

**CHAPTER III**  
**HEALTH AND FAMILY WELFARE DEPARTMENT**  
**Performance Audit of Indian System of Medicine - Ayurveda**

***Highlights***

*Indian Systems of Medicine consists of Ayurveda, Siddha, Unani and Naturopathy. Ayurveda encompasses preventive, promotive and curative components of healthcare with equal importance. It is widely practiced in the State through an extensive network of hospitals and dispensaries both in government as well as in private sector. A Performance Audit on the Ayurveda component of Indian Systems of Medicine including Ayurveda medical education was conducted covering the period 2009 to 2014. The audit revealed underutilisation of funds, non-formation of full-fledged AYUSH department, shortage of staff, shortage in inspection of drug manufacturing units, deficiencies in diet supplied to patients, deficiencies in infrastructure, non-availability of Drug Testing Laboratory for Ayurveda, etc.*

**Failure to furnish Utilisation Certificates to Government of India (GOI) for funds already received resulted in the State losing GOI assistance of ₹12.75 crore receivable during 2012-14.**

*(Paragraph 3.6.1)*

**New departments for Preventive Ayurveda, Yoga, Naturopathy and Vishachikitsa in Government Ayurveda College, Thiruvananthapuram were not setup resulting in refund of GOI assistance of ₹1.50 crore in May 2013.**

*(Paragraph 3.6.2)*

**Inadequacies in infrastructure facilities, non-availability of equipment and inadequate number of Medical Officers and Paramedical staff were noticed in the hospitals and dispensaries test checked.**

*(Paragraphs 3.7.4, 3.8.2 and 3.8.4)*

**In the Government Ayurveda Hospital, Punnapra due to absence of male Nurses/Therapists and Cook, the hospital neither provided therapy treatment to male patients nor provided diet to its patients. The hospital had the lowest bed occupancy of 33 per cent out of 14 test checked hospitals.**

*(Paragraph 3.8.1)*

**In seven test checked hospitals, there was no heating facility in the therapy/treatment rooms forcing patients to bring fuel and stove for heating *Thailam* for oil massage.**

*(Paragraph 3.8.5)*

**Oushadhi, the Government of Kerala Company, did not test the Ayurveda drugs for presence of heavy metals, aflatoxin, toxicity and pesticide residue before supplying to institutions.**

(Paragraph 3.9.1)

**Indents for purchase of drugs were prepared by the Department of ISM without assessing the consolidated annual requirement resulting in overstocking of drugs.**

(Paragraph 3.9.3)

**The Patent Cell did not acquire patent rights for any of the 2505 *oushadha* formulations it deciphered from manuscripts.**

(Paragraph 3.12.2)

### **3.1 Introduction**

Ayurveda means "the science of life" (in Sanskrit 'ayur' means "life" and 'veda' means "science"). Ayurveda is an ancient and comprehensive system of health care. The system aims to prevent illness, heal the sick and preserve life. Ayurveda has its origins in India and extended its wings to various parts of the world. Ayurveda was divided into eight clinical specialities such as *Kayachikitsa* (internal medicine), *Salya Tantra* (surgery), *Salakya* (disease of supra-clavicular origin<sup>25</sup>), *Kaumarabhrtya* (paediatrics, obstetrics and gynaecology), *Bhutavidya* (psychiatry), *Agada Tantra* (toxicology), *Rasayana Tantra* (rejuvenation and geriatrics) and *Vajikarana* (aphrodisiology and eugenics<sup>26</sup>). 'Ayurveda Massage' is part of the treatment protocol.

Kerala's health care system consists of Allopathy, Indian Systems of Medicine (ISM) and Homoeopathy. ISM consists of Ayurveda, Siddha, Unani and Naturopathy of which Ayurveda is widely practiced and has an extensive network of hospitals and dispensaries, both in government and private sector. Ayurveda is an integral part of Kerala's health landscape and encompasses preventive, promotive and curative components of healthcare with equal importance.

There are 118 Ayurveda hospitals including six speciality hospitals, 782 Ayurveda dispensaries, four visha dispensaries and 20 Ayurveda sub-centres delivering healthcare services in the State. Besides, the State Health and Family Welfare Society of Kerala (SHFWS) also operates 208 Ayurveda dispensaries under National Rural Health Mission (NRHM) in various parts of the State. During the year 2013-14, the hospitals and dispensaries had patient footfall of 2.04 crore which included 93,387 in-patients. Medicines required for free distribution to patients in government hospitals/dispensaries were procured from Pharmaceutical Corporation (IM) Kerala Ltd. (Oushadhi), a Government of Kerala undertaking.

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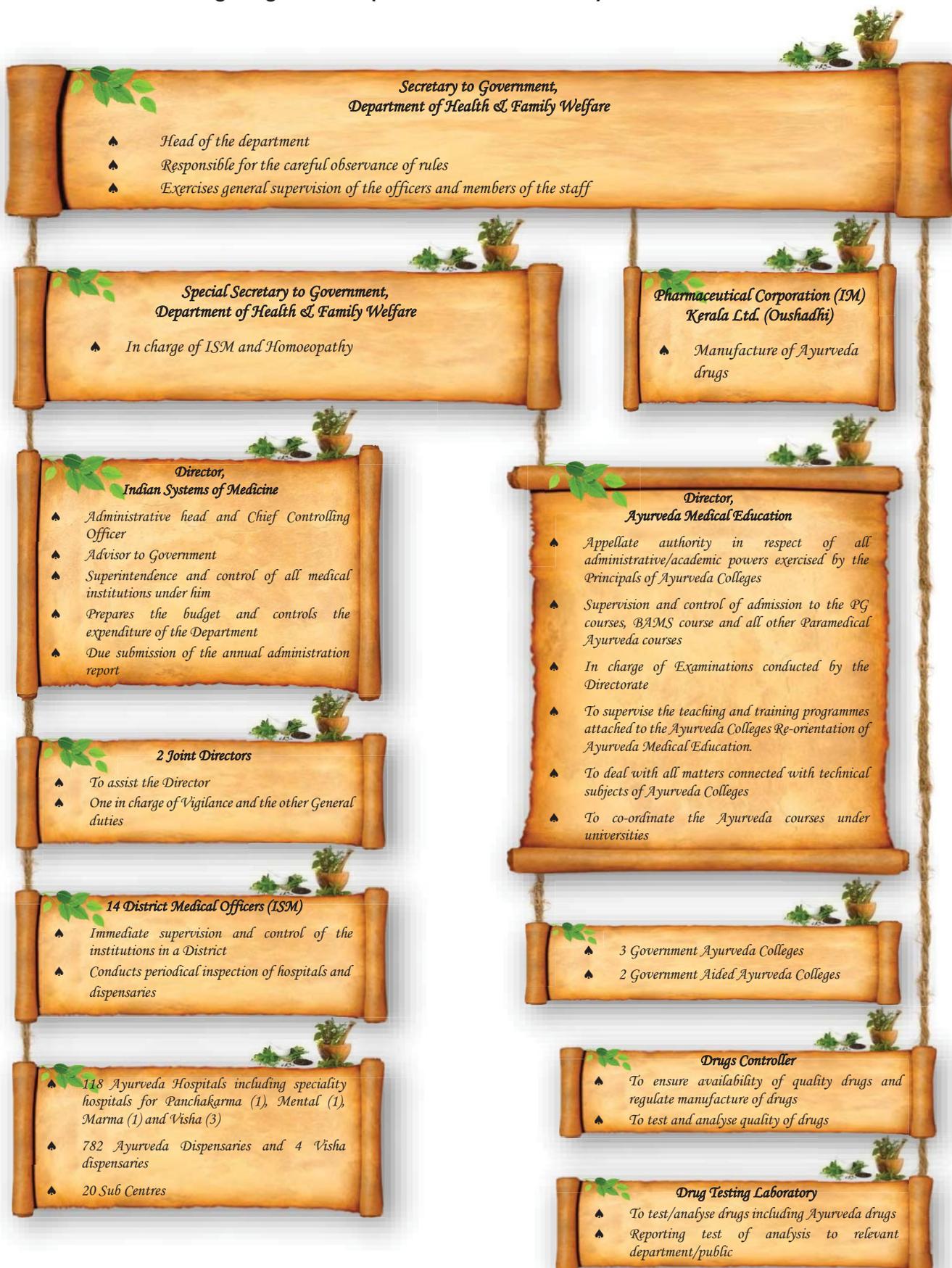
<sup>25</sup> This branch deals with dentistry, disease of ear, nose, throat, head and oral cavity

<sup>26</sup> This branch deals with the means of enhancing sexual vitality and efficiency for producing healthy and ideal progeny

## 3.2 Organizational Setup

The Secretary to Government, Health & Family Welfare Department (H&FWD) is the overall in-charge of the health services in the State. A Special Secretary in the H&FWD has been exclusively looking after the charge of ISM and Homoeopathy with effect from August 2014. The Director of Indian Systems of Medicine (DISM) and the Director of Ayurveda Medical Education (DAME) exercise overall control over the Ayurveda institutions in the government sector. At the district level, the District Medical Officers (ISM) exercise administrative control over the respective hospitals and dispensaries. The organisational set up of H&FWD relating to Ayurveda is given in **Chart 3.1**

**Chart 3.1**  
**Organogram of Departments of ISM and Ayurveda Medical Education**



### 3.3 Audit Objectives

Performance audit was conducted to assess whether:

- Ayurveda hospitals and dispensaries delivered intended services to the public;
- Ayurveda Medical Colleges in the State were imparting quality medical education;
- Research and Development activities in Ayurveda including standardization of drugs, collection and digitization of ancient literature, conservation and cultivation of medicinal plants were adequate; and
- The activities undertaken by Government for promoting Ayurveda Medical Tourism were effective.

### 3.4 Audit Criteria

Audit findings were benchmarked against the criteria derived from the following documents:

- Acts and Regulations issued by Central Council of Indian Medicine,
- The Clinical Establishment (Registration & Regulation) Act 2010, the Drugs and Cosmetics Act 1940 and relevant Rules and Orders,
- Operational guidelines (September 2008) on National Mission on Medicinal Plants, guidelines on Central scheme for evolving pharmacopoeia standards issued by Department of AYUSH<sup>27</sup> for research activities, guidelines issued by National Mission for Manuscripts and Intellectual Property Rights,
- National Policy on Indian Systems of Medicine and Homoeopathy 2002, Kerala Indigenous Medicine Departmental Manual,
- Atomic Energy (Radiation Protection) Rules, 2004 on licensing of X-ray units,
- The Kerala Ayurveda Health Centres (Issue of licence and Control) Act 2007 and Rules made thereunder (2008).

### 3.5 Scope and methodology of Audit

A mention was made in the Audit Report of C&AG of India, Government of Kerala (Civil) for the year ended 31 March 2004 on the Indian Systems of Medicine and Homoeopathy (paragraph 3.3). PAC discussed the report and made recommendations in its 88<sup>th</sup> Report of 2008-11 and remedial action is being taken by the Department. The current Performance Audit on ‘Indian System of Medicine - Ayurveda’ conducted from March to August 2014 covered the Ayurveda health institutions under DISM, Ayurveda colleges and hospitals attached to Ayurveda

<sup>27</sup> Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy

colleges under the DAME, Oushadhi, the State Medicinal Plants Board, State Horticulture Mission (SHM), the Directorate of Tourism, etc.,

The Performance Audit was carried out by test check of records in the Department, Offices of the DISM and DAME, five<sup>28</sup> District Medical Officers (ISM), Oushadhi, 58 Ayurveda health care institutions, three Ayurveda Colleges and attached hospitals selected from five out of 14 districts in the State, selected on the basis of two-tier stratification sampling. Details are given in **Appendix 3.1**. Audit methodology included gathering evidence by conducting joint physical verification along with the department personnel, obtaining photographic evidence wherever possible and conducting patient's survey in selected institutions<sup>29</sup> to assess patient's satisfaction level.

The entry and exit conferences were held with the Secretary to Government, H&FWD in June 2014 and December 2014 respectively, where the audit objectives, audit criteria, audit methodology and audit findings were discussed. Views of the State Government and replies of the departmental officers were taken into consideration while finalising the report.

### ***Audit findings***

The audit findings are given in the succeeding paragraphs with separate sections for Ayurveda healthcare facilities/services, Medical Education, Research and Development activities and Medical Tourism.

## **3.6 Under-utilisation of funds**

Details of budget provision and expenditure of the Health and Family Welfare Department *vis-a-vis* ISM and Ayurveda Medical Education and Government of India (GOI) assistance received through NRHM for AYUSH institutions during 2009-14 are as shown in **Table 3.1**.

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<sup>28</sup> Alappuzha, Malappuram, Palakkad, Thiruvananthapuram and Thrissur

<sup>29</sup> Survey conducted in 57 selected institutions except Government Ayurveda Research Institute for Mental Diseases (GARIM), Kottakkal.

**Table 3.1: Budget provision and expenditure***(₹ in crore)*

Year	Budget Provision		Expenditure		Grant in aid from AYUSH Department, GOI <sup>#</sup>
	H&FWD	ISM*and Ayurveda Medical Education	H&FWD	ISM and Ayurveda Medical Education	
2009-10	1517.45	188.56	1518.82	182.65	13.93
2010-11	1849.23	223.84	1847.63	217.38	32.19
2011-12	2647.23	314.07	2591.44	287.26	14.58
2012-13	2897.66	308.74	2919.77	307.37	0.00
2013-14	3330.89	386.56	3283.68	375.10	0.00
<b>TOTAL</b>	<b>12242.46</b>	<b>1421.77</b>	<b>12161.34</b>	<b>1369.76</b>	<b>60.70</b>

\* ISM includes Ayurveda, Siddha, Unani, Yoga and Naturopathy

# Funds released through NRHM

*(Source: Information compiled by O/o the PAG (A&E), Kerala and NRHM)*

The expenditure of ₹1369.76 crore on ISM constituted 11 per cent of the total expenditure on Health and Family Welfare during 2009-14 in the State. Besides, Local Self Government Institutions (LSGIs) also released funds to the Ayurveda hospitals and dispensaries for procurement of drugs. Audit findings are discussed below:

### 3.6.1 Lapse of GOI assistance

Department of AYUSH, GOI released ₹54.71 crore out of ₹60.70 crore during 2009-12 as grant-in-aid to SHFWS under NRHM for upgradation of AYUSH hospitals and dispensaries including procurement of medicines, engagement of personnel and supply of drugs in the State. The State has not received any assistance from GOI since 2012-13 as Government of Kerala (GOK)/NRHM is yet to furnish UCs for ₹9.38 crore of the ₹54.71 crore received by it due to which the grant of ₹12.75 crore receivable from GOI for the years 2012-14 under this component has lapsed. GOK/NRHM's failure to obtain GOI's share resulted in the non-payment of salary to 68 Ayurveda Medical Officers and 203 Therapists appointed under the scheme, since September 2012. Though the Medical Officers were subsequently redeployed in NRHM dispensaries, contracts of 203 Therapists were not renewed after March 2014.

Audit also noticed that due to failure of SHFWS to submit UCs, ₹0.93 crore sanctioned to VPSV Ayurveda College, Kottakkal under 'Development of AYUSH institutions/colleges' during 2012-13 was also withheld by GOI.

### 3.6.2 Lack of Development of AYUSH institutions

Under the scheme for development of AYUSH institutions/colleges, GOI sanctioned (June 2010) ₹2.19 crore to Government Ayurveda College (GAC), Thiruvananthapuram for construction of buildings for establishing additional departments for Preventive Ayurveda, Yoga, Naturopathy and Vishachikitsa and

released ₹1.5 crore. Audit noticed that GAC Thiruvananthapuram could not start the work due to which the amount was finally refunded to GOI (May 2013).

Government replied (December 2014) that M/s. Habitat Technology Group who were entrusted with the work were not willing to take up the work at the prevailing PWD Schedule of Rates and that the PWD was also not interested in undertaking the work. The reply is an admission of inefficiency of the department to make arrangements for the construction works when funds were available for the purpose and is a matter of concern.

### **3.7 Ayurveda Healthcare facilities**

#### **3.7.1 Lack of formation of full-fledged AYUSH department**

The National Policy on ISM&H 2002 and GOI's directions (March 2011) envisaged formation of a separate AYUSH Department with a full-fledged Secretary in States. The State Government appointed a Special Secretary only in August 2014 exclusively to look after the ISM & Homoeopathy under H&FWD. However, a separate AYUSH department is yet to be established. Government stated (December 2014) that the formation of a separate AYUSH department was under active consideration of the Government.

#### **3.7.2 Opening of new dispensaries**

One of the stated objectives of the Department of ISM was to open an Ayurveda dispensary in every Grama Panchayath (GP). However, no time frame was fixed for attainment of the objective. Audit noticed (March 2014) that 65 out of 425 GPs in the test checked districts did not have either a Government Ayurveda Hospital or Dispensary and hence the objective of having Ayurveda dispensary in every GP was not achieved. However, in 63 of the 65 GPs, temporary dispensaries were being operated by NRHM.

Government admitted (December 2014) that 178 panchayaths in the State were without Government ISM hospitals and dispensaries and that ₹70 lakh was earmarked during 2014-15 for opening such institutions in uncovered GPs.

#### **3.7.3 Co-location of AYUSH facilities**

GOI introduced a Centrally Sponsored Scheme, during the 10<sup>th</sup> plan (2002-03 to 2006-07), to integrate AYUSH health care services with mainstream healthcare services. It was envisaged that there should be a cafeteria approach of making AYUSH and allopathic systems available under one roof at Primary Health Centres (PHC)/Community Health Centres (CHC)/District Hospitals (DH). Apart from improving people's access to healthcare services, it was also intended to provide a choice of treatment to the patients. Under the scheme, GOI made provision for release of grants to State Governments for co-location of AYUSH facilities at PHCs/CHCs/DHs. Audit observed that GOK failed to submit proposals to GOI for co-location of AYUSH facilities with PHCs/CHCs/DHs and thus failed to obtain GOI assistance for the same. In none of the test checked districts, Ayurveda and

Allopathy co-existed at PHCs/CHCs/DHs resulting in denial of facility of quality and cost effective health care under a single roof.

Government replied (December 2014) that presently seven Government Ayurveda Dispensaries (GADs) are functioning in the premises of PHCs/CHCs but the policy of co-location of AYUSH facilities at PHC/CHC/DH level could not materialise in the State due to reluctance of professional and service organizations in Allopathic (modern) medicine sector.

The fact, however, remains that Government's failure to address the misplaced concerns of the practitioners of modern medicine has resulted in denying people easy access to healthcare services of their choice, besides loss of GOI grant.

### **3.7.4 Up-gradation and Standardisation of Ayurveda Hospitals/Dispensaries**

GOK aimed to provide better Ayurveda treatment facilities by upgradation of hospitals in a phased manner under the scheme Upgradation and Standardisation of hospitals after fixing standards for infrastructure facilities and services. GOK had also planned to standardise the facilities in Ayurveda dispensaries in partnership with LSGIs on a project mode under the scheme Strengthening and Improvement of dispensaries. Under the schemes, it was *inter alia* planned to (i) increase the bed strength from the existing 50 to 100 in 10 District Ayurveda Hospitals (DAH), (ii) to provide X-ray facilities, Panchakarma and Ksharasutra units in all DAHs (iii) to provide laboratory facilities in all hospitals and (iv) to provide equipments/furniture/utensils/LPG connection and drugs, etc. in dispensaries. During 2009-14, GOK provided ₹15.75 crore for upgradation of hospitals and ₹4.50 crore for strengthening of dispensaries of which DISM spent ₹14.53 crore and ₹3.77 crore respectively.

Audit noticed that the bed strength was increased to 100 only in DAH Kozhikode against 10 DAHs proposed as GOK is yet to accord sanction for other DAHs. While X-ray units were provided in all DAHs except DAH Ernakulam, Panchakarma and Ksharasutra units were not yet provided in three DAHs and 10 DAHs respectively. Laboratories were provided only in 46 hospitals out of the 118 hospitals in the State. Details of poor infrastructure facilities in the test checked hospitals and dispensaries such as hospitals and dispensaries functioning in old/dilapidated/unfit/leaking buildings, space constraints for functioning of wards/therapy room, non-provision of basic amenities like toilet, drinking water, electricity, water connection, etc., non-functioning X-ray units, laboratory units, etc. noticed in Audit are given in **Appendix 3.2**. GOK/Clinical Establishment (Registration & Regulation) Act 2010 specified 39 common items/equipment required in Ayurveda dispensaries. Audit found non-availability of common items/equipment when compared to the above list as shown in **Appendix 3.3**.

DISM had not fixed any standards for infrastructure facilities and services in hospitals/dispensaries. It had also not prepared any evaluation report on implementation of the schemes for each year specifying the physical targets and

achievements there-against resulting in non-assurance of effective implementation of the schemes.

Government stated (December 2014) that at present there is no provision for standardisation of ISM institutions and a Core Committee would soon be formed for the purpose. It was also stated that presently permission to start X-ray and Laboratory units were granted only to hospitals where adequate space was available.

### 3.8 Healthcare services

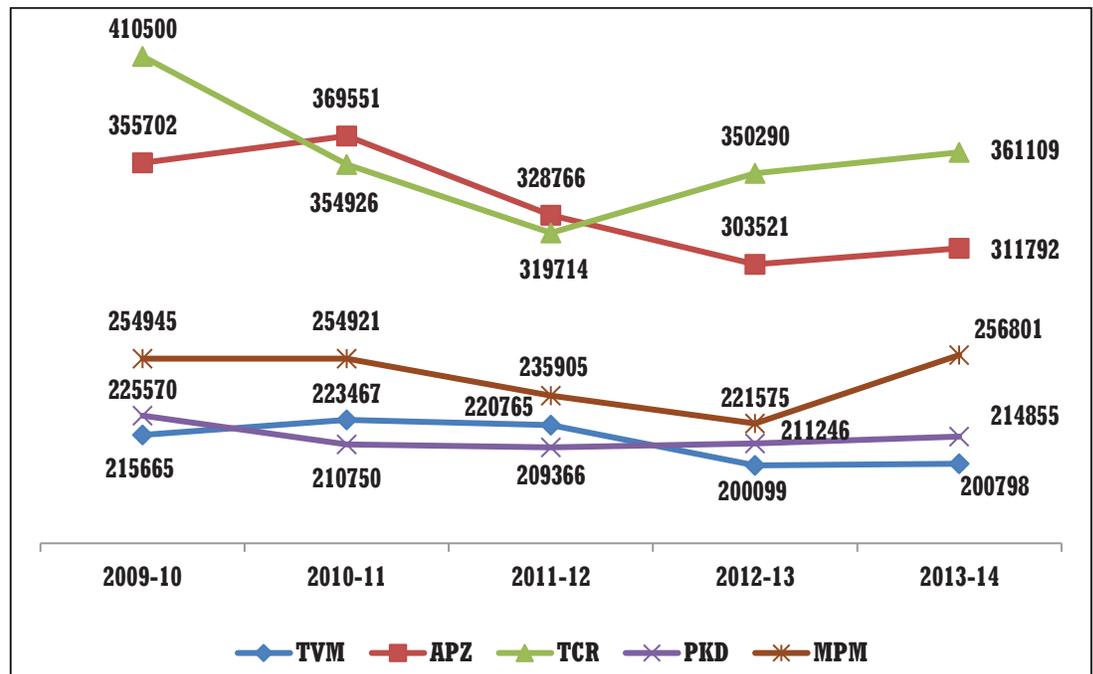
#### 3.8.1 Out-patient and In-patient services

Out-patient services were offered by both hospitals and dispensaries while In-patient services were offered only by hospitals. During the year 2013-14, Government Ayurveda Hospitals (GAH) and dispensaries in the State had patient footfall of 2.04 crore which included 93,387 in-patients. Footfall of out-patients and bed occupancy in respect of test-checked hospitals/dispensaries are discussed below.

Audit analysed the footfall of out-patients in test-checked hospitals and dispensaries under DISM in five selected districts. It was seen that the number of out-patients declined in all test checked districts when compared to the footfalls in the year 2009-10 except in Malappuram where an upward trend was noticed in year 2013-14 as shown in **Chart 3.2**.

Chart 3.2

Trend analysis of Out-patients in selected districts



Audit also noticed that the average bed occupancy against the available bed strength during the period 2009-14 in 10 out of 14 test checked hospitals ranged between 33 and 90 per cent as detailed in **Appendix 3.4**. The lowest bed occupancy of 33 per cent was noticed at GAH, Punnapra. It was noticed that due to the absence of male Nurses/Therapists and Cook, the hospital neither provided therapy treatment to male patients nor provided diet to its patients, which could explain the very low bed occupancy in the hospital. Non-availability of Specialist doctors, Therapists and also the isolated location of the hospitals were cited as reasons for the lower bed occupancy by the Medical Officers of two hospitals (GAH Thiruvai and DAH Valavannur). Government confirmed (December 2014) these reasons.

Government however, did not mention about the measures taken to improve the bed occupancy.

### 3.8.2 Shortage of Medical Officers and paramedical staff

Audit noticed inadequate number of Medical Officers and Paramedical staff in position against sanctioned strength in hospitals/dispensaries under the control of DISM (status as on 1 October 2014) as given in **Table 3.2**.

**Table 3.2: Shortage of staff**

Name of post	Sanctioned	Actual	Shortage
Medical Officers/Specialists	1136	1062	74
Nurses	401	389	12
Therapists	30	19	11
Pharmacists	931	853	78
Lab Technicians	15	5	10
Radiographers	2	0	2
Nursing Assistants/Attenders/ Pharmacy Attenders	1223	1051	172

Staff pattern for Ayurveda hospitals under the DISM with reference to the bed strength was fixed as early as in May 1978. Audit noticed shortage/excess in the number of posts sanctioned when compared with the number of posts required against the average bed occupancy in hospitals test checked. It was seen that in Government Ayurveda Marma Hospital (GAMH), Kanjiramkulam and Government Visha Vaidya Hospital (GVVH), Wadakkanchery, the average bed occupancy during 2009-14 was more than the sanctioned bed strength. However, there was shortage in the sanctioned posts of Medical Officers/ Pharmacists/Nurses. In GAMH, Kanjiramkulam, against sanctioned bed strength of 10, average bed occupancy was 45 indicating that a large number of patients were availing the facilities in the hospital. However, against the required staff strength of three Medical Officers, two Pharmacists and five Nurses, there was a shortage of one Medical Officer, one Pharmacist and three Nurses. Similarly, in the GVVH, Wadakkanchery, there was shortage of two Nurses, while at GAH Nedumangad, the shortage of nurses was three. In view of the fact that certain hospitals with lesser average bed occupancy had the full complement of sanctioned staff strength and in some cases even excess staff (**Appendix 3.5**), failure of GOK to rationalize the staff

strength has resulted in hospitals with higher number of patients having to function with lesser number of staff.

Shortage of manpower significantly affected service delivery in hospitals/dispensaries as elucidated below:

- In Government Ayurveda Research Institute for Mental Diseases (GARIM), Kottakkal in Malappuram district, the post of Hospital Superintendent remained vacant since April 2010 and against three sanctioned posts of Specialists, two posts were vacant from November 2012.
- It was noticed that though sanctioned strength of Nurses were filled up in 13 out of 14 hospitals test checked, no male Nurses were appointed in eight of these hospitals.
- The post of Therapist was essential for carrying out the *Kriyakarmam* i.e., panchakarma procedures. Therapists/Masseurs were assigned the responsibility of application of various massages to the patients on the direction of the physician concerned. Ten out of 14 hospitals test checked did not have sanctioned posts of Therapists. While Hospital Management Committees (HMCs) in five<sup>30</sup> hospitals had engaged Therapists for attending to patients, in five<sup>31</sup> other hospitals test checked, these services were delivered by Nurses/Nursing Assistants/Attenders who were not trained in Therapy.
- In GAH Punnapra, only female Nurses were available and consequently, the male patients were denied therapy.
- In the absence of sanctioned posts of Pharmacists in two<sup>32</sup> of 36 Government dispensaries test checked, Attenders were dispensing the medicines.
- Despite nine of the 14 hospitals test checked having laboratories, the post of Laboratory Technician was not sanctioned for four<sup>33</sup> hospitals. Laboratory Technicians were appointed by Government in two<sup>34</sup> hospitals and laboratories in six<sup>35</sup> hospitals were functioning with technicians appointed by HMC on daily wage basis. In GAH Nedumangad, laboratory was yet to be made operational.

Government stated (December 2014) that DISM had informed that the vacant posts of Medical Officers and paramedical staff were not filled up since advice for appointment from Kerala Public Service Commission (KPSC) was yet to be received and that the posts of Attenders, which were to be filled up by promotion were not done due to shortage of staff in the lower categories. The reply is not acceptable in view of the fact that Government/HMC could have engaged these

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<sup>30</sup> DAH Alappuzha, DAH Palakkad, GAH Guruvayur, GAH Irinjalakuda and GAH Palode

<sup>31</sup> DAH Valavannur, GAH Punnapra, GAH Thiruvalli, GVVH Wadakkanchery and RVDAH Thrissur

<sup>32</sup> GAD Choondal and GAD Kandasankadavu

<sup>33</sup> GAH Guruvayur, GAH Irinjalakuda, GAMH Kanjiramkulam and GAH Nedumangad

<sup>34</sup> GARIM Kottakkal and RVDAH Thrissur

<sup>35</sup> DAH Alappuzha, DAH Palakkad, DAH Valavannur, GAH Guruvayur, GAH Irinjalakuda and GAMH Kanjiramkulam

personnel on temporary basis to address the shortfall in manpower till permanent filling up of these posts.

### 3.8.3 Diet

The Kerala Indigenous Medicine Departmental Manual and subsequent orders of Government prescribed various food items and their quantity to be distributed as diet to patients. The DISM enhanced (August 2013) the cost of diet to in-patients from the existing ₹25 to ₹30 per day per patient, with direction to limit the cost to the prescribed rate of ₹30. Audit noticed (July 2014) that the food items and the quantity supplied in test checked hospitals *viz.*, bread & milk in the morning, rice & green gram at noon and evening were not as prescribed<sup>36</sup> in the Manual and Government orders. Even though 13 out of 14 test checked hospitals provided *Kanji* diet to its patients, it was seen that GAMH Kanjiramkulam did not include bread and milk in its diet. Three hospitals (DAH Valavannur, GAH Guruvayur and Panchakarma Hospital, Alappuzha) failed to supply bread to its patients. Even the hospitals which distributed bread to its patients distributed only 100-200 gms against the stipulated 400 gms. Against the stipulated requirement of 500 ml milk, all the hospitals which distributed milk, supplied only 200 ml to 250 ml to its patients. Audit noticed that out of 14 Ayurveda hospitals, the GAH Punnapra did not provide diet to in-patients as there was no cook in the hospital. The diet was not able to provide nutritive food to injured sportspersons admitted in the Sports unit of GAH Nedumangad and Rama Varma District Ayurveda Hospital (RVDAH), Thrissur.

During survey, 66 *per cent* of the in-patients expressed that diet provided was sufficient, 10.38 *per cent* opined that it was not sufficient, while others either did not respond or were subjected to restricted diet as part of the treatment.

Government replied (December 2014) that the diet charges of ₹30 per day were grossly insufficient to give quality food to patients and enhancement of diet charges is under its consideration.

### 3.8.4 X-ray services

Atomic Energy (Radiation Protection) Rules, 2004 on licensing of X-ray units provide for issuing of licence for operating radiation installations after inspecting the working practices being followed to ensure adherence to prescribed safety standards, availability of appropriate radiation monitors and dosimetry devices for purposes of radiation surveillance, etc. The Director of Radiation Safety (DRS) is the authorised agency in Kerala to issue licences on behalf of Atomic Energy Regulatory Board.

Five of the 14 hospitals test-checked were provided with X-ray units. Out of these, three hospitals (DAH Alappuzha, RVDAH Thrissur and DAH Valavannur) offered X-ray services and in two hospitals (GAMH Kanjiramkulam and DAH Palakkad), the units were not made functional. Audit noticed that X-Ray machines were

<sup>36</sup> Milk Diet: Milk 750ml, Bread 400gm, Butter 20gm, Biscuit 40gm, Egg 1 no.

*Kanji* Diet: Rice 200gm, Green gram 60gm, Milk 500ml, Bread 400gm, Butter 25gm

operated in DAH Alappuzha from May 2012 and in RVDAH Thrissur from December 2011 without obtaining Certification of Safety from the DRS. The technician handling the X-ray unit in DAH Alappuzha was not provided with TLD<sup>37</sup> film badges to indicate levels of exposure to radiation. In the absence of TLD badges and safety certification from the DRS, Audit could not obtain reasonable assurance that patients and technicians were not being exposed to more than permissible radiation levels.

Government replied (December 2014) that action has been initiated to obtain safety certificates from DRS.

### **3.8.5 Oil massage**

Oil massages play a major role in the treatment protocol under Ayurveda. '*Thailam*<sup>38</sup>' used in therapy requires to be heated prior to application on the patients. Audit noticed that in DAH Valavannur in Malappuram district, Panchakarma Hospital, Alappuzha, GAH Nedumangad, GAH Punnapra, GAH Palode, GVVH Wadakkanchery and GAH Thiruvalli there was no heating facility in the therapy/treatment room. Failure of the hospitals to make provision for heating *Thailam* resulted in patients being forced to bring stoves and fuel for warming the *Thailam*, which is a matter of concern.

The inpatient survey showed that 30.19 *per cent* of patients had to bring fuel and stove for heating *Thailam* and 64.15 *per cent* of patients had to bring the raw herbal materials required for the treatment.

CMO, DAH Valavannur stated that the facility was not provided as sanction was not received for LPG installation.

Government replied (December 2014) that majority of in-patients in hospitals have to undergo various treatment procedures and accepted that the allocation for fuel was meagre. It also stated that DISM had since issued directions to District Medical Officers in this regard.

The reply is not acceptable in view of the immense hardships being caused to patients. In the circumstances, the Government/DISM is required to provide these basic facilities.

### **3.8.6 Distribution of Ayurveda drugs to patients**

Government Ayurveda Hospitals and Dispensaries supply free drugs to all patients obtaining treatment from these institutions. Audit noticed following deficiencies in this regard:

- The survey conducted among in-patients and out-patients indicated that 33.02 *per cent* of in-patients and 58.51 *per cent* of out-patients were getting all drugs from Pharmacy, 64.15 *per cent* of in-patients and 35.33 *per cent* of out-patients purchased some drugs from the market due to non-availability of drugs in Pharmacy. Others did not respond. Further,

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<sup>37</sup> Thermo Luminescent Dosimeter

<sup>38</sup> Thailam – Medicated oil

1.89 per cent of in-patients were purchasing drugs from market due to difficulty in coming to the hospitals as drugs were supplied from Pharmacy on alternate days only during treatment period. Moreover, 1.09 per cent of out-patients were skipping the treatment as cost of drugs was not affordable.

- GOI had introduced (October 2009) shelf life for Ayurveda medicines with effect from 1 April 2010 and directed that medicines should not be in circulation after their expiry date. In the test checked hospitals and dispensaries, Audit noticed several items of time expired medicines in main stock and pharmacy and administration of such drugs to patients. The CMO, DAH Valavannur stated that they were not aware of the introduction of expiry dates for Ayurveda drugs as the information was not communicated to them. Audit also noticed that time expired medicines were administered to patients in GAD Mundathikode in Thrissur district, even after having been pointed out about such defects by Audit.

Government stated that DISM have cautioned CMO, DAH Valavannur and GAD Mundathikode about their ignorance on the subject. However, Audit observed that the DISM had not issued any directions to DMOs regarding introduction of shelf life of Ayurveda drugs.

### **3.9 Production and distribution of Ayurveda drugs**

Good Manufacturing Practices (GMP) for Ayurveda, Siddha and Unani medicines prescribed in the Drugs and Cosmetics Rules, 1945 required manufacturers to evolve methodology and procedures to ensure that:

- Raw materials used in manufacture of drugs are authentic, of prescribed quality and free from contamination;
- Adequate quality control measures were adopted in manufacture of drugs and
- Manufactured drugs released for sale are of acceptable quality.

The Rules also prescribe regular inspection of Ayurveda drug manufacturing units. Audit observations on the above are discussed below:

#### **3.9.1 Non-adherence of stipulated standards by Oushadhi**

DISM procured Ayurveda drugs from Oushadhi, a GOK undertaking for free distribution to patients in government hospitals. As part of our audit exercise for assessing the quality of drugs procured by GOK for free distribution among patients, we conducted (July 2014) physical verification of the manufacturing facility of Oushadhi, jointly with its officials which revealed that stipulated standards were not being adhered to by Oushadhi.

- We noticed during audit that '*churnam*' manufactured in the factory was piled on the floor of the factory and the possibility of the drug being contaminated with dirt and sand cannot be ruled out.



**'Churnam' piled on floor of Oushadhi**

- There were no sterile manufacturing areas with bacterial retaining filters, etc. in the factory essential to manufacture sterile drugs like '*Elaneerkuzhambu*', an eye ointment. Routine microbial count of the manufacturing area during operations was also not carried out. Oushadhi admitted that there was no separate area for manufacturing sterile '*Elaneerkuzhambu*' and stated that they have now planned to shift its production to a separate area.
- Ayurvedic Pharmacopeia of India (API) emphasised that all Ayurveda drugs must comply with the limits for heavy metals prescribed in individual Monograph and wherever limits were not stipulated, compliance with the limits given in World Health Organisation publications was stipulated. It was noticed that the products manufactured by Oushadhi were not tested for presence of heavy-metals, aflatoxins, toxicity and pesticide residue. Oushadhi admitted its inability to conduct tests about heavy-metals, aflatoxins, toxicity and pesticide residue and stated that facilities were available for testing only microbial load and physico-chemical parameters.
- Audit noticed reported instances (February 2014) of patients complaining about numbness in the tongue and general fatigue on administration of *Suryaprabha*<sup>39</sup> tablets (Batch No P50-9) in three<sup>40</sup> GADs. Despite receiving several complaints from institutions, the reported batch of the drug was not withdrawn from hospitals/dispensaries. Oushadhi, however, conducted Microbial tests of the returned medicine with reference to the control sample and found no variations. It stated that mode of administration, media of intake and quantity prescribed by the doctors vary from patients to patients and therefore, it was not necessary to withdraw the whole of the batch. However, in view of Oushadhi admitting its inability to test for heavy-metals, aflatoxins, toxicity and pesticide residue, the presence of these elements in the products and resultant patient discomfort cannot be ruled

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<sup>39</sup> A drug containing heavy metals

<sup>40</sup> (1) GAD Chettivilakom, Thiruvananthapuram (2) GAD Karimba, Palakkad and (3) GAD Chazur, Kannur

out. Audit, therefore, could not obtain assurance that the drugs supplied by Oushadhi conformed to stipulated safety standards.

Government replied (December 2014) that steps are being taken by Oushadhi to collect *churnam* in a trolley directly from the machine instead of transferring to the floor, the manufacturing of *Elaneerkuzhambu* will be shifted to a sterilised area where microbial count will be kept minimum and to ensure the hygiene of the production unit and that the installation of new machine procured for testing heavy metals is in progress and machines for testing aflatoxins, etc. would be procured in the next year.

### 3.9.2 Drug production at GAC Thiruvananthapuram

Ayurveda drugs are manufactured at the Pharmacy at GAC Thiruvananthapuram for use of patients in the three hospitals attached *viz.*, GAC Hospital, Women and Children (W&C) Hospital and Panchakarma hospital in Thiruvananthapuram. Audit noticed that the Pharmacy did not possess a licence under D&C Act, though it manufactured drugs on a large scale. A Commission appointed by the Principal to examine the deficiencies and to suggest steps to improve the functioning of the pharmacy recommended (August 2012) setting up of a Pharmacy Advisory Board for overseeing all the activities of pharmacy attached to the GAC Thiruvananthapuram. The report also suggested constituting a Pharmacy Production Committee for scientific production of Ayurveda drugs, laid down procedures for storing of raw materials/finished products, etc. Audit however, noticed that the College was yet to take remedial action on the recommendations.

Government replied (December 2014) that license was not essential since the drugs were manufactured at the Pharmacy for free distribution to the patients and was not intended for sale. The reply is not acceptable in view of the fact that the National Research Institute for Panchakarma, Cheruthuruthy, Thrissur district, a GOI institution manufacturing only three drugs for free distribution to patients in the hospital had obtained manufacturing license. Moreover, possessing a licence under the D&C Act would also have ensured adherence to provisions of the Act and resultant production and distribution of quality drugs to the patients.

### 3.9.3 Procurement process of drugs under DISM

The Directorate of Indian System of Medicine procures medicines once in four months subject to annual monetary ceiling<sup>41</sup> according to the category of institutions. Indents prepared by Medical Officers of institutions were approved by the DMOs concerned and forwarded to Oushadhi for supply of drugs directly to the institutions. The DISM procured drugs directly for implementation of various State

<sup>41</sup> ₹0.66 lakh for dispensaries, ₹6.05 lakh for 100 bedded hospitals, ₹3 lakh for 50 bedded hospitals, ₹1.45 lakh for 30 bedded hospitals, ₹1.32 lakh for 25 bedded hospitals, ₹1.05 lakh for 20 bedded hospitals, ₹0.84 lakh for 10 bedded hospitals, ₹0.78 lakh for six bedded hospitals, ₹0.73 lakh for four bedded hospitals

Plan Schemes<sup>42</sup> to provide Ayurveda oriented health care services through healthcare institutions. Besides, funds were also provided by LSGIs for procurement of medicines from Oushadhi and Ayurdhara<sup>43</sup> for use by hospitals/dispensaries under their control. Audit noticed shortcomings in procurement and distribution of medicines as brought out below:

- As per GOI guidelines, the procurement agencies are to decide about the required medicines out of the medicines listed in Essential Drug List (EDL) as per the prevalence and needs of patients. However, DISM had not prepared a list of medicines in conformity with EDL. Government stated (December 2014) that an expert committee for formulating EDL in the State would be constituted immediately.
- There is no system in place at the DISM to assess centrally the annual requirement of drugs of field units after reckoning the stock available and trend in consumption. In the hospitals/dispensaries visited, Audit noticed that indents for departmental/scheme supply and LSGI supply are prepared without assessing the consolidated annual requirement. Audit further noticed large quantities of medicines stocked in four<sup>44</sup> hospitals/dispensaries in two districts due to procurement in excess of actual requirement. In Malappuram District, three<sup>45</sup> hospitals held huge stock of drugs procured during 2012-14. Audit compared (July 2014) the item-wise stock of drugs available at the DAH Valavannur with that consumed during the years 2012-14 and noticed that the hospital had sufficient stock of drugs supplied by LSGIs to cater to the entire needs of the hospital for the next two to 14 years. The CMO of the hospital attributed the bulk stock to the delayed supply of medicines for the year 2012-13. Audit also noticed during physical verification damage to 10000 numbers of 'Vilwadi Gulika' amounting to ₹13400 (at the rate of ₹134 per 100 numbers) received during 2012-13 in GAH Manjeri.

Government replied (December 2014) that explanation from DMO concerned has been sought for the lapses and implementation of an Inventory Management System for ISM was being seriously looked into.

### **3.9.4 Inspection of manufacturing units**

Quality of drugs procured and distributed to patients in the State can be ensured only by regular inspection of manufacturing units to check the manufacturing processes and testing of products manufactured by them for stipulated quality.

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<sup>42</sup> (1) Control of Communicable Diseases – a scheme implemented during 2009-14 aimed at control of epidemics like Cholera, Jaundice etc. (expenditure ₹1.71crore) (2) Balamukulam – a School Health Programme implemented in selected schools in the districts of Wayanad, Kasaragod and Palakkad during the years 2012-14 (expenditure ₹1.35 crore) and (3) Six other schemes with a total expenditure of ₹1.05crore implemented in 2013-14

<sup>43</sup> An Ayurveda drug manufacturing unit functioning under the control of SC/ST development Co-operative Federation

<sup>44</sup> GAH Irinjalakuda, GADs Anakayam, Edakkara in Malappuram and Kandasankadavu in Thrissur districts

<sup>45</sup> DAH Malappuram, GAH Manjeri and DAH Valavannur

As per the Drugs and Cosmetic Rules, 1945, the Drug Inspectors (DI) are required to inspect all premises licensed to manufacture Ayurveda drugs, not less than twice a year to ensure that the conditions specified in the licence and the statutory provisions were being observed. The number of licensed Ayurveda manufacturers during 2009 to 2013 was 980, 937, 870, 774 and 890 respectively. It was noticed that there was shortfall ranging from 63 to 81 *per cent* in conducting inspection of the Units. GOI insists one DI for every 100 manufacturing units. Minimum number of DIs required for inspection of 890 units (in year 2013) will be eight. However, there were only three DIs and in respect of the four new posts sanctioned in September 2012, appointments were made temporarily from January 2014 and these posts remained vacant from October 2014. The shortage of DIs hampered the inspection process.

Government replied (December 2014) that the shortages in conducting inspections were due to insufficient DIs and also non-availability of vehicles and assured conduct of inspections as stipulated on filling up the four vacant posts by regular hands, for which the recruitment process is in progress.

### **3.9.5 Ayurveda Drug Testing Laboratory**

In the state, Ayurveda drugs are tested for statutory quality control in a division functioning within the State Drug Testing Laboratory (DTL) for allopathic medicines under the administrative control of State Drugs Controller. Quality Council of India during the gap study (June 2009) of DTL recommended (April 2011) to separate the Ayurveda, Siddha and Unani (ASU) testing laboratory from the rest of DTL, which mainly caters to testing of allopathic drugs. But it was noticed that the same was not implemented (December 2014) and the State still does not have a separate State DTL for testing samples of ASU drugs (December 2014).

Audit noticed that under the GOI scheme for strengthening DTL for quality control of ASU drugs in the State, the Drug Standardisation Unit (DSU) attached to the Government Ayurveda College, Thiruvananthapuram obtained ₹1.50 crore. The DSU, despite having spent ₹1.43 crore of GOI grant continues to function as a research unit for supplementing academic activities and not as a DTL for ASU drugs in the State.

Government stated (December 2014) that strict directions were issued to the Principal, GAC Thiruvananthapuram to conduct drug testing at DSU in consultation with DDC (Ayurveda), and that directions of Government (January 2013) to shift the DSU and its employees to the control of DDC (Ayurveda) was kept in abeyance due to strong protest from students/staff.

The reply is not tenable in view of the fact that only the DDC (Ayurveda) is the licensing authority for Ayurveda manufacturing units in the State with powers to initiate action as per provisions of the D&C Act, 1940. Results of drugs tests were also to be authenticated by a notified officer (Government Analyst). No powers were vested with the DAME/Principal in this regard. Hence the direction of Government to DAME/Principal to conduct drug testing was not practical and

against legal provisions. Non-availability of an exclusive DTL for testing statutory samples of ASU drugs even after availing GOI grant of ₹1.5 crore is a matter of concern.

### **3.9.6 Licensing of Ayurveda Health Centres**

The Kerala Ayurveda Health Centres (Issue of Licence and Control) Act, 2007 and Rules made thereunder (2008) provided for categorizing Ayurveda health centres into 'A', 'B' and 'C' on the basis of facilities available like infrastructure, trained manpower and equipment. The Act also stipulated that Ayurveda Health Centres<sup>46</sup> should possess a valid license issued by the DISM after an inspection and certification by a three member committee<sup>47</sup> with a view to ensure that the provisions of the Act are being complied with. The licenses were to be renewed after every three years. Audit noticed that the DISM had not issued a single license (December 2014) to any such Centre. The DISM also did not possess data on the number of Ayurveda Health Centres operating in the State. Failure of DISM to discharge responsibilities entrusted by the Act is significant when viewed in the light of the fact that criminal cases were registered against six illegal Ayurveda health centres in the State during 2013-14 alone.

Government replied (December 2014) that the present Kerala Ayurveda Health Centres (Issue of Licence and Control) Act would be repealed when the Kerala Clinical Establishment (Registration & Regulations) Bill 2013 would be enacted by the Legislature. However, the reply fails to explain why the DISM did not enforce provisions of an Act which was passed by the Legislature and for which rules were also framed for implementation. Besides, there were also no directions from Government restricting the DISM from enforcing the provisions of the Act.

## **3.10 Medical Education**

The Directorate of Ayurveda Medical Education (DAME) was established (November 2000) for the effective administration of matters relating to Ayurveda medical education in the State.

### **3.10.1 Admission of students**

The UG course in Bachelor of Ayurvedic Medicine and Surgery (BAMS) was available in all 16 Government/Aided/Self-financing colleges in the State with an intake capacity of 910 students. Post Graduate (PG) courses were available only in six Government/Aided/Self-financing colleges as of March 2014 with ability to admit only 130 students. Audit noticed that during 2012-13, the CCIM<sup>48</sup> refused

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<sup>46</sup> 'Ayurveda Health Centre' means an establishment or premises by whatever name be known to provide Ayurveda treatment but does not include the establishments under the direct ownership or management of the Government and the dispensaries conducted by the Ayurveda Medical Practitioner only for the mere diagnosis and distribution of medicines or the agencies selling the medicine

<sup>47</sup> A three member committee consisting of the District Ayurveda Medical Officer of the district in which the establishment is situated, a senior Ayurveda Medical officer of the district as suggested by the Director and a Doctor in the department of Kayachikitsa - Panchakarma of any Government Ayurveda College as suggested by the Director of Ayurveda medical Education

<sup>48</sup> Central Council of Indian Medicine

permission to GAC Thiruvananthapuram to admit students to the PG course in *Kaumarabhritya* (5 seats) and also reduced the number of seats for *Agadatantra* from five to three. Thus, as against 10 admissible seats for these two PG courses, permission was granted to operate only three seats since the college did not fulfill the eligibility conditions of CCIM in terms of adequacy of qualified Teachers for conducting these PG courses.

GOK replied (December 2014) that the GAC sought time to fulfill the shortcomings noticed by CCIM during inspection but they denied and reduced the PG seats. However GOK did not clarify why GAC failed to explain inadequacy of teachers.

### **3.10.2 Training in Surgery and Gynaecology**

As per the syllabus for BAMS course, students are required to be trained in Surgery and Gynaecology. Since adequate facilities were not available for imparting such training in Ayurveda Colleges, Government directed (1984 and later) the Directorate of Health Services to provide facilities in Government Allopathy hospitals for imparting training in Surgery and Gynaecology. Government also issued orders (1988) to continue the arrangement till the Ayurveda colleges were equipped with the required facilities. During test check, it was however, noticed that the Ayurveda colleges continued to lack facilities for providing training in Surgery and Gynaecology to their students. Failure to provide requisite facilities in Ayurveda colleges for such training even after a lapse of 30 years, is a matter of concern.

Government replied (December 2014) that DAME had reported that some Allopathy doctors were reluctant to obey Government orders and BAMS students were not well treated in Allopathic hospitals and to overcome the situations, the required facilities for training of BAMS students are to be provided in Ayurveda colleges only. Government also stated that orders were again issued (December 2014) facilitating training in selected Allopathic hospitals in the State.

Failure of Government to enforce its own orders is cause for concern.

### **3.10.3 Ayurveda Paramedical Certificate Course on Therapy**

Qualified Ayurveda Therapists play a major role in providing Ayurveda treatment and were in demand both in Government and private sector. DAME was the sole authority in the State to regulate paramedical certificate courses in Ayurveda Therapist and Ayurveda Pharmacy. Admission to these courses in Government/Government Aided/Self-financing Ayurveda Colleges/Institutions was made on the directions issued by DAME. Audit, however, noticed that during the period 2009-14, certificate course in Ayurveda Therapist was conducted only twice in 2009-10 and 2012-13. Records produced to Audit did not indicate any initiatives taken by the department to conduct such certificate courses in Government sector despite demand. Failure of DAME to conduct sufficient number of Paramedical certificate courses on Therapy led to students depending on unrecognised private institutions for such courses.

Government stated (December 2014) that DAME had reported that it is difficult to conduct the paramedical certificate courses regularly with the existing staff strength and due to inadequacy of other faculties. However, Government did not offer comment about conduct of paramedical certificate courses by unrecognised private institutions.

### **3.10.4 Availability of Teachers in Ayurveda Colleges**

As per Indian Medicine Central Council (Minimum Standards of Education in Indian Medicine) (Amendment) Regulations 1989 and notifications issued subsequently, for appointment of teachers in Ayurveda Colleges with effect from 01 July 1989, a PG qualification in the subject/speciality or in allied subject concerned as notified by CCIM is required. However, Audit noticed that seven<sup>49</sup> out of 167 faculties in the three<sup>50</sup> test checked Ayurveda colleges who were appointed after 01 July 1989 did not possess the required PG qualification. One of the seven faculty (Assistant Professor in Ayurveda college, Ollur) has since been declared (November 2014) by CCIM as ineligible for appointment as faculty.

Government (December 2014) stated that teachers were appointed in accordance with the Special Rules for Kerala State Ayurveda Medical Education (Teaching Services)<sup>51</sup> and hence there will be differences as per the Rules of CCIM. During Exit Conference (December 2014) the Secretary assured that the Special Rules would be amended suitably in line with CCIM norms.

## **3.11 Infrastructure of Ayurveda Colleges and attached hospitals**

### **3.11.1 Execution of Building works**

GOK sanctioned ₹3.85 crore during the period 2011-14 for three construction works<sup>52</sup> in GAC Thiruvananthapuram. Audit noticed that these works were not started/completed as of December 2014 due to non-identification of site, non-preparation of plan and design, etc. Similarly, in VPSV Ayurveda College, Kottakkal also, three works namely Panchakarma block first floor (₹0.68crore), OP block first floor (₹0.53 crore) and Electrical Sub-station (₹0.22 crore) started in 2011 were yet to be completed as of March 2014.

Government replied (December 2014) that follow up action will be taken by DAME for completion of these works.

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<sup>49</sup> One Assistant Professor without any PG in *Rachanasharir* department, one Assistant Professor in *Kriyasarir* department with PG in *Rasasastra* and one Assistant Professor in *Dravyaguna* with PG in *Kayachikitsa* (GAC Thiruvananthapuram), one Professor in *Prasuthitantra* department with PG in *Kayachikitsa* and one Professor in Basic Principles department with PG in *Kayachikitsa* (VPSV Ayurveda college, Kottakkal) and one Assistant Professor in Panchakarma department with PG in *Manovigyan* and one Assistant Professor in *Roganidana* department without any PG (Ayurveda college, Ollur)

<sup>50</sup> GAC Thiruvananthapuram, VAC Ollur and VPSVAC Kottakkal

<sup>51</sup> As per Special Rules, for appointment of Lecturer by direct recruitment in the absence of person with Postgraduate Degree in the concerned subject, person with Graduation will be considered

<sup>52</sup> Construction of Ladies Hostel, Construction of a multi-storied building for laboratory and diagnostic centre and Construction of Sewage Treatment Plant at Panchakarma Hospital

### 3.11.2 Deficiencies in infrastructure in college hospitals

Audit found several deficiencies in infrastructure facilities in the test checked colleges and attached hospitals. It was noticed that the W&C hospital, Poojappura, (*Prasuthithantra* and *Kaumarabhritya* departments of GAC Thiruvananthapuram), with 80 beds including the Ayurveda paediatric ward meant for treating children with complaints of Developmental Diseases, Cerebral Palsy and Autism was functioning in two old tiled roof buildings which were congested due to lack of space while a new four-storied building constructed to increase the bed strength and to accommodate the operation theatre and labour room and inaugurated in October 2013, was not yet put to use as of December 2014 except shifting the OP department.



Congested paediatric ward in Government Ayurveda College Hospital for Women & Children, Thiruvananthapuram

The Government Ayurveda College Panchakarma hospital, under the Panchakarma Department of GAC Thiruvananthapuram was also functioning in an incomplete four storied building constructed in 2011. The building was found damp and wet as rainwater was flowing through the duct provided for electric connection and the opening provided for the staircase. Solid waste was found dumped in the compound near *Kashayam* room.

Government stated (December 2014) that the new building at W&C Hospital, Poojappura can be used only on creation of new posts. But due to resource constraints, Government could not sanction the posts.

Reply of the Government is not acceptable as the shifting of the 80 bedded hospital from the existing two old tiled roof buildings to the newly constructed building could have been made without creation of additional posts. Failure to utilise the building resulted in denial of better facilities to the patients.

### 3.11.3 Deficiencies of Equipment

During physical verification of facilities in test checked College Hospitals, Audit noticed deficiencies in equipments as detailed below in **Table 3.3**:

**Table 3.3: Deficiency in equipments**

Name of Institution	Deficiency
VPSV Ayurveda College hospital, Kottakkal	Ultra sound scanner was not working since 2009. The ECG machine procured in January 2014 was not installed due to lack of space. There was no generator facility in the hospital.
W&C Hospital, Poojappura, Thiruvananthapuram	The Ultra sound scanner in the hospital was not put to use for lack of PNDT registration.
	Hospital furniture procured for the new four storied building were found dumped in the building which includes 56 cots, 65 beds, 75 pillows, 55 bedside lockers pending allotment to new wards.
	Equipment found dumped in the building include items like Anaesthesia Machine, Spot light for labour room, Pulse Oxymeter Infant warmer, Phototherapy unit, etc. pending utilization.

Government admitted (December 2014) the facts and stated that action will be taken on these issues.

## 3.12 Research and Development

### 3.12.1 Functioning of Research Units

Research and Development activities under the Government sector in Ayurveda were carried out in institutions under the DAME like the Patent Cell, the Pharmacognosy and Drug Standardization Units attached to the GAC Thiruvananthapuram and also the Research Cell on Sports Ayurveda under the DISM.

#### 3.12.1.1 Pharmacognosy Unit

A Pharmacognosy<sup>53</sup> Unit for conducting research on medicinal plants with special focus on their identification according to the Ayurveda texts was functional (since March 1966) in the GAC Thiruvananthapuram. As of December 2014, the Unit published 13 volumes of Pharmacognosy of 198 medicinal plants. Even though Pharmacognosy included study of physical, chemical, bio-chemical and biological properties of drugs, records produced to Audit revealed that the Unit conducted studies of only biological properties of the plant. It was admitted by the Unit that physical, chemical and bio-chemical properties of Ayurveda drugs were not studied

<sup>53</sup> The word "pharmacognosy" is derived from the Greek words 'pharmakon' (drug), and 'gnosis' (knowledge). The American Society of Pharmacognosy defines pharmacognosy as "the study of the physical, chemical, biochemical and biological properties of drugs, drug substances or potential drugs or drug substances of natural origin as well as the search for new drugs from natural sources."

due to lack of infrastructure and manpower. The unit in its first publication itself had mentioned that the identity of a plant can be fixed only on study of all properties including chemical, and in the absence of such a study, it is not possible to differentiate any spurious specimen from the genuine one. Thus, a study conducted at Pharmacognosy unit is not comprehensive without analysis of chemical properties.

Government replied (December 2014) that the existing physical facilities were not adequate to conduct the research work as pointed out by Audit. However, Government did not clarify the measures taken to strengthen the unit.

### **3.12.1.2 Drug Standardization Unit (DSU)**

Government established (February 1974) a Drug Standardisation Unit (DSU) under the control of the Principal, GAC Thiruvananthapuram with the objective of evolving methods for standardisation of Ayurveda drugs by prescribing standards of raw material, methods of manufacture and standardization of finished products. The DSU was directed to conduct research on items which were not attended to by the Central Council for Research in Indian Medicine & Homeopathy (CCRIMH). Under the D&C Act, Ayurvedic Pharmacopoeia of India (API) publications (part I and II) are the books of standards for single drugs and compound formulations included therein and would be official.

The DSU published six monographs comprising of 70 medicinal plants/drugs. Though the API was a collective work of various laboratories, no efforts were made by DSU to contribute to API. No action was initiated to obtain technical or financial assistance from GOI for conducting the research activities, though the Department of AYUSH had schemes to provide financial assistance for drug standardisation like 'Extra Mural Research', Scheme for evolving Pharmacopoeial Standards for Ayurveda drugs and Standardised Operating Procedures of Manufacturing Processes of Ayurveda drugs.

Government stated (December 2014) that research methodology of PG students and research works in standardisation are going on in DSU. Government admitted that orders were not issued to DAME to contact API for encouraging the function of DSU.

As DSU has not initiated any action to incorporate their works in API publications, their works have no acceptance at national level and no legal validity.

### **3.12.1.3 Research Cell in Sports Ayurveda**

A Research Cell for Indian System of Sports Medicine was established (December 2009) under the DISM to manage sports injuries, to improve physical fitness of athletes using Ayurveda treatment, to prepare new formulations and to conduct research works on these purposes. During the period 2009-14, ₹3.61 crore was spent (out of ₹3.70 crore allotted) on various activities of the Research Cell, but there were no recorded data on any research work carried out by the Research Cell as of December 2014.

The Ayurveda Sports Medicine State Level Committee (SLC) entrusted the work (August 2011) to the Chief Co-ordinator, Sports Medicine for the manufacture of Sports Special Medicines. SLC awarded (March 2012 & September 2012) the manufacture of sports special medicines (*Thailam I, II, III and Special Lepam*) to the Ayurveda Oushadha Nirmana Vyavasaya Co-operative Society Ltd., Thiruvananthapuram. Necessary clinical trials were not conducted and ethical clearances for these medicines as per World Health Organisation guidelines were not obtained. Audit further noticed that there was no system in place to ensure the quality of raw materials used in the manufacture of these medicines and to conduct quality tests for toxicity/heavy metal in the manufactured drugs.

Government stated (December 2014) that the studies conducted on special medicines prepared by the Research Cell in Sports Ayurveda during 2012-13 and 2013-14 were on a pilot basis and no ethical clearance was needed for pilot studies. Government also stated that an ethical committee would be constituted with immediate effect and the department of ISM would subject future studies to the committee for clearances. It further stated that a High Level Committee headed by the Joint Director of ISM and Chief Co-ordinator had been constituted to effect the procurement and preparation of research medicines.

The department of ISM had however, not produced any documents on conduct of research works with reference to the objectives and efficacy of Sports Ayurveda Medicines.

### **3.12.2 Patent Cell**

Traditional Knowledge Digital Library (TKDL) was a collaborative maiden Indian venture between the Council of Scientific & Industrial Research (CSIR), Ministry of Science and Technology and Earth Sciences and Department of AYUSH to prevent misappropriation of traditional knowledge belonging to India at International Patent Offices.

Government of Kerala constituted (July 2003) a 'Patent Cell' in the DAME to take steps for acquiring patent rights on Ayurveda concepts. The Patent Cell was to conduct survey, identify, collect and digitise Ayurveda literature documents. The Cell has digitised 2505 formulations and five books were published.

Audit noticed that no formulations digitised by Patent Cell were incorporated in the database of TKDL and thereby protection of Traditional Knowledge digitised by the Patent Cell was not ensured. Audit also noticed that no Patent rights for any of the formulations digitised were acquired as of December 2014.

Government stated (December 2014) that the issue was raised before Department of Industrial Policy and Promotion, GOI which is dealing with all Intellectual Property Rights and response from GOI is awaited.

The fact remains that the traditional knowledge digitised by the Patent Cell remained unprotected as of December 2014 as the database was not linked to the TKDL and thus the work of Patent Cell became infructuous.

### 3.12.3 Conservation of Manuscripts

The Publication Division of the GAC Thiruvananthapuram has a collection of 224 manuscripts out of which 99 were deciphered (September 2014). The National Mission for Manuscripts had stipulated Basic Minimum Standards for Conservation of Manuscripts such as protection from fire, water, natural calamities, Insect attack, microbiological attack, dust, environmental pollution and light, fluctuations in temperature and relative humidity, etc. Audit scrutiny revealed the following instances of non-compliance with guidelines in conservation of these invaluable assets.

- Quarantine room or any procedure for checking the newly acquired manuscripts for insect or fungus attacks was not in place.
- The manuscripts were found dumped in a cupboard and no methods were adopted for the scientific preservation of these manuscripts. Training was also not imparted to the staff of the Publication Division on safe handling of the manuscripts.



Ayurveda manuscripts dumped in cupboard

- Index register was not maintained to show the provenance of these manuscripts.

Non-compliance of guidelines laid down by the National Mission for Manuscripts for conservation of the invaluable manuscripts may result in future risks of deterioration of manuscripts. The Head of Publication Division admitted (September 2014) the audit observations on the shortcomings.

Government stated (December 2014) that the Manuscripts in the Publication Division are being kept in safe custody in order to ensure safety from fire, water, natural disasters, insect bites, light, pollution, etc.

The GOK however, did not offer assurance on adhering to guidelines laid down by the National Mission for Manuscripts for conservation of the manuscripts other than that relating to safe custody.

### **3.12.4 Cultivation and promotion of medicinal plants**

Medicinal Plants constitute an important component of the plant resource spectrum of Kerala and plays a vital role in Ayurveda system of treatment. Over 150 species of plants that were either indigenous or naturalised in Kerala were used in the ISM. About 65 per cent of plants required for Ayurveda medicine are found in Kerala.

Under the Centrally sponsored scheme of “National Mission on Medicinal Plants”, implemented by National Medicinal Plant Board, Department of AYUSH, financial as well as management support was available to the Growers/Farmers/Self Help Groups (SHGs)/Growers Co-operatives, etc. for establishing model/small nurseries, cultivating species critical to AYUSH system and storing and processing including quality testing. The SHM was the nodal agency for implementing the scheme.

During 2009-14, the Mission extended financial assistance of ₹2.31 crore to Growers/Farmers/SHGs/Growers Co-operatives for establishing model/small nurseries. Twenty three model nurseries and 38 small nurseries were established during the same period. However, one<sup>54</sup> out of two nursery units visited (July 2014) by Audit team in Thiruvananthapuram District was found to be defunct. Audit noticed that there was no proper system in the SHM to check periodically the functional status of assisted nurseries.

SHM replied that the nursery was functional during 2011-12 and lack of proper technical knowledge and poor administration had led to the closing down of the unit. Similarly, though the SHM extended financial assistance for cultivation of species critical to AYUSH, there was no proper mechanism to ensure effective utilisation of financial assistance for the intended purpose as neither the SHM nor the individual had any details of the quantity of species cultivated and marketed.

Government stated (December 2014) that there was no proper guidance or instruction from National Medicinal Plants Board to conduct periodic monitoring of the activities implemented in the entire State and that the matter would be considered in future projects. Government also stated that the SHM does not have enough manpower or budget allocation for collecting information from the farmer’s field on quantity of raw drugs marketed by them and also that SHM have instructed the farmers to maintain a register comprising data on quantity of plants cultivated and marketed.

The reply is not tenable as extending financial assistance without monitoring mechanism in place is not an acceptable practice.

### **3.13 Ayurveda medical tourism**

Ayurveda is one of the principal tourism products of Kerala. However, the Tourism Department did not possess data on the number of foreign/domestic tourists who visited Kerala for treatment/rejuvenation therapy in Ayurveda. A survey conducted for the years 2010-11 to 2012-13 by a private agency<sup>55</sup> initiated by the Tourism

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<sup>54</sup> Government Mental Health Centre, Thiruvananthapuram

<sup>55</sup> M/s. Great India Tourism Planners and Consultants (GITPAC) International, Thiruvananthapuram

department of the State revealed that, of the total International tourists who visited Kerala, 8.85, 6.44 and 3.92 *per cent* respectively visited for Ayurveda treatment and the percentage of domestic tourists visited Kerala for health treatment was 1.28, 3.19 and 2.96 *per cent* respectively. The survey thus indicated a downward trend in the number of foreign tourists who visited Kerala for Ayurveda treatment/rejuvenation.

### **3.13.1 Ayurveda Massage Centres**

Projection of ‘Ayurveda’ as USP<sup>56</sup> of Kerala resulted in mushrooming of Ayurveda massage centres in and around the major tourist destinations in the State. Since most of these centres operated according to their own terms and often flouted safety and health regulations, the Government of Kerala initiated (January 2002) a scheme *viz.*, ‘Scheme for Classification of Ayurveda centres’. Under the Scheme, the Ayurveda centres were to be classified into ‘Olive leaf’ and ‘Green leaf’ categories on fulfilment of prescribed conditions *viz.* Qualified Physician, Therapist, etc. and based on the recommendations of a committee. There were 71 classified centres in the State in the private sector, 49 with Green leaf certificate and 22 with Olive leaf certificate (September 2014).

As per Scheme guidelines, the officers of Department of Tourism or any other officer deputed by the Department were to inspect the centres from time to time with or without prior notice for ensuring the quality standards of the centres. Audit noticed that inspections of the Ayurveda Centres were conducted by Tourism Department only at the time of granting the approval. No further periodical inspection was conducted to ensure the continued maintenance of stipulated quality standards by these centres.

Director of Tourism Department stated (December 2014) that inspection of classified centres is to be conducted when complaints are received against them. Since no complaint is received against classified centres, the department does not conduct surprise visit in them and that department is now proposing to conduct periodic inspections in the classified units in the district level to ensure quality.

### **3.13.2 Accreditation by National Accreditation Board for Hospitals (NABH)**

NABH offered accreditation to wellness centres (Ayurveda hospitals, Spas, Ayurveda Centres, Yoga & Naturopathy centres, Fitness centres, Skin care centres, etc.) possessing standards of quality prescribed by it after evaluation of such standards. NABH accreditation was offered to assure the tourists and locals that the centres were providing services as per global standards. These accredited wellness centres were entitled to incentives for accreditation by Ministry of Tourism for listing on Incredible India website, display of NABH Mark of Excellence and logo approved by Ministry of Tourism at appropriate locations, financial support from GOI for participation in the international wellness tourism events, etc. These would

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<sup>56</sup> USP - Unique Selling Proposition

facilitate creation of awareness of such centres among potential tourists and eventually help to attract tourists and thereby to promote Ayurveda.

As of March 2014, only five such wellness centres in the private sector in the State had obtained NABH accreditation. Audit noticed that no institution under Government sector obtained NABH accreditation as of March 2014.

### **3.14 Conclusion**

Failure of GOK/NRHM to furnish Utilisation Certificates to GOI for funds already received resulted in the State losing GOI assistance of ₹12.75 crore receivable during 2012-14. Failure to set up new departments for Preventive Ayurveda, Yoga, Naturopathy and Vishachikitsa in GAC Thiruvananthapuram resulted in refund of GOI assistance of ₹1.5 crore in May 2013. DISM did not fix any standards for infrastructure facilities and services in hospitals/dispensaries. Lack of infrastructure and deficient human resources affected the quality of services delivered by the Government Ayurveda hospitals and dispensaries. Among the test checked hospitals, GAH Punnapra had the lowest bed occupancy of 33 *per cent*. The hospital neither provided diet to its patients nor therapy to male patients due to absence of Cook/male Nurses/Therapist. In seven test checked hospitals, there was no heating facility in the therapy/treatment rooms forcing patients to bring fuel and stove for heating *Thailam* for oil massage. Drugs procured from Oushadhi for free distribution to patients in hospitals were not tested for presence of heavy metals, aflatoxin, toxicity and pesticide residue. The DSU attached to the GAC Thiruvananthapuram obtained ₹1.50 crore for setting up a DTL for ASU drugs in the State. However, the DSU continues to function as a research unit for supplementing academic activities and not as a DTL for ASU drugs in the State. GOK could not also enforce its own orders for transferring control of the DSU to the DDC (Ayurveda). The DISM did not enforce provisions of the Kerala Ayurveda Health Centres (Issue of License and Control) Act, 2007 stipulating the issue of licenses to Ayurveda Health Centres. The indents for departmental/scheme supply and LSGI supply of Ayurveda drugs were prepared without assessing the consolidated annual requirement. Database of 2505 Ayurveda formulations created by the Patent Cell under DAME remained unprotected as the database was not linked to that of TKDL.

### **3.15 Recommendations**

State Government may ensure:

- Upgradation and standardization of Ayurveda hospitals and dispensaries in the State in a specific time frame;
- Compliance with its order of January 2013 requiring the Drug Standardization Unit and its employees to be placed under the administrative control of the DDC (Ayurveda) for testing quality of ASU medicines;

- Enforcement of provisions of the Kerala Ayurveda Health Centres (Issue of License and Control) Act 2007 requiring DISM to issue licenses to these Centres after inspection and certification;
- Preparation of an EDL for Ayurveda drugs in conformity with the EDL published by GOI and preparation of purchase indents based on the list and actual requirements of hospitals;
- Scientific assessment about manpower requirement and appropriate placement; and
- Development of Pharmacopoeia for Ayurveda drugs with details of proportion of the ingredients.