeopathy, Janak Puri, New Delhi. Commission submitted its report in June 2005. The Report of the Inquiry Commission was submitted to Government in the middle of June, 2005. After examination of the findings of the Report of Commission of Inquiry, the same was referred to Central Investigating Agency (CBI) on 11.7.2005. The CBI has registered cases on 28.9.2005 against the President/Vice President/Secretary, CCH on the basis of the Enquiry Commission report for irregularities and corrupt practices."

VII. Data Base of AYUSH Practitioners

38. 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 recognised 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 recognised 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.

39. While the Central Register of Homoeopathy was required to be maintained in two parts, Part-I containing the names of practitioners who had a recognised Medical

qualification in Homoeopathy and Part-II the names of other practitioners, the Central Register of Indian Medicine was maintained only for qualified practitioners. 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 both the Councils. Out of 28 States and 7 Union Territories (UTs), records was maintained in only 20 States/UTs

40. The database had not been updated and revised for periods ranging between 3 and 22 years in respect of 20 States i.e. Andhra Pradesh, Assam, Bihar, Chandigarh, Delhi, Gujarat, Haryana, Himachal Pradesh, Jammu & Kashmir, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Meghalaya, Orissa, Punjab, Rajasthan, Tamil Nadu, Uttar Pradesh and West Bengal. Details of practitioners in Arunachal Pradesh, Goa, Manipur, Mizoram, Nagaland and Sikkim had not been maintained in any of the Central Registers. Delay in notification of the Central Register deprived the practitioners of the opportunity to practice in other States or throughout the country.

In September 2005, the Ministry stated (September 2005) that efforts were being made to update and revise the registers of practitioners on priority.

41. When enquired as to why the database of practitioners of AYUSH was not updated and revised promptly and regularly, the Ministry clarified in a written note as under:—

> "The CCIM maintains the Central Register of Indian Medicine in 3 Parts as per the provisions of IMCC Act, 1970. This Register is based on the State Register of Indian Medicine maintained by various State Boards / Councils. Efforts have been made by the Council to update the Central Register. However, updated list of practitioners is not been received from some of the State Boards / Councils in time from some States; Central Government has also been requesting the State Governments to update the Registers in time and to hold elections on time. Hon'ble HFM has also written to the concerned Chief Ministers in this regard. The CCH has published the Central Register (database) in 1993, 1996 and in 2003 and another register is with the Government Press, Nashik for publication in the Gazette. Maintenance of Central Register is done on the basis of updated State Registers of Homoeopathy, which are not furnished in time by the respective State Councils. Keeping in view the various difficulties in maintenance of Register of Homoeopathy faced by CCIM and CCH, a workshop of Registrars of all States' Councils / Boards of Homoeopathy as well as representatives of State Governments / UT Administration would be organized by CCIM/CCH in October, 2006 so that some solution comes out for removal of bottlenecks. Hon'ble Health & Family Welfare Minister has sent a D.O. letter to the concerned Chief Ministers to ensure timely updation of Register of practitioners by the State Boards and holding of timely elections."

VIII. Status of AYUSH Medical Colleges

42. Audit examination revealed that the total number of AYUSH medical colleges under Ayurveda, Unani and Homoeopathy systems 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.

43. When enquired about the measures that have been taken by the Government to set up AYUSH Medical Colleges in the North-Eastern regions particularly in the States of Manipur, Meghalaya, Nagaland and Sikkim which are considered to be a rich store house of biodiversity, the Ministry in their written note stated as under:—

> "There are one Ayurveda and 2 Homoeopathy colleges in Assam and one Homoeopathic College in Arunachal Pradesh. Central Government has also a proposal to set up a North-Eastern Institute of Ayurveda and Homoeopathy. Government of Arunachal Pradesh and NEIGRIMS, Shillong have also identified land for development of this institution. The Central Government may set up an Ayurveda college in Arunachal Pradesh and a Homoeopathy college in NEIGRIMS Shillong. The detailed project reports are being finalized."

IX. Setting up of All India Institute of Ayurveda

44. The Committee are given to understand that foundation stone was laid for setting up of All India Institute of Ayurveda way back in 2001. When enquired about the latest status of the project, the Ministry in a note stated as under:—

> "A State-of-the-Art All India Institute of Ayurveda is proposed to be set up at New Delhi. Accordingly an E.F.C. Memo was prepared in the light of the observations made by the Planning Commission as well as IFD earlier. The project cost was Rs. 325.00 crore. Delhi Development Authority allotted 4.5 acres of land near Apollo Hospital at Sarita Vihar, New Delhi and is constructing a boundary wall around the site. Additional land was also required for setting up the Institute and accordingly, DDA was requested to allot additional land. In September 2004, the DDA allotted approximately 6.00 acres of land at a cost of Rs.13.62 crore for which payment has been made. The land is being taken over."

The proposal was considered by the EFC in its meeting held on 3.10.2005. After discussion, EFC recommended the proposal 'in-principle' subject to the following observations: (i) the proposal should be re-formulated, with a focus on promoting R&D, safety evaluation and quality standards in AYUSH in Phase I. Facility for training of Teachers should also be considered under Phase I, (ii) synergy should be established with NIA, Jaipur and duplication of activities avoided. Capacity of NIA, Jaipur should also be augmented, (iii) the cost norms, staff requirements and budget should be recast and clear commitment of funds obtained from Planning Commission, (iv) upgradation of existing institutes and colleges should be given priority in the 11th Plan, and (v) the revised proposal may be brought back to EFC in due course. In pursuance of the above, the detailed project report is being reformulated."

45. Expressing their concern over the slow progress in construction of All India Institute of Ayurveda, the experts in the field of Ayurveda during the hearing of the Committee on the subject stated as under:—

> "The importance of Ayurveda is increasing all over the world. People from all over the world come here for Ayurvedic treatment because it developed here. They expect quality Ayurvedic hospitals. There are some hospitals in the private sector. We made efforts in this regard. A decision was taken by ex-Prime Minister under which 10.5 acres of land was taken back from Apollo hospital to set up All India Institute of Ayurveda Hospital, for treatment through Unani, Siddha etc. systems. The Vice-President of this country laid the foundation of that hospital. Along with this our Department purchased Rs. 15 crores of land and handed it over to the DDA. Even after two years the construction of the Hospital is yet to begin. It would be a State-of-the Art National referral hospital with provision for Panchkarma and Kayakalpa. It will house a national Pharmacy PGD Centre and research institutions. It was meant to be the biggest referral hospital in the world. But, due to certain reasons construction is yet to begin even after two years. It is a matter of concern that the Department is doing precious little in this regard."

X. Development of Infrastructural Facilities in Educational Institutions

46. A Centrally sponsored scheme for development of infrastructure for AYUSH medical institutions was launched by the Ministry of Health and Family Welfare in 1990-91 comprising of six components. Audit noticed that out of the total allotment of grants of Rs. 76.43 crore between 2000-01 and 2004-05 (till December 2004) under the scheme as much as Rs. 32.80 crore (43 per cent) was released for development of under graduate colleges and Rs. 26.03 crore (34 per cent) was released for development of State Model institutes, indicating the priority that the Ministry accorded to the two areas. The Ministry, however, did not maintain consolidated record of utilisation of grants, thus adversely affecting monitoring of actual utilization. Further, the Ministry did not receive utilisation certificates (UCs) that were mandatory, from the States in 263 cases till February 2005 involving Rs. 28.44 crore representing grants released during 1997-98 to 2001-02.

47. When enquired about the steps taken by the Ministry for expediting furnishing of utilisation certificates by the concerned States, the Ministry in a written note stated as under:—

> "Department has been striving hard and persuading States and Grantee Institutions to submit Utilization Certificates of grants given during 1997-98 to 2001-02. This matter has been taken up in the meetings with the State Health Secretaries / Directors of ISM&H. Further, an exclusive meeting was held on the 21st July, 2006 on the Centrally Sponsored Scheme "Development of Institutions", in which all the representations of State Government and model colleges were asked to submit pending Utilization Certificates immediately and their fresh proposals would be considered only after settlement of Utilization Certificates. Moreover, letters have been written to Health Secretaries / Directors of ISM&H asking them to submit the Utilization Certificates. This matter has also been taken up during the visit of Nodal

Officers of the Department of AYUSH to the States and with the representatives of State Governments/Colleges visiting the Department. Grants are not being given to the defaulting institutions. Besides, this matter has been pursued telephonically. Till date, 135 Utilization Certificates belonging to the period 1997-98 to 2001-02, amounting to Rs. 828.77 lakh have been received, processed and accepted since March 2005. Sending of the Utilization Certificates has improved from the States and Department is maintaining constant pressure for submitting Utilization Certificates by the defaulting institutions and States."

XI. Research Activities of Various Research Councils of AYUSH

48. The Central Council for Research in Indian Medicine and Homoeopathy (CCRIM&H) was established in 1969 to formulate aims and pattern of research on scientific lines with a view to increasing their popularity and acceptance by enabling scientific research in different aspects of respective systems through apex research bodies. The Council was split in 1978 into four separate Research Councils, *viz*., Central Council for Research in Ayurveda and Siddha (CCRAS), Central Council for Research in Unani Medicine (CCRUM), Central Council for Research in Homoeopathy (CCRH) and Central Council for Research in Yoga and Naturopathy (CCRYN), to afford each system maximum opportunity and freedom to develop in consonance with the fundamentals of the respective systems. Audit examination revealed that Rs. 278.44 crore were allocated to the three Councils (CCRAS, CCRUM and CCRH) between 2000-01 and 2004-05 for undertaking various research activities, clinical trials, family welfare, reproductive and child health research and tribal health care research programme. The overall shortage of staff in these Councils ranged between 5 per cent and 40 per cent.

49. The Ministry stated in September 2005 that the regional units of the Councils were being run without sufficient number of pharmacists, compounders, technicians etc. and the Councils were making efforts for filling the vacant posts.

50. The Committee desired to know whether any research was being carried out by the Department in collaboration with big and reputed hospitals—both public and private that are well equipped with clinical facilities. In response, the Ministry submitted in a written note as under:—

"Thrust areas identified by the Department of AYUSH for research and development in AYUSH are as follows: (i) improvement and up-gradation of standards of education, (ii) Quality Control and Standardization, (iii) Sustained availability of raw materials, (iv) Research & Development on the efficacy of the systems, (v) mainstreaming of AYUSH in the National Health Care Delivery System, (vi) Awareness and Information. A Golden Triangle Partnership Scheme has been devised as an integrated technology mission for the development of Ayurveda (in its first phase) using the latest scientific tools and technology. Under this scheme Deptartment of AYUSH/CCRAS, CSIR & ICMR are working together to undertake scientific validation and development of safe, effective and standardized classical Ayurvedic products for the identified disease conditions and to develop new Ayurvedic and herbal products effective in disease conditions of national/global importance.

Reputed organizations in public and private sector are being associated in the research work. The thrust areas identified under the GTP research are: (i) to bring safe, effective and standardized Ayurvedic products for the identified disease conditions; (ii) 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; (iii) the product should have IPR potentials to attract national/multi-national pharmaceutical companies. Following disease conditions have been taken for research on priority: (i) Urolithiasis; (ii) benign Prostrate Hypertrophy (BPH); (iii) Joint disorders; (iv) Rasayana (Rejuvenators/ Immunomodulators) for healthy ageing; (v) Cardiac disorders (cardio-protective & anti-atherosclerosis); (vi) Sleep disorders. Fifty-three medicinal plants from 19 formulations have been selected from the six Priority areas of 1st phase for standardization. Quality Control drug/ development under the already finalized six priority disease conditions are being done by CSIR in collaboration with M/s Nicholas Piramal and M/s Arya Vaidya Sala (AVS), Kottakal. Eight Bhasmas / Rasa Kalpas (Herbo mineral preparations) for carrying out chemical analysis, Safety and Toxicity by CSIR are being manufactured by Maharishi Ayurveda Corporation Ltd. (Selected as manufacturing Pharma for GTP Herbo mineral formulations as per survey report and recommendation of two experts). One batch of Rasa Kalpas (Herbo-mineral preparations) has been sent to IICT, Hyderabad."

51. The Ministry have further informed that considering the strength of Ayurveda and the disease of National/global importance, the following diseases/conditions/ areas have been identified:—

(i) Infective hepatitis, Alcoholic cirrhosis;

(ii) Management of Madhumeha (Diabetes mellitus;

(iii) Prajanana swasthya (Reproductive health) including Prevention of complications of Kamala (Liver disorders) Vandhyatwa (infertility) and Garbh nirodh (Contraception);

(iv) Medoroga obesity & Lipid disorders; leading to Ischaemic Heart Disease, Cardio-vascular disorders, stroke etc.;

(v) Rasayana Chikitsa (for healthy ageing);

(vi) Paurusha granthi vriddhi (Benign prostrate enlargement);

(vii) Chinta Janya Vikara (Management of stress disorders including Hypertension, Anxiety Neurosis etc.); Manovikara (Psychological disorders such as Mental retardation);

(viii) Use of Rasayana drugs as an adjuvant therapy to chemotherapy in Cancer patients and in drug resistant cases of Rajyakshma (Tuberculosis)and also for improving quality of life in HIV/AIDS patients;

(ix) (Dhatu Kshayaja Vikara)Degenerative disorders;

(x) Tamaka Swasa (Bronchial asthma);

(xi) Jalaukavacharana in Gambhira Siragata Rakta Skanda(Leech application in deep vein thrombosis);

(xii) Pandu (Management of sickle cell anaemia);

(xiii) Project on minimal invasive procedures like agnikarma and leech application;

(xiv) Kaphaja Adhimantha (Chronic allergic conjunctivitis);

(xv) Shushkakshipaka (Dry eye syndrome).;

(xvi) Kaphaja Adhimantha (Chronic simple glaucoma);

(xvii) Computer vision syndrome;

(xviii) Hriawa Dristi (Simple myopia);

(xix) Arma (Pterigyum);

(xx) Immature Cataract (Linganasa);

(xxi) Asthi Kshaya (Osteoporosis);

(xxii) Ama Vata (Rheumatoid arthritis);

(xxiii) Apasmara (Epilepsy);

(xxiv) Saundarya Vardhaka (Development of Herbal Cosmetics);

(xxv) Guda roga (Ano-rectal diseases);

(xxvi) Pakshawadha (Hemiplegia);

(xxvii) Seevana karma (Development of suturing material from human hair);

(xxviii) Vishma Jwara (Malaria);

(xxix) Shleepada (Filariasis);

(xxx) Ashmari (Urolithiasis);

(xxxi) Ardhavabhedaka (Migrain);

(xxxii) Atisara/ Pravahika (Diarrhoea/Dysentery);

(xxxiii) Kitibha (Psoriasis);

(xxxiv) Jeerna Vrikka Shotha (Chronic Nephritis);

(xxxv) Mansa Dhatu Gat Vikara (Muscular Dystrophy); and

(xxxvi) Jeerna Shroni Guha Shotha(Chronic PID).

Details of important collaborative Research projects undertaken by the Department of AYUSH are given in *Annexure - I.*

52. When enquired whether the Ministry/Councils periodically review the research projects with reference to the progress made, expenditure incurred, time spent and achievement of the desired objectives etc., the Ministry in a written note stated as under:—

> "The research work undertaken by AYUSH Councils is much broader in nature than narrowly focused R&D work of private companies. They undertake literary research/survey of medicinal plants/folklore medicine/drug standardization/ clinical trial. Many of these activities are of on-going nature. However, the Department of AYUSH is constantly monitoring the work of research councils in addition to review of their work by their Scientific Advisory Committees. Recently a Review Committee comprising of renowned experts has been constituted to review the working of the Central Council of Research in Ayurveda & Siddha. Expert Review Committees are being constituted for other three Research Councils also. All the four Research Councils have been directed to prepare VISION 2015 document based on SWOT analysis with a view to bring about a sharper focus in their research activities. The AYUSH Research Councils have done a large body of work on literary research/survey of medicinal plants/ folklore tribal medicine/standardization of drugs/clinical trials and have published a large number of research papers, monographs which has immensely helped in teaching/research/propagation of AYUSH in the country. The Department of AYUSH has constituted Scientific Advisory Committees for the Research Councils and their major field units for periodic review/Peer Review of their research work."

The details of the activities undertaken by the Scientific Advisory Committees of the Research Councils is given in *Annexure - II.*

53. The Ministry have also stated that the research activities of the Council are regularly reviewed by the Committees namely: (i) the Special Committees on Clinical Research, Homoeopathic Pathogenetic Trial and Drug Standardization and Scientific Advisory Committee (SAC) of the Council periodically review the progress research projects and consider and advise modification(s), if any. SAC also considers continuation or conclusion of any research study, reviews and approve the research data for publication; (ii) The Standing Finance Committee of the Council considers and approves budgetary proposals for research projects; and (iii) The Department of AYUSH has recently appointed a Review Committee headed by the Secretary, Department of AYUSH and has Joint Secretary (AYUSH) and Experts from CSIR, ICMR, Institute of Pharmaceutical Science and Homoeopathy as members. The terms of the Review Committee include identification of priority areas of research and also review the progress of the research studies.

54. The Committee desired to know whether Government propose to introduce "Intellectual Audit" in respect of the various research programmes/activities carried

out by the various AYUSH regulatory Councils and research institutes/hospitals run by the Department of AYUSH. In response, the Ministry stated as under:—

> "Yes. The Government of India, Ministry of Health & F.W., Department of AYUSH have already set up a Review Committee under the Chairmanship of Dr. Nityanand, Former Director, Central Drug Research Institute, Lucknow for an intellectual audit of CCRAS/CCRUM. It is not possible to carry out any audit of Regulatory Councils, *viz*, CCIM/CCH as the Central Government at present has no powers to give them any directions and enforce them except constituting an enquiry commission which was done in case of CCH."

Drug Research

55. Drug standardisation was a pre-requisite for manufacture of quality drugs and involved evolving standards of 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. Audit examination revealed that 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. Further, the Ministry did not find the standards for single drugs developed by CCRAS suitable 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. 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.

In September, 2005, the Ministry have stated that standards have not been published by CCRUM as these require further modification.

56. Audit has pointed out that Ministry did not effectively guide, monitor and coordinate the work of its Research Councils, which continued with their work regardless of its acceptance by the Pharmacopoeia Committees. When asked about the remedial measures taken by the Department of AYUSH in this regard, Ministry in a written reply stated as under:

> "Department of AYUSH has been reviewing the progress of pharmacopoeial work regularly. It was felt that AYUSH Research Councils should be involved more closely with this work and accordingly CCRAS has been declared as the Secretariat of Ayurvedic Pharmacopoeia Committee. Similar action has been taken in respect of CCRUM and Unani Pharmacopoeia.
>
> **CCRAS**
>
> Secretariat assistance for Ayurvedic Pharmacopoeia Committee (APC) & Siddha Pharmacopoeia Committee (SPC) is being provided by CCRAS. Adviser (Ayurveda) of Department of AYUSH & Director, CCRAS are Vice-Chairman

and Member Secretary of APC. They are working very closely and all the work on Quality Standards and Pharmacopoeial Standards of CCRAS is also monitored by APC. CCRAS has been directed to concentrate on development of SOPs/Pharmacopoeial standards for publication in Ayurvedic Pharmacopoeia. This will avoid duplication of work and proper coordination of the scientific work carried out on drug standardization by CCRAS will be monitored and approved by the Ayurvedic Pharmacopoeia Committee headed by a renowned scientist.

CCRUM

There has been a constant mechanism for review of work by the Scientific Advisory Committee and Governing Body. Apart from this, the work is being reviewed by different Committees. The work carried out by the Council particularly in the field of Drug Standardization was endorsed by the Scientific Advisory Committee and the then Pharmacopoeial Committee. It was only very recently, that the UPC realized that some additional parameters have to be added in the case of single drugs and CCRUM has complied with those directions of UPC. For standards of compound formulations, development of SOPs was considered as a pre-requisite. It is, therefore, not true that the Council continued work regardless of its acceptance by the Pharmacopoeia Committees. It is a fact that whatever work in the field of Drug Standardization has been carried out has been done in the Council with the guidance of the then Pharmacopoeia Committee(s). CCRUM is being designated as the Secretariat of Unani Pharmacopoeia Committee.

CCRH

All research proposals are considered by a Scientific Advisory Committee (SAC) nominated by the President of the Governing Body of the Council. This Committee comprises of Experts drawn from amongst Researchers, Teachers and Clinicians in the field of Homoeopathy. SAC is assisted by Special Committees on Clinical Research, Drug Standardization and Homoeopathic Pathogenetic Trial (Drug Proving). These Committees comprise of Experts in Homoeopathy and allied disciplines. The Department of AYUSH has appointed a Review Committee headed by the Secretary, Department of AYUSH and has Joint Secretary (AYUSH) and Experts from CSIR, ICMR, Institute of Pharmaceutical Science and Homoeopathy as members. The terms of the Review Committee include identification of priority areas of research and also review the progress of the research studies. An Expert Review Committee is also being constituted to review the work done by CCRH in last 3 years. So far as conforming to the quality and standards prescribed by the Homoeopathic Pharmacopoeia Committees is concerned, it is clarified that before the establishment of Homoeopathic Pharmacopoeia Laboratory (HPL) in 1975, the Homoeopathic Pharmacopoeia Committee (HPC) considered the standards of drugs worked out by the Council and included them in the Homoeopathic Pharmacopoeia of India (HPI). Although HPL is now engaged in laying down standards of drugs used in Homoeopathy, yet the standards

worked out by the Council continue to be considered by HPC for inclusion in HPI. It is, therefore, evident that standards worked out by the Council are qualitative and accepted by HPC."

57. When asked to state the reasons for the low percentage of documentation in the form of Monographs of drugs standardized under Ayurveda, Unani and Homoeopathy Systems, the Ministry informed the Committee as under:

"Unlike allopathy and homoeopathy the entire work of drug standardization and pharmacopoeial standards on Ayurveda, Siddha and Unani systems had to be started from scratch within the country. Previously only one Pharmacopoeial Laboratory of Indian Medicines, Ghaziabad was doing the work to develop Pharmacopoeial monographs describing the Quality standards of Ayurveda, Siddha, Unani (ASU) drugs. Homoeopathic Pharmacopoeial Laboratory, Ghaziabad is doing the work for Homoeopathic drugs. For Ayurvedic drug standardization, there is no international scientific support. Therefore, the scientific work on the plants and mineral drugs was started from very scratch. Tools, technology and expert manpower was also lacking for standardization of Ayurveda/Siddha/Unani drugs. In spite of these constraints, 418 monographs on single Ayurvedic drugs have been produced and published in 5 Volumes of Ayurvedic Pharmacopoeia of India. In the last 3-4 years, 16 eminent laboratories have been associated in standardization work on multiple ingredient Compound formulations. The standardization work requires development of Standard Operating Procedures (SOPs), Pharmacopoeial Quality Standards and Shelf-life studies etc. We have received scientific data on 144 compound formulations out of which about 100 will be published in the year, 2006. Two labs of CCRAS at Chennai and Kolkata have also been allocated 50 compound drugs under APC Scheme. It is proposed that with the help of these 18 laboratories the work of laying down pharmacopoeial standards for 100 compound Ayurveda drugs would be done every year and standards of 400–500 most widely used compound formulations would be completed in 4 – 5 years. As far as the Unani System of Medicine is concerned, the CCRUM has been able to publish monographs on standards for 250 single and 350 compound formulations. Monographs published by the CCRH include data pertaining to standardization, drug proving and clinical verification studies independent of each other. While standardization studies can be completed in prescribed time limit, studies involving human subjects are dependent on many factors, including ecological and climatic changes, geographical diversity and food habits. Any medical research, therefore, takes 2-5 years and some time more before it is completed. It also takes time to analyze and compile voluminous data generated during the study. It has to be approved by the Special Committee and the Scientific Advisory Committee for publication. As such, actual research and publication of findings does not usually keep pace with each other. The number of monographs published does not include scientific papers published by the Council. In addition to the Monographs, which contain results of Drug Standardization studies, Drug Proving and/or Clinical Verification studies, the Council has also

published results of Standardization studies of 36 drugs in its Quarterly Bulletin between 1980 and 2005, for the benefit of the profession. Results of the clinical studies are usually published in form of papers in scientific journals and official reports. The number of papers published on clinical studies has not been highlighted in the report. The Council has published 45 scientific papers on Clinical Research, 25 papers on Clinical Verification and 52 reports on Drug Proving so far in its Quarterly Bulletin, National and International Journals. Besides, the Council has also published 25 priced publications, 11 non-priced publications for the benefit of the professionals and 39 informative Handouts for lay public."

Drug proving and Clinical verification of Homoeopathic Drugs

58. Unlike conventional medicines, where animal experimentation formed the basis of evolution of drug pathogenesis, homoeopathic medicines were proved on healthy human volunteers. Drug standardisation was followed by proving the drug and finally by clinical verification. Audit examination revealed that out of 122 drugs standardised, 64 were proved and 75 were clinically verified. There was no correlation between the drugs standardised, drugs proved and drugs clinically verified. Forty-four drugs were taken up for proving and 47 for clinical verification without having been standardised. Further, 45 drugs were taken up for clinical verification without proving.

59. According to Audit, there was, therefore, an unsystematic approach to drug proving and clinical verification. The Ministry did not ensure that only those drugs which had been standardised by the Council were taken up for proving and clinical verification, which was the course of action supported by the special committee on clinical research of the Council in its report of February 2003. WHO guidelines also reiterated that only standardised drugs should be taken up for proving and clinical verification.

60. When asked whether the Ministry have conducted any investigation in the cases where homoeopathic drugs have been taken up for proving and clinical verification without having been standardized and how the Ministry ensure that only the standardized drugs are taken up for proving and clinical verification, as prescribed in the WHO Guidelines, the Ministry in a written note stated as under:—

"WHO has issued guidelines for basic drug research for new drugs whose clinical action and toxic effects are not known. WHO Guidelines for Methodologies on Research and Evaluation of Traditional Medicine do not refer to homoeopathic Drug Proving and Clinical Verification. Draft Report on Homoeopathy prepared by WHO is yet to be made public for reference. WHO's 'General guidelines for methodologies on research and evaluation of traditional medicine' *(WHO/EDM/TRM/2000.1)*. Draft Guidelines encompass even those homoeopathic medicines which have been used traditionally and are included in contemporary homoeopathic literature. Here it may be mentioned that homoeopathic proving and clinical verification conducted by the Council are with medicines serially diluted using a technique

traditionally used since the time of Hahnemann, that they do not produce any toxic effect. Further the proving and clinical verification of those drugs are conducted that have one or more references in available homoeopathic literature Moreover, the Council had undertaken proving and clinical verification of those drugs which were approved for such studies by the Scientific Advisory Committee of the Council. The traditional guidelines for preparation of homoeopathic medicines *(as referred to in WHO Guidelines)* were followed and their therapeutic application was based on the symptoms produced by the drug on healthy human beings as has been done traditionally since 1796. It may be seen that the Council has not violated any of the Guidelines prescribed by WHO. It may be appreciated that the Council is a research Organization and to experiment is its mandate. The Council endeavours to make discoveries, but if it does not experiment, it would not be possible to make new discoveries. The Department of AYUSH has recently appointed a Review Committee headed by the Secretary, Department of AYUSH and has Joint Secretary (AYUSH) and Experts from CSIR, ICMR, Institute of Pharmaceutical Science and Homoeopathy as members. The terms of the Review Committee include identification of priority areas of research and also review the progress of the research studies. The Committee had its first meeting on June 6, 2006. An Expert Committee is also being constituted to review the work of CCRH in the last 3 years."

61. When asked to specify the reasons for lack of correlation between the drugs standardized, drugs proved and drugs clinically verified, the Ministry explained in a written reply as under:—

"Drug Standardization, Drug Proving & Clinical Verification are three independent programmes of the Council. But, Drug Standardization and Drug Proving programmes were taken up in 1969 whereas Clinical Verification programmes were taken up after ten years, *i.e.* in 1979. Drug Standardization studies can be carried out on 5-8 drugs simultaneously and completed in 6-9 months. Short Proving of drugs can be done within 6 months whereas Long Proving take about one year. Clinical Verification studies take 2-5 years. After the completion of studies, 6 months—1 year time is required for data compilation and another six months—1 year for approval of Experts/Special Committees/Scientific Advisory Committee and publication of data. Therefore, three programmes cannot keep pace with one another."

Clinical Research

62. 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 Council undertook clinical studies in Tribal Health Care, Family Welfare and Reproductive and Child Health Programmes.

63. Audit noticed 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.

64. With regard to the clinical research carried out by Central Council for Research in Ayurveda and Siddha, the Ministry in their written note submitted to the Committee stated as under:—

> "CCRAS has completed clinical trials on 22 disease conditions and a number of various drugs have been tried on each condition. On the basis of these trials monographs are published for each disease condition. This explains the gap observed by the Committee as a gap between number of clinical trials and documentation. These are made available for educationist, researchers, physicians, manufacturers and general public."

65. The Committee enquired as to why the research activities of the Research Councils have not been able to contribute effectively in the discovery/invention of new drugs in the areas of epidemics diseases and family planning measures. In reply, the Ministry in a written note stated as under:—

> **"CCRAS**:
>
> The Council since inception has been focusing on epidemic diseases and developed Ayush-64 an anti-malarial formulation through extensive pre-clinical standardization, pharmacological and clinical studies on large number of subjects and the trial revealed that the said formulation is highly beneficial in the management of P-Vivax malaria. The AYUSH-64 has been patented and commercialized through different pharmacies which is in use in various Ayurvedic dispensaries of Central and State Government and also available in the market. Filariasis is another important area explored by the Council. The systematic studies have been conducted on 15 sets of various combinations in microfilaria stage and morbid conditions of Filariasis and the results are encouraging. Besides, this the Council has actively participated in various epidemic control programmes on Malaria, Plague, Kala-a-zar etc. in various parts of country and rendered timely services in the prevention and treatment of the conditions. Regarding the development of contraceptives this Council has screened 9 single and compound contraceptive drugs. Taking leads from these pilot-screening studies, extensive clinical trials have been conducted on Pippalyadi yoga—an oral contraceptive for females through pre-clinical formalities viz. standardization, toxicity, teratogenicity studies and phased clinical trials in association with Department of Family Welfare, National Institute of Immunology, NIPER. The Phase II trials are in progress at JIPMER, Pondicherry, KEM Hospital, Mumbai and AIIMS, New Delhi.
>
> **CCRUM:**
>
> Although the CCRUM has not taken up any drug development for epidemic control, yet the Council has been able to effectively counter disease menace during dengue epidemic, dropsy epidemic, plague epidemic etc. During these epidemics the Council have proved successfully the effectiveness of Unani Medicine in different clinical conditions.

CCRH:
HIV/AIDS

A Randomized Placebo Controlled Clinical Trial of Homoeopathic medicine in HIV infection conducted at Mumbai (1195 – 97) carried out on 100 HIV infected persons indicated a positive role of Homoeopathic medicine in the management of HIV infected people. A substantial increase in CD4 + T Cell was reported among subjects to the Homoeopathic medicine group. Results of another open clinical trial of Homoeopathic medicine on 1337 individuals with HIV infection at Mumbai, Chennai, Gudiwada and New Delhi indicate that Homoeopathic therapy has a positive role in the management of asymptomatic HIV infection and also minor infections such as Diarrhoea, Cough, Fever, moth ulcers (Candida albicans).

Filaria

Three most useful Homoeopathic medicines in the management of Filaria (Grade-I Lymphoedmia) identified –Apis Mellifica,.Bryonia Alba, and Rhus Toxicodendron. These three remedies have been able to relieve Grade –I Lymphoedema in more than 75per cent of the cases. Collaborative pilot study with ICMR, Bhubaneswar was also undertaken in which these remedies were able to reduce the level of cytokine TNF-alpha which was found significantly high in Filaria cases.

Malaria

Indian plant based Homoeopathic drugs Ceasalpenia boducella, Amoora rohutika and Nyetanthes arbortristis have been reported in the management of Malaria due to plasmodium vivax parasite, when prescribed on specific indications which are characteristic of these drugs. The successful management of Malaria cases with these drugs underline the efficacy of indigenous drugs when prescribed homoeopathically. Homoeopathy has proven efficacy in microbial infections such as Cholera, Yellow fever, Diphtheria etc. which occurred frequently in epidemic form in 19th Century when antibiotics were not discovered. Homoeopathy has been successfully used during the epidemics of Japanese Encephalitis in Andhra Pradesh and Gorakhpur (U.P.). The Council has undertaken clinical studies in 32 epidemics/ diseases occurring in the aftermath of natural calamities (cyclones, earthquakes). The findings of these studies have underlined the utility of Homoeopathic medicines in epidemics. Discussion with High Security Animal Research Lab (HSARL), Bhopal and Institute of Veterinary Science, Izzatnagar, UP for collaborative studies on Bird Flu is in progress. Efforts are also being made to undertake studies in recurrent epidemics such as Japanese encephalitis in Andhra Pradesh.

Homoeopathy and Family Planning:

The Council has undertaken a study at Department of microbiology, Banaras Hindu University to ascertain anti-fertility effect of homoeopathic medicines on albino rats. The results of the study were not definitively conclusive."

Patenting of Drugs

66. The number of medicines patented is an indicator of the overall achievement of Research Councils in clinical research. The 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. It was stated in the Exit Conference (October 2005) that it had been decided to patent all the drugs that would be developed. It was further stated that since National Research Development Corporation (NRDC), which had been assigned the task of patenting of drugs, was not very active, alternative methods would be explored to overcome the problem.

67. When the Committee enquired whether the patented drugs have been put to use for production and what is their acceptability in the market, the Ministry submitted in a written note as under:—

> "Keeping the commercialization/dissemination of research work aspect in view the Department of AYUSH and AYUSH Research Councils are now involving industry partner in the Golden Triangle Project research initiative at initial stage. Recently during CCRAS – Industry interface Pharma majors like RANBAXY, Dabur, Maharishi Ayurveda have indicated their willingness to participate in R&D projects in areas like Obesity/Diabetes/Hypertension/Heart disease, etc. for developing more effective herbal drugs based on our classical knowledge. From now on at least one major company will be involved with every major R&D project. In CCRS commercialization of the research findings of the Council is being done through National Research Development Corporation from time to time. The summary of patents obtained and commercialization is as follows: (i) Patents obtained—19, (ii) Patents filed/processing for filing—12, (iii) Patents /Processes released to the Industry (commercialized)—6.
>
> In CCRUM upto 1996, it was the policy of the CCRUM to only publish its research work in the form of monographs. Such Monographs were discussed in Seminars and thereafter made available to the Research Institutions/ Hospitals for larger use. CCRUM has published monographs on 12 drugs, filed patents for 8 and 17 drugs (a kit of common remedies for OPD use) have been commercialized through one centralized agency NRDC. 12 drugs are in the pipeline for filing patents. The drugs developed by the Council for different ailments have been widely in use at the Council's outlets and have been accepted by the public taking into confidence because of success rate and their cost effectiveness. The public has also found the Kit medicines, which have been commercially exploited, useful and acceptable.
>
> In CCRH Homoeopathy does not have any patent drug or formulations, except two held by Laboratories Boiron, France and the other held by Biforce in United States. Both of these are Influenza virus based preparations and are made using a special process. The preparation keeps changing in composition as viral strain mutates and changes almost every year. 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 *viz*. identification of drug substance, proving and clinical application for

clinical confirmation. The confidentially of data gets breached after proving. As such no patents are allowed."

XII. Drug Standardisation and Quality Control of AYUSH Drugs

Pharmacopoeial Standards of Ayush Drugs

68. The Drugs and Cosmetics Act of 1940 and the rules framed thereunder, enacted for regulating the standards of allopathic drugs, were amended in 1964 to include Ayurveda, Unani and Siddha medicines under its enforcement and regulatory mechanism. Homoeopathy system was also brought under the ambit of the Act in 1978 through an amendment. The Ministry established Pharmacopoeia Committees between 1962 and 1964 for developing Pharmacopoeial standards in Ayurveda, Unani and Homoeopathy systems. The main function of Pharmacopoeia Committees was to prepare and publish official formularies and pharmacopoeia under the respective systems for evolving uniform standards in preparation of AYUSH drugs and prescribe working standards for single drugs and compound formulations. Development of pharmacopoeial standards was primarily the responsibility of two national level laboratories *viz.*, Pharmacopoeial Laboratory for Indian Medicine, Ghaziabad (PLIM) and Homoeopathic Pharmacopoeial Laboratory, Ghaziabad (HPL), which were set up as standard setting-cum-drug testing laboratories. Standard Operating Procedures (SOPs) were essential for ensuring uniformity in terms of taste, colour and consistency in the formulations and also in analysing the effects of the drugs. The laboratories did not finalise pharmacopoeial standards in respect of compound formulations of Ayurveda and Unani for want of SOPs. The Ministry had published standards for only 916 out of 1500 mother tinctures of Homoeopathy.

69. According to Audit the performance of pharmacopoeia committees set up by the Ministry during 1962-64 for developing pharmacopoeial standards for ensuring safety, quality, purity and efficacy of drugs was far from satisfactory. While standards for 916 mother tinctures (61 *per cent*) in Homoeopathy had been published as of March 2005, pharmocopoeial standards had not been finalised in respect of compound formulations in Ayurveda and Unani even though the Committees were set up more than 40 years back.

The Ministry stated (September 2005) that the development of pharmacopoeial standards required basic R&D and that it took time to design formats and undertake testing. It added that the activity has been accelerated after creation of a separate Department of AYUSH in 1995. It was further stated in the Exit Conference (October 2005) that the Ministry was also considering ways to use the standardisation work being done in the private sector in developing pharmacopoeial standards.

70. When the Committee enquired whether the Government have identified the bottlenecks in the development of Standard Operating Procedure (SOPs) by the Pharmacopoeia Committees as a result of which it had failed to develop Pharmacopoeial Standards for formulation of compound drugs in Ayurveda and Unani even after 40 years of their inception, the Ministry in a written reply stated as under:—

"Unlike allopathy & homoeopathy, all the R&D work for laying down pharmacopoeial standards for Ayurveda/Siddha/Unani medicines had to be

undertaken from scratch within the country. The Department and Pharmacopoeia Committees rightly concentrated on laying down of standards for single crude drugs and so far standards for 418 single crude drugs of Ayurveda have been laid down. Multiple ingredients ASU formulations are prepared by mixing number of herbs. Sometimes minerals and metals are also mixed with the herbs. The preparations of various dosage forms e.g. churna, vati, avaleha formulations require crushing, powdering, mixing, boiling, grinding and other many processes to make them in various doses forms of churna, vati, syrup, avaleha etc. To develop quality standards of these formulations is a cumbersome time consuming scientific activity. First step in this exercise is to authenticate the genuine raw-material, then develop Standard Operating Procedures (SOPs) of manufacturing process, and then to develop scientific quality standards and shelf life studies. 15 laboratories were identified and most commonly used compound formulations were allocated since year 2003-2004. In the last 3 years, about 100 formulations every year were allocated. In this way 300 compound formulations have been allocated. Each formulations is required to be manufactured in 3 batches to standardize the process and Quality Standards. Till July, 2006, we have received the scientific data on 144 compound formulations. Experts of Ayurvedic Pharmacopoeia Committee have analysed the data and some of the corrections, additions, alterations have been suggested. So far as 10 compound formulations have been finally approved by the APC and Department of AYUSH. These formulations have been introduced under the National Reproductive Child Health (RCH) programme also. Another 80 formulations have been screened by the experts and are being placed before the Ayurvedic Pharmacopoeia Committee for approval in its next meeting on 13th & 14th September, 2006. We will be finalizing about 100 Compound formulations this year for publication. To develop pharmacopoeial standards of multiple ingredient formulations, first of all we should know the Quality Standards of individual ingredients. Till March, 2006, we have developed and published pharmacopoeial standards of 418 single drugs of plant origin in 5 Volumes of Ayurvedic Pharmacopoeia of India. Therefore, it can be seen that a considerable work has been done by Ayurveda/Siddha/Unani Pharmacopoeia Committees on single drugs. The work on compound formulations has been accelerated by associating 15 reputed laboratories & 12 manufacturing units under the APC Scheme. This work is time consuming and no shortcut is possible. Department of AYUSH is giving considerable attention to support various activities of Ayurveda/ Siddha/Unani Pharmacopoeial Committees. It is true that a lot of work still needs to be done in respect of compound formulations but the gains/success achieved in formulating quality standards for a large number of single drugs should not be belittled. This issue may kindly be considered in the background of existing situation prevailing in Unani System in which different classical texts provided for preparation of different Unani drugs based on different compositions and different methods of preparation. This was obviously not desirable and therefore the Unani Pharmacopoeia Committee, while taking

note of this situation, decided to standardize formulations and method of preparation. For this purpose, National Formularies were prepared which contained Unani composition of a particular formulation with uniform method of manufacture. Based on this, C.C.R.U.M. initiated work of standardization of single and compound drugs. This work was initiated for the first time in the history of Unani Medicine and as a result of this effort of the Council, 277 single and 385 compound drugs were standardized and their monographs published. Subsequently, U.P.C. desired that some more modern parameters needed to added for which is work is underway in CCRUM and PLIM."

71. When asked as to how does the Ministry ensure safety, quality, purity and efficacy of drugs in the absence of pharmacopoeial standards, the Ministry in a written note clarified as under:—

"Department of AYUSH, Ministry of Health & Family Welfare has published 5 Volumes of Ayurvedic Pharmacopoeia of India containing 418 single drugs of plant origin. The Pharmacopoeia contains standards of identity, purity and strength of the individual drugs. Therefore, in a multiple ingredient formulation standardised for individual ingredient need to be applied in beginning, during the process of preparation as well as in the final product. Ayurvedic Formulary of India containing 636 compound drugs is also available to manufacturers for standardization of compound drugs. For safety and efficacy of drugs, Research Councils and other CSIR laboratories have been associated to establish the safety of the formulations especially with toxic ingredients. To study the efficacy of the drugs is not under the purview of Ayurvedic Pharmacopoeia Committee. However, efficacy studies are carried out by the Research Councils as well as under Extra Mural Research (EMR) projects and Golden Triangle Project (GTP) project of the Department of AYUSH/ICMR/CSIR. In the case of Unani medicines, Unani Formulary of India with 914 compound drugs is available to manufacturers for standardization of compound drugs. Quality standards for 144 Unani single drugs have been notified by the Govt. of India, in the recently published Unani Pharmacopoeia of India. The Ministry of Health & Family Welfare have been constantly emphasizing upon the manufacturers to ensure standards of raw drugs in the process of manufacture of compound formulations as well as Patent and propriety items. In case of classical drugs, they are supposed to manufacture drugs according to composition and method prescribed in National formulary whereas they themselves are responsible for developing SOPs and quality standards for their Patent and Proprietary medicines."

Drug Standardisation

72. According to Audit, the Central Research Councils had developed their own standards for single and compound drugs in Ayurveda, Unani and Homoeopathy systems over the years. However, the Ayurveda Pharmacopoeia Committee did not accept the standards for Ayurvedic drugs developed and published by Ayurveda Research Council, as there was large-scale variation in data. Similarly, the standards

developed by Unani Research Council were not being published in the Unani Pharmacopoeia of India as the mandate for publishing the standards lay with the Pharmacopoeia Committee.

73. The Ministry separately launched a Central Scheme in 1997 in order to expedite the work of development of pharmacopoeial standards. Though the Ministry identified 921 formulations including 427 single and 494 compound drugs, for development of standards and also awarded the work to 32 laboratories in 1997-98 involving an expenditure of Rs. 5.26 crore, the laboratories did not develop pharmacopoeial standards for compound drugs. The Ministry thereafter assigned the work of development of Standard Operating Procedure (SOPs) to 16 laboratories for 225 drugs in 2002 and released grant-in-aid of Rs. 2.01 crore between 2002-2005. The final report was awaited (October 2005).

74. As regards single drugs, Audit pointed out that standards in 120 (38 *per cent*) out of 315 of Ayurveda/Siddha and 51 (46 *per cent*) out of 112 in the case of Unani drugs were approved by the Pharmacopoeia Committees. The following Table gives the status of single drugs standardised by these laboratories upto March 2005.

System-wise position of standardization of drugs

System	No. of drugs allotted	Cases in which work could not be taken up due to non-availability of plants	Standards approved by Pharmacopoeia Committee and under Publication	Standards ready for placing before Pharmacopoeia Committees	Standards under evaluation
Ayurveda/ Siddha	315	17	120	37	141
Unani	112	14	51	24	23

Thus, there was a duplication of efforts and wastage of resources by the Central Research Councils and Pharmacopoeia Committees in the field of standardisation of drugs. The Ministry did not ensure finalization and publication of standards for formulation of compound drugs in particular, even after incurring an expenditure of Rs. 7.85 crore on the committees between 2000 and 2005 and when more than forty years had passed since the establishment of Pharmacopoeia Committees.

75. Regarding development of pharmacopoeia standards of drugs in India, one of the experts during the evidence deposed as under:—

> "Very little was done in the field of pharmacopoeia. However, during the past several years the Government has prepared single drug pharmacopoeia of about 480 drugs. Work is also going on regarding 290 compound drugs, out of which work has been completed for 90 drugs. It is very essential to prepare a pharmacopoeia of other drugs also. Work in this regard is very slow due to low funding, lack of infrastructure and manpower. In such a scenario how will the preparation of pharmacopoeia gather pace. We cannot achieve this without strengthening the PLMT laboratories."

76. When asked about the efforts made to put into use the standardization work being done in the private sector in developing pharmacopoeial standards, the Ministry in a written reply stated as under:—

> "Under the Ayurvedic Pharmacopoeia Committee (APC) Scheme, Department of AYUSH has associated 12 private drug manufacturing units to develop SOP of manufacturing process, which ultimately helps to standardise the product. In this regard, we have received the research data of 144 compound formulations which is a joint activity of private Pharmacies and reputed laboratories. To develop the Pharmacopoeial standards of water and hydro-alcoholic extracts of ASU drugs, 3 private sector laboratories have been associated and given a target of 15 drugs. These laboratories are Natural Remedies, Bangalore, SAMI Labs, Bangalore and Chemloids, Vijayawada."

77. When the Committee desired to know how the Ministry ensure avoidance of the duplication of efforts by the Central Research Councils and Pharmacopoeia Committees in the field of standardization, the Ministry in a written note submitted as under:—

> "To avoid the duplication of efforts in developing Pharmacopoeial standards, the Directors of the Research Councils have been made the Member Secretaries of the Pharmacopoeia Committees. Central Council for Research in Ayurveda and Siddha (CCRAS) is already providing Secretarial Assistance for Ayurveda & Siddha Pharmacopoeia Committees and CCRUM has been designated as the Secretariat for Unani Pharmacopoeia Committee. Laboratories of CCRAS/CCRUM have been fully involved in the Pharmacopoeial work. All the drugs allocated for Pharmacopoeial work are jointly decided by the Pharmacopoeia Committees in which Advisers of the Department and Director of Research Councils are members. In so far as the Unani Medicine is concerned, the Council has been working in close collaboration with Unani Pharmacopoeia Committee and PLIM, Ghaziabad for developing pharmacopoeial standards."

78. When asked whether the final Report in respect of development of SOPs for 225 drugs that were assigned to 16 laboratories in 2002, been received, the Ministry in their written reply stated as under:—

> "We have received SOP, Quality Standard data in respect of 144 compound formulations till July, 2006. The data has been screened by the experts and is at different levels of approval. In the coming meeting of Ayurvedic Pharmacopoeia Committee scheduled on 13-14th September, 2006, SOPs for 40 formulations are being placed for approval. We have a target to publish first Pharmacopoeial volume of Compound Ayurvedic medicines in 2006-07."

Quality Control of Ayush Drugs

79. With a view to restoring public faith in AYUSH systems, 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, the Ministry launched a Centrally Sponsored Scheme—'Quality control of AYUSH drugs' in 2000-01. 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 DTLs 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 Ministry stated (September 2005) that the State Governments were being reminded to complete the work and submit the utilisation certificates.

80. Test check of records in the States revealed that the Ministry did not release any grant for establishing drug control mechanism to Haryana though it had 375 licensed pharmacies while Rs.1.07 crore was released to Tripura though it had only one private pharmacy in the State. Reasons for assisting the States on a selective basis were not on record. Funds amounting to Rs. 3.20 crore meant for purchase of machinery and equipment remained unutilised while the machinery and equipment valuing Rs. 4.89 crore though purchased, remained uninstalled in the states owing to non-completion of civil work and/or trained manpower.

81. When the Committee enquired whether the Government have analysed the reasons as to why none of the Drug Testing Laboratories have been able to utilise the grant-in-aids even after a lapse of five years of implementation of the Scheme, the Ministry in a written note stated as under:—

> "The Department of AYUSH has funded 24 Drug Testing laboratories (DTLs) for various States. The building component as well as equipments/ procurement has been completed in more than 18 DTLs. The technical manpower is one of the constraint shown by the State authorities. The Scheme has been amended to provide Rs. 20 lakh for contractual scientific manpower. Training workshops are being organized to train the existing scientific manpower in the latest tools and technologies for testing of AYUSH drugs."

82. Explaining about the steps taken to strengthen the drug testing laboratories, the Ministry in a written note submitted as under:—

> "The Quality Control infrastructure of AYUSH system was weak in term of non-availability of Drug Testing Laboratories (DTLs) for AYUSH drugs, poor conditions of the manufacturing units and lack of manpower in the Drug Control organizations in the Centre and States. To fill up these gaps, a Centrally Sponsored Scheme (CSS) is being implemented in the last 5 years to provide financial assistance to strengthen DTL and Pharmacies of Government sector under this Scheme. Every State should have one DTL for AYUSH drugs to meet the statutory requirements of drug testing. For this purpose, the Scheme provides financial assistance for building, machinery and scientific manpower on contractual basis. Earlier, the Scheme was having provisions of Rs. one crore. During the year 2005-06, the financial provisions have been raised to Rs. 1.5 crore. Under this Scheme, 21 DTLs were funded till 2004-05.

> The construction work, procurement of machinery require lot of codal formalities on an average it takes 2-3 years to complete the utilization. Out of 21 DTL funded under the Scheme, 14 labs are functional and carrying out testing of ASU drugs. During the year 2005-06, 4 more laboratories have been supported. For north-east region *i.e.* Tripura, Sikkim, Nagaland, Mizoram, Meghalaya, Arunachal Pradesh labs were funded during the last one year. It will take some more time to make them functional. The 2nd component of the Scheme relates to strengthening of Government Pharmacies manufacturing ASU & H drugs. 40 Pharmacies were supported under the Scheme upto Rs. 1 crore per pharmacy. This includes money for building, machinery and equipments. 36 pharmacies are functional and producing ASU & H drugs. 4 pharmacies funded within last one year belonging to Arunachal Pradesh, Nagaland, Tripura and Meghalaya are under construction. The 36 pharmacies are manufacturing medicines to meet the need of State Government dispensaries and hospitals. With the Central assistance, their production capacity has been increased. It is, therefore, further clarified that the amount of Rs. 51.13 crore has been meaningfully utilized under the Scheme and will have far reaching effects to improve the quality and quantity of ASU & H drugs. So far 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."

83. When asked to state the number of inspections carried out by the Central/ State Governments for testing drug samples manufactured by AYUSH drug companies during the last three years and what are the results of the samples tested, the Ministry submitted in a written note as under:—

> "The Department of AYUSH has issued order to the Director Pharmacopoeial Laboratory of Indian Medicine, Ghaziabad and Homeopathic Pharmacopoeial Laboratory to obtain 10 samples of Ayurveda, Siddha, Unani medicines from CGHS stores and 40 samples from open market every month for the purpose of testing contents, heavy metals and other adulterants. Test reports should be submitted to the Department of AYUSH for the first week of every month for the preceding month for initiation of necessary action by the Department for sensitizing ASU&H drugs manufacturing units and for boosting public confidence in such medicines. It has been directed that while lifting random samples from CGHS and the market, PLIM should ensure that most widely used ASU medicines are selected which should include all groups of medicines which claim to contain precious metals should also be included in this random testing with a view to verify their claims. The sample should be tested for presence of ingredients, heavy metals any other adulterants. Reference samples of all such medicines should be maintained by these laboratories for atleast a period of 12 months. The State Govt. have also been asked to test their samples in Govt./ NABL accredited laboratories."

84. When asked whether the Ministry have brought out any guidelines regarding standardization of drugs so as to maintain the quality and authenticity of the drug

formulations which have been laid down in the Ancient Ayurvedic Texts, the Ministry in their written reply stated as under:—

> "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. 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."

XIII. Pricing of AYUSH Drugs by Pharma Companies

85. The Committee have come to notice that quite often the price of a drug product is quite cheaper as compared to the ingredients that are used in its preparation, which are quite expensive. In this regard, the Committee enquired about the measures Government have taken or proposed to be taken by Government to ensure that the ingredients as shown to be used in the manufacture of the medicines are actually used in the production and the quality of the end product is maintained. In response, the Ministry have stated as under:—

> "Important action taken to ensure that the ingredients as shown to be used in the composition of the medicine are actually used and the quality of the end product is maintained are as follows: (i) Department has made self-certification mandatory for the export of ASU drugs; (ii) Department has been supporting establishment and functioning of Drug Testing Laboratories in the States, (iii) Department has asked the Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad to test 50 samples every month, (iv) GMP has been notified, and (v) Labeling provision has been made mandatory. Department has written to all States to get ASU drugs tested from NABL accredited laboratories for which, Rs. 500/- per sample will be reimbursed by this Department."

XIV. Use of Heavy and Banned Metals in the Manufacture of AYUSH Drugs

86. The Committee came to know from several news reports that heavy and banned metals & toxic substances are being used in manufacture of Ayurvedic Drugs. During the hearing of the AYUSH experts/drug manufacturers by the Committee one of the representative of Ayurvedic Drug Companies had stated that there was no truth in these allegations as also in the article published by the Journal of American Medical Association (JAMA) regarding use of heavy and banned metals in Ayurvedic drugs. They emphatically stated that the metals use in the drugs are safe and are permissible under the ancient texts.

87. When asked whether the Ministry have taken measures for rebutting the allegations made in the journal (JAMA) and educate the public about the safety of ayurvedic medicines, the Ministry in their reply stated as under:—

> "Metals and minerals should be used in ASU drugs after detoxification as prescribed in Ayurvedic and Unani classical texts. However, the Department has taken up the study of validity of such drugs under the Golden Triangle Project. The Council for Scientific and Industrial Research (CSIR) has been given study for most commonly used 8 herbo-mineral drugs for their study on Physio Clinical Character and safety and toxicity studies. The majority of drugs came into criticism of containing heavy metals in JAMA article were purely herbal drugs. Therefore Department of AYUSH adopted multi-pronged integrated strategy for handling the situation. The strategy includes self-certification, development of drug testing laboratories across the country, involving PLIM in drug testing etc. Important action taken are as follows: (i) Department has made self-certification mandatory for the export of ASU drugs, (ii) Department has been supporting establishment and functioning of Drug Testing Laboratories in the States, (iii) Department has asked the Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad to test 50 samples every month. Department has written to all States to get ASU drugs tested from NABL accredited laboratories for which, Rs. 500/- will be reimbursed by this Department. As per the direction of the Deptt. of AYUSH, CCRAS has taken nine available Ayurvedic formulations manufactured by different companies as per reference for heavy metal contents & toxicity studies. None of the tested drugs shows any toxic effect on acute and sub acute studies in laboratory animals."

88. Explaining the scientific evaluation and safety efficacy data in respect of Ayurvedic drugs, the Secretary, Ministry of Health and Family Welfare (Department of AYUSH) during the evidence deposed as under:—

> "In 2005… we have launched this Golden Triangle Project with the help of the ICAR and ICMR, for the simple reason that we want scientific evaluation and safety efficacy data. We need that data to tell these countries that this has been scientifically evaluated and this is what is coming out of it even if we may know that this is not harmful, but we need those stamps of scientific authorities. That process has been launched quite aggressively; it has been taken up not in isolation. I would like to submit that it is in partnership with the industry. In the first case, Maharishi Ayurvedic drugs have been taken and evaluated and now we had a meeting with some other industry partners; they are also going to be giving their drugs for this because it is in their own interest. While initially there might have been some resistance on the part of the industry as to why we are going in for mandatory testing or self-certification or random testing, now even they understand that if this is all done and the certification is in place, they have a better chance in the outside market. But with select Missions, we are in constant touch; we are taking up this matter; they are also asking us; everyday, we get 3-4 letters from our Embassies on this aspect."

XV. Research Journals on AYUSH

89. The Committee are given to understand that presently there is no separate journal on Ayurveda System and research in Ayurveda. In this regard, the Committee enquired about the measures taken by the Government to bring out a separate journal on Ayurveda which can provide a platform for Ayurvedic Drug Companies to put forth their views/suggestions and also to counter the allegations made by some countries on the quality of Ayurvedic medicines etc. In response, the Ministry replied as under:—

> "Central Council for Research in Ayurveda and Siddha, Department of AYUSH is publishing specific Journal on Ayurvedic System and research in Ayurveda entitled "Journal of Research in Ayurveda and Siddha". JRAS is bilingual Journal on the work carried out of fundamental, anthropological and behavioral details referred to in medicinal systems, critical and literary studies, observations and interpretations emanating the clinical research in all its facets, divisions and dimensions. As far as the CCRUM is concerned, the Council have already launched Hippocratic Journal of Unani Medicine on six monthly basis since 2005. Periodicity is now being revised to quarterly. The Council publishes a Research Journal in Urdu language titled "Jehan-e-Tibb" which is constantly published on quarterly basis. Apart from this a Research bulletin in the form of CCRUM Newsletter is published in every two months which carries success stories of CCRUM for the benefit and exchange with the Industry and profession."

XVI. Good Manufacturing Practices (GMP)

90. The Department of AYUSH issued a notification in June 2000 directing the drug manufacturers to mandatorily adhere to Good Manufacturing Practices (GMP) standards as laid down in the Drugs and Cosmetics Rules, 1945, the time limit for which was extended up to June 2003 with a view to enabling the drug manufacturers to improve their infrastructure, comply with statutory requirements and obtain GMP certificates from the concerned State Drug Control Authorities. Audit examination revealed that out of 7849 manufacturing units, only 707 pharmacies possessed GMP certificate. The respective State Governments/UTs *i.e.* Gujarat, Rajasthan, Karnataka, Pondichery, Daman & Diu, Himachal Pradesh, Kerala, Uttaranchal, Haryana , Delhi, Chandigarh, Andhra Pradesh, Uttar Pradesh, West Bengal, Orrisa, Punjab, Madya Pradesh and Tamil Nadu did not cancel the licenses of non-GMP manufactures for not adhering to norms. It has further revealed that 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 because of 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.

91. When asked to explain the measures taken for enforcing Good Manufacturing Practices (GMP) standards as laid down in the Drugs and Cosmetics Rules, 1945, the Ministry in a written note stated as under:—

> "Schedule–T, under Drugs and Cosmetics Act & Rules, making provision for Good Manufacturing Practices of ASU drugs was issued in the June, 2000 giving 2 years period for the existing units to improve their manufacturing facilities. In October, 2005, Department of AYUSH has issued orders to the State Secretaries under Section 33 (P) of Drugs & Cosmetic Act to cancel the manufacturing licenses of non-GMP complying units. Secretary (AYUSH) has written D.O. letters to all Chief Secretaries on 8th Feb. 2006 for ensuring for implementation of GMP. The matter also taken up in a meeting of Ayurveda, Siddha, and Unani Drugs Consultative Committee held on 29 June 2006. It is evident that Department of AYUSH has constantly pursued with the State Governments and drug manufacturers to improve the infrastructure to comply GMP norms. It is worthwhile to mention that most of the manufacturing units are medium and small scale and therefore, the constraints of resources is also one of the major factors. However, gradually the industry is moving ahead and the number of GMP complying units is increasing. In due course, the non-GMP complying units will be closed as there will be no renewal of their manufacturing licenses."

92. Explaining the efforts made by the Government for enforcement of GMPs, the Secretary, Ministry of Health (Department of AYUSH) during evidence deposed as under:—

> "….. I would like to say that we have over 8,000 manufacturing units and as of now we have almost 4.500 GMPs because sometime has elapsed since the Performance Audit was done. As of today we have 4,500 GMPs. But we have expressed our own concern about the fact that 2000 GMPs have been reported from one State alone. That is because there may be an error and it could not be correct. We are not ourselves very satisfied with the report given by that particular State alone. That is because there may be an error and it could not be correct. We are not ourselves very satisfied with the report given by that particular State that all the units are GMP certified. We cannot believe that situation as given because GMP became mandatory in 2003. It was introduced in 2000. So, the effort is on to find out the details. We have asked the State Governments also to gear up their inspections, visits, testing of drugs, etc., to see that the units move in that direction."

93. When enquired about the current status with regard to obtaining of GMP certification by the remaining 3500 manufacturing units, the Ministry replied in a written note as under:—

> "The current status of GMP compliance in various States till September, 2006 for Ayurveda/Siddha/Unani Drugs are as under:—

Status of GMP compliance in various States (September, 2006) for Ayurveda/Siddha/ Unani drug manufacturing units

S. No.	State	GMP Complying Units	Non-GMP Complying Units	Legal Notices Issued/ Cancelled
1	2	3	4	5
1	Andhra Pradesh	300	149	76/153
2.	Gujarat	394	0	222

1	2	3	4	5
3.	Uttar Pradesh	1855	0	18/27
4.	Orissa	27	168	92
5.	Karnataka	144	0	0
6.	Delhi	70	36	36
7.	Rajasthan	166	300	300
8.	Himachal Pradesh	60	13	13
9.	Uttaranchal	97	54	17
10.	Madhya Pradesh	293	325	0
11.	Kerala	352	100	150
12.	Maharashtra	275	0	400
13.	Punjab	226	111	79
14.	Haryana	165	288	11/1
15.	Sikkim	1	1	1
16.	Dadra & Nagar Haveli	5	0	0
17.	Chhattisgarh	21	24	24/2
	Total	4451	1569	6020/183"

94. When asked about the action taken by the Ministry against the remaining units for not possessing GMPs, the Ministry replied in a written note as under:—

> "In pursuance of the section 33P of Drugs and Cosmetics Act, 1940, Central Government has issued another order dated 13.10.05 directing all the State Ayurveda, Siddha & Unani (ASU) Drug Licensing Authority to take action against the defaulting ASU drug manufacturers for revocation of their licenses under Rules 157, 158 & 159 of the Drugs and Cosmetics Rules, 1945 for failure to comply with the Good Manufacturing Practices (GMP) notified under Schedule 'T' of the Drugs and Cosmetics Rules, 1945. Department of AYUSH is pursuing with State Government and Drug Licensing Authority for getting GMP complied at the earliest. The matter has been taken in the meeting with State Health Secretaries/ directors and Ayurveda, Siddha and Unani Consultative Committee (ASUDCC)."

95. The Committee desired to know whether the Ministry periodically monitor/ review the action taken by the State Governments in cancelling the licenses of those manufacturers who failed to adhere to GMPs standards. In reply the Ministry submitted in a written note as under:—

> "The Department of AYUSH have written letters to state drug licensing authorities to make periodical inspection of ASU drug manufacturing units and sent their monthly progress for enforcement mechanism of the provisions

of the Drugs and Cosmetics Act and Rules thereunder. In pursuance of the section 33P of Drugs and Cosmetics Act, 1940, Central Government has issued another order dated 13.10.05 directing all the State Ayurveda, Siddha & Unani (ASU) Drug Licensing Authority to taken action against the defaulting ASU drug manufacturers for revocation of their licenses under Rules 157, 158 & 159 of the Drugs and Cosmetics Rules, 1945 for failure to comply with the Good Manufacturing Practices (GMP) notified under Schedule 'T' of the Drugs and Cosmetics Rules, 1945. Department of AYUSH has been regularly monitoring GMP compliance. The status of compliance of GMP has improved in recent months due to regular monitoring."

96. Explaining the importance of adherence to Good Manufacturing Practices by drug manufacturing units, one of the AYUSH experts during hearing of the Committee stated as under:—

"GMP should be compulsory for all pharmacies. Good quality medicine is not possible without this. Similarly, after great efforts we succeeded in convincing the Government to set up a Medicine Plant Board. However its co-ordination needs to be fine tuned with agricultural university and forest department. The medicines provided by the Medicine Plant Board to the Vaidyas were not upto the mark. We are not able to cultivate the herbs needed to prepare medicines. Co-ordination in this regard is also poor."

The Expert further added:

"Apart from this as far as GMP is concerned, practically it has been observed that small-scale industries are mushrooming in the field of Ayurveda now a days and it has been made compulsory for them to follow these norms but they do not imbibe these norms in their system. They have got their own system and they either by-pass these norms or follow their own system. Hence, it is my suggestion to make them follow the GMP norms more strictly as these small-scale industries spread misconception among the people about this system that is not good."

XVII. Conservation and Development of Medicinal Plants for AYUSH Drugs

97. Medicinal plants constituted about 80 per cent of the raw materials required for manufacture of AYUSH drugs. Most of these 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, the Ministry had set up a National Medicinal Plant Board (NMPB) 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 NMPB, State Medicinal Plant Boards (SMPB) were set up in all the States/UTs (except Delhi and Meghalaya) between 2001 and 2004 to assist the NMPB in implementation of schemes and policies. With a view to achieving its goals, NMPB implemented various promotional and contractual farming schemes.

98. During the years 2000-01 to 2004-05, 472 promotional schemes and 1389 contractual farming scheme were sanctioned and expenditure of Rs. 59.37 crore and Rs. 34.02 crore respectively was incurred. Out of 472 Promotional Scheme Projects and 1389 contractual farming scheme projects only 6 and 36 projects respectively were completed. Further, out of 1077 projects in all, sanctioned under the promotional and contractual farming schemes during 2001-04 involving financial assistanceof Rs. 62.16 crore, only 210 projects were assigned by the State Medicinal Plant Board to the Indian Institute of Forest Management and Directorate of Research for monitoring and the remaining 867 projects were neither supervised nor monitored. The Ministry was, thus, not able to ascertain the status of utilisation of grants released and achievement of projected increase in production of medicinal plant material in these cases.

99. A test-check of records revealed that out of 98 projects covering all the activities, in 51 cases applications were received directly by NMPB, which should have been routed through respective SMPBs/State Governments with their recommendations as per guidelines of the scheme. Himachal Pradesh and Orissa did not utilise funds amounting to Rs. 12.45 lakh sanctioned by the Ministry for infrastructural development, standardisation of drying and storage, development of herbal gardens, and promotion of medicinal plants due to delay in granting administrative approval and other reasons.

100. The Ministry stated (September 2005) that since SMPBs had not been formed in all the States upto 2003, some projects were considered without their recommendation and that now only the projects recommended by SMPBs were being considered. The reply is not tenable as in the absence of SMPBs, the project proposals should have been forwarded through the respective State Governments/ Directorates of AYUSH.

101. When the Committee desired to know about the status of the 1819 incomplete projects, which were sanctioned during 2000-01 and 2004-05, the Ministry in a written note stated as under:—

> "A total of 472 projects under Promotional Scheme and 1389 projects under Contractual Farming Scheme were sanctioned between the years 2000-01 to 2004-05 (till the period of report). Out of these, 5 projects under Promotional scheme and 134 projects under Contractual Farming scheme were cancelled due to various reasons of non-fulfilment of the terms and conditions of operational guidelines. The revised status of the projects sanctioned and those completed during the period is as under:—

Year	Promotional Scheme				Contractual Farming Scheme			
	Projects sanctioned	Cancelled	Balance	Completed	Projects sanctioned	Cancelled	Balance	Completed
2000–01	5	—	5	—	—	—	—	—
2001–02	144	1	143	90	—	—	—	—
2002–03	101	—	101	48	79	16	63	36
2003–04	66	1	65	28	687	60	627	110
2004–05	156	3	153	26	623	58	565	30
Total	472	5	467	192	1389	134	1255	176

''From the above table it may be seen that 192 projects out of 467 projects under Promotional scheme have been completed so far. Similarly, 176 projects out of 1255 projects under Contractual Farming scheme have been completed. Thus, a total of 368 (21per cent) of the projects have been completed so far. It may also kindly be noted that out of 1861 projects sanctioned during the period under report, 41per cent (753 projects) pertained to the year 2003-2004 and 42per cent (779 projects) to the year 2004-2005. Since the project period is usually three years, only those projects which were sanctioned during 2003-2004 or earlier could have been completed by March 2006. The project sanctioned during 2004-2005 would be completed by March 2007. In the light of this the progress of completion of projects as indicated above appears to be satisfactory."

102. When the Committee desired to know whether the Ministry have developed any monitoring and evaluation mechanism for various plantation schemes in respect of the utilization of grants released and achievements of the Scheme, the Ministry in a written reply explained as under:—

> "The National Medicinal Plants Board has facilitated setting up of 35 State Medicinal Plants Boards (SMPBs) in States/UTs. Grants under the schemes are sanctioned on the basis of recommendations of the SMPBs. The NMPB has taken the following measures to strengthen monitoring and evaluation: (i) The State level Boards have been asked to carry out pre-appraisal of the projects before these are recommended to Government of India and also carry out monitoring and evaluation. The NMPB is also providing financial support to augment the infrastructure of the State Boards for this purpose. In addition, 5 per cent of the total funds released to a particular State during the last financial year is provided to SMPBs for the purpose of strengthening appraisal and monitoring mechanism. Detailed guidelines have been issued to State Boards to engage the services of researchers, university staff and other professionals on short term consultancies for carrying out monitoring and evaluation in view of the general restriction on creation of new posts, (ii) The projects are also technically and financially appraised and monitored by the Banks providing credit to the farmers, (iii) All the projects that are implemented by NGOs under the Promotional scheme, and those under the Contractual Farming scheme under which financial assistance/subsidy is provided to the farmers are necessarily required to be inspected and monitored by the officials of the SMPB before 2nd/3rd installments are released, (iv) Officials of NMPB also visit the project sites from time to time to review and monitor the progress made and suggest corrective action wherever required, and (v) An independent evaluation has also been carried out through two organizations, namely, Indian Council of Forestry Research and Education, Dehradun and Indian Institute of Forest Management (IIFM), Bhopal. The report of IIFM, Bhopal has been received and the suggestion made therein for improvement of the programme will be suitably incorporated during the 11th Plan."

Cultivation of Medicinal Plants and Development of Agro-techniques

103. The Ministry launched (1990-91) an innovative scheme for development and cultivation of medicinal plants before NMPB was set up in November 2000, which aimed at enhancing the availability of medicinal raw material and provided grants in aid for the development of agro-techniques and cultivation of medicinal plants. This scheme continued to be implemented even after NMPB and SMPB were set up. Ministry provided financial assistance of Rs. 73.85 lakh during 2000-01 and 2002-03 to various institutions/State Governments under 18 projects for setting up demonstration medicinal plant gardens. The Boards did not, however, monitor the status of medicinal plant gardens set up under the scheme, such as details of production, survival/mortality of plants raised and utilisation of funds as of December 2004.

104. Audit examination revealed that 45 medicinal plants were identified for development of agro-techniques under the component Development of agro-techniques. Rs. 5.05 crore was released under 33 projects for development of agro techniques for 133 plants. Audit noticed that out of 45 species identified for agro-techniques, projects in respect of 25 species only had been undertaken and no patents were obtained. The Ministry wound up the scheme for development of agro-techniques in 2001 rendering the entire expenditure of Rs 5.05 crore unproductive. The Board stated (December 2004) that the agro-techniques developed were being compiled for publication for dissemination of the research finding among the masses.

105. Absence of an authentic database of demand and supply of prioritized medicinal plants coupled with the failure in monitoring and evaluation of various plantation schemes by the NMPB prevented the attainment of the objectives of increasing production of plant based quality raw material and conservation, marketing and export of AYUSH drugs.

106. When asked to explain the reasons for delay in completion of projects relating to development of agro-techniques, the Ministry informed the Committee in a written note as under:—

> "Projects were allocated to 33 specialized scientific organizations in government sector consisting of Agriculture Universities and Research Laboratories etc. for development of agro-techniques of identified medicinal plants. Each organization was normally allocated 4 plant species under a project which was for a period of 3 – 4 years. However, the agro-techniques could not be finalized early due to the following reasons: (i) The allocated plants included tree varieties also which had a long gestation period. These species require longer period of observation to study growth parameters, seeding and germination patterns and studies relating to harvesting of the produce. Some of the tree species like Guggal and Ashok require a much longer period of study ranging from 10 – 15 years, (ii) In some cases the projects got delayed due to poor/infrequent seeding behaviour of certain species making it difficult to carry out trials of seed germination, nursery development, planting and harvesting etc., and (iii) All parameters required for finalization of agro techniques of a plant could not be worked out in some cases and technical gaps were observed by the Project Evaluation Committee.

Therefore, the reports could not be finalized and published so far. Agro-techniques of 120 medicinal plants allocated under the projects have been finalized. Out of these, in the first stage, agro techniques of 50 medicinal plants are proposed to be published after necessary editorial corrections and removal of minor technical gaps, if any, within next three months. Since agro-techniques are in the nature of agronomic practices, these may not be patentable."

107. Enumerating the reasons for undertaking only 25 out of 45 species identified for agro-techniques and no patents for the same, the Ministry explained in a written note as under:—

"A total of 120 plants were identified and included for development of agro techniques under the scheme *viz* "Central Scheme for development of agro techniques and cultivation of medicinal plants". In all 33 specialized scientific organization in government sector consisting of Agricultural Universities and Research Laboratories etc. were selected for development of agro-techniques under a project mode. As per status position given under question no. 64, the agro-techniques are being finalized for publication for bringing in public domain. Since agro-techniques are in the nature of agronomic practices, these may not be patentable."

108. To a query as to why assessment of the demand and supply of prioritized medicinal plants not made a pre-requisite for the projects before sanctioning and releasing funds for the cultivation of medicinal plants, the Ministry replied as under:—

"Study was conducted for assessment of demand and supply of medicinal plants during the year 2000. The study conducted by Centre for Research, Planning and Action (CERPA) covered 162 species used in trade. In addition the Task Force set up by the Planning Commission on Conservation and sustainable utilization of medicinal plants had identified 100 medicinal plants for conservation/cultivation. Accordingly, the Medicinal Plants Board had prioritized 32 species of medicinal plants for development and cultivation. Therefore, the projects for cultivation through farmers as well as those for conservation, R&D and value addition primarily focused on prioritized species. In fact, projects for cultivation were supported only for those species which were included in the list of prioritized plants and those that had a ready market. A fresh Demand and Supply study has been initiated through the Foundation for Revitalization of Local Health Traditions (FRLHT), Bangalore— a centre of excellence of Ministry of Environment and Forest for Medicinal Plants, with a view to carrying out a nation wide survey and to assess medicinal plants in demand in trade and industry. This will help the Board to provide sharper focus while approving projects on species important from the point of view of trade as well as their conservation status."

XVIII. Development of Healthcare Facilities, Integration and Expansion of Outreach in Healthcare under AYUSH

Specialised Therapy Centres/Speciality Clinics

109. The Ministry introduced a Centrally Sponsored Scheme in 2002-03 for 'Promoting Development of Healthcare Facilities' in AYUSH in order to make AYUSH systems

available to the public at large and also to bridge the gaps between AYUSH and modern medicine. The scheme provided financial assistance to the States for setting up specialised therapy centres with hospitalisation facility in AYUSH system, specialiIty clinics of AYUSH *i.e.* system specific outdoor treatment centres, 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 year 2002-03 to 2004-05, Rs. 33.74 crore were released to cover 8819 units in 24 States under the scheme. Audit scrutiny further 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 unutilised as the State Governments did not release the funds to the implementing agencies.

110. Explaining the problems in implementation of the scheme, the Ministry in a written note stated as under:—

> "It is new a Centrally Sponsored Scheme for mainstreaming AYUSH System of medicine with modern system. It has been emphasized on State Govt. to release the fund to implementing agencies in time and get the schemes implemented in letter and spirit. The scheme is gaining acceptance in the States and implementation problems are being sorted out by rigorous monitoring."

111. When enquired about the reasons/constraints due to which the State Governments of Andhra Pradesh, Himachal Pradesh, Jammu and Kashmir, Manipur, Tripura and West Bengal did not release funds to the implementing agencies, the Ministry in a written note replied as under:—

> "Under the federal structure of Government, States have their own constitutional responsibilities in respect of timely and proper utilization of Central grants received by them. There are variety of reasons for delay in release of funds by the States to the implementing agencies and their proper utilization, relating to weak AYUSH infrastructure in the States and budgetary constraints of the States. This matter has been taken up with the concerned States through meetings with the State secretaries and letters from the Secretary and Joint Secretary in Department of AYUSH to the Chief Secretaries and Health Secretaries in the States, besides through visits by other officers of the Department of AYUSH to the concerned States. No further assistance is being released to the defaulting States until the UCs are received for the grants released earlier."

Promotion of AYUSH under The Central Government Health Scheme (CGHS)

112. The Central Government Health Scheme (CGHS) network had 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 DGHS. As of June 2004, only 2 dispensaries had been opened. The Ministry sanctioned seven more dispensaries

during 2004-05 at a cost of Rs. 1.30 crore but none of the sanctioned dispensaries could be set-up during 2004-05 due to shortage of doctors and para-medical staff.

113. In view of the declining trend in the attendance of patients in Ayurveda and Homoeopathy dispensaries from 1994-95 to 2001-02, the Ministry released Rs. 17.10 lakh in three installments to the Indian Council for Medical Research (ICMR) between September 2002 and December 2004 for conducting a survey and submitting a report within one year from the release of first installment. The survey aimed at assessing the acceptability/non-acceptability level of AYUSH facilities under CGHS, perception of CGHS beneficiaries about AYUSH, availability of AYUSH facilities under CGHS in the country and the level of availability of infrastructure and facilities in the selected teaching hospitals of AYUSH. The survey report had not been received as of March 2005, 30 months after the release of the first instalment of the grant, which delayed implementation of the required policy initiatives based on the survey findings.

114. In this regard, the Ministry in a written note explained their position as under:—

> "For the survey on ' ISM&H Beneficiaries covered under CGHS and Selected Teaching Hospitals attached to ISM&H colleges' assigned to ICMR , the 1st instalment of Rs 7.6 lakh was released in Sept. 2002 as an advance payment. Subsequently, the instalments were released on assessment of the progress. The 2nd instalment of Rs 5.7 lakh was released in Nov. 2003 on completion of 50 per cent of the survey work. Afterwards, on submission of first draft survey report, 3rd instalment of Rs 3.8 lakh was released in Jan. 2005. Inputs from this report are being utilized in policy formulation. Final report is under printing."

115. When asked about the number of new AYUSH (CGHS) dispensaries opened during the X Plan (till 2006) as against the target of 21 set under the Plan, the Ministry in a written reply stated as under:—

> "Seven out of target of 21 AYUSH units, which were proposed to be opened during the X Five Year Plan has been opened so far. Post of doctors and para-medical staff could not be filled due to instructions of DOPT dated 16th May, 2001 for optimization in direct recruitment in civil post and non-implementation of SIU report. The Union Cabinet has since exempted the technical post in the Ministry of Health including Department of AYUSH for the provision of DOPT order dated 16.5.2001 and action to fill up the post of ISM&H physicians through UPSC has already been taken and recommendation of the Commission is expected shortly. Likewise, with the implementation of SIU report *w.e.f.* 29th June, 2006 with the approval of Hon'ble HFM, action to fill up the post of para-medical staff has been initiated by Director CGHS who is the appointing authority."

116. To a query whether ICMR had submitted its report on the survey regarding acceptability of AYUSH facilities under CGHS, the Ministry in a written note stated as under:—

> "Yes, the survey report of ICMR regarding AYUSH facilities under CGHS has

been received. The findings of the survey 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 building 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."

Procurement of Ayush Drugs in CGHS

117. The Committee understand that there is a tender system for procurement of AYUSH drugs for use in CGHS hospital/dispensaries, while there is no such system for Allopathic medicines. When asked about the reasons for having a tender system for purchase of AYUSH medicines in CGHS, the Ministry in a written note replied as under:—

> "There is no tender system in the procurement of Siddha drugs to the Siddha Units under CGHS at Delhi and Chennai. All the classic Siddha drugs are being purchased either from TAMPCOL, Chennai-106 (Tamil Nadu Medicinal Plants Corporation Ltd.), a Govt. of Tamil Nadu undertaking or from IMPCOPS, Chennai – 41 (Indian Medicine Practitioners Co-operative Pharmacy and Stores Ltd.), a co-operative drug manufacturing unit. As far as the supply of classical Ayurveda and Unani drugs to Central Government Health Scheme (CGHS) is concerned and other institutions of Health Ministry of Government of India are purchasing medicines from Indian Medicines Pharmaceutical Corporation Ltd. (IMPCL), a joint-venture company of Government of India and Government of Uttaranchal. Prices of their products are fixed on the basis of cost of production including the raw material and 30% margin. Therefore, there is no question of drugs purchased from IMPCL on the basis of tender. The existing system of tendering has to be followed at present in

accordance with the existing General Financial Rules (GFR) in respect of open market purchase by States. However, separate technical and price bids are invited and it should be possible for the purchase committees to weed out sub standard suppliers under the technical criterion and not open the price bids of sub standard suppliers. These instructions will once again be reiterated to all concerned States/Central agencies."

118. The Committee desired to know about the measures Government propose to take to supply quality medicines in CGHS dispensaries of AYUSH. In reply, the Ministry in a written note replied as under:—

"As far as the supply of quality Siddha medicine to CGHS Siddha dispensary, the Department advised the CGHS to procure Siddha drugs either from TAMPCOL, Chennai-106 (Tamil Nadu Medicinal Plants Corporation Ltd.), a Govt. of Tamil Nadu undertaking or from IMPCOPS, Chennai – 41 (Indian Medicine Practitioners Co-operative Pharmacy and Stores Ltd.), a co-operative drug manufacturing unit. As regards Ayurveda/Unani medicines, they are procured from the Indian Medicines Pharmaceutical Corporation Ltd. (IMPCL), Mohan, Uttranchal, an AYUSH Department's PSU."

119. As regard the extant system available in the Department of AYUSH for selection/ shortlisting of Homoeopathy medicines dispensed in the Government hospitals/ dispensaries, the Ministry submitted in a written note as under:—

"The Department of AYUSH has prepared a list of essential medicines which has been circulated to all the State Governments to procure essential drugs. The Centre is providing Rs. 25,000 p.a. per AYUSH dispensary under the Centrally Sponsored scheme for procuring essential drugs for Government AYUSH dispensaries and the medicines are procured under the scheme are as per their prevailing State purchase procedures. Suggestions regarding short listing of companies for procuring quality medicines would be sent to the State Governments for necessary action."

XIX. Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

120. The main objective of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 [DMR(OA)] is to control the advertisement of drugs in certain cases, to prohibit the advertisements for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith. Under this Act "Magic Remedy" includes a talisman, mantra, Kavacha 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. It has been noticed that several advertisements appear in print and beamed in electronic media regarding false claims made by quacks for the cure of various chronic ailments under various disciplines of AYUSH.

121. In pursuance of recommendation of the Parliamentary Standing Committee on Human Resource Development (118th Report), the Department of AYUSH have informed

the State Drug Licensing Authorities and Directors of Indian Systems of Medicine of the State 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 had also issued general guidelines on action proposed to be taken under the Act on 30.9.1999, whereunder all the licensing authorities were asked 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.

122. Explaining the measures taken for implementation of the DMR(OA)Act, the Ministry stated that during the year 2003-2004 Department of AYUSH had engaged Akhil Bhartiya Grahak Panchayat, Osmanabad an NGO for one year with the objectives: (i) to provide the services for monitoring National Local News Papers in different languages for the misleading advertisement with respect to ASU drugs under DMR(OA) Act 1954, and (ii) to compile the relevant advertisement clipping from identify newspapers and magazine to facilitate State Drug Licensing Authorities to take action against the companies/agents issuing misleading advertisements under DMR(OA) Act in the country. This agency had collected 23051 misleading advertisements from different magazines and newspapers and reputed Journals within one year and send them to the concerned State Drug Licensing Authorities for taking action under DMR(OA) Act. Later the Department of AYUSH had reviewed the work of this agency and the project was closed after due approval of Secretary (AYUSH).

123. It had also been stated that the status of implementation of DMR(OA) Act was reviewed in the meeting of State Drug Controllers from time to time. Government have also issued a letter to all States on 10.11.2005 along with the proforma for seeking information on the action taken under DMR(OA) Act. Some States have responded to the said letter and provided requisite information. Recently a meeting of Ayurvedic, Siddha, Unani Drug Consultative Committee (ASUDCC) was held on 29.6.2006 during which the matter was reviewed. It was decided that State Drug Controllers should initiate action against the defaulters and issue notices as per the Act to check such practices. The Department had issued a D.O. letter on 11.7.2006 addressed to Principal Secretary (Health and Family Welfare) Government of Punjab to take action against the violator, the Prince Pharma (Regd.) Kailash Cinema Chowk, Ludhiana and to cancel the license under Rule 159 (1)(2) of the Drugs and Cosmetic Rule 1945.

124. The Ministry have further stated that the Government have proposed that the matter regarding the misleading advertisements would be taken up with the State Drug Licensing Authorities of Indian System of Medicine and Homoeopathy to give priority to the compliance of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954. Further Department of AYUSH would also put advertisement in National Dailies urging manufacturers, Newspapers, practitioners and regulating agencies to ensure compliance of the Act.

125. The Committee enquired about the steps taken by the Ministry to stop these advertisements as well as booking of the quacks under the Drugs and Magic Remedies

(Objectionable Advertisements) Act, 1954. In response, the Ministry replied in a written note as under:—

> "The Ministry has written to Secretary, Information and Broadcasting, Government of India for getting the Act complied with by the print and electronic media. The Ministry has also written to PIB for getting the Act complied across the country. Further, all State Governments have been requested to ensure strict compliance with the Act. Advertisement is also being issued in national/regional newspapers through the DAVP for drawing attention of health professionals/drug manufactures/general public and the print and electronic media regarding the provisions of the Act and cautioning them against contravention of the same."

126. When enquired whether Government have written to all newspapers and the electronic media asking them to prohibit publishing/telecasting of objectionable advertisements under DMR (OA) Act, the Ministry in a written note replied as under:—

> "A Public Notice is being issued through national/regional newspapers for attracting the attention of general public/health care professionals/drug manufacturers /print and electronic media to the provisions of the Act and cautioning them against contravention thereof. Print and electronic media is also being cautioned by the Ministry of Information and Broadcasting and PIB."

127. When asked about the steps the Government have taken or propose to take for setting up an effective surveillance mechanism to check the advertisements, which make false claims for cure of different ailments through the Indian Systems of Medicine, the Ministry in their written reply stated as under:—

> "The Ministry has written to Secretary, Information and Broadcasting, Government of India for getting the Act complied with by the print and electronic media. The Ministry has also written to PIB for getting the Act complied with across the country. Further, all State Governments have been requested to ensure strict compliance of the Act. Further, a Public Notice is being issued. Further, AYUSH Research Councils have been asked to set up surveillance units for monitoring such advertisements."

128. When enquired whether any amendments are required in the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 so as to make it more effective, the Ministry submitted in a written note as under:—

> "Government is considering amendment of the Act for following reasons: (i) to bring treatment within the scope of the Act to prevent luring of patients through advertisements offering cure or treatment,(ii)Increase penalties 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 revisions."

XX. Study Visit of The Public Accounts Committee to Shimla and Jaipur in connection with Examination of the Subject

129. Keeping in view the topicality and public importance of the subject, the Committee held informal discussions with the representatives of the State Governments of

Himachal Pradesh and Rajasthan and Ministry of Health and Family Welfare (Department of AYUSH) at Shimla and Jaipur during the months of June and September 2006 respectively as a part of their on-the-spot study visit programmes. During these discussions the Committee enquired about the corrective/remedial measures taken by the State Government on the various Audit findings till date. The Committee also desired to know the reasons for the delay if any, in furnishing Action Taken Notes to the Audit as well as in rectifying the flaws which have been pointed out in the Audit Report.

Visit to Shimla

130. During their study visit to Shimla in June, 2006 the Committee held informal discussions with representatives of the Ministry of Health & Family Welfare (Department of AYUSH), and Secretary (Department of Health) and other senior officials of the Government of Himachal Pradesh on various aspects relating to Audit Report *viz* enforcement, regulation and adherence to Good Manufacturing Practices (GMP) standards by the drug manufacturing companies/units, establishment of specialised therapy centers/speciality clinics and setting up of health resort clinics for tourists in Himachal Pradesh.

131. The important points/issues that emanated from the informal discussions were as follows:—

(i) The Government of Himachal Pradesh should streamline the system and procedure of transfer of funds to implementing agencies so that funds do not remain unutilized. Stricter monitoring of the performance of the field agencies by the State Government at regular intervals should be ensured.

(ii) The State Government should formulate appropriate guidelines for taking up research and development of Ayurvedic products by adhering to Good Manufacturing Practices within a time bound period.

(iii) The State Government should encourage more research work in different fields of AYUSH and the research finding should be disseminated to the rest of the country. The ongoing projects in the State should also be completed at the earliest.

(iv) The State Medicinal Plant Board of Himachal Pradesh should be entrusted with clear and direct responsibility of monitoring and evaluating various plantation schemes of herbal plants.

(v) The Government should encourage farmers to grow more medicinal plants so as to supplement the natural herbs that are available in the natural vegetation.

(vi) The outreach and healthcare facilities in AYUSH should be properly maintained and kept well equipped. Before undertaking expansion, the existing facilities should be optimally utilised and at the same time the Government should make extra efforts to make AYUSH systems of medicine easily available to the rural population.

(vii) The Government should have a strict vigil on the various claims made by unscrupulous practitioners about their claims of curing different ailments

through AYUSH systems of medicine. All such claims should be brought under the penal provisions of the Drugs Magic Remedies (Objectionable Advertisement) Act, 1954 at the earliest. State Government should also co-operate and co-ordinate with the Central Government in overcoming this malady.

Visit to Jaipur

132. During their study visit to Jaipur, the Committee visited National Institute of Ayurveda and held informal discussion with the Chief Secretary, and other senior officials of the Government of Rajasthan and the Director, National Institute of Ayurveda and representatives of the Ministry of Health & Family Welfare (Department of AYUSH) on the functioning of National Institute of Ayurveda. The Committee also discussed the issues arising out of enforcement, regulation and adherence to Good Manufacturing Practices (GMP) standards by drug manufacturing units and cultivation of medicinal plants and development of ago-techniques in the State of Rajasthan.

133. The important points/issues that emanated from the informal discussions were as follows:—

(i) The good work done by the National Institute of Ayurveda should be disseminated to all the Ayurvedic Colleges, Institutions, Organizations and Hospitals and Dispensaries in the country.

(ii) Significant achievements and research results of the Institute in respect of a medicine should be made known to general public as well as other Ayurvedic Colleges/Institutes in the country.

(iii) The National Institute of Ayurveda should publish their research work in international journals so that Ayurveda can get more attraction and publicity in foreign countries. All related documents regarding the research findings may also be send to the Parliament library for information of People's Representatives.

(iv) Drugs manufactured in the National Institute of Ayurveda should undergo stringent testing to check whether they contain toxic elements, so as to prove to the rest of the world that their medicines are not harmful and are safe.

(v) Drugs for the institute should as far as possible be procured from the Pharmacy of the institute. For this the institute should make all out effort to increase the drugs/medicines production capacity of the institute.

(vi) The State Government of Rajasthan should take immediate steps to hand over the land to National Institute of Ayurveda for developing Medicinal Plants Garden and extend all support to the institute so that it can compete with Allopathic Hospitals. Further, Government should also increase the fund allocation of the institute.

(vii) Government of Rajasthan should also open Ayurvedic Resorts in the State on the lines of Kerala.

Observations/Recommendations

134. Inspite 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 medicine 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.

135. 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.

136. 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 for 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.

137. The Committee regret to observe that the Department of AYUSH had achieved very little success in achieving the objectives of growth and development, propogation 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 updation 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 blockade of funds to the tune of Rs. 5.05 crore. These issues have been discussed in detail in the succeeding paragraphs.

138. 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 the 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.

139. 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 per cent) 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 Governments 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.

140. 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.

141. 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.

142. 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 or staff in Library. The test-check of records of educational institutes in Andhra Pradesh, Chhattisgarh, Delhi, Haryana, Madhya Pradesh, Maharasthra, Rajasthan, Uttar Pradesh and West Bengal revealed shortage of teaching staff ranging between 19 and 72 per cent of paramedical 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 percent 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 centres of excellence.

143. 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) Bills, 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.

144. 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 enrolment 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 the database 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.

145. 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 setup 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.

146. The Committee note 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 regret 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 indicate that the Ministry have 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.

147. 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 specialised therapy centres

with hospitalisation facility in AYUSH system, speciality clinics of AYUSH *i.e.* system specific outdoor treatment centres, 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 year 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 unutilised 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.

148. 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.

149. 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 an 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 understand 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 recommend 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.

150. 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 Boards (SMPB) were 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 2003-2004 and 42 per cent (779 projects) to the year 2004-2005. Since the project period is usually three years, only those projects which were sanctioned during 2003-2004 or earlier could have been completed by March 2006. The project sanctioned during 2004-2005 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 Government 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.

151. 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 have 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 recommend that Government should make all out efforts for setting up Drug Testing Laboratories in the remaining States where they have not been setup and also to ensure that they become functional within a year.

152. 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.

153. In June 2000 the Department of AYUSH had issued a notification directing the drug manufacturers 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 manufactures 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 & Cosmetics 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) compliant. 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.

154. 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 recommend 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.

155. 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 have stated that the effectiveness of Unani medicine have 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 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 recommend 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 educationist, researchers, manufacturers and Government Institutions through internet and research journals.

156. 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 filing 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 use) have been commercialized through National Research and Development Centre (NRDC). 12 drugs are in the pipeline for filing 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.

157. Recently some of the Ayurvedic medicines manufactured 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.**

158. 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 a talisman, mantra, Kavacha 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 aliments such as epilepsy, migraine, etc. and rejuvenation of sex powers. Explaining the measures taken for implementation of the Act, and rules frame 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 news papers for strict compliance. It has also been stated 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. AYSUH 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 advertisement regarding AYSUH 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 are 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.

159. 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 concieved 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 be apprised of the steps taken/proposed to be taken in this regard.

NEW DELHI;
15 *December*, 2006
24, *Agrahayana*, 1928 *(Saka)*

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

ANNEXURE - I

DETAILS OF IMPORTANT COLLABORATIVE RESEARCH PROJECTS UNDERTAKEN BY THE DEPARTMENT OF AYUSH ARE AS FOLLOWS

Sl. No.	CCRAS Institutes	Collaborating Institutes	Research Area
1.	CCRAS, Hqrs.	University of Delhi National Institute of immunology and Holy Family Hospital, Delhi	Genetic susceptibility to rheumatoid arthritis using a novel combination of prakriti based control selection & molecular analysis tools
2.	CCRAS Hqrs / CRI, New Delhi	CCMB (CSIR) Hyderabad	Clinical evaluation of AYUSH-CT drops in improving the quality of vision and visual acuity in age related immature cataract (In progress)
3.	CCRAS Hqrs / CRI, New Delhi	AIIMS Delhi Under process	Clinical Studies of AYUSH-CT in age related immature cataract (In progress, Ethical clearance awaited)
4.	CCRAS Hqrs / CRI, New Delhi	AIIMS Delhi Under process	Clinical Evaluation of AYUSH-DE Drops in Dry Eye Syndrome (In progress, Ethical clearance awaited)
5.	CCRAS Hqrs / CRI,	AIIMS Delhi Under process	Clinical Evaluation of AYUSH-AC Drops in Simple Allergic Conjunctivitis (In progress, Ethical clearance awaited)
6.	Clinical Research Unit, Bangalore	NIMHANS, Bangalore	Autonomic functions tests in patients with depression (vishada) Role of Ayurvedic therapy and transcranial magnetic stimulation. Efficacy of Manasamitram Vadakam on Generalized Anxiety Disorder : A polysomnographic Study – Efficacy of Ayurvedic treatment for motor weakness due to ischemic stroke a prospective, randomized, controlled study
7.	Central Research Institute, Mumbai	TATA Cancer Research Institute	1. Improvement of quality of life in Cancer patients (Study will be initiated shortly) 2.Screening of Herbal drugs for potential anti-Cancer activity (in the process of finalization)
8.	CCRUM	Deccan Medical College	Liver disorders
9.	CCRUM	Patel Chest Institute, New Delhi	Bronchial Asthma

Sl. No.	CCRAS Institutes	Collaborating Institutes	Research Area
10.	CCRUM	KG Medical University, Lucknow	Gingivitis
11.	CCRH	Department of Medical Elementology and Toxicology, Jamia Hamdard	Study on Homoeopathic Medicines for the treatment of Cerebral Ischaemia.
12.	CCRH	Jawahar Lal Institute of Post-Graduate Medical Education and Research (JIPMER), Pondicherry	Effect of Homoeopathic Drugs used in Insomnia on Serum melatonin and Cortisol levels in Healthy volunteers.
13.	CCRYN	Instt. Rotary Cancer Hospital, AIIMS, New Delhi	Effect of breathing techniques & meditation on normal individuals & those with cancer in remission
14.	CCRYN	Deptt. of Pharmacology, JIPMER, Pondicherry	Effect of Yoga based therapy in Insomnia
15.	CCRYN	Department of Physiology, AIIMS, New Delhi	A randomized controlled trial on the efficacy of Yoga in the Management of Bronchial Asthma
16.	CCRYN	Deptt. of Neurophysiology, NIMHANS,Bangalore	Autonomic function tests in epilepsy-Effect of Hatha Yoga
17.	CCRYN	Department of Physiology, AIIMS, New Delhi	Yogic relaxation in the management of ulcerative colitis
18.	CCRYN	Department of Biophysics, AIIMS, New Delhi	Randomized Clinical Trial (RCT) of Reflexology Therapy and usual drug treatment in the Management of intractable Epilepsy
19.	CCRYN	Deptt. of Physiology, AIIMS, New Delhi	A study to assess acute mental stress induced changes in EEG, cognitive behaviour and neurosteroids across the menstrual cycle and effect of meditation on stress-induced changes
20.	CCRYN	Deptt. of Psychiatry, Dr. R.M.L. Hospital, New Delhi	An exploratory analysis of genetic correlates and effects of Yoga on circadian rhythms, cognitive functions and social burden in major mental disorders: schizophrenia, bipolar disorder and depression and their comparison with a cardiac group (Collaborative project between CCRYN and Dr. RML Hospital)

Sl. No.	CCRAS Institutes	Collaborating Institutes	Research Area
21.	CCRYN	Deptt. of Neuro-physiology, NIMHANS, Bangalore	Assessment of the efficacy of Vipassana Meditation on different age groups: A polysomnographic and Endocrine function evaluation
22.	MDNIY	Escorts Heart Institute and Research Centre, Okhla, New Delhi	Study of the effect of Yoga practices on management of Techno-Stress in Computer users: a quantitative approach using psycho-neuro-physio-motor functions

ANNEXURE - II

DETAILS OF THE ACTIVITIES OF THE SCIENTIFIC ADVISORY COMMITTEES FOR THE RESEARCH COUNCILS

Extra Mural Research

CCRAS

- During last 10 yrs. the Council has executed Clinical Research Programmes on 22 clinical conditions for evaluating the efficacy of 46 sets of various formulations. The research outcome has been compiled in the form of monographs for use researchers and physician etc.
  - Currently 9 monographs on Slipada, Madhumeha, Vyanabala-vaisamya, Arsha, Parinamashula, Amlapitta, Kamala, Amavata and Tamak shwasa have been completed and being processed for Publication.
  - In the year 2003 the Council identified 30 priority areas considering the strength of Ayurveda and Siddha work is in progress [standardization (physico chemical analysis, TLC, HPLC, HPTL, Microbial load, pesticide residue, Heavy metal content etc), toxicity, targeted biological activity studies] in respect of 8 formulations *viz.* AYUSH Rasayan-A and AYUSH Rasayan-B for Improving QOL in elderly persons, AYUSH-RP for Sickle Cell Anaemia, AYUSH-Osto for Osteoporosis and fractures, AYUSH-LIV for Hepatitis B & C, AYUSH-M for Migraine, AYUSH-SL Capsules and AYUSH-SL External application for Morbid cases of Filariasis, AYUSH Manas for Mental retardation, AYUSH QOL-2 for improvement of quality of life in HIV/AIDS and cancer patients The standardisation and pre-clinical studies of all these formulations are completed. The targeted biological activity study of AYUSH QOL-2 is completed and the study on rest of these formulations is under progress.
  - The projects of national importance that have been taken up by the council include Feasibility of introducing Indian systems of medicine (Ayurveda & Siddha) in the "*National RCH programme at the primary health care (PHC) Level*" for which 17 Ayurveda and 16 Siddha interventions for 12 different conditions/ diseases related to women and children have been prepared. The standardization, Safety and toxicity studies are completed and the project will be launched after getting the approval from Ayurvedic pharmacopoeia committee for standards and SOPs.
  - Another landmark is standardization and automation of Panchkarma instrumentations in collaboration with IIT Delhi and development of Sarva Dhara instrument. The automation of Vaspasweda yantra (steam bath) and instrument for preparation of ksharsutra are in progress.
- 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, National Institute of Naturopathy

and Amul India. The Council has participated in Annual Indian Scientific Expeditions to Antarctica in 2003 and developed Ayurvedic Rasayana—Food Supplement and Drink (*Antartica Tea and Antartica laddu)* for improving physical and mental endurance in cold climate conditions. Significant Immunomodulatory action, Anti-oxidant effects, besides improvement in physical and physiological parameters have been observed. Further studies on assessment of nutrition value, self-life, etc. are under progress at IIT Chennai.

- AYUSH face pack – an Ayurvedic cosmetic agent is being developed through systematic studies. Ayurvedic Anti-dandruff agent, Anti fungal Agent and Anti Pollutant Air Refresher are been developed with raw drugs collected from garden of Rashtrapati Bhawan in collaboration with Fragrance & Flavour Development Centre, Kannauj.

- Under Tribal Health care research programme during last ten years 167 villages covering 182301 persons has been surveyed and instant health care services provided to 83,442 patients besides collecting socio demographic data.

- In the pharmacological research during the past ten years about 17 Ayurvedic and 10 Siddha drugs screened for their detailed pharmacological activity 20 plants screened for their antifertility activity under research scheme on screening of contraceptive agent (RSSCA).

- Council has taken up a project to formulate standard operative procedures of selected herbomineral preparation (Raskalpas) through extensive analytical physico-chemical studies and is safety evaluation to create referral data.

- After the publication of an article in Journal of American Medicine alleging that 14 out of 70 herbal products originating from India and collected from grocery stores in Boston area contained heavy metals above permissible limits there have been lot of concerns regarding the safety of herbo-metallic Ayurveda formulations. Hence, CCRAS carried out acute, sub-acute toxicity studies. Chronic toxicity studies are in progress.

- Under Drug standardization research programme, standardisation of 326 single drugs, 20 drugs of animal origin, 36 drugs of Mineral origin, 271 formulations, TLC/HPTLC of 84 drugs, Microbial load on 65 drugs, Isolation of marker compound of 24 drugs and Shelf life studies on 4 drugs have been completed.

- Under cultivation of medicinal plants programme 1121 species have been cultivated along with 14081 Guggulu plants. The area under cultivation is 83.14 acres. Experimental studies on plant tissue culture of 15 rare, endangered, important Ayurveda & Siddha medicinal plants have been done and developed protocol for 6 plants.

- Under medico Ethano botanical survey programme, 8819 species and 2289 raw drugs have been collected through 490 survey tours. 2272 samples have been

supplied to 269 institutes for various purposes. Besides this 11002-museum specimens collected and 11294 herbarium sheets have been prepared. 342 folk medical Claims have been collected.

- Under literary Research during last 10 years, the Council has undertaken transcription and revival of the sacred lore of Ayurveda and Siddha System of Medicine which lay inscribed on Manuscript in Bhurjpatra (Brich Bark) and Tadpatra (Palm Leaf), besides covering Medic-historical studies as well as preparing inventory of Sanskrit Medical Manuscripts. As a result of the efforts put in, periodical reviews undertaken and planned evaluation, the Council has brought out the following classical works on Ayurveda & Siddha:

Ayurveda:

- Abhinav Cintamani
- Ashtanga Sangrah (Indutika) – Critical editions
- Ashtanga Hrdayam
- Charucharya
- Dhanvantri Saranidhi
- Metra Prakashika
- Netra Roga Nidanam
- Nanavidh Vaidyam
- Samgamuni Visha Vaidyam-100
- Pathyapathy Vinischaya
- Shatashloki
- Rasapradipika
- Ratanprabha (Residual Section)
- Publication of 26 Research Monographs.

Siddha:

- Agasthiyar Pooranam 205
- Theriyar Kudineer
- Konganar Mudal Kandam - 1000
- Konganar Nadu Kandam – 1000
- Publication of 2 monographs

Misc. Ayurveda & Siddha Works

- Research in Ayurveda & Siddha – Bibliography of CCRAS Contributions
- A Check list of Sanskrit Medical Manuscript in India (Under revision)

The council has published 53 books and monographs during past ten Years under literary research.

- The time taken for completion of a project depends upon its nature. In general the average period of completion of new drug developed right from literary survey, formulation of coded drug, collection of authentic raw material, formulation of SOPs, standardization, toxicity, targeted activities studies, drafting of clinical protocol and initiation of clinical trial takes about 10-15 years. For Ayurvedic and Siddha drugs it may take about 6-7 years as Phase-I studies are not be required.
- The Council's research activities are periodically reviewed by SAC (Ayurveda and Siddha) respectively twice or thrice in a year and SAC issues necessary suggestions/modifications and guidelines. The Standing Finance Committee approves the financial demands for research activities and also assesses the expenditure from time to time. The governing body of the council chaired by Honorable Minister of Health and Family Welfare review and approves the issues related to policy matters.
- Concerning the dissemination of the research findings among educationists, researchers, manufacturers etc., the finding of the studies are published by the Council 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 melas and distributing to visiting delegates.

CCRUM:

In the Clinical Research Programme, the Council took up work on 55 formulations in 18 different disease conditions either of national importance or those of chronic nature for which other systems did not have much to offer. Out of these 55 formulations, the Council have been able to finalize 31 drugs. Out of this, results of 12 drugs were published in the form of monographs and for 8 drugs, the Council have applied for patent rights. 11 drugs are in the pipeline for obtaining patents. These conditions included Leucoderma, Infective Hepatitis, Filaria, Gingivitis and Malaria. The Council have also been able to have provisional patent rights for 17 Kit Medicines which have been commercially exploited through NRDC.

Under the Drug Standardization Research Programme during last 10 years, standards for 87 compound drugs were finalized, standardization of methods of manufacture of 27 formulations, quality control of 81 research drugs and standardization of 12 mineral drugs was done. Some of the standardization work done by the Council's Units earlier

was repeated for some additional parameters based on the recommendations of the Unani Pharmacopoeia Committee. Based on Drug Standardization work carried out by the council on single drugs, standards for 145 single drugs have been approved and adopted by the UPC and have since been published in the Unani Pharmacopoeia of India.

Under the Literary Research Programme, 44 monographs have been edited/ translated and published.

In the area of Survey, Collection and Cultivation of Medicinal Plants, the Council has done the following work during the last 10 years:

> During the reporting period the Council surveyed the forest areas in the States of Andhra Pradesh, Bihar, Jammu & Kashmir, Orissa, Tamil Nadu, Uttar Pradesh and Uttaranchal. The survey teams of the Council collected 29, 608 botanical specimens of medicinal plants; besides collection of 2,682 folk medicinal claims through interviews of tribal medicine men. A total of 39,078 herbarium sheets of medicinal plants were prepared with a write-up on each and deposited in the herbarium of respective regional centres.
>
> The Council has also taken up cultivation of some important plant drugs on field scale. These include Punica granatum L. (Gulnar farsi), Vitex negundo L. (Sambhalu), Adhatoda zeylanica L. (Arusa), Cichorium intybus L. (Kasni), Acorus Calamus L. (Waj), Caesaleinia bonduc L. Roxb.(Karanjwa), Gymnema sylvestre R. Br. (Gurmar buti), Withania somnifera Dunal. (Asgandh) etc. Besides, experimental cultivation trials on Delphinium denudatum Wall. ex H & T (Jadwar) and Withania somnifera Dunal. (Asgandh) were also conducted at different centres.

Farmers' Meetings

The Farmers' meetings organized for training of farmers on cultivation of prioritised medicinal plants at:

> Chevella Mandal, Ranga Reddy district; Rajindernagar Mandal, Ranga Reddy district (Andhra Pradesh); Padapai village, Kurathur Block, Kanchenpuram district; Perampakam village, Kadampathur Block, Tiruvallur district (Tamil Nadu); and Aligarh, Etah, Ferozabad districts (Uttar Pradesh).

Maintenance of Nurseries

Aimed at demonstration of Medicinal plants to the public, nurseries of medicinal plants were maintained in the institutes attached to survey components. About 100 species of medicinal plants were maintained during the period 2005 – 2006.

Development/ maintenance of herbal garden at Lucknow

More than 150 plant species of medicinal value were planted and maintained in the herbal garden under CRIUM, Lucknow.

Compilation of data on folklore claims

Data on folklore claims recorded during the reporting period by Council's Survey of Medicinal plants units were compiled and published by the Council. There is a permanent mechanism of periodical review of Research Projects by the Ministry of Health & F.W. in the form of monthly reports as well as periodical reviews and the Council's Scientific Advisory Committee which comprises of experts in the field of Unani Medicine, Botany, Chemistry, Pharmacology and Modern Medicine constantly reviews the progress of work of different Units/Institutes under the Council. In the Council's Headquarters also there is a mechanism of regular interaction with the Research Centres about conduct of Programme and the guidelines are issued by the Council based on the recommendations of the S.A.C. and directions of the Ministry of Health & F.W. During such reviews different aspects such as progress of work, expenditure incurred *vis-à-vis* targets assigned are taken into account. There has never been any major shortfalls observed in any research programme and by and large the targets assigned are achieved/fulfilled.

As regards dissemination of research findings, the Council has been regularly taking steps or disseminating the research outcome by way of organizing seminars/ conferences, Health Exhibitions and other public contact programmes Nationally and Internationally to ensure that all stakeholders which include educational institutions, drug industry, research organizations and other institutions are aware of the work done under the Council. The Council has been able to organize one International Conference, eight National Seminars, ten workshops besides participation in Health Exhibition and other Expos. The Council had also the advantage of participating in 545 health melas organized during this period in Parliamentary Constituencies. The Council has been directed by the Department of AYUSH to have a regular Quarterly Scientific Journal which should be peer reviewed.

CCRYN:

The Central Council for Research in Yoga and Naturopathy (CCRYN), New Delhi has so far completed 20 clinical research projects since 1995. The duration of a research project is 3 years. However, extension of period from 2-3 months to 1 year is made due to some reasons. The Council conducts a review meeting every year to find out the progress made under the research projects. In the meeting, the Principal Investigators/ Co-investigators are invited to present the progress made before the expert members. Regarding the dissemination of research findings the Council has already started publishing the monograph of each research projects with a view to propagate the research outcome for the use of common public. The monograph titled, *"Coronary athero-sclerosis reversal potential of Yoga life style intervention"* was published and sent to various Naturopathy & Yoga hospitals in the Country so that the information may be used in the treatment to such patients. The Council also publishes the abstract of each completed research projects in its quarterly newsletter "Yogic Prakritik Jeevan Sandesh".

The monographs of all 20 completed research projects are being published.

CCRH:

The Central Council for Research in Homoeopathy is engaged in research in the following areas since its inception in 1979.

1. Drug standardization,
2. Proving of drugs used in Homoeopathy,
3. Clinical verification of pathogenesis obtained through drug proving,
4. Clinical trial of homoeopathic medicine in specific diseases,
5. Literary research, and
6. Survey and collection of medicinal plants.

Drug Standardization

Formulation and establishment of botanical, physico-chemical and pharmacological standards are essential for drugs used in Homoeopathy, as therapeutic properties are dependent on the quality of drugs. Standardization studies require expertise of a number of specialists in allied sciences *viz.* Botany, Chemistry, Pharmacology, etc. The Council has undertaken drug standardization as a continuing programme since its establishment in 1979.

Publications:

- 9 Monographs
- 28 Research papers in CCRH Quarterly Bulletin (1980 and 2005).
- Standardization of Homoeopathic Drugs, Volume-1: Book containing profiles of 11 drugs

Drug Proving Research

Proving of a drug substance in Homoeopathy is a unique process. Unlike modern medicine where animal experimentation forms the basis of evolution of drug pathogenesis, homoeopathic medicines are proved on healthy human volunteers, including controls. Two types of proving are conducted by the Council (i) Short-term lasting 6-8 months and (ii) Long-term proving lasting for 1-2 years. The entire process takes about 2-3 years and has to be repeated more than once at different places and in different settings. The voluminous data of subjective symptomatic changes, recorded by each prover is then compiled, sifted and sieved to remove symptoms recorded by controls and those of doubtful nature. Obviously, the entire process from initiation of proving to final compilation of proving data and its publication is time consuming and takes about 3 years (Earlier the proving of a drug used to continue for 3-5 years on account of longer observational period).

The Council has proved 33 drugs during the last ten years (1995-2005). Proving of six new drugs was started in 2005. These provings are expected to be completed in 2007.

Proving Reports Published so far

- 52 drugs in CCRH Quarterly Bulletin (1980—2005)
- Homoeopathic Drug Provings—conducted by CCRH- (2005) containing pathogenesis of 38 drugs (Proving reports were already published in CCRH Quarterly Bulletin)
- 8 Monographs

Clinical Verification

Clinical confirmation of the signs and symptoms produced during proving of a drug on healthy human volunteers is essential for validation of proving results and facilitate therapeutic application of respective drug. Clinical verification study in signs and symptoms specific and not disease specific. The Council had undertaken clinical verification of 65 drugs in 1996—2004. These included fragmentarily proved Homoeopathic medicines that are clinically useful but infrequently used in clinical practice. Most of these drugs were of Indian origin. In 2004, the Scientific Advisory Committee felt that the Council has proved a significant number of drugs since its inception. Therefore, it decided that the Council should now focus on clinical verification of drugs proved by it. The Council has, therefore, confined its clinical verification studies to 35 drugs proved by the Council and whose data have already been published.

Publications

- Clinically verified data of 25 drugs have been published in CCRH Quarterly Bulletin (1990—2005)
- 9 Monographs containing verified data

Clinical Research

Clinical studies facilitate assessment of therapeutic utility of drug substances in specific disease conditions thereby prompting their proper and optimum therapeutic use. The Council has therefore, undertaken disease specific and drug specific clinical studies.

Like proving of drugs on healthy individuals, clinical studies also entail enrollment of a prefixed number of subjects and a prefixed duration of study including follow-up. Entire process is time consuming and takes about 2—5 years depending on the nature of the disease under study.

The Council has concluded 56 clinical studies, including 14 in tribal dominated areas. Forty five (45) of these studies were concluded in the year 2003—05. The Council has undertaken 18 new clinical studies in 2005-06 on protocols formulated in consultation with Experts from ICMR, AIIMS, NICD, NACO and Homoeopathy. These studies have prefixed number of subjects and time frame of 2—5 years. These studies also have Expert Consultant in respective disciplines for assessment of progress and valid outcome.

The Council has, apart from carrying out planned clinical studies, over the years, undertaken clinical studies in 32 epidemics of different diseases. The findings of these studies have underlined the utility of Homoeopathic medicines in epidemics.

Publications

- 45 Research papers on clinical studies undertaken by the Council have been published in the Quarterly Bulletin of the Council and foreign Journals (1985—2005)
- Final Reports on 23 clinical studies are being prepared for publication

Literary Research

James Tyler Kent's Homoeopathic Repertory was compiled in early 20th Century, but continues to top the list of frequently used reference books by clinicians all over the world. Since its publication, hundreds of drugs have been proved but their proving data is scattered at various sources. Many of these drugs, which could prove to be very effective therapeutically, are not used as frequently as they should be. To see that optimum clinical use of their pathogenic data is made, Council had undertaken revision of Kent's Repertory in the light of data available in various source books. Work on the revision of 18 chapters of Kent's Repertory has been completed. Seventeen of the revised chapters have already been published and work on chapter 'Generalities' is being reviewed for publication.

Publications

- 9 Books containing 17 revised chapters of Kent's Repertory

Survey and Collection of Medicinal Plants

To identify and locate plants used in medicine and collect them for reference and standardization studies is an important factor that contributes to the growth of any system of medicine. In Homoeopathy, the drugs of vegetable origin constitute about 80 per cent of the total drugs proved thus far. Most of these drugs are exotic and were proved overseas. Although their therapeutic utility is repeatedly confirmed on people in our country, yet reported variation in active constituents of the raw drug necessitates re-proving of drugs prepared from plants available in India. It is also necessary for economic and other reasons, that most frequently used exotic vegetable drugs are cultivated in the country. CCRH has accorded due importance to this aspect and has established a Survey, Collection and Cultivation of Medicinal Plants Unit at Udagamandalam (Ooty), Tamilnadu. This Unit has acquired 12.70 acres of land on lease from the Government of Tamilnadu. Cineraria maritima, an exotic plant used in the preparation of widely used homoeopathic eye drops, has successfully been cultivated by the Unit. Efforts are on to cultivate two other exotic plants namely Arnica montana and Hydrastis canadenesis which are also widely used in Homoeopathy.

This Unit has also collected 8041 medicinal plants and has prepared Herbarium Sheets of 7417 medicinal plants. Germ plasms of 65 Drugs are being maintained. 407 raw drugs have been supplied to Drug Standardization Units of the Council for physico-chemical studies being carried out.

Publications

- A check List of Homoeopathic Medicinal Plants of India containing information on 369 plants used in Homoeopathy (*seen two editions*)
- A Handbook of Medicinal Plants used in Homoeopathy-Vol.1

Other Activities of the Council

(i) Publications

- Council publishes a Quarterly Bulletin containing scientific papers for Homoeopathic students, physicians, teachers, research scholars and homoeopathic industry (28 volumes of the Bulletin, including 10 volumes in the last 10 years, have been published so far)
- CCRH News containing highlights of activities of the Council for free distribution amongst Registrars of State Boards and Councils, Directorates of ISM & H, Homoeopathic Medical Colleges, eminent Homoeopathic physicians in the country (37 Issues, including 17 in the last ten years, have been published so far)
- 18 Volumes of Current Health Literature Awareness Service (CHLAS) have been published in the last 10 years
- Medico-abstracts on 6 disease conditions have also been published in the last 10 years. Work on Medico-abstracts on 'Cancer' is in progress.
- 15 priced and 7 Non-priced publications have also been published during the last 10 years
- 39 Informative Handouts (including 15 in Hindi) on Homoeopathy and some common disease conditions for lay public have also been published.

(ii) Collaborative/fundamental research studies

National Collaboration

- The Council had undertaken research studies in collaboration with other Organizations and Scientists from reputed Institutes. Main objective of such studies is to scientifically validate the principle and efficacy of Homoeopathy. Eight (8) collaborative studies have already been concluded.
- Seven (7) Collaborative studies with Organizations in the country have been undertaken in 2005-06.
- One Collaborative study with Scientist from Defence Institute of Physiology and Allied Sciences (DIPAS) is being finalized and is expected to be undertaken in 2006-07.

International Collaboration

- One International collaborative study with University of California, Los Angeles (UCLA) on prevention of HIV/AIDS has also been concluded (2002-04).
- Another study has been undertaken in collaboration with UCLA in 2005-06.

(iii) Reorientation and Training Programmes and Seminars/Workshops/ Conferences

Continuing medical education (CME) plays an important role in updating the knowledge of Scientists engaged in research in health, disease and medicine. The Council has been conducting Reorientation Training Programmes for its Scientists and Workshops/Seminars for Scientists and Members of the Profession and Homoeopathic Industry. It has conducted 13 Reorientation Training Programmes and 24 Workshops/ Seminars during the last 10 years (1996-2006).

The Council regularly disseminates its research findings through Quarterly Bulletin and CCRH News; Current Health Literature Awareness Service (CHLAS) and Medico-abstracts on specific disease conditions; Books, Monographs (priced and non-priced); Informative handouts (including 15 in Hindi) on Homoeopathy and some common disease conditions for lay public. It may be seen that the Council do disseminate its research findings in the manner any Research Organization does. The feed back it receives indicate that most of the results are reproducible. A consortium of International Homoeopathic Organizations, including International Federation of Classical Homoeopathy; Royal London Homoeopathic Hospital; European Committee of Homoeopathy and American Institute of Homoeopathy which met during the International Conference held at London in January, 2006, recognized the contribution of the Council to Homoeopathic Research and decided to involve the Council in future researches, particularly in Influenza and Avian flu.

The time taken for completion of a project depends upon its nature. In general the average period completion of new drug developed right from literary survey, formulation coded drug, collection of raw material, verification for authenticity formulation of SOPs standardization, toxicity, targeted activities studies, drafting of clinical protocol and initiation of clinical trial takes about 10-15 years. For Ayurvedic and Siddha drugs it may take about 6-7 years as phase-I studies may not be required for this purpose.

APPENDIX-I

Performance audit of

Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

(Ministry of Health and Family Welfare)

Report of the
Comptroller and Auditor General
of India
for the year ended March 2004

Union Government (Civil)
No. 16 of 2005

CONTENTS

PREFACE

This report of the Comptroller and Auditor General of India containing performance appraisal of **Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH),** Ministry of Health and Family Welfare has been prepared for submission to the President of India under Article 151 of the Constitution.

The performance audit was conducted through test check of records of the Department of AYUSH including its subordinate offices and implementing agencies in 29 States and Union Territories during 2004-05.

OVERVIEW

Government of India established the Department of Indian Systems of Medicine and Homoeopathy (renamed AYUSH from November 2003) in March 1995 with the main objectives of promoting good health, expanding the outreach of AYUSH healthcare through preventive, promotive, mitigating and curative interventions, improving the quality of teachers and clinicians, ensuring affordable and efficacious AYUSH services and drugs and integrating AYUSH in healthcare delivery system and National Health Programmes.

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 pronouncement 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.

The Regulatory Councils responsible for prescribing minimum standards of infrastructure in medical institutions, maintaining a centralized database of medical practitioners and monitoring the prescribed standards of medical education had failed in checking the growth of substandard institutions. Most of the 444 colleges of Ayurveda, Unani and Homoeopathy in the country lacked minimum required faculty, attached hospitals and teaching facilities. The central register of practitioners had either not been maintained or had not been updated and revised for very long periods. The independence and autonomy of the regulatory bodies had also been diluted.

Research activities were not undertaken under fixed parameters within specified time period and their results had not been disseminated for the benefit of educationists, researchers, manufacturers and the common man. During the last 25 years, the Councils had obtained patents for only three Ayurveda drugs and did not contribute concrete research findings in the core area of family planning/contraceptive measures.

Pharmacopoeial Committees did not finalise standards in respect of any of the compound formulations in Ayurveda and Unani even after 40 years of their establishment, though the National Policy-2002 had envisaged completion of this work by 2005.

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.

Performance Audit report on 'AYUSH'

Highlights

- Ministry's allocation of funding for the programmes under AYUSH was inadequate considering the objectives to be achieved. Ministry allocated 2 *per cent* of the total Health budget (2000-2005) to AYUSH as against 10 *per cent* envisaged in the National Policy. State Governments did not transfer Rs. 16.94 crore (55 per cent) to implementing agencies for periods up to 36 months.

(Paragraphs 5.1.2 and 5.1.5)

- Ministry did not maintain any consolidated record of utilisation of grants depriving it of an effective monitoring tool. Thus, Rs. 36.52 crore (72 *per cent*) remained unutilised with the implementing agencies as of December 2004 out of the grant in aid of Rs. 50.87 crore released to 12 States during 2000-05. Similarly, out of Rs. 4.95 crore released by the Ministry to the States for establishing specialised therapy centres/specialty clinics, ISM&H wings and supply of essential drugs, Rs. 4.90 crore (99 per cent) remained unutilised. An amount of Rs. 53.19 lakh released to the Government of Himachal Pradesh under the Pilot scheme for setting up AYUSH Health Resort Clinics for Tourists also remained unutilised, which defeated the very purpose of attracting tourists.

(Paragraphs 5.1.4, 5.6.6 and 5.6.9)

- None of the 142 colleges whose records Audit test checked, out of total 444 colleges, possessed adequate infrastructural facilities, faculty, attached hospitals with requisite bed strength and 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 updation ranged between 3 and 22 years in 20 States, which deprived the practitioners of the opportunity of practicing in other States and reduced the outreach of AYUSH Medicare.

(Paragraphs 5.2.4, 5.2.16 and 5.2.13)

- 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. Besides, out of 66 projects funded at a cost of Rs. 7.13 crore, 59 projects under the scheme 'Extra Mural Research' under 'AYUSH' remained incomplete even after seven years, depriving the people of the benefits accruing out of research.

(Paragraphs 5.3.5 and 5.3.12)

- **Pharmacopoeia Committees, established in 1962—64, 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. Moreover, only 707 out of 7849 manufacturing units had obtained the mandatory 'Good Manufacturing Practices' certificate from Government as of December 2004. Similarly, none of the 61 State Drug Testing Laboratories/Pharmacies, which were provided assistance of Rs. 50.09 crore under the scheme 'strengthening of DTLs/ Pharmacies', was fully functional as of December 2004.

(Paragraphs 5.4.7, 5.4.12 and 5.4.8)

- **Ministry did not monitor the progress of implementation of the Centrally Sponsored Scheme of 'Development of Health care facilities in AYUSH' by 24 States though assistance of Rs. 33.74 crore was released during 2002-05. Progress of 1077 projects funded under promotional and farming schemes at a cost of Rs. 62.16 crore during 2001-04 was not monitored through State Medicinal Plant Boards. 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 blockade of funds to the tune of Rs. 5.05 crore.**

(Paragraphs 5.6.5, 5.5.3, 5.5.4 and 5.5.5)

Recommendations

Ministry may

- 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,
- introduce a computer based tracking system for released grants so that their utilisation improves significantly and also insist on obtaining refund of unutilised balances retained by State Governments for over a year which would help avoid blocking of resources when competing sectors face funds crunch,
- ensure that adequate and identifiable measures are taken 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,
- ensure that permission to open new colleges, starting PG courses and increasing admission capacity are accorded only after minimum standards of infrastructure prescribed by Regulatory Councils are achieved,
- ensure autonomy and independence of the Regulatory Councils for promoting transparency and accountability and arrange to get the Central Registers of Practitioners updated covering all the States/Union territories through a time bound programme,

- 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 finalised, patented and disseminated among the stakeholders. The ongoing projects would need to be completed early and findings disseminated to stakeholders such as educationist, researchers, manufacturers and Government Institutions,
- ensure that reasons for slackness in development of pharmacopoeial standards are investigated and specific bottlenecks for ensuring their expeditious publication in the respective pharmacopoeia are identified. Result oriented supervision would need to be carried out and drug standardisation work done by Research Councils in consultation with the Pharmacopoeia committees monitored by fixing clear areas of responsibility so that efforts are not duplicated and resources not wasted,
- consider introducing suitable penal measures so that the drug manufacturing units strictly adhere to GMPs,
- entrust State Medical Plant Boards with clear and direct responsibility of monitoring and evaluating various plantation schemes and preparing an authentic database of prioritised medicinal plants and
- critically review the status of expansion of outreach of healthcare and introduce appropriate control mechanisms with clearly defined responsibility centres to monitor and ensure optimal utilisation of the existing facilities.

MINISTRY OF HEALTH AND FAMILY WELFARE

Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy Performance Audit Report on 'AYUSH'

1. Introduction

1.1 National Health Policy, 1983 referred to our rich heritage of medical and health sciences and highlighted under utilisation of the vast infrastructure available in the Indian System of Medicine and Homoeopathy. For addressing the health care delivery services through the Indian system of Medicine and Homoeopathy, Government of India (GOI) established (1995) an independent department of Indian Systems of Medicine and Homoeopathy (ISM&H) under the Ministry of Health and Family Welfare. Government thereafter, approved a separate 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.

1.2 The Department of AYUSH headed by the Secretary to Government, in the Ministry of Health and Family Welfare is the nodal agency for overall direction, coordination, budgetary control and policy interventions for implementation of the policy. Out of the 35 States/UTs, 21 States established a separate Directorate to coordinate and implement AYUSH related programmes. An infrastructure of 3845 hospitals with 65159 beds, 23630 dispensaries, 6.91 lakh registered practitioners, 439 and 96 under-graduate and post-graduate colleges with admission capacity of 23555 and 1888 students respectively and 9226 licensed pharmacies, was created in the country as of March 2003.

1.3 With a view to augmenting educational facilities, carrying out research activities, ensuring availability of adequate plant based raw material and quality control of drugs, mainstreaming of AYUSH drugs in the National health care delivery system, the Ministry launched several centrally sponsored and central plan schemes. The Ministry set up two Regulatory bodies, namely, the Central Council of Indian Medicine (CCIM) and the Central Council of Homoeopathy (CCH) for prescribing standards for infrastructure, developing curriculum, inspection of medical colleges/institutions and maintaining Central Register of Practitioners. The Ministry also established Research Councils for identifying and prioritising research activities/areas and Apex level bodies to act as centres of excellence.

2. Objectives of the Scheme

2.1 The objectives under the National Policy on AYUSH of 2002, can be grouped under the following heads:

- Strengthening the standards of medical, nursing and pharmacy education through strong regulatory control, upgradation of course curricula, strengthening of infrastructural facilities in AYUSH educational institutes and setting up of model colleges and centres of excellence,
- Re-orientation and prioritisation of research activities and areas in 'AYUSH' covering clinical trials, pharmacology and toxicology keeping in view the strength of each system and contemporary relevance,
- Drug standardisation, regulation and enforcement including adherence to good manufacturing practices (GMPs) and publication of formulations and pharmacopoeial standards,
- Conservation and sustainable use of medicinal plants including remunerative farming for ensuring availability of authentic and quality raw drugs with essential components as required under pharmacopoeial standards,
- Integration of AYUSH with health care delivery systems for optimal use of the vast infrastructure of hospitals, dispensaries and physicians, and
- Ensuring affordable AYUSH services and safe and efficacious drugs

3. Audit objectives

3.1 The performance audit of Department of AYUSH sought 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 for 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

4. Audit methodology and audit criteria

4.1 The performance audit of AYUSH covered the period 2000-01 to 2004-05 and was conducted through sample check of the records in the Ministry of Health and

Family Welfare including its subordinate offices and implementing agencies in 29 States and Union Territories. The sample for audit covered all Regulatory bodies, Research councils and Apex level institutions and 25 to 30 per cent of the expenditure in the subordinate offices. Details of samples are indicated in **Annex-1**.

4.2 The criteria used for the performance audit were:—

- attainment of the prescribed levels of performance of each scheme and programme including level of coordination between the Central and State Governments towards integrating various schemes,
- progress in review of minimum standards of education comprising faculty, infrastructure and hospital facilities prescribed by the regulatory bodies,
- inspection of new colleges recommended for recognition, upgradation of colleges recommended and number of colleges in which recognition was withdrawn based on inspections made,
- outcome of research culminating in the shape of patents, development of new drugs and curing endemic diseases,
- achievement of promotional and commercial schemes run by the Ministry on the development of medicinal plant sector,
- performance of pharmacopoeial committees with reference to which standards, if any, were developed for AYUSH,
- extent to which drug testing laboratories and pharmacies of States were strengthened under Centrally Sponsored Scheme, and
- extent to which the Ministry had been able to integrate the AYUSH systems with the modern health care and how far their reach had expanded.

4.3 Director General of Audit, Central Revenues/Principal Accountants General, Accountants General and their subordinate officers discussed the audit plan and audit objectives in entry and exit conferences between November 2004 and March 2005 with the representatives of the Ministry of Health and Family Welfare and departments of AYUSH in respective States as also respective heads of Regulatory bodies, Research Councils and other senior officers. The recommendations were discussed with the Secretary (AYUSH) and other senior officers of the Department including the Regulatory and Research Councils on 6 October 2005. Their views as expressed in the meeting have been appropriately reflected in the report.

5. Audit findings

5.1 **Efficacy of Planning, Budgetary Allocation and utilisation of funds.**

5.1.1 Table 1 below contains the details of Budget Estimates, Revised Estimates and actual expenditure incurred by the Department of AYUSH from 2000-01 to 2004-05.

Table 1: Budget Estimates, Revised Estimates & Actual Expenditure

(Rupees in crore)

Year	Budget Estimates			Revised Estimates			Actual Expenditure			Percentage utilisation of plan funds w.r.t. BE
	Plan	Non Plan	Total	Plan	Non Plan	Total	Plan	Non Plan	Total	
2000-01	100.00	43.50	143.50	90.00	44.14	134.14	79.46	43.51	122.97	79
2001-02	120.00	45.56	165.56	90.00	44.84	134.84	82.15	43.58	125.73	68
2002-03	150.00	50.86	200.86	105.00	50.66	155.66	89.78	49.31	139.09	60
2003-04	145.00	51.47	196.47	135.00	51.47	186.47	133.96	51.01	184.97	92
2004-05	173.00	52.73	225.73	200.00	59.20	259.20	198.76	62.07	260.83	115
Total	688.00	244.12	932.12	620.00	250.31	870.31	584.11	249.48	833.59	85

5.1.2 Audit noticed that Budget provisions during 2000-05 constituted only two per cent of total health budget of the Union Government as against 10% envisaged in the National Policy on ISM&H-2002 which sought to raise the share of allocation for AYUSH in the total health plan at the central level to 10 per cent to be increased at the rate of 5 per cent in every Five Year Plan. Government did not allocate the targeted funds till 2005-06, when Rs. 350 crore were provided for the scheme in the budget, which meant inadequate support all along, for the achievement of envisaged objectives.

5.1.3 Table 2 contains activity-wise allocation of funds between 2000-01 and 2004-05. Research and Education alone accounted for 65 percent of the total allocation of funds under AYUSH indicating the priority that Government accorded to these activities. Detailed allocation of funds under different schemes and activities is given in Annexure-2.

Table 2: Activity-wise allocation of funds (2000-01 to 2004-05)

Sl.No.	Items of expenditure	Rs. in crore	Percentage
1.	Education	256.77	30
2.	Research	294.78	35
3.	Quality control	155.46	19
4.	Health Care	74.44	9
5.	Information, Education and Communication	21.95	3
6.	Administrative and others	30.19	4
	Total	833.59	100

5.1.4 Audit examination revealed that out of Rs. 50.87 crore that the Ministry released to 12 states during 2000-01 to 2004-05, Rs. 30.98 crore (61 per cent) were routed through the States whereas Rs. 19.89 crore (39 per cent) were released directly to the implementing agencies. Out of the total funds of Rs. 50.87 crore that the Ministry had released, Rs. 36.52 crore (72 per cent) remained unutilised.

The Ministry stated (September 2005) 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).

5.1.5 Further examination of the promptness of release of funds by the State Governments to implementing agencies revealed that State Governments did not release Rs. 16.94 crore that represented 55 percent of the total amount released, the delay going upto 36 months. Out of the total amount of Rs. 62.63 crore that the Ministry had released 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.

5.1.6 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 utilisation 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, abinitio, doubtful and difficult.

5.1.7 **Recommendations**

- The Ministry needs to install a system for querying the data through a computer based tracking system to suit its monitoring requirements;
- The Ministry needs to avoid release of funds at the fag end of each financial year, streamline the system and procedure 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; and
- The Ministry may consider insisting on refund of unutilised balances retained by the State Governments for over a year, which would help avoid blocking of resources when competing sectors face resource crunch.

5.1.8 The Ministry stated (September 2005) that Secretary (AYUSH) had been writing to the Chief Secretaries of the States to make the funds available to the implementing agencies expeditiously and ensure proper utilisation thereof within the stipulated period. It was further stated during the Exit Conference (October 2005) that the Ministry was constantly rationalising and reprioritising various schemes and that the Planning Commission had been requested to allow release of funds to different States through the State Health Societies instead of routing these through the State Governments. The Ministry also agreed to the suggestion of audit of installing a system for querying the data through a computer based tracking system to suit its monitoring requirements.

5.2 Results of efforts of Strengthening Medical Education

5.2.1 The Ministry adopted the mechanism of strengthening medical education through Regulatory Councils and National/Apex level institutions. Accordingly, the Ministry 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 which were responsible 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.

5.2.2 Government brought about amendments in 2002-2003 to both the Acts referred to in Para 5.2.1 requiring that prior permission of the Ministry be obtained for opening new colleges, starting new courses and increasing intake of students.

5.2.3 Records of CCIM and CCH indicated that as of March 2005, medical qualification awarded by 69 out of 444 colleges was yet to be recognised. 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[1] students had already passed out from various colleges of Ayurveda and Unani systems during 1997-2005. Ministry 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 students passing out of such colleges would face the prospect of not being considered recognised AYUSH practitioners, that could be not only detrimental to the growth of the system but also put a question mark on their future career.

5.2.4 Test check of records of 142[2] colleges including 35 new colleges, which were inspected by the representatives of Regulatory Councils during 2000-05, revealed that none of these colleges met the minimum requirement of infrastructural and teaching facility standards prescribed by the Councils. Table 3 contains the brief description of the deficiencies noticed in audit.

Table 3: Deficiencies in infrastructural facilities in AYUSH colleges

Sl. No.	Ayurvedic and Unani Colleges	No. of Colleges		Remarks
		Ayurvedic (Total 58)	Unani (Total 14)	
1.	Deficiency in faculty or in minimum covered area of college building	55	14	—
2.	Deficiency in minimum covered area, bed strength, essential or other staff, IPD or OPD in attached hospital	49	14	—
3.	Deficiency in minimum sitting capacity, books or staff in library	42	11	In one Ayurvedic college, sitting facility was not available in the library.
4.	Deficiency in herbal garden with regard to minimum prescribed area, maintenance of required number of plants or sufficient staff	46	11	In three Ayurvedic and one Unani colleges, herbal gardens had not been set up.
5.	Deficiency in space, staff or equipment in respect of laboratory	48	12	Two Ayurvedic colleges were operating without laboratory facilities.
6.	Deficiency in space, staff or equipment in respect of pharmacy	38	10	Nine colleges were functioning without the facility of attached pharmacy.

Sl. No.	Ayurvedic and Unani Colleges	No. of Colleges Ayurvedic (Total 58)	Unani (Total 14)	Remarks
7.	Deficiency in panchkarma[3] facilities	13	Not applicable	Panchkarma facilities were not available in two Ayurvedic colleges.

[1]Excludes position of Homoeopathy students passed out as this information was not available
[2]Ayurveda: 58; Unani: 14 and Homoeopathy: 70
[3]Panchkarma is a renowned therapeutic treatment in Ayurveda and aims at removal of causative factors of somatic and psychosomatic diseases.

Sl. No.	Homoeopathy Colleges	No. of Colleges (Total 70)	Remarks
1.	Non-availability of own college building, deficiency in library, minimum number of class rooms or faculty	57	Four colleges were operating from 2-3 class rooms
2.	Deficiency in bed strength, IPD, OPD, essential or other hospital staff in attached hospital or non-availability of own building	69	In eight colleges, number of patients in IPD ranged from 1 to 10
3.	Non-availability of required number of departments, faculty, other staff, library or equipment	70	In two cases, there was no separate staff for attached hospital

5.2.5 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 paramedical and other staff ranging between 13 and 78 per cent while bed occupancy ranged between 1 and 71 per cent.

The Ministry while accepting the deficiencies pointed out in audit agreed (September 2005) to strengthen the regulatory oversight by giving permission to new colleges strictly on meeting minimum standards.

5.2.6 The Councils (CCIM & 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 college. In case the representatives of the Councils did not inspect a specific college in a particular year, permission for admission in the next academic session was given on the basis of previous inspection. However, CCH was granting permission on a one-time basis instead of session to session basis until specifically revoked by the Council/Ministry, notwithstanding the fact that these colleges did not have the required infrastructural facilities including faculty as per prescribed norms and standards.

5.2.7 Table 4 indicates the year-wise position of the number of colleges inspected, colleges permitted to run courses on the basis of new inspections or on the basis of previous inspections and cases in which the Councils disallowed permission.

Table 4: Year-wise institutions inspected and status of permission

Year	System	Total No. of institutions	Institutions inspected (percentage)	Cases in which permission given on the basis of inspection	Cases in which permission refused	Cases in which permission given on the basis of previous inspection (percentage)
1	2	3	4	5	6	7
2000-01	Ayurveda	190	113 (59)	105	8	68* (36)
	Unani	34	34 (100)	33	1	-
	Homoeopathy	150	97 (65)	96	1	53 (35)
2001-02	Ayurveda	194	63 (32)	50	13	126* (65)
	Unani	34	27 (79)	25	2	7 (21)
	Homoeopathy	160	114 (71)	113	1	45* (28)
2002-03	Ayurveda	211	100 (47)	93	7	105* (50)
	Unani	38	27 (71)	26	1	10* (26)
	Homoeopathy	182	100 (55)	98	2	80* (44)
2003-04	Ayurveda	211	96 (45)	94	2	103* (49)
	Unani	38	29 (76)	26	3	9 (24)
	Homoeopathy	182	72 (40)	67	5	110 (60)
2004-05	Ayurveda	221	127 (57)	123	4	84* (38)
	Unani	39	34 (87)	31	3	5 (13)
	Homoeopathy	184	40 (23)	37	3	138* (75)

* Variation between the total number of institutions (col. 3), institutions inspected (col. 4) and institutions in which permission given on the basis of previous inspections (col. 7) is on account of cases where permission was not given in earlier years and no further inspection was conducted in the absence of replies, or cases being sub-judice etc.

5.2.8 **Audit scrutiny revealed that:**

- only 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 2000-05.
- colleges with persistent deficiencies in infrastructure that were denied permission to run courses during 2000-05 ranged between 1 and 13 during these years.
- 61 to 62 per cent colleges of Ayurveda and Homoeopathy were inspected only once or twice in the last five years.
- 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, and
- no systematic or rational system for inspecting the colleges had been devised or followed and visits were generally carried out randomly.

5.2.9 Well-equipped colleges with attached hospitals were a pre-requisite for improving educational standards, clinical experience and research. The Ministry in its reply (September 2005) stated that there was growing concern over mushrooming of sub-standard colleges.

5.2.10 Audit examination also revealed that the Ministry had constituted a Commission of Inquiry headed by a retired judge of Delhi High Court in January 2004 to investigate complaints made by certain individuals and institutions and 52 Parliamentarians against the functioning of CCH. The terms of reference of the Commission, *inter-alia*, included investigation into violations of section 20(1) of the CCH Act, 1973 in granting recognition to new colleges and deputing executive committee members, who participated in the decision making process for inspection of the colleges. The report of the Commission was awaited as of March 2005. Audit noticed that though complaints had mentioned involvement of the Vice-President of CCH, he was nominated by the Council as a member of the Inquiry Commission.

The Ministry, while agreeing with the audit observations stated (September 2005) that the system of inspection of colleges would be considered by the Councils at the earliest. The Ministry while acknowledging in the Exit Conference (October 2005) that the inspections made by Regulatory bodies had been deficient, stated that strict adherence to prescribed norms was now being ensured while granting recognition to colleges and that amendments to different laws was being actively considered to overcome various bottlenecks.

5.2.11 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 recognised 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 recognised 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.

5.2.12 While the Central Register of Homoeopathy was required to be maintained in two parts, Part-I containing the names of practitioners who had a recognised Medical qualification in Homoeopathy and Part-II the names of other practitioners, the Central Register of Indian Medicine was maintained only for qualified practitioners. 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 both the Councils. Out of 29 States and 7 Union Territories (UTs), records was maintained in only 20 States/UTs and notified upto the year indicated against each state in Table 5.

Table 5: Notification of data of registered practitioners maintained upto the year ended

Sl. No.	States/Union Territories	Ayurved & Unani	Homoeopathy
1.	Andhra Pradesh	March 1994	1989
2.	Assam	December 1986	1988
3.	Bihar	March 1997	—
4.	Chandigarh	—	1988
5.	Delhi	March 2001	1988
6.	Gujarat	December 1999	1988
7.	Haryana	December 1999	1988
8.	Himachal Pradesh	March 1997	1989
9.	Jammu & Kashmir	1983	-
10.	Karnataka	March 1994	1988
11.	Kerala	March 1994	1988
12.	Madhya Pradesh	March 2000	1988
13.	Maharashtra	March 1991	1988
14.	Meghalaya	—	1988
15.	Orissa	March 2002	1988
16.	Punjab	December 1998	1988
17.	Rajasthan	March 2002	1988
18.	Tamil Nadu	March 2001	1988
19.	Uttar Pradesh	March 2000	1989
20.	West Bengal	March 1994	1989

5.2.13 The database had not been updated and revised for periods ranging between 3 and 22 years in respect of the above States. Details of practitioners in Arunachal Pradesh, Goa, Manipur, Mizoram, Nagaland and Sikkim had not been maintained in any of the Central Registers. Delay in notification of the Central Register deprived the practitioners of the opportunity to practice in other States or throughout the country.

The Ministry stated (September 2005) that efforts were being made to update and revise the registers of practitioners on priority.

5.2.14 **Status of AYUSH medical colleges**

Table 6 below depicts the status of AYUSH colleges imparting education in 'Ayurveda', 'Unani', and 'Homoeopathy' systems in the country.

Table 6: Position of AYUSH colleges

Systems	Total no. of colleges during the year									
	2000-01		2001-02		2002-03		2003-04		2004-05	
	Total colleges*	PG	Total colleges*	PG	Total colleges*	PG	Total colleges*	PG	Total colleges*	PG
Ayurvedic	190	52	194	55	211	60	211	60	221	60
Unani	34	4	34	5	38	6	38	6	39	7
Homoeopathy	150	15	160	21	182	31	182	31	184	31
Total	374	71	388	81	431	97	431	97	444	98

*Includes colleges imparting PG courses

5.2.15 Audit noticed that the total number of AYUSH medical colleges under Ayurveda, Unani and Homoeopathy systems increased by 19 per cent, from 374 at the end of March 2001 to 444 at the end of March 2005. **Annex-3** contains state-wise

details of government and non-government colleges. 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.

5.2.16 **National/Apex level institutes**

Department of AYUSH had been financing five apex level institutions of Ayurveda, Unani and Homoeopathy in different parts of the country which were to act as centres of excellence and were expected to develop high standards of teaching, training, research and high quality patient care. Details of financial assistance provided to the apex institutions, courses run by them and intake capacity are given in **Annex-4.** Table 7 contains the gist of audit findings from a test check of records of National/Apex level institutes.

Table 7: Gist of audit findings in National/Apex level Institutions.

Sl. No.	Name of the institute	Audit observation/comments	Period involved	Expenditure involved (Rs. in crore)
1.	National Institute of Homoeopathy, Kolkata (NIH)	i) There was shortage of 19 teachers. ii) 17 posts sanctioned by the Ministry for PG courses in April 2004 were not filled. iii) Minimum targets of theoretical and practical classes were not achieved. iv) Bed occupancy ranged between 47 and 65 *per cent* due to shortage of medical/nursing personnel. v) Shortfall of essential equipment/ material ranged between 34 and 86 per cent in various departments. vi) There were no facilities for conducting clinical trials. vii) Old equipment in the operation theatre needed replacement.	2000-01 to 2004-05	31.23
2.	National Institute of Ayurveda, Jaipur (NIA)	i) Shortage of nine teaching staff and 13 and 36 *per cent* paramedical staff. ii) Bed occupancy declined from 71 to 54 *per cent* during 2000-01 and 2003-04	-do-	48.64
3.	Institute of Post Graduate Training & Research in Ayurveda, Gujarat (IPGTRA)	In 150 bed attached hospital, patients declined by 21 *per cent* during 2000-01 and 2003-04.	-do-	25.81
4.	National Institute of Unani Medicine, Bangalore (NIUM)	i) Post of professors/readers were not filled. ii) Post graduate classes were taken by lecturers.	2004-05	16.50
5.	Rashtriya Ayurveda Vidyapeeth, New Delhi (RAV)	i) No specific targets in terms of admission of students were fixed. ii) There was poor response to courses conducted. iii) CCIM did not recognise the courses.	2000-01 to 2004-05	2.45

The Ministry stated (September 2005) that:

- out of 17 posts of teachers in NIH sanctioned in April 2004, 11 had since been filled and the Institute was in the process of filling the remaining 6 posts. It was also stated that NIH had engaged part-time teachers to overcome the shortages,
- NIH had undertaken measures to upgrade the bed strength from 60 to 100,
- the Staff Inspection Unit of the Ministry of Finance in April 2005 had recommended reduction in the staff strength of NIA and thus there was no need to augment the staff strength. The reply is not tenable as teaching and paramedical staff were to be provided as per norms prescribed by regulatory Councils,
- the bed occupancy in NIA had declined as the hospital building was under repair and maintenance,
- the decrease in number of patients in IPGTRA was due to the decrease in the number of doctors as some of the posts had been abolished and new appointments were not made,
- NIUM had started functioning only from the academic year 2004-05 and the posts of teachers could not be filled due to non-availability of suitable candidates and that the PG courses were being managed by three Professors on contract basis, and
- the courses offered by RAV were to enhance the knowledge of students and not for according any recognition. The reply is inconsistent with the recommendations made by the Committee constituted by the Ministry in May 2000 according to which the courses run by RAV should be recognised as M.Phil degree and PG Diploma in Ayurveda.

5.2.17 **Development of infrastructural facilities in educational institutions:**

Ministry launched (1990-91) a centrally sponsored scheme for development of infrastructure for AYUSH medical institutions, which had six components. Table 8 below indicates year-wise position of grants released to the States under each component during 2000-01 to 2004-05.

5.2.18 Audit noticed that out of the total allotment of grants of Rs. 76.43 crore between 2000-01 and 2004-05 (till December 2004) as much as Rs. 32.80 crore (43%) was released for development of under graduate colleges and Rs. 26.03 crore (34%) was released for development of State Model institutes, indicating the priority that the Ministry accorded to the two areas. The Ministry, however, did not maintain consolidated record of utilisation of grants, thus adversely affecting monitoring of actual utilisation. Ministry did not receive Utilisation Certificates (UCs) that were mandatory, from the States in 263 cases till February 2005 involving Rs. 28.44 crore representing grants released during 1997-98 to 2001-02. State-wise position of grants in-aid released under different components of the scheme during 2000-05 is given in Annex-5.

Table 8: Year-wise and component-wise position of grant-in-aid released

(Rupees in lakh)

Sl. No.	Period	Development of U.G. colleges	Assistance for P.G. education	Reorientation training	Renovation and strengthening of hospital wards	State model institutes	Establishment of computer laboratory	Total
1.	2000-01	815.00	204.93	36.11	—	—	110.00	1166.04
2.	2001-02	684.46	256.07	40.47	—	—	40.00	1021.00
3.	2002-03	403.90	213.24	19.96	—	—	—	637.10
4.	2003-04	653.79	119.78	71.08	269.61	1286.00	50.00	2450.26
5.	2004-05*	721.95	150.88	31.46	77.59	1317.00	70.00	2368.88
	Total	3279.10	944.90	199.08	347.20	2603.00	270.00	7643.28

*position as of December 2004

The Ministry stated (September 2005) that the need for submission of UCs in respect of funds released to the states was regularly being emphasised in the meetings with State Health Secretaries who were also asked to furnish progress of scheme-wise utilisation of funds on monthly basis.

5.2.19 Audit scrutiny further revealed that Goa and Jharkhand were not considered for financial assistance under any of the components of the scheme during the last 5 years. No grant was released to Arunachal Pradesh, Chandigarh, Jammu & Kashmir and Tamil Nadu under the components 'Assistance for Post Graduate medical education', 'Re-orientation training programme' and 'Renovation and strengthening of hospitals wards.' Bihar, Chandigarh, Haryana, Jammu & Kashmir, Punjab and Tamil Nadu were not considered for assistance under the component 'Upgradation of colleges into Model institutes', and grant under 'Establishment of Computer laboratory' was not released to Arunachal Pradesh, Chandigarh, Haryana and Jammu & Kashmir.

5.2.20 Table 9 contains a gist of irregularities that audit noticed in the utilisation of grants received by the States, which adversely impacted the development of undergraduate, post graduate colleges and also in the upgradation of colleges as model institutes.

Table 9: Gist of irregularities noticed in development of colleges

Sl. No.	Name of programme	Irregularities/deficiencies noticed
1	2	3
1.	***Development of undergraduate colleges*** (Records of 42 out of 157 colleges were test checked involving grant of Rs. 32.79 crore in Assam, Andhra Pradesh, Bihar, Haryana, Himachal Pradesh, Maharashtra, Orissa, Punjab, Rajasthan, Tamil Nadu, Uttar Pradesh and West Bengal)	i) Financial assistance was released to 5 colleges though UCs of earlier years were not submitted. ii) 7 colleges did not furnish sufficient justification for or details of equipment to be purchased in the proposal for grant. iii) 25 colleges did not furnish NOC from local Municipal bodies in support of construction plan. iv) Status of fulfilment of prescribed conditions was not verifiable from the inspection reports of 41 colleges. v) Advance payment of Rs. 93.50 lakh was made for building construction which should have been reimbursed. vi) Out of Rs. 298.20 lakh, grants amounting to Rs. 117.44 lakh were lying unspent with the governments of Andhra Pradesh, Bihar, Haryana, Orissa, Punjab, Rajasthan, Uttar Pradesh and West Bengal. vii) Grants amounting to Rs. 65.20 lakh were released with delays ranging from 6 to 39 months in Andhra Pradesh, Arunachal Pradesh, J&K & Uttar Pradesh. viii) Civil works involving Rs. 53.94 lakh were incomplete in Assam, Bihar and West Bengal, and ix) Grant of Rs. 20 lakh was irregularly released to two private colleges in Maharashtra.

1	2	3
2.	***Development of Post-graduate medical education*** (Records of 12 out of 31 institutions were test checked involving grant of Rs. 9.46 crore in Andhra Pradesh, Himachal Pradesh, Orissa and Rajasthan)	i) Assistance was released to 3 colleges though infrastructural requirements as laid down in the guidelines were not met. ii) In 5 cases, permission of regulatory bodies was not verifiable from records. iii) 8 institutions did not furnish the undertaking as required under the scheme guidelines. iv) In Orissa grant of Rs.83.28 lakh was released upto March 2002 but no admissions were made between 2001-2003. v) Out of Rs.59.91 lakh released to Andhra Pradesh, Orissa and Rajasthan, Rs.36.58 lakh, remained unutilised.
3.	***Reorientation training programme for AYUSH personnel*** (Records of 20 out of 73 institutions were test checked involving grant of Rs. 1.99 crore in Chhattisgarh, Haryana, Uttar Pradesh and West Bengal)	i) 19 institutions did not submit feedback of training programme. ii) In 20 cases, UCs were not furnished. iii) Out of the grant of Rs.15.10 lakh released to colleges in Chhattisgarh, Uttar Pradesh and West Bengal during the period 1996 and 2004, Rs.11.42 lakh remained unutilised.
4.	***Renovation and strengthening of teaching hospitals*** (Records of 6 out of 18 colleges were test checked involving grant of Rs. 3.47 crore in Andhra Pradesh)	i) In 2 cases, copies of inspection reports of Regulatory bodies were not found. ii) In one case, justification or estimate seeking grant was not submitted. iii) Ministry released Rs.20 lakh to a college in Andhra Pradesh without an attached hospital.
5.	***Establishment of computer laboratory*** (Records of 15 out of 27 colleges involving grant of Rs. 2.70 crore test checked in Bihar, Delhi and Madhya Pradesh)	i) Four institutions purchased inadmissible items or items in excess of the prescribed quantities. ii) Though the scheme provided for regular monitoring, Ministry or regional units of Central Research Councils did not monitor in five cases, iii) Out of the grant of Rs. 20 lakh released to Bihar and Delhi, Rs. 2.14 lakh remained unspent.
6.	***State Model institute of Ayurveda/Siddha/Unani/ Homoeopathy*** (Records of 7 out of 19 colleges involving grant of Rs. 26.03 crore were test checked in Andhra Pradesh and Maharashtra)	i) Two colleges did not meet the prescribed norm of 50% of the teaching staff in position as posts of Professors and Readers were lying vacant. ii) Andhra Pradesh government released grant of Rs. 100 lakh only out of Rs.150 lakh, after a delay of 11 months. ii) Maharashtra government had not released grant of Rs.171 lakh (December 2004), sanctioned by the Ministry in September 2003.

5.2.21 Audit examination revealed that the Ministry needed to refine and improve the existing system of release of grants for development of under-graduate, post graduate colleges, model institutes and computer laboratories.

5.2.22 **Recommendations**

Ministry may ensure that

- permission to open new colleges to start post graduate courses and to increase admission capacity is accorded only after minimum standards of infrastructure prescribed by the Regulatory Councils are achieved,
- autonomy and independence of the Regulatory Councils are maintained for promoting transparency and accountability,
- Central Registers of practitioners are updated covering all the States/UTs,
- adequate measures are taken in accordance with a time bound programme for removing disparity in medical education across the country and infrastructure in apex level institutes is strengthened so as to enable them to function as Centres of excellence, and
- a computer based tracking system for released grants is introduced so that utilisation of funds improves significantly.

5.3 **Achievement of Research Activities**

5.3.1 **Formulation of aims and pattern of research on scientific lines**

Ministry established the Central Council for Research in Indian Medicine and Homoeopathy (CCRIM&H) in 1969 to formulate aims and pattern of research on scientific lines with a view to increasing their popularity and acceptance by enabling scientific research in different aspects of respective systems through apex research bodies. The Council was split in 1978 into four separate Research Councils to afford each system maximum opportunity and freedom to develop in consonance with the fundamentals of the respective systems, as follows:

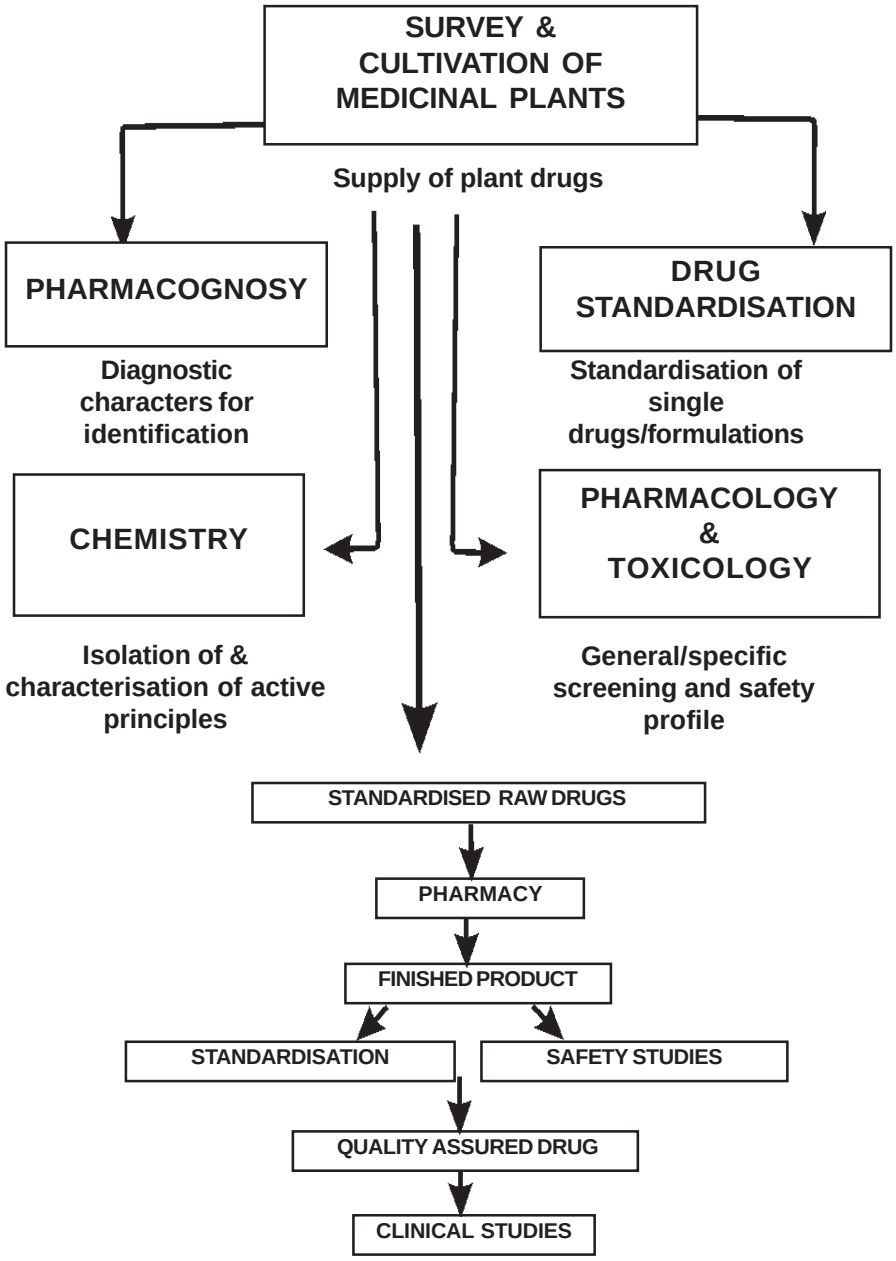
- Central Council for Research in Ayurveda and Siddha (CCRAS),
- Central Council for Research in Unani Medicine (CCRUM),
- Central Council for Research in Homoeopathy (CCRH), and
- Central Council for Research in Yoga and Naturopathy (CCRYN).

Audit examination revealed that Rs. 278.44 crore were allocated to the three councils (CCRAS, CCRUM and CCRH) selected for examination between 2000-01 and 2004-05 for undertaking various research activities, clinical trials, family welfare, reproductive and child health research and tribal health care research programme. The overall shortage of staff in these Councils ranged between 5 per cent and 40 per cent; while 40 per cent shortage existed in CCRAS which stated (July 2005) that action for filling up the vacant posts was underway**.**

The Ministry stated (September 2005) that the regional units of the Councils were being run without sufficient number of pharmacists, compounders, technicians, etc. and the Councils were making efforts for filling the vacant posts.

5.3.2 Drug Research

Drug research consisted of drug standardisation research programme, pharmacological/toxicological studies and medico-ethno-botanical surveys. A flow chart of various activities of the drug research programme is given below:



5.3.3 Drug standardisation was a pre-requisite for manufacture of quality drugs and involved evolving standards of 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. Table 10 indicates the details of drug standardisation work undertaken by each Council.

Table 10: Council-wise drugs standardised, monographs and research findings published

Name of the Council	No. of drug standardisation units	Drugs standardised since inception		Monographs published	Percentage col (4) to (3)
(1)	(2)	(3)		(4)	(5)
CCRAS	18	Single	500	259	
		Compound	500	496	76%
CCRUM	6	Single	277	150	
		Compound	385	300	68%
CCRH	2	Single	122	19	16%

5.3.4 Audit examination revealed that 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. Further, the Ministry did not find the standards for single drugs developed by CCRAS suitable for inclusion in the Ayurvedic Pharmacopoeia of India due to large variations in the data and absence of Standard Operating Procedures (SOPs). 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. 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 Ministry stated (September 2005) that the standards had not been published by CCRUM as these required further modification.

5.3.5 **Drug proving and clinical verification of homoeopathic drugs**

Unlike conventional medicines, where animal experimentation formed the basis of evolution of drug pathogenesis, homoeopathic medicines were proved on healthy human volunteers. Drug standardisation was followed by proving the drug and finally by clinical verification. Audit examination revealed that out of 122 drugs standardised, 64 were proved and 75 were clinically verified. There was no correlation between the drugs standardised, drugs proved and drugs clinically verified. Forty-four drugs were taken up for proving and 47 for clinical verification without having been standardised. Further, 45 drugs were taken up for clinical verification without proving.

5.3.6 There was, therefore, an unsystematic approach to drug proving and clinical verification. The Ministry did not ensure that only those drugs which had been standardised by the Council were taken up for proving and clinical verification, which

was the course of action supported by the special committee on clinical research of the Council in its report of February 2003. WHO guidelines also reiterated that only standardised drugs should be taken up for proving and clinical verification.

The Ministry stated (September 2005) that on the advice of the Scientific Advisory Committee, it was decided to focus on 35 drugs proved by the Council and the drug-proving programme had been revised from 2005-06.

5.3.7 **Clinical Research**

Clinical research facilitated 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 Councils undertook clinical studies in Tribal Health Care, Family Welfare and Reproductive and Child Health Programmes, details of which are in Table 11.

Table 11: Council-wise position of clinical trials taken up, completed, continued and monograph Published

Name of the Research Council	Clinical trials taken up since inception		Clinical trials abandoned		Clinical trials completed		Clinical trials continued		Number of drugs for which Monographs published
	No. of diseases	No. of drugs	No. of diseases	No. of drugs	No. of diseases	No. of drugs	No. of diseases	No. of drugs	
CCRAS	28	217	1	1	27	164	22*	52	36
CCRUM	30	120	20	65	11	31	8*	50	12
CCRH	97	-	-	-	56	—	4	—	—

*Further trials continued with new drug

5.3.8 Audit noticed 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.

5.3.9 CCRAS had initiated a study (1986-87) of three oral and local ayurvedic contraceptives under the Family Welfare Research Programme. Though some drugs showed encouraging results their trial was postponed due to variation in composition of drugs. Drug standardisation studies were eventually assigned to National Institute of Pharmaceutical Education and Research, Mumbai. The study on Neem Oil, introduced in 1988-89 indicated encouraging results but due to its bad odour, was not popular among the women volunteers. The trial was re-initiated by adding lemon grass oil to improve the odour of the drug. The study was still continuing.

5.3.10 CCRUM undertook a research project on clinical screening of contraceptive agents in Unani medicine in 1969 in Hyderabad, which was extended to another unit in Mumbai in 1981. Clinical trials of 18 drugs were conducted but none of the drugs was found to be *cent per cent* safe. Further, during 1994—99, the council undertook trials of a new coded contraceptive drug but discontinued the project (1999-2000) on which an expenditure of Rs. 88.50 lakh was incurred, on the grounds that none of the drug trials could provide 100 *per cent* contraceptive assurance. There were, therefore, no concrete research results even after 20 years of initiation.

5.3.11 **HIV Infection Research Programme through Homoeopathy**

CCRH undertook studies at the Regional Research Institutes in Mumbai, Chennai and New Delhi (1989, 1991 and 1998 respectively) for evaluating the role of homoeopathic therapy in HIV infection. In 690 cases, the study indicated the role of homoeopathic drugs in inhibiting and delaying progression of infection and improving the quality of life of HIV infected individuals and was extended to seven centres (2003). However, no common protocol for the study and laboratory investigations were planned and carried out. The Council decided only in 2005 to take up the study afresh with a common protocol and laboratory investigations and therefore ended up duplicating the efforts, which meant unproductive expenditure and wasteful deployment of human resources during the last 15 years.

5.3.12 **Extra Mural Research**

Research in AYUSH sector was limited to the efforts made by Central Research Councils and was largely in the nature of clinical research. Ministry, therefore, conceived of research in collaboration with reputed research institutions and Universities (called Extra Mural Research) in order to generate scientifically acceptable outcomes and launched a Centrally Sponsored Scheme (1997-98) for undertaking timebound research projects of one to three years duration whose final outcomes were to be evaluated by an expert group. Ministry revised the scheme in 2001 as the response was not encouraging and sought to restrict research only to areas where studies could result in quicker documentation and dissemination.

5.3.13 Audit noticed that 59 out of 66 research projects had remained incomplete and though the Ministry had accepted only seven research projects during 2001—05, their results had not been published or disseminated, as of March 2005. The Ministry did not obtain any value for the expenditure of Rs. 7.13 crore incurred on the 66 projects even after 7 years, which deprived the public of the benefits accruing out of research.

5.3.14 Audit examination revealed that the Ministry allowed research activities to be undertaken by Research councils and external research agencies without fixed parameters and specific time frame. Findings were not disseminated for the benefit of researchers, manufacturers and the common man.

The Ministry stated (September 2005) that in order to disseminate the research findings, specific provision for mandatory publication of the findings had since been made in the scheme. During the discussions in the Exit Conference (October 2005), the Ministry stated that the possibility of getting the research activities reviewed and assessed by a peer group of eminent scientists for identifying such research activities, which were not promising and could be substituted by other activities, would be explored.

5.3.15 **Patenting of drugs**

The number of medicines patented is an indicator of the overall achievement of Research Councils in clinical research. Table 12 indicates the position of drugs patented or under process.

Table 12: System-wise position of drugs patented

System of Medicine	No. of drugs patented/ under process	Name of drug	Year of patent	Therapeutic use
Ayurveda	5	Ayush-56	1976	Anti-epileptic
		Ayush-64	1980	Anti-malaria
		Kshar Sutra	2002	Medicinal thread for ano-rectal diseases
		Ayush Ghutti	Under process	Cough, cold, fever, diarrhoea in children
		Bal Rasayan	Under process	General resistance in children
Unani	3	UNIM-352	Under process	Bronchial asthma (semi solid)
		UNIM-301	Under process	Rheumatoid arthritis
		UNIM-354	Under process	Bronchial asthma (capsules)

The 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. It was stated in the Exit Conference (October 2005) that it had been decided to patent all the drugs that would be developed. It was further stated that since National Research Development Corporation (NRDC), which had been assigned the task of patenting of drugs, was not very active, alternative methods would be explored to overcome the problem.

5.3.16 **Recommendations**

Ministry may ensure that—

- the aims and patterns of research are formulated on scientific lines,
- the standards for drugs are in conformity with the quality prescribed by the Pharmacopoeial committees,
- the approach to drug proving and clinical verification is systematic, and
- the appropriate guidelines are drawn up for taking up research activities under fixed parameters in a time bound manner. The ongoing projects would need to be completed at the earliest and findings disseminated to stakeholders *i.e.* educationists, researchers, manufacturers and Government institutions.

5.4 **Drug standardisation and quality control of AYUSH Drugs**

5.4.1 The Ministry through its enforcement and regulatory mechanism planned drug standardisation, regulation, enforcement and adherence to GMPs through regulatory councils and national level laboratories.

5.4.2 **Pharmacopoeial standards of AYUSH drugs**

The Drugs and Cosmetics Act of 1940 and the rules framed thereunder, enacted for regulating the standards of allopathic drugs, were amended in 1964 to include Ayurveda, Unani and Siddha medicines under its enforcement and regulatory mechanism. Homoeopathy system was also brought under the ambit of the Act in 1978 through an amendment. The Ministry established Pharmacopoeia Committees between 1962 and 1964 for developing Pharmacopoeial standards in Ayurveda, Unani and Homoeopathy systems. The main function of Pharmacopoeia Committees was to prepare and publish official formularies[4] and pharmacopoeia[5] under the respective systems for evolving uniform standards in preparation of AYUSH drugs and prescribe working standards for single drugs and compound formulations. Development of pharmacopoeial standards was primarily the responsibility of two national level laboratories *viz.*, Pharmacopoeial Laboratory for Indian Medicine, Ghaziabad (PLIM) and Homoeopathic Pharmacopoeial Laboratory, Ghaziabad (HPL), which were set up as standard setting-cum-drug testing laboratories. Standard Operating Procedures (SOPs) were essential for ensuring uniformity in terms of taste, colour and consistency in the formulations and also in analysing the effects of the drugs. The laboratories did not finalise pharmacopoeial standards in respect of compound formulations of Ayurveda and Unani for want of SOPs. The Ministry had published standards for only 916 out of 1500 mother tinctures of Homoeopathy. Table 13 indicates the status of the preparation of official formularies in pharmacopoeia of India and number of single drugs and formulations included therein as of March 2005:

Table 13: Status of preparation of formularies and pharmacopoeia

Sl. No.	Name of Committee and date of first setting-up	Formulations included in formularies			
		No. of formulations/ compound drugs	Year of publication	Single	Year of publication
1.	Ayurvedic Pharmacopoeia Committee (APC) (Sept. 1962)	635	April, 1978 (444) January 2000 (191)	326	1986 (80) 1999 (78) 2001 (100) 2004 (68)
2.	Unani Pharmacopoeia Committee (UPC) (March 1964)	912	1981 (441) 1998 (202) 1999 (103) Under publication (166)	150	1997 (45) Under publication (105)
3.	Homoepathic Pharmacopoeia Committee (HPC) (1962)	1500*	-	916	1971–2000
	Total	3047		1392	

*Indicates the estimated number of mother tinctures in Homoeopathy, as no compound drugs exist in this system. No formulary of Homoeopathy had been published.

5.4.3 Performance of pharmacopoeia committees set up by the Ministry during 1962-64 for developing pharmacopoeial standards for ensuring safety, quality, purity and efficacy of drugs was far from satisfactory. While standards for 916 mother tinctures

[4]Formulary is a list of compound drugs prepared from classical texts and other sources. Formulary also includes list of single drugs used in the preparation of compound drugs.

[5]Pharmacopoeia is the official compilation of the pharmacopoeial standards finalised by the Pharmacopoeia Committees.

(61 per cent) in Homoeopathy had been published as of March 2005, pharmocopoeial standards had not been finalised in respect of compound formulations in Ayurveda and Unani even though the Committees were set up more than 40 years back.

The Ministry stated (September 2005) that the development of pharmacopoeial standards required basic R&D and that it took time to design formats and undertake testing. It added that the activity has been accelerated after creation of a separate Department of AYUSH in 1995. It was further stated in the Exit Conference (October 2005) that the Ministry was also considering ways to use the standardisation work being done in the private sector in developing pharmacopeial standards.

5.4.4 **Drug standardisation**

The Central Research Councils had developed their own standards for single and compound drugs in Ayurveda, Unani and Homoeopathy systems over the years. However, the Ayurveda Pharmacopoeia Committee did not accept the standards for Ayurvedic drugs developed and published by Ayurveda Research Council, as there was large-scale variation in data. Similarly, the standards developed by Unani research Council were not being published in the Unani Pharmacopoeia of India as the mandate for publishing the standards lay with the Pharmacopoeia Committee.

5.4.5 The Ministry separately launched a Central Scheme in 1997 in order to expedite the work of development of pharmacopoeial standards. Though Ministry identified 921 formulations including 427 single and 494 compound drugs, for development of standards and also awarded the work to 32 laboratories in 1997-98 involving an expenditure of Rs. 5.26 crore, the laboratories did not develop pharmacopoeial standards for compound drugs. Ministry thereafter assigned the work of development of SOPs to 16 laboratories for 225 drugs in 2002 and released grant-in-aid of Rs. 2.01 crore between 2002—2005. The final report was awaited (October 2005).

5.4.6 Coming to single drugs, standards in 120 (38 *per cent*) out of 315 of Ayurveda/ Siddha and 51 (46 *per cent*) out of 112 in the case of Unani drugs were approved by the pharmacopoeia committees. Table 14 contains the status of single drugs standardised by these laboratories upto March 2005.

Table 14: System-wise position of standardisation of drugs

System	No. of drugs allotted	Cases in which work could not be taken up due to non-availability of plants	Standards approved by Pharmacopoeia committee and under publication	Standards ready for placing before Pharmacopoeia Committees	Standards under evaluation
Ayurveda/ Siddha	315	17	120	37	141
Unani	112	14	51	24	23

5.4.7 Thus, there was a duplication of efforts and wastage of resources by the Central Research Councils and Pharmacopoeia Committees in the field of standardisation of drugs. The Ministry did not ensure finalisation and publication of standards for formulation of compound drugs in particular, even after incurring an expenditure of Rs. 7.85 crore on the committees between 2000 and 2005 and when more than forty years had passed since the establishment of Pharmacopoeia Committees.

5.4.8 **Quality control of AYUSH drugs**

With a view to restoring public faith in AYUSH systems, 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, the Ministry launched a Centrally Sponsored Scheme -*'Quality control of AYUSH drugs'* in 2000-01. Table 15 contains the component-wise details of grants released and the number of units assisted during 2000-05.

Table 15: Number of units assisted and grants released

(Rupees in crore)

Sl. No.	Name of the component	Purpose	Number of units assisted	Amount released during 2000-05
1.	Strengthening of State Government AYUSH Drug Testing Laboratories and Pharmacies. Assistance limited to Rs. one crore per unit.	Renovation of building, equipment and strengthening of human resource.	61	50.09
2.	Strengthening of State Drug Controllers of AYUSH.	Setting up an exclusive office for State AYUSH Drug Controller to help undertake quality control implementation.	11	0.81
3.	Assistance upto a maximum of Rs. 3 lakh per drug manufacturing unit to meet Good Manufacturing Practices (GMP) requirements.	Improving the infrastructure of private drug manufacturers.	21	0.23

5.4.9 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 DTLs and pharmacies had been able to utilise the entire grant-in-aid and make the facilities functional even after 5 years of implementation. 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 slow progress of capital work and delays in completion of procedural formalities. **Annex-6** contains the details of grants in aid of Rs. 51.13 crore released to 93 units in 23 States/UTs during 2000-05 under the scheme.

The Ministry stated (September 2005) that the State Governments were being reminded to complete the work and submit the utilisation certificates.

5.4.10 Test check of records in the States revealed that the Ministry did not release any grant for establishing drug control mechanism to Haryana though it had 375 licenced pharmacies while Rs.1.07 crore was released to Tripura though it had only one private pharmacy in the State. Reasons for assisting the States on a selective basis were not on record. Funds amounting to Rs. 3.20 crore meant for purchase of machinery and equipment remained unutilised while the machinery and equipment valuing

Rs. 4.89 crore though purchased, remained uninstalled in the states owing to non-completion of civil work and/or trained manpower.

5.4.11 **Enforcement, regulation and adherence to Good Manufacturing Practices (GMP) standards by drug manufacturers**

The Department of AYUSH issued a notification in June 2000 directing the drug manufacturers to mandatorily adhere to GMP standards as laid down in the Drugs and Cosmetics Rules, 1945, the time limit for which was extended up to June 2003 with a view to enabling the drug manufacturers to improve their infrastructure, comply with statutory requirements and obtain GMP certificates from the concerned State Drug Control Authorities.

5.4.12 Audit examination revealed that out of 7849 manufacturing units, only 707 pharmacies possessed GMP certificate (**Annex-7** refers). The respective State Governments did not cancel the licences of non-GMP manufactures for not adhering to norms. 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 because of 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.

5.4.13 **Recommendations**

Ministry may ensure that—

- reasons for the slackness in development of pharmacopoeial standards are investigated and the specific bottlenecks for ensuring their expeditious publication in the respective pharmacopoeia are identified,
- result oriented supervision is carried out and drug standardisation work done by Research Councils in consultation with the pharmacopoeia committees is monitored by fixing clear areas of responsibility so that efforts are not duplicated and resources not wasted, and
- suitable penal measures are introduced and enforced so that the drug manufacturing units strictly adhere to GMPs.

The Ministry stated (September 2005) that the State Licencing Authorities were being pursued to implement GMP provisions. It was further stated in the Exit Conference (October 2005) that with a view to ensuring strict compliance to GMP provisions, a notification had been issued according to which the licences of noncompliant manufacturing units would not be renewed after 1 January, 2006 and that the Ministry was emphasising on the States for strengthening the enforcement mechanism for GMP.

5.5 **Production of raw material for AYUSH drugs**

5.5.1 **Conservation and development of medicinal plants for AYUSH drugs**

Medicinal plants constituted about 80 per cent of the raw materials required for manufacture of AYUSH drugs. Most of these plants grew 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, the Ministry had set up a National Medicinal Plant Board (NMPB) 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 materials and protecting, sustaining and developing this sector.

5.5.2 At the initiative of NMPB, State Medicinal Plant Boards (SMPB) were set up in all the States/UTs (except Delhi and Meghalaya) between 2001 and 2004 to assist NMPB in implementation of schemes and policies. With a view to achieving its goals, NMPB implemented various promotional and contractual farming schemes. Table 16 contains the year-wise position of projects sanctioned, amount paid and projects completed during 2000-2005 (upto December 2004).

Table 16: Year-wise and scheme-wise projects sanctioned, expenditure incurred and projects completed

(Rupees in lakh)

Year	Promotional scheme			Contractual farming scheme		
	No. of projects sanctioned	No. of projects completed	Expenditure	No. of projects sanctioned	No. of projects completed	Expenditure
2000-01	5	Not available	93.51	0	-	0
2001-02	144	5	2404.26	0	-	0
2002-03	101	1	995.76	79	36	422.50
2003-04	66	Nil	755.10	687	Nil	1638.82
2004-05	156	Nil	1688.20	623	Nil	1340.18
Total	472	6	5936.83	1389	36	3401.50

5.5.3 A test-check of records revealed that out of 98 projects covering all the activities, in 51 cases applications were received directly by NMPB, which should have been routed through respective SMPBs/State Governments with their recommendations as per guidelines of the scheme. Himachal Pradesh and Orissa did not utilise funds amounting to Rs. 12.45 lakh sanctioned by the Ministry for infrastructural development, standardisation of drying and storage, development of herbal gardens, and promotion of medicinal plants due to delay in granting administrative approval and other reasons. Further, out of 1077 projects in all, sanctioned under the promotional and contractual farming schemes during 2001-04 involving financial assistance of Rs. 62.16 crore, only 210 projects were assigned by the State Medicinal Plant Board to the Indian Institute of Forest Management and Directorate of Research for monitoring and the remaining 867 projects were neither supervised nor monitored. The Ministry was, thus, not able to ascertain the status of utilisation of grants released and achievement of projected increase in production of medicinal plant material in these cases.

The Ministry stated (September 2005) that since SMPBs had not been formed in all the States upto 2003, some projects were considered without their recommendation and that now only the projects recommended by SMPBs were being considered. The reply is not tenable as in the absence of SMPBs, the project proposals should have been forwarded through the respective State Governments/ Directorates of AYUSH.

5.5.4 **Cultivation of medicinal plants and development of agro-techniques**

The Ministry launched (1990-91) an innovative scheme for development and cultivation of medicinal plants before NMPB was set up in November 2000 which aimed at enhancing the availability of medicinal raw material and provided grants in aid for the development of agro-techniques and cultivation of medicinal plants. This scheme continued to be implemented even after NMPB and SMPB were set up. Ministry provided financial assistance of Rs. 73.85 lakh during 2000-01 and 2002-03 to various institutions/State Governments under 18 projects for setting up *demonstration medicinal plant gardens*. The Boards did not, however, monitor the status of medicinal plant gardens set up under the scheme, such as details of production, survival/mortality of plants raised and utilisation of funds as of December 2004.

5.5.5 Audit examination revealed that 45 medicinal plants were identified for development of agro-techniques under the component *Development of agrotechniques*. An amount of Rs. 5.05 crore was released under 33 projects for development of agro techniques for 133 plants. Audit noticed that out of 45 species identified for agro-techniques, projects in respect of 25 species only had been undertaken and no patents were obtained. The Board stated (December 2004) that the developed agro-techniques were being compiled for publication for dissemination of the research finding among the masses.

5.5.6 Absence of an authentic database of demand and supply of prioritised medicinal plants coupled with failure in monitoring and evaluation of various plantation schemes by the NMPB prevented the attainment of the objectives of increasing production of plant based quality raw material and conservation, marketing and export of AYUSH drugs.

5.5.7 An amount of Rs.7.10 lakh released to Madhya Pradesh and Orissa remained unutilised due to delay in granting administrative approval. Further, Rs. 25.48 lakh released to Rajasthan remained idle as the State Government did not provide a matching share.

5.5.8 The Ministry failed in covering all the identified species for development of agro-techniques and the undue delay in completion of projects defeated the very purpose of the scheme. Ministry wound up the scheme for development of agro-techniques in 2001 rendering the entire expenditure of Rs 5.05 crore unproductive.

The Ministry stated (September 2005) that it had been decided in May 2005—

- to conduct a study involving an agency of competent professionals for assessing demand and supply position of medicinal plants,
- to strengthen the NMPB and SMPBs and

- to constitute a committee to revise the operational guidelines for schemes run by NMPB and consider mechanism to involve SMPBs more actively in appraisal and implementation of the projects. It added that project reports on agro-techniques developed after experimental cultivation had been received from most of the organisations and an expert agency had been engaged for finalisation of manuscripts of agro-techniques developed for about 50-55 plants.

5.5.9 **Contractual Farming Scheme**

The contractual farming schemes run by NMPB aimed at expansion of area of cultivation on commercial scale with assured market for 32 identified species. The scheme provided financial assistance to cultivators of these identified medicinal plants in the form of grants in aid restricted to 30 per cent of the project cost subject to a ceiling of Rs.9 lakh. Audit noticed that out of 79 projects sanctioned by the Board during 2002-03, financial assistance of Rs. 59 lakh was paid in excess of the prescribed norms in 23 cases**.**

5.5.10 Audit examination further revealed that the scheme was not being implemented under a proper plan of action for achieving uniform and balanced increase in the plantation and prioritisation of each of the 32 identified species. During the period 2002-05, the Ministry released total assistance of Rs.34.02 crore under the scheme, out of which as much as Rs.14.68 crore (43 per cent) was meant for cultivation of one species only namely Safed Musli which had a low gestation period but the highest input cost of Rs.2.25 lakh per acre. A similar imbalance in promoting production was found in 2002-03 when out of the total area of 3946 acres used for cultivation of 32 identified species as much as 2600 acres (66 per cent) was used for cultivation of only one species namely Senna. In the area of monitoring the actual production of crop also, there were deficiencies. The Ministry was not aware of the total quantity of production of these identified species not did it have any information on the actual marketing of the produce though as per the scheme guidelines, the farmers were expected to sell the produce only to pre-identified traders with whom they were to sign the Memorandum of Understanding (MoU). This aspect of the scheme was not monitored by the Ministry at all.

The Ministry stated (September 2005) that:—

(i) the projects were sanctioned as per the requirements of farmers and were recommended by a Project Screening Committee and approved by Standing Finance Committee,

(ii) selection of species was always in the hands of farmers who cultivated only the profitable species of plants and that the species where profit margin was less were not taken up, and

(iii) though there was an MoU between the grower and the buyer, the farmers sold their produce in the open market as the market prices were higher than those agreed in the MoU.

The Ministry's reply clearly showed their lack of control over the implementation of the scheme.

5.5.11 **Recommendations**

Ministry may ensure that—

- State Medicinal Plant Boards are entrusted with clear and direct responsibility of monitoring and evaluating various plantation schemes,
- research findings relating to development of agro-techniques are finalised, patented and disseminated among the stakeholders through a well planned and monitored action plan, and
- an authentic database in respect of prioritised medicinal plants is prepared.

5.6 Development of healthcare facilities, integration and expansion of outreach in healthcare under AYUSH

5.6.1 **Clinical treatment facilities:** The Research Councils provided IPD and OPD patient care facilities as a part of clinical research programmes and for creating awareness about preventive and promotive health care among the masses. While CCRAS and CCRH provided clinical treatment facilities in tribal areas through units specifically set up for the purpose, CCRUM also provided Medicare to the population in urban slums, rural areas and SC/ST pockets through mobile clinics. Table 17 indicates the position of patient care provided by the Councils between 2000-01 and 2003-04.

Table 17: System-wise number of clinical units, bed strength and number of patients treated

Name of the System	Nature of services		No. of units	Bed strength	No. of patients			
					2000-01	2001-02	2002-03	2003-04
Ayurvedic	Clinical Research	IPD	22	520	1465	1685	2201	2285
		OPD	25	-	366377	379521	424344	467899
	Tribal Health Care	Door steps	6	-	8029	6636	7299	5668
	Clinical unit, Safdarjung Hospital	OPD	1	-	18136	18243	29303	32337
Unani	Clinical Research	IPD	9	162	890	1032	932	714
		OPD	15	-	304354	338859	338547	329783
	Mobile Health Care Services	Door steps	13	-	60020	62666	35119	35855
	School Health Care Services	Door steps/ Schools	10	-	1372	2556	3740	3984
	Clinical Unit, RML Hospital	OPD	1	-	58553	66165	57288	48901
Homoeo-pathy	Clinical Research	IPD	3	85	6840	7938	12102	9296
		OPD	21	-	243857	308506	321412	281780
	Tribal Health Care	Door steps	12	-	3273	3473	3425	2806
	Clinical Unit, Safdarjung Hospital	OPD	1	-	25002	25558	28174	30868

Note: Up to date position for 2004-05 not available.

5.6.2 Against the bed strength of 520 under Ayurveda, the number of patients per bed/annum ranged from 3 to 4 only while in the case of Unani, against the bed strength of 162 there were 4 to 6 patients per year. The number of patients treated by CCRUM through its mobile health care services in urban slums and SC/ST pockets was reduced to half the number during 2003-04 as compared to 2000-01. Test check of records in Bihar, Gujarat, Himachal Pradesh, Jammu & Kashmir, Madhya Pradesh, Maharashtra, Orissa and Punjab revealed that trial medicines and IPD facilities were not available and bed occupancy declined due to withdrawal of free distribution of medicine and poor infrastructure.

The Ministry stated (September 2005) that decrease in flow of patients in Mobile Health Care Services covering SC/ST pockets had been due to non-availability of vehicles and action for replacement of old and condemned vehicles was being taken. It further stated that IPD Services in a number of centres could not function due to non-availability of functional accommodation, unsafe buildings and non-availability of staff.

5.6.3 **Mainstreaming of 'AYUSH' in national healthcare**

With a view to mainstreaming the Indian Systems of Medicine, the Ministry initiated a 'National Reproductive and Child Health Programme' at the Primary Health care Centre (PHC) level, in April 2001. The total estimated expenditure of Rs. 497.67 lakh was to be funded jointly and equally by the Departments of Ayush and Family Welfare. A total of 17 Ayurveda and 16 Siddha interventions were identified for 12 different conditions/diseases related to women and children. Ministry did not approve the drugs manufactured by the Council as SOPs were not followed, acute and sub-acute toxicity studies of drugs selected for the project were not made, and clearance from ethical committee was not obtained. Out of an amount of Rs. 149.50 lakh incurred by CCRAS, Rs. 104.81 lakh turned out to be unfruitful as Ministry did not approve the drugs manufactured by the Council.

5.6.4 **Establishment of specialised therapy centers/specialty clinics**

The Ministry introduced a Centrally Sponsored Scheme in 2002-03 for 'Promoting Development of Health Care Facilities' in AYUSH in order to make AYUSH systems available to the public at large and also to bridge the gaps between AYUSH and modern medicine. The scheme provided financial assistance to States for setting up specialised therapy centres with hospitalisation facility in AYUSH system, specialty clinics of AYUSH i.e. system specific outdoor treatment centres, 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. Table 18 contains component-wise details of expenditure under the programme incurred between 2002-03 and 2004-05. **Annex-8** contains statewise details of funds released during the same period.

Table 18: Component-wise grant-in-aid released and number of units covered

(*Rupees in crore*)

Component	Amount paid and units covered					
	2002-03		2003-04		2004-05	
	Amount	Units covered	Amount	Units covered	Amount	Units covered
Specialised Therapy Centre	-	-	0	0	1.70	8
Specialty Clinic	-	-	1.46	15	2.72	28
ISM&H wing in District Allopathic Hospitals	-	-	4.32	18	1.68	5
Supply of essential drugs	1.20	480	8.76	3504	11.90	4761
Total	1.20	480	14.54	3537	18.00	4802

5.6.5 Audit scrutiny revealed that Ministry released grants in aid of Rs. 1.44 crore to Andhra Pradesh and Madhya Pradesh for setting up two specialised therapy centres and 10 speciality clinics although the State governments did not fulfil the essential conditions governing the scheme. Similarly, the Ministry also released Rs. 21.47 lakh to Kerala for setting up specialised therapy centres' though the proposal actually related to allopathic hospitals. No progress report had, however, been received from any of the units assisted through their respective State Governments, as required under the programme.

5.6.6 Audit scrutiny further 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 unutilised as the State governments did not release the funds to implementing agencies. Besides, medicines costing Rs. 20.09 lakh were diverted to other hospitals in Tamil Nadu and essential medicines worth Rs. 5.58 lakh were supplied to dispensaries not covered under the proposals while medicines costing Rs. 8.61 lakh were lying unused in the Medical Store Depot as of January 2005 in Haryana.

5.6.7 **Promotion of AYUSH under Central Government Health Scheme (CGHS)**

The Central Government Health Scheme (CGHS) network had 78 AYUSH (CGHS) dispensaries functioning at the end of the IXth Plan. During the Xth 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 DGHS. As of June 2004, only 2 dispensaries had been opened. The Ministry sanctioned seven more dispensaries during 2004-05 at a cost of Rs. 1.30 crore but none of the sanctioned dispensaries was set-up during 2004-05 due to shortage of doctors and paramedical staff.

5.6.8 In view of the declining trend in the attendance of patients in Ayurveda and Homoeopathy dispensaries from 1994-95 to 2001-02, the Ministry released Rs. 17.10 lakh in three instalments to the Indian Council for Medical Research (ICMR) between September 2002 and December 2004 for conducting a survey and submitting a report within one year from the release of first instalment. The survey aimed at assessing the acceptability/non-acceptability level of AYUSH facilities under CGHS, perception of CGHS beneficiaries about AYUSH, availability of AYUSH facilities under CGHS in the country and the level of availability of infrastructure and facilities in the selected teaching hospitals of AYUSH. The survey report had not been received as of March 2005, 30 months after the release of the first instalment of the grant, which delayed implementation of the required policy initiatives based on the survey findings.

5.6.9 **Setting up health resort clinics for tourists**

With a view to providing specialised facilities, available under the AYUSH to both domestic and foreign tourists, the Ministry initiated a scheme involving setting up of Health Resort Clinics with AYUSH component for tourists in 2001-02. Under the scheme, panchakarma centres were to be set up in the identified ITDC hotels of repute. Ministry released (March 2002) Rs.73.72 lakh to the Government of Himachal Pradesh, for setting up panchakarma centres in four identified hotels in the State. The grants in aid was to

be utilised, within six months as a one time expenditure on purchase of equipment, training manpower, essential medicines and advertisements through newspapers. Audit examination revealed that Rs. 53.19 lakh (72 %) out of the total grant of Rs. 73.72 lakh was lying unspent as of March 2005. Panchakarma centres were not made operational due to poor response from tourists. The Ministry was thus, not able to expand the outreach of healthcare under AYUSH and optimally utilise existing AYUSH facilities.

The Ministry stated (September 2005) that the scheme had since been wound up in consultation with the Ministry of Tourism and the Government of Himachal Pradesh had been asked to immediately refund the entire amount of Rs. 73.72 lakh released under the scheme.

5.6.10 **Recommendation**

Ministry may critically review the status of expansion of the outreach of healthcare and put in place appropriate control mechanisms with clearly defined responsibility centres to monitor and ensure optimal utilisation of existing facilities. During the discussions in the Exit Conference (October 2005), the Ministry stated that regular meetings were being held with the State Governments and that the States where the implementation of this scheme was weak, were being encouraged to visit the states, that were doing well to determine the rectificatory measures that could be adopted by the former.

6. **Conclusion**

The main objectives of Department of AYUSH were to harness the Indian Systems of Medicine including Homoeopathy for promoting good health and augmenting the existing health care delivery system by ensuring availability of affordable and efficacious AYUSH medicines and services as well as by improving the standards of education in the Indian Systems of Medicine. Audit examination revealed that the Department attempted to implement a large number of schemes without adequate budgetary support, which resulted in dissipation of much of the efforts as well as lack of proper focus in the implementation of the schemes. The Ministry did not raise the budgetary allocation to the promised level of 10 per cent of the total health plan. There were problems of management like lack of coordination between the Ministry and the regulatory and research bodies, absence of an effective monitoring and evaluation system and failure to remove different kinds of procedural hurdles. Educational institutions, hospitals and the apex research bodies suffered from poor infrastructural facilities including serious shortage of manpower even decades after they were set up. The regulatory bodies did not exercise their autonomy judiciously resulting in the Ministry curtailing their delegated authority in some cases. The quality control activities did not make any impact as the Pharmacopoeia Committees failed to finalise pharmacopoeial standards in respect of any of the compound formulations in the Ayurveda and Unani systems. Research activities undertaken by the Research Councils had not been taken up under any fixed parameters and within any specified time frame nor had research findings been disseminated for the benefit of stakeholders. Various promotional and contractual farming schemes were undertaken for increasing production of medicinal plants without any authentic database on the

demand and supply position of prioritised medicinal plants. Poor supervision, monitoring and coordination among the functionaries only compounded the problems, as there was no perceptible impact on the production of medicinal plants. The Ministry did not succeed in achieving the objective of expanding the outreach of health care under AYUSH.

Sd/-

NEW DELHI;
Dated: 9 *December*, 2005

(Dr. A.K. BANERJEE)
Director General of Audit,
Central Revenues.

Countersigned

Sd/-

NEW DELHI;
Dated: 12 *December*, 2005

(VIJAYENDRA. N. KAUL)
Comptroller and Auditor General of India.

ANNEXURE-1

(Refers to Paragraph 4.1)

DETAILS OF SAMPLES TEST CHECKED DURING PERFORMANCE AUDIT

Sl. No.	Name of the office/ establishment	No. of units audited	No. of units	Nature of records checked	Percentage test checked
1.	Department of AYUSH	1	1	(a) Records relating to Centrally Sponsored Schemes of: -Development of Education -Quality control of Ayush Drugs -Setting up of speciality clinics etc. (b)Records relating to Central Schemes of: **National Apex level institutes** -Development of Pharmacopoeial standards -Extra mural research programme -Setting up of health resorts	27-56 per cent of the cases of assistance released during 2000-05 100 per cent
2.	Regulatory Bodies	2	2	(a) Permission for opening of new colleges etc., (b) Recognition of medical qualification and monitoring of examination	32 per cent of the colleges during 2000-05
3.	Research Councils	3	3	Records relating to drug standardisation, clinical research, treatment facilities etc.	100 per cent
4.	National Medicinal Plant Board	1	1	Records relating to promotional schemes, contractual schemes, and schemes relating to development of agro-techniques etc.	25 per cent of cases of assistance during 2000-05

ANNEXURE-2

(Refers to Paragraph 5.1.3)

EXPENDITURE UNDER VARIOUS SCHEMES AND ACTIVITIES DURING 2000-01 TO 2004-05

(Rs. in lakh)

Sl. No.	Name of the activity	2000-01		2001-02		2002-03		2003-04		2004-05	
		Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
1	2	3	4	5	6	7	8	9	10	11	12
1.	**Secretariat**	337.76	18.58	312.38	19.23	450.95	30.65	381.62	43.48	419.60	14.89
	Total	**337.76**	**18.58**	**312.38**	**19.23**	**450.95**	**30.65**	**381.62**	**43.48**	**419.60**	**14.89**
2.	**Regulatory Bodies**										
	(i) CCIM, New Delhi	14.00	47.03	10.00	58.34	12.00	64.41	10.89	78.89	12.00	84.90
	(ii) CCH, New Delhi	-	61.50	-	64.50	-	151.50	-	55.71	10.00	87.00
	Total	**14.00**	**108.53**	**10.00**	**122.84**	**12.00**	**215.91**	**10.89**	**134.60**	**22.00**	**171.90**
3.	**Central Research Council**										
	(i) CCRAS	688.47	1872.53	772.60	1786.50	741.00	2041.50	931.10	2090.00	840.00	2691.00
	(ii) CCRUM	849.00	641.00	807.00	714.52	838.49	780.00	957.25	830.25	1375.00	1082.07
	(iii) CCRH	330.80	374.20	370.71	395.30	391.87	440.00	517.80	455.00	719.00	520.00
	(iv) CCRYN	164.50	44.86	175.00	48.72	175.00	54.00	133.25	58.00	175.00	65.00
	Total	**2032.77**	**2932.59**	**2125.31**	**2945.04**	**2146.36**	**3315.50**	**2539.40**	**3433.25**	**3109.00**	**4358.07**
4.	**Extra Mural Research (Centrally Sponsored Scheme)**	62.69	-	147.08	-	90.00	-	110.00	-	130.00	-
	Total	**62.69**	**-**	**147.08**	**-**	**90.00**	**-**	**110.00**	**-**	**130.00**	**-**
5.	**Apex Level Institutions**										
	(i) IGPTRA, Jamnagar	75.00	375.00	60.00	423.25	30.00	481.92	92.00	460.00	100.00	484.00
	(ii) NIA, Jaipur	316.00	516.10	357.00	493.70	593.64	498.00	459.87	604.00	397.00	628.98
	(iii) RAV, New Delhi	40.58	-	46.65	-	50.84	-	53.17	-	51.00	3.00
	(iv) NIS, Chennai	-	-	-	-	400.00	-	1000.00	-	475.00	-
	(v) NIH, Kolkata	463.87	73.50	400.00	85.90	600.00	100.00	500.00	100.00	799.54	105.00
	(vi) NIUM, Bangalore	200.00	-	150.00	-	300.00	-	300.00	-	700.00	-
	(vii) MDNIY, New Delhi	53.05	134.00	109.00	137.47	317.40	146.00	217.50	149.50	200.00	157.00

(viii)	Vishwayatan Yogashram, Delhi	16.75	-	19.00	-	17.00	-	17.50	-	21.50	-
(ix)	NIN, Pune	77.00	-	80.00	-	97.50	-	145.00	-	195.00	-
		1242.25	**1098.60**	**1221.65**	**1140.32**	**2406.38**	**1225.92**	**2785.04**	**1313.50**	**2939.04**	**1377.98**
6.	**Development of Education (Centrally Sponsored Schemes)**										
(i)	Development of AYUSH UG Colleges	815.00	-	686.46	-	403.90	-	653.79	-	800.00	-
(ii)	Assistance to PG Medical Education in AYUSH	204.93	-	256.07	-	213.24	-	119.78	-	200.00	-
(iii)	Information Technology	110.00	-	40.00	-	-	-	50.00	-	80.00	-
(iv)	Establishment of Model Institutes/Centres of Excellence	-	-	-	-	-	-	1286.00	-	1589.80	-
(v)	Renovation/strengthening of AYUSH teaching Hospitals	-	-	-	-	-	-	269.61	-	100.00	-
(vi)	Reorientation and Training Programme (ROTP)	36.08	-	43.94	-	19.96	-	71.07	-	54.17	-
	Total	**1166.01**	**-**	**1026.47**	**-**	**637.10**	**-**	**2450.25**	**-**	**2823.97**	**-**
7.	**Standardisation of AYUSH Drugs**										
(i)	National Medical Plants Board	88.24	-	1175.17	-	1580.12	-	1829.09	-	2755.58	-
(ii)	PLIM, Ghaziabad	7.04	40.16	7.31	43.54	18.00	47.49	9.86	46.62	6.31	50.99
(iii)	HPL, Ghaziabad	17.61	36.31	22.19	37.06	17.38	53.00	15.41	50.84	20.76	62.48
(iv)	Strengthening of PLIM/HPL	-	-	20.00	-	-	-	-	-	-	-
(v)	Strengthening of Pharma-copoeias Committees	164.90	29.80	86.58	34.10	39.23	29.89	122.30	33.08	145.49	38.19
(vi)	Homoeopathic Pharma-copoeias Committees	-	4.06	-	6.04	-	0.55	-	6.83	-	44.45
(vii)	TKDL Patent Cell for AYUSH/PR	11.00	-	75.00	-	65.00	-	50.00	-	353.38	-
	Total	**288.79**	**110.33**	**1386.25**	**120.74**	**1719.73**	**130.93**	**2026.66**	**137.37**	**3281.52**	**196.11**
8.	**Quality Control of drugs (Centrally Sponsored Schemes)**										
(i)	Innovative scheme for develop-ment of Medicinal Plants	144.48	-	75.39	-	49.60		4.35	-	-	-
(ii)	Incentive for Industry for fairs/market study	-	-	-	-	-	-	0.56	-	9.50	-

1	2	3	4	5	6	7	8	9	10	11	12
	(iii) Assistance to State drug Testing Labs./Pharmacies	2046.88	-	1099.55	-	546.02	-	869.72	-	1088.30	-
	(iv) Strengthening of State Enforcement Mechanism	-	-	-	-	-	-	52.97	-	27.85	-
	(v) Assistance to Units for obtaining GMP Certificates	-	-	-	-	-	-	13.21	-	16.85	-
	Total	**2191.36**	**-**	**1174.94**	**-**	**595.62**	**-**	**940.81**	**-**	**1142.50**	**-**
9.	**Health Care Services**										
	(i) Advance Ayurvedic Centre, NIMHANS	25.00	-	26.00	-	26.00	-	9.57	-	-	-
	(ii) National Ayurveda Hospital, Delhi	-	-	217.80	-	12.60	-	15.00	-	1369.50	-
	(iii) Expansion of CGHS Dispensaries	-	-	-	-	-	-	7.76	-	6.46	-
	(iv) Ayurveda Hospital, Lodhi Road	-	-	-	-	-	-	10.00	29.45	19.00	72.95
	Total	**25.00**	**-**	**243.80**	**-**	**38.60**	**-**	**42.33**	**29.45**	**1394.96**	**72.95**
10.	**Health Care Services (Centrally Sponsored Schemes)**										
	(i) Ayurveda Park/Panchkarma in Hotels (CSS)	-	-	73.72	-	-	-	-	-	-	-
	(ii) Setting up of ISM Wings in Distt. Hospitals (CSS)	-	-	-	-	-	-	431.84	-	1070.00	-
	(iii) ISM Poly Clinic (CSS)	-	-	-	-	-	-	-	-	235.86	-
	(iv) Specialty Clinic in ISM&H (CSS)	-	-	-	-	-	-	146.28	-	349.14	-
	(v) Establishment of demonstrative AYUSH units for popularization of AYUSH (CSS)	-	-	-	-	-	-	-	-	-	-
	(vi) Essential drugs for AYUSH dispensaries/Home Remedy kits/Health for all (CSS)	-	-	-	-	234.03	-	881.24	-	2175.00	-
	Total	**-**	**-**	**73.72**	**-**	**234.03**	**-**	**1459.36**	**-**	**3830.00**	**-**

11.	**Information, Education & Communication**										
	(i) International Exchange Programme	65.61	-	73.52	-	68.09	-	89.87	-	75.00	-
	(ii) Information, Education & Communication	357.34	-	208.24	-	474.67	-	328.57	-	393.66	-
	(iii) Awareness Building on Merits of AYUSH	-	-	-	-	-	-	-	-	-	-
	(iv) Manuscript, Publication & Acquisition	-	-	-	-	-	-	55.00	-	5.00	-
	Total	**422.95**	**-**	**281.76**	**-**	**542.76**	**-**	**473.44**	**-**	**437.66**	**-**
12.	**Pharmaceutical Company**										
	(i) IMPCL, Mohan, Uttaranchal	51.00	-	-	-	-	-	-	-	51.00	-
	Total	**51.00**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**51.00**	**-**
13.	**Others**										
	(i) Central Councils Combined Building Complex	88.00	7.20	82.55	6.54	96.80	8.00	120.00	8.00	250.00	8.00
	(ii) Survey on usage and acceptability of AYUSH	22.98	-	-	-	7.60	-	5.70	-	3.80	-
	(iii) CCIM Elections	-	75.08	-	3.06	-	3.98	-	1.86	-	7.19
	(iv) Lump-sum provision for North Eastern Areas	-	-	128.63	-	-	-	-	-	2000.00*	-
	(v) Publication of Text Books	-	-	-	-	-	-	50.00	-	4.84	-
	(vi) Programme training/ fellowship exposure visits for AYUSH personnel	-	-	-	-	-	-	-	-	0.10	-
	Total	**110.98**	**82.28**	**211.18**	**9.60**	**104.40**	**11.98**	**175.70**	**9.86**	**258.74**	**15.19**
	Grand Total	**7945.79**	**4350.91**	**8214.54**	**4357.77**	**8977.93**	**4930.89**	**13395.50**	**5101.51**	**19875.99**	**6207.09**

*Indicates the total allocation for the North Eastern States. The actual expenditure has been accounted for under the respective schemes.

ANNEXURE-3

(Refers to Paragraph 5.2.15)

STATE-WISE DETAILS OF GOVERNMENT AND NON-GOVERNMENT U.G. AND P.G. COLLEGES

Sl. No.	Name of the States/ Union Territories	Ayurveda*			Unani*			Homoeopathy*			Grand Total
		Govt.	Others	Total	Govt.	Others	Total	Govt.	Others	Total	
1	2	3	4	5	6	7	8	9	10	11	12
1.	Andhra Pradesh	03	01	04	01	01	02	04	-	04	10
2.	Arunachal Pradesh	-	-	-	-	-	-	-	01	01	01
3.	Assam	01	-	01	-	-	-	03	-	03	04
4.	Bihar	05	06	11	01	03	04	01	13	14	29
5.	Chhatisgarh	01	01	02	-	01	01	-	03	03	06
6.	Chandigarh	-	01	01	-	-	-	-	01	01	02
7.	Delhi	01	-	01	01	01	02	02	-	02	05
8.	Goa	-	01	01	-	-	-	-	01	01	02
9.	Gujarat	06	04	10	-	-	-	-	15	15	25
10.	Haryana	02	04	06	-	-	-	-	02	02	08
11.	Himachal Pradesh	01	-	01	-	-	-	-	02	02	03
12.	Jammu & Kashmir	-	01	01	-	02	02	-	-	-	03
13.	Jharkhand	-	01	01	-	-	-	-	02	02	03
14.	Karnataka	04	45	49	02	03	05	01	10	11	65
15.	Kerala	03	09	12	-	-	-	02	03	05	17
16.	Madhya Pradesh	07	07	14	01	03	04	01	18	19	37
17.	Maharashtra	03	54	57	-	07	07	-	47	47	111
18.	Orissa	03	03	06	-	-	-	04	03	07	13
19.	Punjab	01	10	11	-	-	-	-	05	05	16
20.	Rajasthan	01	05	06	01	-	01	-	07	07	14
21.	Tamil Nadu	-	06	06	01	-	01	01	09	10	17
22.	Uttaranchal	02	01	03	-	-	-	-	01	01	04
23.	Uttar Pradesh	08	06	14	02	07	09	07	02	09	32
24.	West Bengal	01	02	03	-	01	01	05	08	13	17
	TOTAL	53	168	221	10	29	39	31	153	184	444

*includes 2 Ayurvedic,1 Unani and 2 Homoeopathy college with PG facility only.

ANNEXURE-4

(Refers to Paragraph 5.2.16)

PERFORMANCE OF APEX INSTITUTES

(Rs. in crore)

Sl. No.	Name of the Institute	Year of establishment	Courses run	Intake capacity	Grant released during 2000-05
1.	Institute of Post Graduate Training & Research (Ayurveda), Jamnagar (IGPTRA)	1956	PG Ph.D	42 14	25.81
2.	National Institute of Homoeopathy, Kolkata (NIH)	December, 1975	UG PG	50 18	31.23
3.	National Institute of Ayurveda, Jaipur (NIA)	February, 1976	UG PG Ph.D	60 45 10	48.64
4.	National Institute of Unani Medicine, Bangalore (NIUM)	December, 1984*	PG	28	16.50
5.	Rashtriya Ayurveda Vidyapeeth, New Delhi (RAV)	1988	CRAV[1] MRAV[2]	** **	2.45

* OPD started in April 2001,IPD in 2003-04 & PG courses from 2004-05.

** varies from year to year depending upon the number of 'gurus/shishyas' available.

[1] Certificate of Rashtriya Ayurveda Vidyapeeth.

[2] Member of Rashtriya Ayurveda Vidyapeeth.

ANNEXURE-5

(Refers to Paragraph 5.2.18)

STATE-WISE AND YEAR-WISE DETAILS OF GRANT SANCTIONED BY AYUSH UNDER CENTRALLY SPONSORED SCHEME FOR 'DEVELOPMENT OF INSTITUTIONS' DURING 2000-01 TO 2004-05

(Rs. in lakh)

Sl. No.	State/UT	2000-01	2001-02	2002-03	2003-04	2004-05	Total
1.	Andhra Pradesh	104.59 (5)	95.02 (5)	42.56 (4)	319.79 (21)	257.00 (4)	818.96
2.	Arunachal Pradesh	-	-	10.00 (1)	-	-	10.00
3.	Assam	-	2.00 (1)	7.20 (1)	20.00 (1)	128.95 (4)	158.15
4.	Bihar	71.16 (5)	11.16 (2)	-	3.73 (2)	15.00 (1)	101.05
5.	Chhattisgarh	-	2.55 (1)	-	55.83 (3)	107.59 (2)	165.97
6.	Chandigarh	-	-	-	-	12.00 (1)	12.00
7.	Delhi	38.61 (6)	16.86 (1)	-	12.00 (1)	148.86 (2)	216.33
8.	Goa	-	-	-	-	-	-
9.	Gujarat	48.85 (4)	102.22 (8)	54.00 (5)	99.00 (5)	185.51 (3)	489.58
10.	Haryana	-	27.00 (1)	-	2.94 (1)	-	29.94
11.	Himachal Pradesh	17.49 (2)	-	13.59 (1)	210.29 (4)	56.90 (1)	298.27
12.	Jammu & Kashmir	14.00 (2)	4.00 (1)	-	12.00 (1)	-	30.00
13.	Jharkhand	-	-	-	-	-	-
14.	Karnataka	121.94 (14)	94.73 (10)	122.25 (13)	272.64 (8)	158.36 (12)	769.92
15.	Kerala	63.87 (5)	76.44 (7)	79.53 (8)	176.97 (2)	294.35 (11)	691.16
16.	Madhya Pradesh	39.23 (3)	70.46 (4)	35.42 (6)	260.99 (8)	164.59 (9)	570.69
17.	Maharashtra	276.69 (27)	185.02 (20)	163.60 (15)	208.74 (6)	95.45 (10)	929.50
18.	Manipur	-	2.92 (3)	-	0.93 (1)	-	3.85
19.	Orissa	68.84 (4)	16.05 (5)	22.93 (3)	381.44 (16)	10.00 (1)	499.26
20.	Punjab	13.16 (2)	45.16 (4)	-	84.99 (2)	12.00 (1)	155.31
21.	Rajasthan	30.94 (3)	18.17 (3)	5.37 (1)	35.97 (4)	162.93 (3)	253.38
22.	Tamil Nadu	123.13 (5)	37.21 (1)	-	15.00 (1)	265.00 (3)	440.34
23.	Tripura	-	-	-	-	1.02 (3)	2.02
24.	Uttar Pradesh	121.54 (8)	122.03 (9)	36.04 (3)	31.87 (3)	104.74 (4)	416.22
25.	Uttaranchal	-	-	10.00 (1)	235.14 (7)	62.93 (4)	308.07
26.	West Bengal	12.00 (1)	92.00 (6)	34.61 (4)	10.00 (1)	125.69 (5)	274.30
	TOTAL	1166.04	1021.00	637.10	2450.26	2368.87	7643.27

Note: Figures within brackets indicate the number of institutions assisted.

ANNEXURE-6

(Refers to Paragraph 5.4.9)

STATE-WISE & SCHEME-WISE RELEASE OF FUNDS UNDER THE CENTRALLY SPONSORED SCHEME FOR QUALITY CONTROL OF AYUSH DRUGS DURING 2000-01 TO 2004-05

(Rs. in lakh)

Sl. No.	State	2000-01		2001-02		2002-03		2003-04				2004-05				Total
		DTL	Pharmacies	DTL	Pharmacies	DTL	Pharmacies	DTL	Pharmacies	Enf. Mech.	GMP Sch. 'T'	DTL	Pharmacies	Enf. Mech.	GMP Sch. 'T'	
1.	Andhra Pradesh	55.00	50.00	-	115.00	-	85.00	45.00	-	7.94	-	-	76.90	-	-	434.84
2.	Arunachal Pradesh	-	-	-	-	-	-	95.00	-	7.40	-	-	50.00	-	-	152.40
3.	Assam	-	-	-	-	65.00	45.00	28.50	50.00	3.27	0.60	-	-	-	-	192.37
4.	Bihar	-	75.00	-	-	-	-	-	-	-	-	-	15.70	-	-	90.70
5.	Chhattisgarh	-	75.00	95.00	-	-	-	-	-	-	-	-	15.00	-	-	185.00
6.	Delhi	-	-	95.00	-	-	-	-	-	-	-	-	-	-	-	95.00
7.	Goa	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8.	Gujarat	58.00	75.00	-	90.00	-	-	-	65.00	-	-	-	10.00	-	-	298.00
9.	Haryana	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10.	Himachal Pradesh	56.24	75.00	19.55	95.00	-	106.02	-	-	-	-	-	15.00	8.055	-	374.865
11.	Jammu & Kashmir	-	-	80.00	90.00	-	-	-	-	-	-	-	10.00	-	-	180.00
12.	Jharkhand	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13.	Karnataka	57.88	55.00	-	-	-	-	-	45.00	-	-	-	-	-	-	157.88
14.	Kerala	75.00	-	-	-	-	90.00	-	35.00	7.78	12.39	-	10.00	-	10.31	240.48
15.	Madhya Pradesh	-	150.00	95.00	-	-	-	-	-	-	-	5.00	30.00	10.90	-	290.90
16.	Maharashtra	79.04	52.65	-	-	-	-	-	-	9.52	0.25	-	-	-	-	141.46
17.	Manipur	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18.	Meghalaya	-	-	-	-	-	-	88.62	-	-	-	-	-	-	-	88.62
19.	Mizoram	-	-	-	-	-	-	97.60	-	-	-	-	-	-	-	97.60
20.	Nagaland	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21.	Orissa	54.00	116.63	-	-	-	-	-	-	-	-	16.00	-	8.91	-	195.54
22.	Punjab	-	70.39	-	-	-	-	-	-	5.245	-	-	24.61	-	-	100.245
23.	Rajasthan	80.00	150.00	-	95.00	-	90.00	-	-	5.03	-	20.00	55.00	-	-	495.03
24.	Sikkim	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25.	Tamil Nadu	50.00	120.00	-	-	35.00	10.00	-	20.00	-	-	-	-	-	-	235.00
26.	Tripura	-	-	-	-	-	-	100.0	100.00	6.78	-	-	-	-	-	206.78
27.	Uttar Pradesh	65.00	195.00	-	85.00	-	20.00	-	-	-	-	-	-	-	-	365.00
28.	Uttaranchal	81.05	76.00	-	-	-	-	-	100.00	-	-	-	80.00	-	-	337.05
29.	West Bengal	-	-	80.00	65.00	-	-	-	-	-	-	5.00	8.22	-	-	158.22
	Total	711.21	1335.67	464.55	635.00	100.00	446.02	454.72	415.00	52.965	13.24	46.00	400.43	27.865	10.31	5112.98

ANNEXURE-7

(Refers to Paragraph 5.4.12)

STATUS OF IMPLEMENTATION OF GMP IN AYURVEDA, SIDDHA & UNANI (ASU) PHARMACIES IN THE STATES AS ON OCTOBER 2004

Sl. No.	Name of the State/UT	Total no. of drug manufacturing units Ayush/Unani/Siddha	No. of drug manufacturing units to whom GMP Certificate was issued
1.	Gujarat	684 (Ayu) 4 (Unani)	30
2.	Rajasthan	374 (Ayush)	12
3.	Karnataka	167	16
4.	Pondicherry	37 (Ayu) 15 (Siddha)	4
5.	Daman & Diu	17	2
6.	Himachal Pradesh	72	40
7.	Kerala	850	222
8.	Uttranchal	118	17
9.	Haryana	395	59
10.	Delhi	58 (Ayu) 17 (Unani) 3 (Ayu. & Unani)	35 (Ayu) 19 (Unani) 1 (Ayu & Unani)
11.	Chandigarh	3	-
12.	Andhra Pradesh	582 (Ayu) 128 (Unani)	23 (Ayu) 5 (Unani)
13.	Uttar Pradesh	2018 (Ayu) 170 (Unani)	27 (Ayu)
14.	Chhattisgarh	48	Nil
15.	West Bengal	321 (Ayu) 15 (Unani)	Nil
16.	Orissa	273	2
17.	Punjab	549 (Ayu)	175
18.	Madhya Pradesh	436 (Ayu) 22 (Unani)	1
19.	Tamil Nadu	473	17
	Total	7849	707

ANNEXURE-8

(Refers to Paragraph 5.6.5)

STATE-WISE DETAILS OF FUND RELEASED UNDER SCHEME OF SETTING UP OF SPECIALISED THERAPY CENTRE/SPECIALITY CLINICS/AYUSH WING IN DISTRICT HOSPITALS AND SUPPLY OF ESSENTIAL DRUGS

(Rs. in lakh)

Sl. No.	States/U.T.	2002-03		2003-04			2004-05		
		Supply of essential drugs	Speciality Clinics	AYUSH wing in District HQs/hospitals	Supply of essential drugs	Specialized Therapy Centre	Speciality Clinics	AYUSH wing in District HQs/hospitals	Supply of essential drugs
1.	Andhra Pradesh	15.00(60)	10.00(1)		15.50(62)	22.00(1)	100.00(10)	—	43.50(174)
2.	Arunachal Pradesh	0.75(03)	46.76(5)	30.24(1)	16.75(67)		20.00(2)		—
3.	Assam	—	—		—				67.75(271)
4.	Bihar	—	—		11.25(45)				—
5.	Chhatisgarh	—	—		16.50(66)				—
6.	Gujarat	—	—		—				89.00(356)
7.	Haryana	15.00(60)	—		47.50(190)	22.00(1)	30.00(3)		59.75(239)
8.	Himachal Pradesh	24.25(97)	—		50.00(200)				202.00(808)
9.	Jammu & Kashmir	—	—		14.25(57)				100.00(400)
10.	Karnataka	15.00(60)	—		80.00(320)	42.50(2)	14.62(2)	70.00(2)	63.50(254)
11.	Kerala	05.00(20)	—		287.75(1151)	43.47(2)	7.00(1)		—
12.	Madhya Pradesh	—	—		124.50(498)	22.00(1)			243.00(972)
13.	Maharashtra		19.52(2)			17.89(1)			
14.	Manipur	—	—	35.00(1)	2.75(11)				—
15.	Meghalaya			166.60(8)					
16.	Nagaland	—	—		2.50(10)				—
17.	Mizoram	—	—		2.50(10)				—
18.	Orissa	—	—		15.00(60)				—
19.	Punjab	15.00(60)	—		18.75(75)				18.75(75)
20.	Rajasthan	15.00(60)	10.00(1)		—				114.50(458)
21.	Tamil Nadu	—	60.00(6)	100.00(4)	58.50(234)		100.00(10)	70.00*(2)	27.00(108)
22.	Tripura	—			14.69(59)			27.68(1)	—
23.	Uttaranchal	15.00(60)			51.75(207)				134.75(539)
24.	West Bengal	—		100.00(4)	45.50(182)				26.75(107)
	Total	120.00 (480)	146.28 (15)	431.84 (18)	875.94 (3504)	169.86 (8)	271.62 (28)	167.68 (5)	1190.25 (4761)

NOTE: figures in bracket indicate the number of units involved.
*Recurring expenditure on medicine Rs.28.00 lakh not included.

APPENDIX- II

Statement of Observations/Recommendations

S. No.	Para	Ministry	Observations/Recommendations
1	2	3	4
1.	134	M/o Health and Family Welfare (D/o AYUSH)	Inspite 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 medicine 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.
2.	135	M/o Health and Family Welfare (D/o AYUSH)	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

1	2	3	4
			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.
3.	136	M/o Health and Family Welfare (D/o AYUSH)	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,

1	2	3	4
			extent of conservation and sustainable supply of medicinal plants for 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.
4.	137	M/o Health and Family Welfare (D/o AYUSH)	The Committee regret to observe that the Department of AYUSH had achieved very little success in achieving the objectives of growth and development, propogation 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 updation ranged

1	2	3	4
			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 blockade of funds to the tune of Rs. 5.05 crore. These issues have been discussed in detail in the succeeding paragraphs.
5.	138	M/o Health and Family Welfare (D/o AYUSH)	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

1	2	3	4
			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 by 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 3.38per 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 the 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.
6.	139	M/o Health and Family Welfare (D/o AYUSH)	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

1	2	3	4
			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 per cent) 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 Governments 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.

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7.	140	M/o Health and Family Welfare (D/o AYUSH)	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.
8.	141	M/o Health and Family Welfare (D/o AYUSH)	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

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			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 Homeopathy 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,

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			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.
9.	142	M/o Health and Family Welfare (D/o AYUSH)	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 or 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 paramedical 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 college. 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 percent 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.

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			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.
10.	143	M/o Health and Family Welfare (D/o AYUSH)	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

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			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.
11.	144	M/o Health and Family Welfare (D/o AYUSH)	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 enrolment 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 the database 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

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			practitioners so that the Central Register of practitioners are kept updated by Central Council of Indian Medicine.
12.	145	M/o Health and Family Welfare (D/o AYUSH)	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 setup 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.
13.	146	-do-	The Committee note 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

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			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 regret 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 indicate that the Ministry have 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.
14.	147	M/o Health and Family Welfare (D/o AYUSH)	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 specialised therapy centres with hospitalisation facility in AYUSH system, speciality clinics of AYUSH i.e. system specific outdoor treatment centres, an AYUSH wing in district allopathic hospitals with outdoor as well indoor facility in one or two systems of AYUSH

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			and purchase of essential drugs for identified AYUSH dispensaries in rural and backward areas. During the year 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 unutilised 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.
15.	148	M/o Health and Family Welfare (D/o AYUSH)	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

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			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.
16.	149	M/o Health and Family Welfare (D/o AYUSH)	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 an 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 understand that presently there is shortage of quality raw-material in the form of medicinal plants

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			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 recommend 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.
17.	150	M/o Health and Family Welfare (D/o AYUSH)	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 Boards (SMPB) were set up in all the States/UTs (except Delhi and Meghalaya) between 2001 and 2004. During the

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			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 (21per 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, 41per cent (753 projects) pertained to the year 2003-2004 and 42per cent (779 projects) to the year 2004-2005. Since the project period is usually three years, only those projects which were sanctioned during 2003-2004 or earlier could have been completed by March 2006. The project sanctioned during 2004-2005 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-Government 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.

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18.	151	M/o Health and Family Welfare (D/o AYUSH)	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 have 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 recommend that Government should make all out

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			efforts for setting up Drug Testing Laboratories in the remaining States where they have not been setup and also to ensure that they become functional within a year.
19.	152	M/o Health and Family Welfare (D/o AYUSH)	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 quantity 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 labeling 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.
20.	153	-do-	In June 2000 the Department of AYUSH had issued a notification directing the drug manufacturers to mandatorily adhere to Good Manufacturing Practices (GMP) standards as laid down in the Drugs and Cosmetics Rules, 1945. The time limit

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			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, Chattisgarh, West Bengal, Orrisa, Punjab, Madhya Pradesh and Tamil Nadu did not cancel the licences of non- Good Manufacturing Practices manufactures 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 & 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

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			to the Ayurveda, Siddha, Unani drug units so that they are motivated to upgrade their manufacturing facilities and become Good Manufacturing Practices (GMP) compliant. 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.
21.	154	M/o Health and Family Welfare (D/o AYUSH)	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 recommend that the Department of

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			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.
22.	155	M/o Health and Family Welfare (D/o AYUSH)	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 have stated that the effectiveness of Unani medicine have 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 research has been conducted in respect of life style related diseases and other diseases like diabetes, AIDS, Cancer, Tuberculosis etc. To

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			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 recommend 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 educationist, researchers, manufacturers and Government Institutions through internet and research journals.
23.	156	M/o Health and Family Welfare (D/o AYUSH)	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 filing 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 use) have been commercialized through National Research and Development Centre (NRDC). 12 drugs are in the pipeline for filing patents.

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			In sofar 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 confidentially 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.
24.	157	M/o Health and family welfare (D/o AYUSH)	Recently some of the Ayurvedic medicines manufactured 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

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			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.

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25.	158	M/o Health and Family Welfare (D/o AYUSH)	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 a talisman, mantra, Kavacha 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 aliments such as epilepsy, migraine, etc. and rejuvenation of sex powers. Explaining the measures taken for implementation of the Act, and rules frame 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 licencsing 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 news papers for strict compliance. It has also been stated 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. AYSUH Research Councils have also been asked to set up surveillance units for

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			monitoring such advertisements. Obviously, such measures have proved ineffective so far. It is a matter of concern that several misleading advertisement regarding AYSUH 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 are 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.

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26.	159	M/o Health and Family Welfare (D/o AYUSH)	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 concieved 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 be apprised of the steps taken/proposed to be taken in this regard.

PART-II

MINUTES OF THE FOURTH SITTING OF THE PUBLIC ACCOUNTS COMMITTEE (2006-2007) HELD ON THIRTEENTH JUNE, 2006

The Committee sat from 1100 hours to 1300 hours on 13th June, 2006 in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Prof. Vijay Kumar Malhotra — *Chairman*

MEMBERS

Lok Sabha

2. Shri Khagen Das
3. Shri Raghunath Jha
4. Shri Bhartruhari Mahtab
5. Shri Rajiv Ranjan 'Lalan' Singh
6. Shri Kharabela Swain
7. Shri Tarit Baran Topdar

Rajya Sabha

8. Shri Janardhana Poojary
9. Shri Prasanta Chatterjee
10. Dr. K. Malaisamy

SECRETARIAT

Shri Ashok Sarin — *Director*

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

1. Shri U. Bhattacharya, ADAI (RC)
2. Dr. A.K. Banerjee, DGA
3. Shri P. Sesh Kumar, Principal Director

Experts in the field of Ayurveda and Unani

Ayurveda

1. Vaidya Devender Triguna	—	President, All India Ayurveda Congress
2. Dr. V.N. Pandey	—	Former Director, Central Council for Research in Ayurveda and Siddha (CCRAS)
3. Dr. K.K. Sijoria	—	Reader, Ayurveda Tibia College, Karol Bagh, New Delhi.

4. Shri Rajeev Bansal	—	Chief General Manager, Divya Pharmacy, Divya Yog Mandir (Trust), Kankhal, Hardwar.
5. Dr. M.K. Bhardwaj	—	Practitioner, Divya Pharmacy, Divya Yog Mandir (Trust), Kankhal, Hardwar.

Unani

1. Prof. Shakir Jameel	—	Dean, Faculty of Medicine Hamdard University, New Delhi
2. Hakim Madan Saroop Gupta	—	Practitioner and Member of Central Council of Indian Medicine (CCIM)
3. Hakim A.J. Khan	—	Former Professor, Ayurveda Tibia College, Karol Bagh, New Delhi
4. Dr. M. Khalid Shiddqui	—	Director, Central Council for Research in Unani Medicine (CCRUM)

2. At the outset, the Chairman welcomed the Members, the experts in the fields of Ayurveda and Unani and the Audit Officers to the sitting of the Committee. The Chairman informed the experts that the Committee have selected C&AG's Report No. 16 of 2005 relating to the "Performance Audit of Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)" for detailed examination. In view of the importance of the subject, the Committee considered it appropriate to hear the views and suggestions of the experts in the fields of Ayurveda & Unani, in the first instance, on the present status of AYUSH in the country, the various constraints and challenges being faced by Ayurveda and Unani Systems of Medicines and suggestions to improve and strengthen the Indian Systems of Medicine in general and Ayurveda & Unani in particular. The Chairman stated that experts from Yoga, Naturopathy, Homoeopathy, etc. would also be called before taking evidence of the representatives of the Ministry of Health and Family Welfare (Department of AYUSH).

3. Thereafter, the experts explained briefly their views on Ayurveda and Unani Systems of Medicine and also gave important suggestions to improve and strengthen the Indian Systems of Medicine. The experts explained to the various points and queries raised by the Members. As regards some queries which remained unresolved, the Hon'ble Chairman suggested that the experts might submit the clarifications/ explanations thereon together with their suggestions so as to improve, strengthen and popularise the Ayurvedic and Unani Systems of Medicine.

4. A copy of the verbatim proceedings of the sitting has been kept on record.

The Committee then adjourned.

MINUTES OF THE EIGHTH SITTING OF THE PUBLIC ACCOUNTS COMMITTEE (2006-2007) HELD ON FIFTH SEPTEMBER, 2006

The Committee sat from 1600 hours to 1800 hours on 5th September, 2006 in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Prof. Vijay Kumar Malhotra — *Chairman*

MEMBERS

Lok Sabha

2. Shri Khagen Das
3. Shri P.S. Gadhavi
4. Shri R.L. Jalappa
5. Shri Bhartruhari Mahtab
6. Prof. M. Ramadass
7. Shri Magunta Sreenivasulu Reddy
8. Shri Rajiv Ranjan 'Lalan' Singh
9. Shri Tarit Baran Topdar

Rajya Sabha

10. Shri R.K. Dhawan
11. Shri Janardhana Poojary
12. Shri Prasanta Chatterjee
13. Dr. K. Malaisamy
14. Shri Ravula Chandra Sekar Reddy

SECRETARIAT

1. Shri Ashok Sarin — *Director*
2. Shri M.K. Madhusudhan — *Under Secretary*

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

1. Shri B.K. Chattopadhyaya, ADAI (RC)
2. Dr. A.K. Banerjee, DGACR
3. Shri A.N. Chatterji, DG (PA)
4. Shri P.S. Das, Director

Experts in the fields of Yoga, Naturopathy and Homoeopathy and representatives of drugs companies

Yoga

1.	Swami Ananta Bharati	—	Director, Keshavanand Yoga Institute, New Delhi.
2.	Yogiraj Swami M. Lal Ji	—	Director, Yoga Divya Mandir, New Delhi.
3.	Prof. Acharya Chandrahas Sharma	—	Director, Central Council for Research in Yoga & Naturopathy, New Delhi.

Naturopathy

1.	Dr. S.N. Pandey	—	Assistant Research Officer, Central Council for Research in Yoga and Naturopathy, New Delhi.
2.	Dr. Preeti Agarwal	—	Senior Research Fellow, Department of Psychiatry, Dr. R.M.L. Hospital, New Delhi.

Homoeopathy

1.	Dr. Ramjee Singh	—	Vice President, Central Council of Homoeopathy, New Delhi.
2.	Dr. Lalit Verma	—	Secretary, Central Council of Homoeopathy, New Delhi.
3.	Dr. V.T. Augustine	—	Practitioner
4.	Dr. Diwan Harish Chand	—	Practitioner

Ayurvedic Drug Companies

1.	Dr. Narendra Bhatt	—	Chief Executive Officer, M/s Zandu Pharmaceuticals Ltd., Mumbai.
2.	Shri R.K. Kohli	—	Director, M/s Dabur India Ltd., Ghaziabad , (UP).
3.	Shri Anurag Sharma	—	Director, M/s Shri Baidyanath Ayurveda Bhawan Ltd. Nagpur.
4.	Dr. Raj Kumar Rawat	—	General Manager, Gurukul Kangri Pharmacy, Haridwar (Uttaranchal).

Unani Drug Manufacturing Companies

1.	Mr. Hamid Ahmed	—	Managing Director, Hamdard Laboratories, New Delhi.
2.	Dr. Shamshad Ahmad	—	Director, Rex Remedies (A&U) Pvt. Ltd. Delhi.
3.	Dr. Ghayoor	—	Research Manager, Rex Remedies (A&U) Pvt. Ltd. Delhi.

Homoeopathic Drug Companies

Mr. Rajneesh Chandan	—	General Manager, M/s SBL Ltd., Sahibabad, UP

2. At the outset, the Chairman welcomed the Members and the Officers of the Comptroller & Auditor General of India to the sitting. The Chairman informed the Members that five Performance Audit Reports have been presented by C&AG of India during the Monsoon Session (August 2006). The Committee, then decided to select all the five subjects contained in the Audit Reports as mentioned in *"Annexure* for examination during 2006-2007 and out of these five subjects, two namely "Sarva Shiksha Abhiyan (SSA)'' and "Management of Foodgrains" were priortized.

3. Thereafter, the Chairman welcomed the experts in the fields of Yoga, Naturopathy and Homoeopathy and the representatives of Ayurveda, Unani and Homoeopathy drug companies to the sitting of the Public Accounts Committee. The Chairman informed the experts and the representatives of drug companies that the Committee had selected C&AG's Report No. 16 of 2005 relating to the "Performance Audit of Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)" for detailed examination. The Chairman stated that the Committee had already heard the views and suggestions of the experts in the fields of Ayurveda and Unani on the various issues relating to present status of AYUSH in the country, the constraints and challenges being faced by AYUSH Systems of Medicines and measures to improve and strengthen the system. The Chairman informed that the Committee would now interact with experts in the fields of Yoga, Naturopathy and Homoeopathy and the representatives of Ayurveda, Unani and Homoepathy drug companies on the subject, before taking evidence of the representatives of the concerned Ministry.

4. Thereafter, the experts and the representatives of drug companies explained in brief the constraints/problems faced by AYUSH Systems of Medicine and also gave suggestions to improve, strengthen and popularize these Systems. They also clarified the various points and queries raised by the Members. The Chairman asked the experts/representatives of the drug companies to submit a written note giving their views/suggestions for improving, strengthening and popularising the AYUSH Systems of Medicine.

5. A copy of the verbatim proceedings of the sitting has been kept on record.

The Committee then adjourned.

ANNEXURE

LIST OF ADDITIONAL SUBJECTS SELECTED BY THE PUBLIC ACCOUNTS COMMITTEE (2006-2007) FOR EXAMINATION DURING 2006-2007

Audit Report No.	Subject
15 of 2006	Performance Audit of Sarva Shiksha Abhiyan (SSA)-Department of Elementary Education and Literacy (Ministry of Human Resource Development) (P)
16 of 2006	Performance Audit of Management of Food Grains (P)
17 of 2006	Performance Audit of Disinvestment of Government Shareholding in Selected Public Sector Undertakings during 1999—2003
18 of 2006	Performance Audit of Conservation and Protection of Tigers in Tiger Reserves
19 of 2006	Performance Audit of the System of Revenue Generation by Doordarshan and All India Radio-Prasar Bharti.

MINUTES OF THE NINTH SITTING OF THE PUBLIC ACCOUNTS COMMITTEE (2006-2007) HELD ON SIXTH SEPTEMBER, 2006

The Committee sat from 1100 hours to 1250 hours on Sixth September, 2006 in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Prof. Vijay Kumar Malhotra — *Chairman*

MEMBERS

Lok Sabha

2. Shri P.S. Gadhavi
3. Shri R.L. Jalappa
4. Shri Raghunath Jha
5. Shri Bhartruhari Mahtab
6. Prof. M. Ramadass
7. Shri Madan Lal Sharma
8. Shri Kharabela Swain
9. Shri Tarit Baran Topdar

Rajya Sabha

10. Shri V. Narayanasamy
11. Shri Prasanta Chatterjee
12. Dr. K. Malaisamy
13. Shri Ravula Chandra Sekar Reddy

SECRETARIAT

1. Shri A. Mukhopadhyay — *Joint Secretary*
2. Shri Ashok Sarin — *Director*
3. Shri M.K. Madhusudhan — *Under Secretary*

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

1. Shri V.N. Kaul, C&AG
2. Shri B.K. Chattopadhyaya, ADAI (RC)
3. Dr. A.K. Banerjee, DGACR
4. Shri A.N. Chatterji, DG (PA)
5. Shri P.S. Das, Director

Representatives of the Ministry of Health and Family Welfare (Department of Ayush)

1.	Smt. Anita Das	—	Secretary
2.	Shri Raghubir Singh	—	Addl. Secretary & Financial Advisor
3.	Shri Shiv Basant	—	Joint Secretary
4.	Shri Vergsese Samuel	—	Joint Secretary
5.	Shri B.S. Sajwan	—	Chief Executive Officer (National) Medicinal Plant Board
6.	Dr. S. K. Sharma	—	Advisor (Ayurveda)
7.	Dr. S.P. Singh	—	Advisor (Homoeopathy)
8.	Dr. A.A. Ansari	—	Advisor (Unani)

2. At the outset, the Chairman, PAC welcomed the Members and the C&AG of India and his team of Officers to the sitting of the Committee. The Chairman informed the Members that the sitting has been convened to take oral evidence of the representatives of the Ministry of Health and Family Welfare (Department of AYUSH) on C&AG's Report No. 16 of 2005 relating to "Performance Audit of Department of AYUSH". Then the representatives of Ministry of Health and Family Welfare (Department of AYUSH) were called in.

3. The Committee then commenced oral evidence on the subject. The Secretary, Ministry of Health and Family Welfare (Department of AYUSH) gave a power point presentation showing the action taken by the Ministry on the Audit observations as well as the achievements made by the Department and steps proposed to be taken to strengthen the AYUSH Systems. Thereafter, the Members sought certain clarifications on the issues arising out of the power point presentation and the Audit Report. The Secretary explained to the various points arising out of the Audit Report and the queries raised by the Members. To certain queries, for which the witnesses could not give satisfactory replies, the Hon'ble Chairman directed that the Ministry might furnish the requisite information in writing at the earliest.

4. A copy of the verbatim proceedings of the sitting has been kept on record.

The Committee then adjourned.

MINUTES OF THE SIXTEENTH SITTING OF THE PUBLIC ACCOUNTS COMMITTEE (2006-2007) HELD ON FIFTEENTH DECEMBER, 2006

The Committee sat from 1600 hours to 1650 hours on 15th December, 2006 in Room No. 51, Parliament House, New Delhi.

PRESENT

Prof. Vijay Kumar Malhotra — *Chairman*

MEMBERS

Lok Sabha

2. Shri Khagen Das
3. Shri P.S. Gadhavi
4. Shri Bhartruhari Mahtab
5. Shri Brajesh Pathak
6. Shri M. Ramadass
7. Shri Mohan Singh
8. Shri Rajiv Ranjan 'Lalan' Singh
9. Shri Kharabela Swain
10. Shri Tarit Baran Topdar

Rajya Sabha

11. Shri Suresh Bhardwaj
12. Shri Prasanta Chatterjee
13. Shri Ravula Chandra Sekar Reddy

SECRETARIAT

1. Shri S.K. Sharma — *Additional Secretary*
2. Shri A. Mukhopadhyay — *Joint Secretary*
3. Shri Ashok Sarin — *Director*
4. Shri M.K. Madhusudhan — *Under Secretary*

Officers of the office of the C&AG of India

1. Dr. A.K. Banerjee, DGACR
2. Shri A.N. Chatterjee, DG (Performance Audit)

2. At the outset, the Chairman, welcomed the Members and Audit Officials to the sitting. Thereafter, the Committee took up for consideration and adoption of the Draft Report on ''Performance Audit of Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)''.

3. After some deliberations, the Committee adopted the Draft Report without any amendments/modifications and authorized the Chairman to finalise and present the same to Parliament in the light of factual verification done by Audit.

The Committee then adjourned.

MGIPMRND—35LS—02-03-2007.

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