GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 3049
TO BE ANSWERED ON 28th MARCH, 2023

STANDARDS FOR TESTING AYUSH MEDICINES

†3049 SHRI ABDUL WAHAB:

Will the Minister of AYUSH be pleased to state:

(a) whether there are any guidelines by the ICMR regarding the adherence of standards in testing of Ayush medicines;
(b) if so, the details thereof;
(c) what steps are being taken to bring research on ayurvedic drugs and formulations closer to international standards;
(d) whether Government has established ethical principles under which drug trials are conducted for research on traditional medicines involving human participation;
(e) if so, the details thereof and if not, the reasons therefor;
(f) whether any measures are being adopted to monitor the testing of ayurvedic and other traditional medicines; and
(g) if so, the details thereof?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) & (b) No, Sir.

(c) Following are the steps taken by the Ministry of Ayush to bring research on Ayurvedic drugs and formulations closer to international standards:

- Signed 24 Country to Country MoUs, 40 Institute level MoUs and 15 Ayush Chair MoUs for Cooperation in the field of 'Ayush System of Medicine' to promote academic research at the international level.
- Signed MoUs with the London School of Hygiene & Tropical Medicine (LSH&TM), UK and Frankfurter InnovationszentrumBiotechnologie GmbH (FIZ), Frankfurt Germany for clinical research studies on mitigation of Covid-19 through Ayurveda.
- Signed an MoU with the National Institute of Advanced Industrial Science and Technology (AIST), Tokyo (Japan) on research Collaboration in Ayurveda on

06.08.2022. Under this MoU, the AYUCENTER project proposal is going on between AIIA, New Delhi and AIST, Japan.

- An AYUSH PHFI research Project/study entitled "Assessment of integration of AYUSH into the public health system for combating COVID-19" is being conducted with the support of WHO. The areas of Collaboration are Development of WHO terminology in Ayurveda, Unani, Siddha, and WHO publication on standard terminology in Ayurveda, Unani, and Siddha.
- Ministry of Ayush and WHO has signed an agreement to establish WHO-GCTM in Jamnagar, Gujarat which aims to support to implement WHO's traditional medicine strategy (2014-23), to support nations in developing policies & action plans to strengthen the role of traditional medicine as part of their journey to universal health coverage, to establish research methodology standards and develop standards for clinical practice and protocols in traditional medicine.

Pharmacopoeia Commission for Indian Medicine PCIM&H, lays down the Formulary specifications and Pharmacopoeial Standards for Ayurvedic drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the Ayurvedic drugs, included therein, as per Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder. Further, PCIM&H in 2021 singed an MOU with American Herbal Pharmacopoeia, USA for developing standards of Ayurveda and other Indian systems of Medicine drugs on international parameters.

The Central Council for Research in Ayurvedic Sciences (CCRAS) is conducting research studies adopting prevalent guidelines such as Good Clinical Practices Guidelines for ASU drugs (GCP-ASU), Ministry of Ayush and Ethical guidelines for Bio-Medical Research (ICMR), WHO guidelines for traditional medicines etc. as per requirement.

(d) & (e) Yes, Sir.

The Central Council for Research in Ayurvedic Sciences (CCRAS) has published Good Clinical Practice Guidelines for Clinical trial in Ayurveda, Siddha, and Unani Medicines (2013), and Central Council for Research in Homoeopathy (CCRH) has also published Good Clinical Practice Guidelines for Clinical Trial in Homoeopathy. These guidelines encompass the design, conduct, termination, audit, analysis, reporting and documentation of studies involving human subjects for determining the safety and efficacy of Ayurvedic drugs.

Details of the documents are under:-

(i) Good Clinical Practice guidelines for clinical trials in Ayurveda, Siddha and Unani medicines published by Ministry of Ayush (Erstwhile Department of Ayush).

(ii) National Ethical Guidelines for biomedical and health research involving human participants published by the ICMR in 2017.

(iii) General Guidelines For Drug Development of Ayurvedic Formulations published by CCRAS.
(iv) General Guidelines of Safety/Toxicity Evaluation of Ayurvedic published by CCRAS.
(v) General Guidelines for Clinical Evaluation of Ayurvedic Interventions published by CCRAS.
The National Ethical Guidelines for Biomedical and Health Research envloving human participants issued by ICMR (2017) are adopted by all the research councils and National institutes under Ministry of Ayush to ensure ethical conduct of clinical trials in human participants.

(f) & (g) Yes, Sir.
Phramacopoeia Commission for Indian Medicine and Homeopathy being the appellate laboratory for Ayurveda, Siddha, Unani, Homeopathy drugs, is testing the ayurvedic drugs as per the standards / parameters published in respective Pharmacopoaia of India.

As on date, there are 35 State Drug Testing Laboratories and 86 private Drug Testing Laboratories approved or licensed under Rule – 160 A to J of Drugs and Cosmetics Rules 1945, for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials, as per Drug Policy Section (DPS).
Central Council for Research in Homoeopathy (CCRH) with prior approval of the Government has constituted following Scientific Committees/Board to monitor testing of homoeopathic medicines:-

- Scientific Advisory Board
- Scientific Advisory Committee
- Special Committee for Clinical Research
- Special Committee for Drug Proving
- Special Committee for Drug Standardization
- Special Committee for Fundamental & Basic Research

These Committees/Board examine, supervises, and reviews the progress of the research undertaken with homoeopathic medicines.

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