GOVERNMENT OF INDIA MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)

LOK SABHA STARRED QUESTION NO.63 TO BE ANSWERED ON 23RD JULY, 2021 BRICS COOPERATION IN TRADITIONAL MEDICINES

*63. SHRI ADALA PRABHAKARA REDDY: SHRIMATI CHINTA ANURADHA:

Will the Minister of AYUSH be pleased to state:

- (a) whether the Government is planning to sign an MoU on BRICS Cooperation in Traditional Medicines;
- (b) if so, whether the Government plans to constitute a BRICS Forum on Traditional Medicine (BFTM) and if so, the details thereof;
- (c) whether the Government has any plans to harmonize, regulate and standardize traditional medicinal products amongst BRICS countries and if so, the details thereof; and
- (d) the initiatives taken by the Government for the mitigation of COVID-19 through AYUSH system of medicine and to showcase it globally?

ANSWER THE MINISTER OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY(AYUSH)

(SHRI SARBANANDA SONOWAL)

(a) to (d) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.63* FOR 23RD JULY, 2021

- (a) Government of India has proposed BRICS Members States to develop a consensus on signing an Memorandum of Understanding (MoU) for Cooperation on Traditional System of Medicines. The Draft Memorandum of Understanding (MoU) developed by Ministry of AYUSH has been shared with BRICS Members for their comments/suggestions.
- (b) The Government of India has proposed to BRICS Member States for constitution of a BRICS Forum on Traditional Medicine (BFTM). Ministry of AYUSH organized a virtual meeting of "BRICS experts in Traditional Medicines" under India's Chairship of BRICS 2021 on 25th March, 2021. The meeting was attended by Traditional Medicines Experts from Brazil, Russia, China, and South Africa. The proposed BFTM aims at supporting the BRICS Member States in strengthening their respective national capacities in the area of Traditional Medicines and implementing a Traditional Medicine Action plan with particular emphasis on the safe and effective use of Traditional Medicine and its appropriate integration into respective national healthcare systems. Draft Terms of Reference (ToR) on constitution of BFTM developed by the Ministry of AYUSH has been shared with BRICS Member States for their comments/suggestions. The copy of Draft Terms of Reference (ToR) is enclosed at Annexure-1.
- (c) Government of India has proposed to the BRICS Members for the Harmonization of the regulations pertaining to the Traditional Medicine including the products and services. In this regard, Ministry of Ayush has also conducted a webinar on "Harmonization of Regulation of standardization of Traditional Medicinal Products of BRICS Countries" on 28thMay 2021under India's BRICS Chairship of 2021. The webinar was attended by the eminent experts and stakeholders from the field of Traditional Medicine from India, China, South Africa, Russia and Brazil. Country presentations were made by India, China and Brazil.
- (d) Ministry of AYUSH has undertaken various steps for the mitigation of COVID-19 through AYUSH system of medicine and to showcase it globally, which are as follows:

Administrative

1. Ministry of Ayush issued advisories on protecting people from COVID and staying healthy. In these advisories, in addition to maintaining hygiene like hand wash, use of mask etc. simple Ayush home remedies were also suggested for people. These advisories have been revised as per the need of the current scenario. The AYUSH advisories were translated in French, German, Portuguese, Spanish, Japanese, Russian,

Arabic and Chinese Language and sent to all Indian Missions in various countries and various foreign embassies in New Delhi.

- 2. Ministry of Ayush developed self-care guidelines for preventive health measures and boosting immunity with special reference to respiratory health.
 - o General Measures
 - Ayurvedic/Homeopathy/ Unani and Siddha preventive measures for self-care and Immunity Promoting Measures
 - o Simple Ayurvedic Procedures
 - During dry cough/sore throat
- 3. Ministry of AYUSH has released Home care guidelines for children and Advisory for AYUSH Practitioners about prophylactic care in Children during the COVID-19 Pandemic.
- 4. Guidelines regarding ethical practices during Covid 19 for Registered Practitioners of respective system of Ayush have been prepared by Director Generals of Research Councils and Directors of National Institutes with their team of experts and same is vetted by the Inter-disciplinary Ayush Research and Development Task Force of Ministry of Ayush. These guidelines are made available in the public domain to benefit registered Ayush practitioners including Homoeopathy to help in the management of COVID 19 pandemic uniformly.
- 5. States/ UTs licensing authorities / Drug Controllers has been informed to allow the licensed manufactures for AYUSH-64 under their jurisdiction to include a new indication of AYUSH-64 for repurposing as an intervention for the management of asymptomatic, mild to moderate COVID-19 in addition to existing indication (s). Further, States/ UTs Licensing Authorities have been requested to expedite the process of the licensing/approval of the application for the manufacturing of AYUSH-64.
- 6. The Ministry of AYUSH launched a three-month campaign on "Ayush for Immunity", through webinar and published bulletins on AYUSH for Immunity. More than 50 thousand people participated in the Webinar.
- 7. A letter to all Chief Secretaries of States / Union territories was sent from the Ministry with more specific suggestions on augmentation of General Immunity of people and possible Ayush intervention wherever required in coordination with Health departments of the States / UTs.
- 8. A letter was sent to the Ministry of Health & Family welfare offering to integrate and utilize huge Ayush infrastructure to combat the COVID-19 pandemic.

- 9. Ministry of Ayush vide its D.O. letter no. Y-18020/2/2020 –EP-III has requested all States/UTs to issue appropriate instructions to District Authorities urgently to involve District Ayurveda Officers in the management and mitigation of Covid-19 in the districts and utilize the services of Ayush doctors, Ayush healthcare providers and Ayush health care facilities extensively so that the shortage of manpower and infrastructure for the management of Covid-19 can be duly addressed.
- 10. On the suggestions of Ministry of Ayush, all available infrastructure facilities like Hospital (IPD & OPD), pathology laboratory, ICU and manpower including medical & Paramedical Staff of various Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) colleges (approximately 727 colleges) were offered to local health authorities for utilization. Accordingly, the various Ayush institutes hospital were utilized by State Governments and designated as quarantine centre, isolation centre, Covid care centre and Covid health centre.
- 11. Ministry of Ayush issued Gazette notification (No. 107 dated: 21.04.2020) for undertaking research on COVID-19 through Ayurveda, Siddha, Unani and Homeopathy Systems including prophylactic measures, intervention during the quarantine, asymptomatic and symptomatic cases of COVID-19, Public Health Research, Survey, Lab Based Research etc. to generate evidence.
- 12. Ministry directed to all State/UT Licensing Authorities to forward license application of such formulations with details and results of the clinical trial/research study for verification by the Central Government in the Ministry of Ayush and also directed that all State/UT Licensing Authorities shall grant the approval or license to manufacture for sale of any such formulation only after obtaining clearance from the Central Government for effective quality control of AYUSH medicines underwent clinical trials/research studies for COVID-19,
- 13. For continuing with the efforts to augment human resources for the management of COVID-19 cases, the Ministry of Ayush has issued an advisory to deploy the trained Ayush human resources available with them for clinical management of COVID-19 cases.
- 14. The MoA launched the Ayush COVID-19 Dashboard to furnish the details of guidelines, official communications, research on COVID-19 and Ayush drugs for prophylaxis and management.

- 15. MoA also developed National Repository on Ayush to provide information related to Ayush R&D initiatives, and COVID-19 related scientific publications and Ayush Guidelines.
- 16. The Ministry of Ayush issued the National Clinical Management Protocol based on Ayurveda and Yoga for the management of COVID-19 on October 6, 2020 enabling uniform clinical management.
- 17. Vide Notification No. 40-3/2020-DM-I)A(dated: 02 April, 2020, Ayush Sector was included in essential services during lockdown and as a result it facilitated the Manufacturing of Ayush Medicine for public distribution
- 18. To strengthen the community-wide effort to limit the spread of COVID-19, Ministry of Ayush has also operationalized a dedicated community support helpline i.e. toll-free number 14443, to provide AYUSH-based approaches and solutions for the challenges raised by Covid-19.

Public Health Interventions

- 19. Considering the importance of immunity boosting measures in the wake of COVID-19 outbreak, Ministry of AYUSH has promoted use of ready-made Ayush formulation i.e. 'Ayush Kwath' or 'Ayush Kudineer' or 'Ayush Joshanda' in the interest of health promotion to the masses.
- 20. In order to provide maximum benefit of Ayush systems of medicine, a Nation-wide campaign for distribution of AYUSH-64 and Kabasura Kudineer through Research Councils and National Institute under Ministry of Ayush across the country.
- 21. To reduce the burden on the hospital-based healthcare delivery system during the recent "second wave" outbreak of COVID-19 in India, the Ministry of Ayush launched a nation-wide campaign through its Research Councils and National Institutes for the mass distribution of AYUSH-64 and Kabasura Kudineer to asymptomatic, mild to moderate COVID-19 patients, at isolation centres/ Covid Care Centre / Covid Health Centre, Ayush hospitals/ dispensary and patients in home isolation.
- 22. Ministry of Ayush has also approached Indian Missions/ Indian Embassy at abroad to explore the possible scope to make the AYUSH 64 available in the International markets. The MoA also sent the scientific and research information regarding the role of AYUSH 64 in combating Covid-19 for circulating the same to generate publicity.

- 23. All India Institute of Ayurveda (AIIA)(under Ministry of Ayush) has conducted a large cohort study on 80,000 front line workers of Delhi police who were given 'Ayu-Raksha' kit containing Samshamani vati (Tinospora cordifolia tablet), a poly-herbal powder containing holy basil, ginger, Cinnamon and pepper to prepare fresh concoction and 'Anu taila' an Ayurveda herbal oil for nasal application.
- 24. Ministry of Ayush distributed of Homoeopathy medicine i.e. Arsenic album 30 in 1,50,000 police personnel (Maharashtra Police).
- 25. Yoga instructors were deputed to COVID/quarantine centres in Delhi to conduct yoga sessions to COVID patients and health care workers during the COVID first wave.
- and has documented the impact assessment of effectiveness, acceptance and usage of AYUSH advisories & measures in the prevention of COVID-19 through Mobile app base population study in around 1.35 crores respondents. 85.1% of the respondents reported use of AYUSH measures for prevention of COVID-19, among which 89.8% respondents agreed to have benefitted from the practice of AYUSH advisory.
- 27. Ministry of Ayush and MoHFW have jointly provided training to 33,000 Ayush master trainers. Total 66045 AYUSH Personnel had obtained training at igot.in platform on continual basis. Ministry of Ayush has coordinated with MoHFW for utilisation of Ayush manpower as COVID warrior to manage COVID-19 with identified roles.
- 28. A unique and innovative example has been set through the Dhanvatri Rath (a mobile van) launched by Institute of Teaching & Research in Ayurveda (ITRA), Jamnagar for extending the Ayurveda preventive and promotive health services, to the door step of the people. Total 53405 healthy individuals and 3505 patients were taken the benefit of Ayurvedic medicines for their routine healthcare problems as well as knowledge of measures for boosting their general immunity through Ayurveda till date.

Research

29. Ministry of Ayush has also constituted core group of experts to identify and propose formulations on COVID-19 which are in line with Classical Ayurveda principles and have substantial leads on COVID-19 viz. one for prophylaxis as immunomodulatory, another for management of COVID-19 with antiviral properties and one product for post COVID-19 care.

- 30. Ministry of Ayush has formed an Interdisciplinary Ayush R&D Task Force having representation from scientists including ICMR, DBT, CSIR, AIIMS and AYUSH Institutions. The Interdisciplinary Ayush Research and Development Task Force has formulated and designed clinical research protocols for prophylactic studies and add-on interventions in COVID-19 positive cases through thorough review and consultative process of high repute experts from different organizations across the country for studying four different interventions viz. Ashwagandha, Yashtimadhu, Guduchi + Pippali and a polyherbal formulation (AYUSH-64).
- 31. The Ministry signed a MoU with Council of Scientific & Industrial Research (CSIR) and Department of Biotechnology, Government of India for furtherance of evidence-based research.
- 32. Ministry of Ayush has also launched interdisciplinary studies involving Ayush interventions for COVID-19 based on Task force recommendations. Under various research organizations and National Institutes under the Ministry of Ayush, 126 research studies at approx 152 centres in the country have been initiated on Ayush interventions.
- 33. The researches includes 42 prophylactic, 40 stand-alone and add-on treatment, 11 observational, 8 survey studies along with two pharmacopoeial standards development and one systematic review, and 22 pre-clinical/experimental studies.
- Ministry of Ayush has undertaken 02 prophylactic studies conducted at COVID-19 containment zones, to understand effect of Arsenic album 30C in prevention of COVID-19. Arsenic album 30C was administered twice in day for 7 days.
- 35. Considering the strength of AYUSH system in mitigation of Covid-19 and outcome of the clinical trials conducted on AYUSH formulations for mitigation of Covid19 in India; Ministry of AYUSH with collaboration of foreign reputed institutes/organizations from USA, UK, Germany, Brazil, and South Africa has initiated to undertake clinical trials on mutual identified AYUSH formulations for the mitigation of Covid19.
- 36. AYUSH PHFI research study entitled "Assessment of integration of AYUSH into the public health system for combating COVID-19" is being conducted with the support of WHO

37. COVID research studies undertaken by Research Councils/ Institutions under Ministry of AYUSH are as follows:

Number of COVID-19 related studies - 126

- Prophylactic studies 42
- Interventional studies 40
- Observational studies 11
- Pre-clinical/experimental studies 22 (including 13 AYUSH-DBT studies)
- Systematic Review 01
- Other studies 10 (08 Survey studies; 02 Monographs preparation)
- Study Sites Approx. 152 (including pre-clinical study centres)
- Studies Completed 90

> AYUSH System-wise

Ayurveda	66
Homeopathy	26
Siddha	13
Unani	08
Yoga &	13
Naturopathy	

➤ Manuscripts Drafted – 62

- Manuscripts Published 09 (Also Published, 03 Case Reports and 02 Study Protocols)
- Manuscripts accepted for Publication 06
- Manuscripts submitted to indexed Journals- 28
- Manuscripts finalized for submission in Journal 09
- Manuscripts Under review 10
- Manuscripts available as Preprints 19

Terms of Reference (ToR) for Constitution of

BRICS Forum on Traditional Medicine

(BFTM)

BACKGROUND:

Traditional medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses. It plays an important role in meeting demands of primary health care in many developing countries and thus occupies a key space in contemporary community health education. The BRICS region has an abundance of natural resources and has their own Traditional system of medicine. It has been observed that there are many similarities in principles, practices and therapies among different systems of traditional medicine worldwide including Ayurveda, Traditional Chinese Medicine (TCM), African Medicine etc.

The traditional medicine is already exiting in most of the member state of BRICS wherein, it is developed in some member state and in some country, it is in developing stage i.e. Indian Traditional system of Medicine - Ayurveda, Yoga etc. (AYUSH); Traditional Chinese Medicine; Folk Medicine/Traditional Medicine (In Russia), Traditional Brazilian medicine and African traditional medicine. Herbal products/medicines are being used at large scale in all member states of BRICS to countermine various diseases. All member states manufacture herbal products/medicine in various forms.

During 6th BRICS Health Minister's Meeting held on 15th -16th December, 2016 at New Delhi, it was decided to constitute BRICS Traditional Medicine Forum to share experience and collaborate in policies, approaches, strategies, institutional & regulatory frameworks of Traditional Medicine amongst BRICS countries. This Forum shall develop a plan, aligned with the working statement emanated from BRICS Wellness Workshop and High Level Meeting on Traditional Medicinal Knowledge, listing mechanisms for collaboration amongst BRICS countries.

BRICS has established more than thirty cooperation areas including economy and finance; health; science, technology & innovation; security and business. Altogether, these initiatives have resulted in a relevant set of achievements, which aim to provide concrete benefits to our societies. Cooperation in the field of Traditional Medicine is being discussed under health dialogue of BRICS.

The utility of traditional systems of medicines to protect people from COVID-19 has been well experienced by many countries. The herbal medicine and formulations containing spices have become popular owing to their immunity boosting properties resulting in multi-fold rise in their demand.

Keeping in view the presence of Traditional Medicine in BRICS Member States, immense potential of Traditional Medicine in reducing the disease burden including the epidemics, wide scope for integration of TM in primary health care and their likely role in reducing health expenditure by promoting health and wellness it is proposed to constitute a BRICS Forum on Traditional Medicine (BFTM).

01. OBJECTIVE:

To strengthen the cooperation on Traditional Medicine for holistic health care and to collaborate in policies, approaches, strategies, institutional and regulatory framework of TM amongst BRICS countries and sharing of knowledge of TM among BRICS Countries.

02. MISSION:

- a. To promote and protect public health in BRICS countries through TM through sharing of authentic information on TM, sharing on information of relevant legislation, guidelines, and experiences in TM.
- b. To support Member States in developing proactive policies & implementing action plans that will strengthen the role TM plays in keeping populations healthy and to enhance cooperation in the health sector on Traditional Medicine.

- c. To promote quality Traditional Medicine services and products and sharing lessons learned and best practices;
- d. To explore the possibility of approximating the regulations of Traditional Medicine;
- e. Promotion of Trade in Traditional Medicine of BRICS countries
- f. To generate and share evidence-based information on Traditional Medicine knowledge and practices among BRICS Countries;
- g. To cooperate in human resource development in Traditional Medicine within BRICS Countries.

03. STRATEGIES:

- a. Development and implementation of comprehensive work plans and cooperative mechanisms for regional collaboration on Traditional Medicine by establishing BRICS Forum for Traditional Medicine (BFTM) and developing BFTM work plan.
- b. Sharing knowledge, experience and information regarding different Traditional Medicine systems, services, products and raw materials among BRICS Countries.
- c. Exchange of human resource for capacity building by ways of granting scholarship and organizing workshops/ training/seminars etc.
- d. To promote cooperation among industries and academia by arranging industrial meets in the area of TM for trade promotion.

04. COMPOSITION:

The BFTM will consist of officials from the related offices of each Member Countries, policy makers, regulators, technical experts, scientists, researchers, academician, and industry representative on Traditional Medicine in Member Countries upon nomination by respective government. The BFTM may, in consultation with concerned office of each Member State, invite additional resource persons for its Meetings, based on their areas of expertise.

The BFTM may constitute sub working groups as per need to undertake the identified activities by nominating experts of relevant field for the said period and for the said purpose to expedite the task.

05. SCOPE OF WORK:

In line with the above objective, mission and strategies, the work of the BRICS Traditional Medicine Forum (BTMF) will be guided by the following:

- a. To organize Joint Workshop/Seminars on TM for regulators and other stakeholders for better understanding on TM, holistic approach behind manufacturing TM products as well as regulatory framework;
- b. To formulate a set of procedure for cooperation in traditional medicine within BRICS Countries and for regional cooperation in Traditional Medicine sector for consideration;
- c. To work towards Mutual recognition of TM in BRICS countries.
- d. To facilitate the understanding about the requirements prescribed in legislations in respective member states for the registration of TM drugs/products and for capacity building.
- e. Development of Long term and sustainable guidelines for promoting the use, practice, research and education of Traditional Medicine in BRICS countries.
- f. To develop cooperation in the field of Collaborative Research on traditional medicine on the issues and health problems common in BRICS member states such as COVID 19, Non-Communicable diseases etc.
- g. To build up academic collaboration and cooperation among the academic institutes identified by respective member states to work on strengthening education and training in Traditional Medicine.
- h. Developing academic standards, courses in the field of Traditional Medicine and medical education guidelines for TM education in the BRICS country.

- i. Encourage strategic research in Traditional Medicine by providing support for clinical research projects on its safety and effectiveness;
- j. Develop cooperation in the field of medicinal plants including their conservation, cultivation, sustainable harvesting etc.
- k. Developing evidence-based guidelines for integrating Traditional Medicine principles and practices with modern medicine.
- l. Sharing and recognition of mutual Herbal/Plant Pharmacopeia of for harmonization on common plants.
- m. To evaluate and monitor outcome of the work programmes/plan of action.
- n. To identify specific areas of cooperation that will be updated, as needed.

06. MECHANISMS AND RULES OF PROCEDURES:

- a. The BFTM will meet yearly and the BFTM Meeting will be held on rotation among BRICS Countries and additional Meeting may be held whenever necessary;
- b. The BFTM Meeting shall be attended by the representatives of all BRICS Countries and international organizations as agreed by BFTM;
- c. The Chairperson shall be from the host country and the Vice Chairperson shall be elected from the country hosting the next Meeting; the tenure of both positions shall be held until next BFTM Meeting:
- d. The Chairperson of BFTM shall be the BFTM regional coordinator and has the following duties and responsibilities:
 - i. Attend relevant BFTM Meetings and present highlights of BFTM Meeting;
 - ii. Be the focal point of information for any progress of BFTM activities with the assistance of the lead country of each activity;

- iii. Work closely with the BFTM Secretariat on matters pertaining to BFTM in particular submission of proposals and funding;
- e. The host country shall have the following duties and responsibilities;
 - i. To propose the date and venue of a meeting in consultation with BRICS Secretariat, at least six months prior to the Meeting;
 - ii. To provide necessary logistics for hosting the Meeting: and
 - iii. To follow-up and coordinate the inputs received from various BRICS countries for the Meeting of BFTM with the assistance of BRICS Secretariat.
- f. The BRICS Secretariat shall prepare the Reports of Meetings with the assistance from the host country.
- g. The Report shall be finalized and adopted by the Meeting;
- h. The BFTM shall, at each meeting recommend the date and venue of its next meeting;
- i. The BFTM Meeting shall be convened on a cost-sharing basis whereby the hosting of the Meeting, accommodation, meals and local transportation shall be borne by the Host Country whilst the participation of the delegations shall be borne by the respective Member Countries. The number of delegates who will be provided local hospitality shall be determined by the host country.
- **075. GENERAL PROVISION:** This Term of Reference will be revised when required on consensus.
