SCHEME FOR RIGHT SOURCING SCIENTIFIC WORK OF PHARMACOPOEIA COMMISSION FOR INDIAN MEDICINE (PCIM)

Background:

To meet the objects of the PCIM it is essential to right source (outsource) the scientific work to other reputed institutions. The solitary lab PLIM cannot undertake the work, therefore the proposed scheme is for right sourcing of the scientific work of the PCIM. The scheme will meet the following components.

1. To develop Pharmacopoeial monographs on single drugs of plant, mineral, metal and animal origin.

Annual target: 10 drugs, @ of Rs. 1.00 lacs per drug.

Component of financial assistance

- Two JRF one each from Botany (M.Sc) and Chemistry (M.Sc).
 Emoluments for JRF as per ICMR/DST/DBT/CSIR norms.
- ii. Qualification

JRF - Master Degree in Concerned Subject.

- iii. Host Institutions charges 15% of the total project cost.
- iv. Minor equipments:
- v. Consumables:

Note: The project can be allocated as turn-key project @ of Rs.1.00 lac per monograph and the Institutions may not require the above subheads.

The target may be increased considering the expertise and the amount of fund allocation.

2. To develop monograph on standard operational procedures (SoPs) of manufacturing process and quality standards of ASU Formulations (including stability studies).

<u>Annual Target</u>: 5- 10 formulations @ of 3 lacs per formulation with the ingredients upto 10 drugs and Rs. 5 lacs if the ingredients goes from 10 - 70 in a formulation.

Component of financial assistance

i. Two JRF one each from Botany and Chemistry and one SRF (Ay.).

Emoluments for JRF/SRF as per ICMR/DST/DBT/CSIR norms.

Qualification

JRF - Master Degree in Concerned Subject.

Research Associate – M.D. (Ayurveda/Unani/Siddha) with a total emoulment of Rs. 35,000/- per month and 10% increase per year.

- ii. Host Institutions charges 15% of the total project cost.
- iii. Minor equipments:

Consumables:

Note: The project can be allocated as turn-key project @ of Rs.3.00 lac/ 5.0 lac per monograph and the Institutions may not require the above subheads.

3. To develop standard operating procedure and manufacturing process and quality standards of extracts (water and hydro-alcoholic) of ASU Plant Drugs.

Financial Assistance @ of Rs. 1.00 lac for water extract and Rs. 1.00 lakhs for alcoholic extract monograph, for development of SOP and qualitative and quantitative estimation of markers in the extract with other Physico-chemical parameters.

4. To develop Atlas of chromatography, and Macro and Microscopy Atlas to facilitate the testing procedures of ASU drugs.

Annual target: 10-50 drugs

- A. Financial Assistance @ Rs. 20,000 per drug each for microscopy and macroscopy atlas.
- B. Rs. 0.5 lac per drug for TLC Atlas including separation of marker compound.
- 5. To develop Phyto-chemical reference standard (PRS) of ASU drugs (plant drugs).

Annual targets: 5-10 PRS

Financial Assistance @ of Rs. 2.00 lacs – Rs. 5.00 lacs per PRS drug depending upon the complexity of the marker compound during isolation process. The P.I. will deposit atleast one gm marker compound with spectroscopic and purity data of to the markers repository library at PLIM, Ghaziabad and transferring technology of isolation procedure to PCIM.

6. To undertake toxicity studies of ASU drugs/Formulations.

Financial Assistance @ of Rs. 25.00 lacs per drug for 90 toxicity days studies in NABL lab.

7. To undertake Biological Activity studies of ASU drugs (in vitro) for extracts.

Financial Assistance @ Rs. 50,000 - Rs. 1,00,000 per activity for IC-50 value.

Translation of Pharmacopoeias of India @ of Rs. 1500 per page for translation, typing and proof reading (for one language).

8. Assistance for repository of ASU drugs (Botanical and PRS) at PLIM, Ghz.

To established the National Repository at PLIM infrastructure and manpower requirement will be supported by PCIM under the scheme. The manpower requirement to initiate the activity will be 3 SRF (2 Botany and 1 Chemistry). The contingency grant for procuring of the samples and PRS will also Rs. 2.00 lac per year. Total annual grant will be around Rs. 10.00 lacs the Annual target will be addition of 100 BRS drugs and 20 PRS.

9. Any other issue of human resource development on quality testing in the form of short trainings, workshops, consultancy relating to the editorial work of Pharmacopoeias will be also permissible in the scheme as per the actual expenditure.

Mode of Operation of the scheme

- I. The scheme for funding under the PCIM will be operationalized through the research institutions, laboratories, pharmacies and other capable institutions, individual experts in Goyt./Semi Goyt./Private Sector.
- II. The applicant institution can be identified directly by the PCIM, research councils/Pharmacopoeial laboratories to undertake the Pharmacopoeial work.
- III. The institutions which have the infrastructure and expertise on botany, chemistry, toxicology, organic chemistry, pharmaceutical sciences, pharmacy of Ayurveda, Unani, Siddha can apply in this scheme. (Relevant with the specific proposals).
- IV. The application received for the grant will be screened by respective Pharmacopoeia Committees. The Principal Investigator (PI) may be asked to make presentation of his/her working in the field of expertise depicting his/her capabilities to handle this project with explicitly strong commitment of honouring the milestones and meeting the final targets to the entire satisfaction of the funding agency. The recommendations of the Pharmacopoeia

- V. Each project will be monitored six monthly by Committee constituted by the Scientific Body and grant will be released yearly on the basis of progress of work.
- VI. The outcomes of the project will be included in the different volumes of ASU pharmacopoeias.

Financial Assistance under the Scheme:

This scheme is being introduced by PCIM w.e.f 1st February, 2012.

With the recent creation of Pharmacopoeia Commission for Indian Medicine (PCIM) the targets for APC/UPC/SPC are manifold than the 10th and 11th Plan. There is a clear cut mandate to use high technology and the cooperation of eminent scientific institutions to implement the scheme and complete the Pharmacopoeial Standards in the coming five years.

- I. Out of the total scientific manpower at least one expert should be of Ayurveda/Siddha/Unani systems and one each of Chemistry, Botany or other specialty relating to the project.
- II. Based on the quantum of work involved in a particular project, the Committee can sanction lump sum money as a turn-key project with specific targets. In such case, the above said distribution of the financial sub-heads will not be applicable but the money will be released on annual basis matching with the progress.
- III. If the targets are not achieved within the prescribed time and the expert committee is convinced with the genuine reason of the delay of the implementation of the project, the project can be extended without giving additional grant.
- IV. In addition to the above indicated sub-heads for financial grant, the money can be utilized for Hindi translations, printing, consultation regarding editing of the Pharmacopoeia and Formularies.

V. Outcome of the Scheme

The outcome of the scheme related activities will be published in various volumes of the Pharmacopoeias/Formulary/Atlas and other such literature of PCIM.

Mode of application:

The applicants will apply to the Director, PCIM on the following proforma. All the applications will be forwarded to the Chairmen of the respective Pharmacopoeial Committees on the basis of proposal related to A/S/U system of Medicine.

Proforma for application:

- I. Stream of the Project : Ayurveda/Siddha/Unani
- II. Project title
- III. Name and address of the institution with Telephone Number/Fax/Email
- IV. Status of Organization (Govt./Semi Govt./Autonomous/Private/Statutory Bodies or any other body)
- V. Year of establishment
- VI. Covered area available for the activity
- VII. Present activity of the institution specially relating with the project
- VIII. PI (name and address)
 - IX. Co-I (name and address)
 - X. Existing infrastructure (relevant to the project)
 - a. Building
 - b. Equipment
 - c. Expert Manpower
 - XI. Duration of the Project
- XII. Objectives of the proposal
- XIII. Please indicate the details of the activities to be undertaken under the project previously.
- XIV. Implementation plan indicating six monthly milestones
- XV. Annual targets
- XVI. Fund requirements for the activities as per the provisions of the scheme.
- XVII. How are the account of Organization being audited (Govt. Auditor/C.A.).
- XVIII. Any other relevant information justifying the request for Financial assistance under the Scheme. Qualifications, experience and list of research publications of the Principal Investigator (PI) (attach complete bio-data with all publications)

(Signature, Name and Designation of the Head of Institution with seal)

Date Place

Recommendation by Head of the Eminent institution Central/State/Autonomous/Eminent Scientist