SHORT COMMUNICATION

CCRAS Policy for Commercialization of Technologies: A Short Appraisal

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The Central Council for Research in Ayurvedic Sciences has been engaged in clinical research and drug development of new/coded formulations based on leads from classical texts, contemporary scientific and pharmacological leads for important diseases of national importance based on strength of Ayurveda.

The research policy of CCRAS is aimed at encouraging its scientists for the formulation, submission and execution of research projects aimed at generating quality data for scientific validation of safety and efficacy of formulations/therapies and other interventions including basic principles.

To meet the objectives of quality research, CCRAS has adopted following schemes: Intra Mural Research Scheme: the regular scientific staff of CCRAS are at liberty to develop the project keeping in view the following areas: National priority areas, mandate of the institute and strength areas of Ayurveda. Collaborative research scheme at National level: there are certain areas in which infrastructure/facilities available at CCRAS peripheral institutes are not adequate. There is a need of support from other reputed institutes where adequate facilities along with expertise are available such as for research in Cancer, HIV/AIDS, tuberculosis, malaria, leprosy etc. Further, there are some other areas like filariasis, bronchial asthma, metabolic syndrome, hypertension, diabetes mellitus including complication, rheumatoid arthritis, etc. in which the association of other specialized institutes will boost the quality of research. Collaborative research scheme at International level: due to increasing global interest in Ayurveda, very often foreign countries have shown interest to collaborate in the field of research in Ayurveda and it has became imperative on the part of the Council to initiate/execute/coordinate or monitor such activities. CCRAS has laid guidelines for such collaborations. Collaborative research in Ayurveda with industries: benchmarks have been laid for undertaking research/research consultation for already commercialized/marketed Ayurveda products.[1]

Further the council has been putting efforts to translate the research findings into practice and make available to the needful at large. In this direction, Council is developing and validating drugs, technologies and process etc. at in house research and development facilities and also in collaboration with reputed organizations, as per the provisions of CCRAS Research Policy 2018 duly approved by the Governing Body of the Council and transfers it to the Industry through National Research Development Corporation, Department of Scientific and Industrial Research, Ministry of Science and Technology, Government of India as per the provisions of Memorandum of Understanding entered with NRDC.

The Council has a dedicated IPR and business development cell, and to regularize it a policy for commercialization of technologies has been framed. This policy has provisions regarding benchmarks for undertaking research/research consultation for already commercialized/marketed Ayurveda products in the existing CCRAS research policy. The provisions and modus operandi of CCRAS commercialization policy for technologies (Drugs, Processes, and Instrumentation etc.) has been broadly classified into three major categories, viz. *Category I*: Technologies developed by CCRAS, *Category II*: Technologies developed by CCRAS with Collaborative Institute or Industry jointly involving all the steps of drug development including clinical trials and or development of any other technology or instrumentation etc. (from conceptualization till drug development). *Category III*: Value addition and further development of technologies developed by any organization or industry, etc. by CCRAS (already patented or marketed).[2] This will bring transparency and will address various issues of transfer of technology, commercialization and benefit sharing to ensure its compliance.

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ANNEXURE

CCRAS POLICY FOR COMMERCIALISATION OF TECHNOLOGIES

Background

The Central Council for Research in Ayurvedic Sciences (CCRAS), an autonomous body under Ministry of AYUSH, Govt. of India is an apex body in India for undertaking, coordinating, formulating, developing and promoting research on scientific lines in Ayurvedic Sciences. The activities are carried out through its 30 Institutes/Centres/Units located all over India and also through collaborative studies with various Universities, Hospitals and Institutes. The research activities of the Council include Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and Tissue Culture), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research and Documentation and Tribal Health Care Research Programme.

Preamble

Vision

To develop scientific evidence in Ayurvedic Principles, drug therapies by way of integrating ancient wisdom with modern technology and to bring Ayurveda to the people through innovations related diagnostics, preventive, promotive as well as treatment methods and also introduce scientific research for sustained availability of quality natural resources, to translate them into products and processes and in synergy with concerned organizations to introduce these innovations into public health systems.

Mission

- To aim for AYUSHMAN Bharat by way of promoting better health through evidence based Ayurvedic principles and practices.
- To develop CCRAS into a dynamic, vibrant, and model research organization for undertaking, coordinating, aiding and promoting research in Ayurveda.
- To bring-up modern scientific knowledge, technology to explore Ayurveda scientific treasure following prevalent scientific methods.
- To attain global leadership in research for treatment and prevention of emerging important life style related disease and health requirement.

Objectives

- To undertake research on principles and practices of Ayurveda including diet, formulation, dosage forms, drug delivery system, panchakarma procedures, marma therapy, Shalya-Shalakya procedures etc.
- To undertake epidemiological surveys for various purposes like Prakriti, Sarata other health indicators, dietary habits, changing disease patterns etc.
- To develop scientific assessment tools and parameters suitable to Ayurveda.
- To conduct research on natural resources for their sustained availability, quality etc.
- Identifying newer natural resources for purpose of prevention and treatment of various diseases.
- Clinical Research for safety and efficacy evaluation of Ayurvedic Pharmacopoeial formulations and other Drugs and Approaches in identified diseases/conditions.
- Medico ethno Botanical Survey across the country.
- To establish novel methods of analysis for standardization and quality control of single drugs and compound formulations.
- Experimental studies to establish safety profile of Ayurvedic drugs/formulations.
- Tribal Health Care Research Programme including documentation of Local Health Traditions/folk claims.
- Retrieval and revival of Ayurvedic texts from ancient manuscripts and publication of journals, monographs, books, technical reports, Information, Education and Communication material (IEC) etc.

CCRAS Policy for Commercialization of Technologies

In the light of the background, Council is developing and validating drugs and technologies, process etc. at in house Research and Development facilities and also in collaboration with reputed organizations, as per the provisions of CCRAS Research Policy 2018 duly approved by the Governing Body of the Council. This policy has provisions for Benchmarks for undertaking research/research consultation for already commercialized/marketed Ayurveda Products in the existing CCRAS Research Policy.

Further, the Drugs, Technologies and process etc. developed by the Council are being commercialized through National Research Development Corporation (NRDC), New Delhi under Ministry of Science and Technology as per the provisions of Memorandum of Understanding entered with NRDC.

In view of expansion of the scope of R&D and its commercialisation as per the provisions of CCRAS Research Policy, different categories of the products/technologies and processes need to be transferred for further commercialization. The provisions and modus operandi of CCRAS Commercialisation Policy for Technologies (Drugs, Processes, Instrumentation etc.) is depicted in Table 1.

Table 1: Categorization and modus operandi of CCRAS commercialization policy for technologies (drugs, process, and instrumentation etc.)*

S.no.	*Category*	*Commercial rights*	*Lumpsum premia*	*Royalty*	*IPR and other administrative issues*
1	Category I: technologies developed by CCRAS	Non exclusive	Case to case basis vased on commercial viability and translational value	4% ex-factory sales	As per the CCRAS research policy provisions Sl.4.
2	Category II: technologies developed by CCRAS with collaborative institute or industry jointly involving all the steps of drug development including clinical trials and or development of any other technology or instrumentation etc. (from conceptualization till drug development)	Non exclusive	Case to case basis based on commercial viability and translational value	4% ex-factory sales	As per the CCRAS research policy provisions Sl.4.
3	Category III: value addition and further development of technologies developed by any organization or industry etc. by CCRAS (already patented or marketed)	Non exclusive	Case to case basis based on commercial viability and translational value	4% ex-factory sales	As per the CCRAS research policy provisions Sl.4.

*The provisions of CCRAS research policy and MoU with NRDC are applicable