No. 35025/08/2021-Scheme Government of India Ministry of Chemicals & Fertilizers Department of Pharmaceuticals ****

> Shastri Bhawan, New Delhi Dated 22nd October, 2021

TENDER NOTICE

Subject:- Invitation of Tender for selection of reputed empanelled agencies with Government of India for conducting studies and submission of report thereof-regarding.

The Department of Pharmaceuticals is inviting sealed bids from reputed experienced empanelled agencies with Government of India to conduct studies related to Pharmaceutical and Medical Devices Sector. The detail Request for Proposal (RFP) is attached.

2. Eligible bidders are requested to submit their proposal as per details mentioned in R.F.P. to this Department by 03:00 P.M. of 17.11.2021 positively.

Hoh.

(N.K. Joshi) Under Secretary to the Govt. of India <u>Tel:-</u> 23383392 Email:- <u>navin.26@gov.in</u>

F. No. 35025/08/2021/Scheme /RFP dated 22nd October, 2021

Request for Proposal (RFP)

for

Selection of reputed empanelled agencies with Government of India for conducting studies and submission of report thereof under the

Pharmaceutical Promotion and Development Scheme.

Government of India Ministry of Chemicals & Fertilizers Department of Pharmaceuticals Shastri Bhawan, New Delhi- 110001

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Invitation for RFP

1. Objective of Pharmaceutical Promotion and Development Scheme

1.1 The objective of Pharmaceutical Promotion Development Scheme ("PPDS") is promotion, development and export promotion in pharmaceutical sector by extending financial support for conduct of seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma and medical devices sector.

2. Terms of Reference

2.1 Department of Pharmaceuticals ("DoP") intends to conduct studies related to Pharmaceutical and Medical Devices sector under the Pharmaceutical Promotion and Development Scheme ("PPDS"). Reputed agencies will be selected by DoP for conducting various studies and submitting reports thereof for effective creation and utilization of database of pharmaceuticals and medical devices sector, production/manufacturing, EXIM, raw material availability, etc., which will help in framing the policies, monitoring and corrective measures, if necessary, or any other purpose deemed necessary. In this context, DoP invites RFP from reputed empanelled agencies with the Government of India ("GoI") for conducting Studies and submitting reports thereof. The successful Bidders will provide Original Study report in accordance with the Scope and Terms of reference. A list of topics, total 8 (Eight) in numbers, which are selected for study is annexed in this RFP as **Annexure-I**.

3. Advertisement for RFP

3.1 Prospective bidders desirous of participating in this tender may view and download the tender document free of cost from the websitehttps://pharmaceuticals.gov.in/whats-new. The RFP for this bid is in two stages, *viz.*,

- **3.1.1** The Technical Evaluation Criteria
- **3.1.2** The Financial Evaluation Criteria

4. Definitions

4.1 "**Bidders** means "Service Provider" or agency/firm, which participates in this tender and submits its bid.

4.2 "**Bidders Representative**" Shall mean a person in supervisory capacity who shall be so declared by the Bidder and who shall be authorized under a duly executed power of attorney. He shall be responsible for proper execution of contract and shall take orders from DoP and carry out the same.

4.3 "**DoP**" means Department of Pharmaceuticals, under the Government of India, Ministry of Chemicals and Fertilizers and having its office at Shastri Bhawan, Dr. Rajendra Prasad Road New Delhi – 110 001.

4.4 "Substantially responsive bid" is one, which conforms to all the terms and conditions of the Bid documents without material deviations.

5. **Prospective bidder**

5.1. The prospective bidder shall be an empanelled agency with the Government of India ("GoI") having experience of at least 5 years and whose annual turnover in the last financial years was not less than <u>*Rs*</u> 20.00 lakhs for all <u>Bidders</u>. Further, the bidder should have capability and experience in:

5.1.1. Market intelligence study/ Research / consultancy or similar professional services in India.

5.1.2. Conducting various studies related to Pharmaceuticals, Chemicals, Health, Electronic and Medical Devices sector with capability in primary and secondary data mining/survey etc.

6. Deliverables

6.1. Successful bidder shall submit to the satisfaction of the DoP a comprehensive report, both in physical and electronic form, within four and six

months respectively as per the Scope of the Study illustrated in **Annexure-I**. The Report shall be to the satisfaction of the DoP.

6.2. The successful bidder shall have to make presentations to the DoP on key findings of their study /suggestions/recommendations/analysis of data.

7. Pre-bid meeting and corrigendum

7.1. A pre-bid meeting with the prospective Bidders will be held to explain the scope of tender and other details on **10.11.2021 at 11:00 A.M.** through Webinar. Details of the same shall be available on website well in advance.

7.2. The Bidders will ensure that their queries with regard to the RFP, to be addressed by the DoP during the RFP (Pre-Bid meeting) shall reach by post or email **on or before 05:00 P.M. on 05.11.2021** to the officer whose details are provided below:

Shri. Navin Kishor Joshi, Under Secretary (Scheme), Room no. 235, A-wing, Shastri Bhawan, New Delhi – 110001 [<u>Email: -</u> navin.26@gov.in]

7.3. The Nodal Officer notified by the DoP will endeavor to provide timely response to all queries. However, DoP makes no representation as to the completeness or accuracy of any response made in good faith.

7.4. At any time prior to the last date for receipt of bids, DoP may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder(s), modify the RFP document by issuing a corrigendum.

7.5. The corrigendum & clarifications to the queries from the prospective bidders or otherwise will be posted on the website of the Department, viz., www.pharmaceuticals.gov.in.

7.6. Any such corrigendum shall be deemed to be incorporated into this RFP.

7.7. In order to afford reasonable time to the prospective bidders to affect the corrigendum in the preparation of their bids, DoP may, at its discretion, extend or modify the last date for the receipt of RFP Bids.

8. Bid submission

8.1. All bids must be submitted and received by DoP on or before 17.11.2021 at 03:00 P.M.

8.2. Three separate sealed envelopes should be used for submitting (i) Technical Bid; (ii) Financial Bid; and (iii) EMD with Form-1 and Form-2 and documents incidental thereto superscribed as (a) Technical Bid; (b) Financial Bid; and (c) Earnest Money Deposit upon the respective envelopes which it relates to.

8.3. After putting the envelopes as mentioned in this para afore in one big sealed cover superscribed as "Request for Proposal (RFP) for "<u>(Name of the study as per Annexure-I)</u>" should be submitted personally, or through Speed post/ Registered A.D. post, addressed to the Shri Navin Kishor Joshi, US (Scheme), Room no. 235, A-wing, Shastri Bhawan, New Delhi – 110001.

8.4. All bid documents should be signed by the authorized signatory of the Agency.

8.5. In case, the day of bid submission is declared holiday by GoI, the next working day shall be treated as day for submission of the bids. There will be no change in the timings.

9. Earnest money deposit [EMD]

9.1. The bidder must submit <u>**Rs. 20,000**/-</u> (Rupees Twenty Thousand) towards EMD along with the tender for each study.

9.2. EMD has to be submitted in the form of a Demand Draft from a scheduled Commercial Bank in India in favour of "Department of Pharmaceuticals, New Delhi", payable at New Delhi.

9.3. Bids received without EMD will be considered unresponsive and will be summarily rejected.

9.4. EMD shall be submitted in a separate cover along with bid.

9.5. DoP shall not be liable to pay any interest on the EMD pending evaluation.

9.6. Unsuccessful bidder's EMD will be discharged/ returned back after 15 days from the date DoP enters into an agreement with the Successful bidder.

9.7. The EMD shall be forfeited if a bidder withdraws its bid during the period of bid validity.

9.8. In the case of successful bidder, EMD shall be forfeited if the Bidder-

| 9.8.1 | Fails to accept the assignment; or |
|-------|---|
| 9.8.2 | Fails to furnish performance guarantee; or |
| 9.8.3 | Fails to deliver the relevant services within stipulated period; or |
| 9.8.4 | Fails to comply any of the terms of RFP. |

10. Bid opening.

10.1. Bids complete in all respects received along with Bank Drafts in respect of cost of EMD will be opened by the Tender Opening Committee (TOC) in the presence of bidders' representative, if available on **18.11.2021 at 03:00 P.M.** at Room no. 235, A-wing, Shastri Bhawan, New Delhi - 110001. At this stage, completeness of the submission and EMD will be examined. Bids received without EMD will be rejected straight way.

10.2. Technical bids of only those bidders will be evaluated on **23.11.2021** from **11:00 A.M.** onwards whose EMD and supporting documents (any if required) are found to be in order.

10.3. After the Technical evaluation, financial bids of only those bidders, whose bids are found to be technically qualified by the Technical Evaluation Committee ("TEC"), will be opened in the presence of the bidder's representatives. The eligible financial bids will be opened on **25.11.2021** at **12:00 P.M.**

11. Technical evaluation of bid

11.1. A duly constituted TEC will evaluate bidders on the basis of marking criteria as stipulated in this document.

11.2. While doing the technical evaluation, DoP shall evaluate the bids to determine whether they are complete, whether any computational errors have been made, and whether the bids are generally in order. Arithmetical errors shall be rectified on the following basis:

11.2.1 If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be corrected by the DoP.

11.2.2 If there is a discrepancy between words and figures, the amount in words shall prevail. If the bidder does not accept the correction of the errors, his bid shall be rejected.

11.3. Bids which are found responsive and qualify Technical Evaluation, will go to the financial bid opening stage. A minimum score of 15 out of 50 marks in technical evaluation are required to qualify for the financial bid. The following marking criteria shall be followed:

| S1. | Aspects | Technical Selection Criteria | Score | Max | Minimum |
|-----|-----------|--------------------------------|-------|-------|---------------|
| No. | | | | Score | score to be |
| | | | | | obtained for |
| | | | | | qualification |
| | | Average Rs. 20 lakh per | | | |
| | Turnover | year, for the FY 2018-19, | 5 | | |
| 1 | Turnover | FY 2019-20 and FY 2020- | | 15 | 5 |
| | | 21. | | | |
| | | For every additional | 2 | | |
| | | average Rs.5 lakh turnover. | | | |
| | | At least (4) Four numbers | | | |
| | | of study in the sectors /field | | | |
| | Technical | of Pharmaceuticals, | 5 | 15 | 5 |
| 2 | strength | Chemicals, Health, | | | |
| | | Electronics and Medical | | | |

| | | Devices must be completed in last five years. | | | |
|---|------------|---|---|----|----|
| | | For every additional of similar assignments/Study. | 2 | | |
| 3 | Experience | Five years of Experience in the field of market intelligence study/ Research intelligence study/ professional services consultation (Market Research) in India. | 5 | 20 | 5 |
| | | For every additional of one year in market intelligence study/ Research intelligence study/ professional services consultation (Market Research) in India. | 3 | | |
| | | Total | | 50 | 15 |

11.4. The Technical bids must comprise of filled in Form-3 along with duly signed, stamped and properly paginated documents in an order indicated in the table below:

| Sl. No. | Basic | Specific requirements | Supporting Documents |
|---------|----------------|------------------------------------|--------------------------|
| | requirement | | |
| 1. | Registration | The bidder should be registered | -Certificate of |
| | certificate of | with appropriate authority for | incorporation/ |
| | the Agency. | not less than a period of 5 (five) | Partnership or Trust |
| | | years. | deed |
| | | | -GST registration |
| | | | certificate |
| | | | - Certificate of |
| | | | commencement of |
| | | | business (if applicable) |
| | | | -Udhyog Aadhar issued |
| | | | by MSME. |

| | Board's resolution OR Power of Attorney in the name of the person executing the bid, authorizing the signatory to commit the Bidder. | OR Power of attorney with |
|---|--|---|
| 3. Annual turnover from similar nature of work | Annual turnover generated from business of market intelligence study/ Research intelligence study/ professional services consultation (Market Research) in India at least for five years as on 31 st March 2021. (As per the last published Balance sheets), should be in INR. | audited balance sheet and profit &loss OR Certificate from the |
| 4. Technical capability | i. Annual Turnover: Annual turnover of the bidder should be at least Rs. 20 lakhs during the last three financial years. ii. Number of similar assignments completed in the past: Minimum four such similar assignments in the Sector of Pharmaceuticals, Chemical, Health, Electronics and Medical Devices must be completed. iii. Team Size: The bidder must have at least five professionals as its employees with certifications in related field (for evaluation purpose an employee with multiple certifications shall be counted as one). iv. Key professionals of the team: There must be at least one key professional in the proposed engagement team with certification(s) in related field. v. Team Leader's experience: Team leader who will be | certificates from the client. Work order Certified by the statutory auditor and Work Order and Phase Completion Certificate from the client. |

| engaged in the proposed assignment must have at least five years of experience in related field. vi. Association with an International Agency, if any. vii. Members and Strength of Economic Research Team. viii. Whether the Agency has a dedicated Market Intelligence Research Team. ix. Proportion of revenue from research and other key operational areas. x. Strong sectors of the Agency where extensive research work are being done. xi. Number of years the research team is functioning in India. xii. Whether the agency has customized research vertical. xiii. Number of sector/industry wise research projects/Study completed in the last Financial Year. | |
|--|--|
| research and other key | |
| x. Strong sectors of the Agency where extensive research | |
| xi. Number of years the research | |
| xii. Whether the agency has customized research | |
| xiii. Number of sector/industry wise research projects/Study completed in the last | |
| | |
| xiv. Presentation on Methodology & Approach: Demonstration of in-depth understanding of | |
| the proposed study requirements through the | |
| technical proposal and presentation, with detailed | |
| broken-down activities to be performed, effort estimation, | |
| timeline, manpower to be deployed etc. | |

12. Financial Bids opening, Evaluation and selection of bidder

12.1. The Financial Bids of tenderers qualifying eligibility criteria of technical evaluation i.e. Scoring 15 (score) will be opened in the presence of their representatives on **25.11.2021 by 12:00 P.M.** a duly constituted Financial

Evaluation Committee ("FEC") for evaluation. The bid should not have any alteration(s) or overwriting.

12.2. The commercial terms i.e., Professional Fee shall be on a fixed price basis. The price must include all costs, out of pocket expenses inclusive of taxes. Price variation other than applicable taxes shall not be permitted

12.3. Lowest Quoting Bidder for each study respectively will score the highest mark in financial bids as per the scoring criteria.

12.4. For every study the proposal with the highest weighted combined score (Technical Plus Financial) shall be selected (HS-1), i.e., Company which secured the highest score (HS-1) in the selection criteria (Technical and Financial evaluation) shall be selected for awarding the Study Report. In case of tie, the company having higher turnover shall be selected.

12.5. Department reserves the right that not more than three (3) studies will be awarded to one agency concurrently.

12.6. In case HS-1 bidder refuses the tender awarded or does not enter into the contract within the time stipulated by the DoP, EMD submitted by the bidder will be forfeited and their respective tender will be scrapped and the offer shall be passed on to the next highest scorer.

12.7. Enquiries made by the bidder(s) during the course of evaluation of the tender, after opening of bid, till final decision is conveyed to the bidder(s) shall not be entertained in any manner. However, the Committee/its authorized representative at DoP can make any enquiry/seek clarification from the bidders, which the bidders must furnish within the stipulated time else bid of such defaulting bidders will be rejected.

12.8. The financial bid in Form-4 for conducting Study on the given topic shall be evaluated against the criteria set forth herein below:

| Sl. No. | Financial Criteria | Max. Score |
|---------|---|------------|
| 1 | The Company quoting the lowest rate (Single rate/ Fixed Price basis) for one of the studies | 50 |
| | Total | 50 |

| The Lowest bidder will ge | t the | highest | Max | score | and | further | score | will | be |
|------------------------------|-------|---------|-----|-------|-----|---------|-------|------|----|
| calculated based on Pro rata | basis | | | | | | | | |
| | | - | 1 | | | | | | |

| | Example | |
|---------|--|------------|
| Sl. No. | Financial Criteria | Max. Score |
| 1 | The company quoting 5 lacs fee for one of the Study Report | 50 |
| 2 | The company quoting 6 lacs fee for one of the Study Report | 41.67 |
| 3 | The company quoting 7 lacs fee for one of the Study Report | 35.71 |
| | Score = (Lowest rate quoted * Max. Score) / Quoted Rate | 2 |

13. Bid validity

13.1. Ninety days from the date of opening of Bids. Bids having validity of less than Ninety days is liable for rejection.

14. Work-order and Agreement

14.1. On qualifying a bid ("Selection"), a Work Order shall be issued, in duplicate, by the DoP to the Selected Agency and the agency shall, within 7 (seven) days of the receipt of the Work Order, sign and return the duplicate copy of the Work Order in acknowledgement thereof. In the event the duplicate copy of the work order duly signed by the Successful Applicant is not received by the stipulated date, the DoP may, unless it consents to extension of time for submission thereof, appropriate the EMD of such tenderer, and the next highest-ranking tenderer may be considered. In continuation of the foregoing, selected tenderer shall have to enter into a written agreement with DoP for honouring all tender conditions and adherence to all aspects of fair-trade practices. In continuation of foregoing, DoP reserves the right to propose additional terms in the Agreement. A copy of the Agreement is attached as **Annexure-II** and incorporated for reference in this RFP.

15. Termination of contract/ work-order

15.1. DoP may, at any time, terminate the contract by giving written notice to the tenderer without any compensation, if the selected tenderer becomes bankrupt or otherwise insolvent, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to DoP.

15.2. Termination for default is said to have occurred:

15.2.1 If the bidder fails to deliver any or all of the services as specified in the work order or any extension thereof granted by DoP.

15.2.2 If the bidder fails to perform any other obligation(s) under the Agreement, RFP, Scheme or documents incidental thereto

16. Right to terminate the RFP process

16.1. DoP may terminate the RFP process at any time without assigning any reason.

16.2. DoP makes no commitments, expression or implied that this process will result in a business transaction with anyone.

16.3. This RFP is an invitation to participate, does not constitute an offer by the DoP.

17. Right to reject any or all proposals

17.1. Notwithstanding anything contained in this RFP, the DoP reserves the right to accept or reject any Proposal and to annul the Selection Process and reject all Proposals, at any time without any liability or any obligation for such acceptance, rejection, or annulment, and without assigning any reasons thereof.

17.2. DoP reserves the right to reject any Proposal if:

17.2.1. At any time, a material misrepresentation is made or discovered;

17.2.2 The agency did not provide, within the time specified by the DoP, the additional information sought for evaluation of the Proposal;

17.2.3 In case it is found during the evaluation or at any time before issue of Work Order that one or more of the eligibility conditions have not been met by the agency or the agency has made material misrepresentation or has given any materially incorrect or false information, the agency shall be disqualified forthwith along with forfeiting their EMD.

17.2.4 Failure to furnish all information required in the RFP documents or submission of a proposal not substantially responsive to the RFP documents in every respect;

17.3. The bids submitted by Fax/ E-mail etc. shall not be entertained.

17.4. Bids submitted without enclosing the EMD will be rejected.

17.5. Bids not submitted as per the specified format will be outrightly rejected.

17.6. Bids which do not qualify eligibility criteria will be rejected.

17.7. Any bid received after the last date of submission will be summarily rejected.

18. Penalty

18.1. The DoP shall reserve the right to impose penalty for delay in submission and poor quality of the report. The DoP may finalise amount of penalty up to 10% of work order value. The DoP may also reserves the right to not to release the final payment in case the report is inconclusive.

19. Terms of Payment. Payment Terms is in respect of implementation of the Study Report and subsequently release of funds by the Department.

| Instalment | Percentage of | Remarks/ Pre-requisite |
|------------|---------------|---|
| | funds | |
| | | As an advance after signing of the MoU by |
| | | both the parties concerned and after executing |
| 1 | 30 | a surety bond in the prescribed format on a Rs. |

| | | 100/- stamp paper duly signed by the obligers, | | |
|---|----|--|--|--|
| | | 2 sureties and 2 witnesses. | | |
| | | On submission of the draft report along with | | |
| 2 | 30 | the executive summary. | | |
| | | On submission and acceptance of the final | | |
| 3 | 40 | report (10 hard copies and CDs/Pen Drive) by | | |
| | | DoP. | | |
| The terms and conditions of release of payment shall be as per the scheme | | | | |
| guidelines. | | | | |

20. Rights of Department of Pharmaceuticals (DoP)

20.1. DoP reserves the right to cancel, modify or reschedule the scope of work due to any other related developments.

20.2. In case the DoP intends to conduct additional studies in addition to indicated at **Annexure-I**, the DoP may obtain sealed quotes for such studies from all the finalised agencies and award the work to lowest fixed price.

21. Disqualification

21.1. DoP may at it sole discretion and at any time, disqualify any bidder, who is found trying to influence the decision making process of this tender.

22. Subsequent assignment

22.1. Obligation to fulfil the terms of engagement/ work order lies with agency whom the contract has been awarded. The agency shall not assign or sublet the work order to any other agency, in whole or in part, to perform its obligation under the contract/ agreement, without prior written consent of DoP.

23. Dispute resolution

23.1. In the event of any dispute or difference between the parties hereto with respect to the RFP, its terms or conditions or otherwise, such disputes or differences shall be resolved amicably by mutual consultation. Failing resolution of the dispute amicably, the unresolved dispute or difference shall be referred to

arbitration under the aegis of Delhi International Arbitration Centre (DIAC), Delhi High Court Campus, New Delhi. The provisions of Arbitration and Conciliation Act, 1996 including its amendments, if any, shall be applicable to the arbitration. DIAC rules shall govern the proceedings of arbitration. The RFP shall be governed by the laws of India for the time being in force.

* * *

<u>Form 1</u>

(On Letter Head of the Agency)

To,

Shri N.K. Joshi Under Secretary Department of Pharmaceuticals Room No. 235, A-Wing, Shastri Bhawan, New Delhi-110001

Sir,

I/We, the undersigned Applicant, have read and fully understood in detail the "Request for Proposal" (RFP) for providing the Study report under Pharmaceutical Promotion and Development Scheme (PPDS).

2. Our correspondence details with regard to this RFP are:

| Sl. No. | Information | Details |
|---------|--|---------|
| 1. | Name of the Contact Person | |
| 2. | Address of the Contact Person | |
| 3. | Name, designation and contact, address of the person to whom, all references shall be made, regarding this RFP | |
| 4. | Telephone number of the Contact Person | |
| 5. | Mobile number of the Contact Person | |
| 6. | Fax number of the Contact Person | |
| 7. | Email ID of the Contact Person | |
| 8. | Corporate website URL | |

- 3. We are hereby submitting our Request for Proposal (RFP) in printed format.
- 4. We understand you are not bound to accept any proposal you receive.
- 5. We understand and agree to comply that on verification if any of the information provided here is found to be false/misleading DoP reserve the right to disqualify and terminate the work order at any point of time.
- 6. We are liable to be dismissed from the selection process or termination of the resultant contract during the project.

- 7. We hereby declare that our proposal submitted in response to this RFP is made in good faith and the information contained is true and correct to the best of our knowledge and belief. In case you require any further information in this regard, we agree to furnish the same.
- 8. We, hereby, declare that only the Agency interested for engagement is named herein and that no other persons or Agencies other than herein mentioned have any interest in this engagement and that this application is in all respect for and in good faith, without misrepresentation, collusion or fraud.

Dated this..... day of..... 20.....

Yours faithfully

Date :

Place:

(Signature of the authorized

signatory)

(Name) ______ (Designation) ______

(corporate Seal) Business Address:

Form 2

Details of the Bidder

| S1. | Information sought | Details to be |
|-----|---|---------------|
| No. | C | furnished |
| 1 | Name and address of the bidding company | |
| | Incorporation status of the firm | |
| | (Public limited/private limited, etc.) | |
| 3 | Year of establishment | |
| 4 | Date of registration | |
| 5 | Registration of Companies (RoC) | |
| | reference no. | |
| 6 | Details of company registration | |
| | Details of registration with appropriate authorities for service tax | |
| 8 | Details related to Five years of Experience in the field of in the business | |
| | of market intelligence study/ consultation (Market Research) | |
| | Name, address, email, phone nos. and mobile number of the contact | |
| | person | |
| 10 | Proportion of revenue from research and other key operational areas | |
| 11 | Team Size: The bidder must have at least five professionals as its | |
| | employees with certifications in related field (for evaluation purpose | |
| | an employee with multiple certifications shall be counted as one). | |
| 12 | Key professionals of the team: There must be at least one key | |
| | professional in the proposed engagement team with certification(s) in | |
| | related field. Association with an International Agency, if any. | |
| | Members and Strength of Economic Research Team. Whether the | |
| | Agency has a dedicated Market Intelligence Research Team. | |
| 13 | Proportion of revenue from research and other key operational areas. | |
| | Strong sectors of the Agency where extensive research work are | |
| | being done. | |
| | Number of years the research team is functioning in India. Whether | |
| | the agency has customized research vertical. Number of | |
| | sector/industry wise research projects/Study completed in the last | |
| 1.7 | Financial Year. | |
| | Presentation on Methodology & Approach: Demonstration of in- | |
| | depth understanding of the proposed study requirements through the | |
| | technical proposal and presentation, with detailed broken-down | |
| | activities to be performed, effort estimation, timeline, manpower to | |
| | be deployed etc. | |

<u>Form 3</u>

Compliance sheet for Technical Evaluation

:

:

Name of the Agency and registered office :

Year of establishment

Telephone No

| Sl. No. | Basic requirement | Documents required | Provided (Yes/No) | Reference & page number |
|---------|--|--|----------------------|-------------------------------|
| 1. 1. | Registration certificate of the Agency | -Certificate of incorporation/ Partnership or Trust deed -GST registration certificate -Certificate of commencement of business (if applicable) -Udhyog Aadhar issued by MSME. | | |
| 2 | / Power of attorney in | Board's resolution; OR Power of attorney with appropriate supporting documents | | |
| 3 | Annual turnover | Extracts from the audited balance sheet and profit &loss OR Certificate by the statutory auditor | | |
| 4 | Technical capability | Completion certificates from the client Work order Certified by the statutory auditor and Work Order and Study phase Completion Certificate by the client in the field of Pharmaceuticals, Chemicals, Health, Electronics and Medical Devices. Bidder must have Five years of Experience in the field of Market intelligence study/ Research intelligence study/ professional services consultation (Market Research) in India | | |

Form 4

Financial Bid Quotation format (Financial Evaluation)

| S1. | Name of Study | Name of the | Single | Price |
|-----|---------------|-------------|---------------------|-------|
| No. | | Agency | Single Quotation | (In |
| | | | Rs.) | |
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |

*Single Price Quotation for each study, i.e., to be submitted to DoP for each study. **Inclusive of all applicable taxes and expenses**.

It is to certify that the above quotation is submitted after fully understanding all the terms and conditions of the RFP and scheme guidelines.

For and on behalf of <<Legal name of bidding entity>> <<Authorised Signatory's signature affixed with corporate seal>> Name: <<Insert Name of Contact>> Title: <<Insert Name of Contact>> Signature: <<Insert Signature>>

Annexure-I

Topics with terms and reference and Scope of the proposed studies

<u>Study No.1:</u> To study the impact of DPCO 2013 on the prices of Cardiac stents, Knee implants and six medical devices viz. Oxygen Concentrators, Pulse Oximeter, Glucometer, BP Monitor, Nebulizer and Digital Thermometer on the industry and consumers in terms of availability and affordability.

Objective of the study: To assess the impact of price control on medical devices and equipment on the industry and consumers in terms of availability and affordability.

Scope of the study:

- a. The study shall be on a pan India level and shall cover both domestically manufactured and imported products.
- b. Impact on availability in all geographical regions, urban/ rural, public/ private health systems and through all channels like pharmacies/ hospitals etc.
- c. Impact on affordability on devices as to impact on out-of-pocket expenses for consumers, especially for vulnerable sections
- d. Impact of price control on medical devices and equipment on the domestic industry and imports
- e. The study shall cover the impact on product quality, business profitability/sustainability, market competition, further research and development etc.
- f. Strategies adopted by various business segments in response to DPCO, 2013 or notifications issued thereunder and impact thereof.

Methodology of the study:

- a. Primary data collection through various research instruments like questionnaire, Focus group discussion, field visits, interview etc.
- b. Collection of secondary data, literature review etc.
- c. Data analysis, data correlation and validation, using statistical tools.
- d. The study shall cover at least 50 districts and 20 states/ UTs. Further, it shall cover at least 10,000 respondents, out of which 25% shall be Rural.
- e. The study shall also cover impact on MSME sector too.

Time frame to complete study: Four months

<u>Study No. 2</u>: Assessment of procurement of medical devices in the public sector (Central Government)

Terms of Reference:

- a. Evaluating the procurement of medical devices by Central Government procuring entities.
- b. Assessment of procurement from domestic manufacturers done by the procuring entities.
- c. Provide recommendations regarding the medical devices for which the domestic value addition is less than 25% and ways to improve the same

Scope of Work:

- a. Database required in study will cover following medical device segments: Electronics equipment, Implants, Surgical instruments, IVD reagents and Consumables & Disposables.
- b. Quantifying the procurement of medical devices procured by the various Ministries/Departments/Organisations under the Central Govt. in last five years
- c. Segregation of such procurement into various categories as mentioned above
- d. Segregation of such procurement into sourcing done from domestic manufacturers and foreign manufacturers.
- e. Assessment and Quantification of AMC contracts for maintenance of such procured equipment.

Time frame of the study: Four months

<u>Study No. 3</u>: Survey of Medical Devices Clusters

Terms of Reference:

- a. Evaluating contribution of Medical Devices clusters to overall production, supplies and exports
- b. Assessment of infrastructure and logistics framework and suggest improvements
- c. Provide recommendations to boost efficiency and cost competitiveness of clusters.

Scope of study:

- a. Diagnosis of Medical Devices Clusters of the Country w.r.t their geographical spread.
- b. Cluster-wise and aggregate analysis w.r.t.:
 - Assessment of common facilities viz., testing & prototyping infrastructure, warehousing infrastructure, accreditation labs etc.

- Size including contribution to domestic output including production as well as exports at product and aggregate level
- Assessment of Government interventions under various Schemes of State Governments and Central Government
- Recommendations to promote cost competitiveness and boost infrastructure for each cluster

Time frame of the study: Four months

<u>Study No. 4</u>: Survey of Pharma Clusters

Terms of Reference:

- a. Evaluating contribution of Pharma clusters to overall production, supplies and exports
- b. Assessment of infrastructure and logistics framework and suggest improvements
- c. Provide recommendations to boost efficiency and cost competitiveness of clusters

Scope of study:

- a. Diagnosis of Pharma Clusters of the Country w.r.t their geographical spread
- b. Cluster-wise and aggregate analysis w.r.t.:
 - Size including contribution to domestic output including production as well as exports at product and aggregate level
 - Assessment of common facilities viz., common effluent treatment plants, accreditation labs, etc.
 - Assessment of Government interventions under various Schemes of State Governments and Central Government
 - Recommendations to promote cost competitiveness and boost infrastructure for each cluster

Time frame of the study: Four months

<u>Study No. 5</u>: Uniform Code for Pharmaceutical Marketing Practices - A Study of Indian experience vis- a- vis Best Global Practices

Terms of Reference:

- a. Performance evaluation of the Code, i.e., assess the current extent of implementation of the Code and identify challenges therein.
- b. Evaluate global best practices and their empirical efficacy in achieving the desired outcomes
- c. In the above context, recommend steps for better implementation of UCPMP to achieve more efficient outcomes

Scope of study:

- a. Region-wise, scale-wise, major-operations wise and pan-India analysis of Pharmaceutical firms and recommendations w.r.t.:
 - i. Importance of UCPMP in the context of the Pharma industry operations in its current nature.
 - ii. Review of Implementation of UCPMP in India
 - iii. Effectiveness in achieving laid down outcomes
 - iv. Challenges in effective implementation of UCPMP, if any
 - v. Evaluation of global best practices and their empirical efficacy in achieving the desired outcomes
 - vi. Evaluating the requirement and implications of making the Code mandatory.
 - vii. Evaluate the case of a voluntary code in its extant form as compared to a mandatory code, in view of the above.

Time frame of the study: Six months

<u>Study No. 6</u>: An Analysis on leveraging the patent cliff, with drug sales worth USD 251 billion going off-patent

Terms of Reference:

- a. Identification of drugs that may be leveraged in the context of the patent cliff
- b. Identification of generic-counterparts thereof available in the Indian market.
- c. Assessment of market potential in this regard.

Background:

In the year 2021, the pharmaceutical sector in India will undergo landmark changes as a number of drugs are expected to go off-patent and make entry in the market as generic products. Expiry of patents is very promising for the generic drug market as it is expected to expand and grow further with inclusion of these new drugs. With ongoing developments, India has started focusing on self-reliance at a large scale. Hence it is imperative to identify these drugs beforehand, draft and implement strategies which help in their timely entry into the market by promoting generic drug manufacturing.

Scope of the study

- a. Identification of Drugs:
 - Identification of drugs which will go off-patent in the FY 2021 2022.
 - Prepare a prioritization matrix for drugs based on chronology of patent expiry and importance to be rolled out as generic product.
- b. Assessment of -
 - Patent Expiry of Blockbuster Drugs
 - Significant Price Differential between Generics and Innovator Drugs
 - Savings for the Government and Third-Party Payers
 - Incentives for Dispensing and Prescribing Generic Drugs
- c. Recommending actions and roadmap for implementation w.r.t. each stakeholder to actualise the potential identified.

Time frame of the study: Six months

<u>Study No. 7</u>: Survey for novel / innovative and cost-effective technologies for route of synthesis to decrease cost of production of APIs which are currently being imported to reduce Import dependency.

Terms of Reference:

- a. Assessment of current development as well as adoption of technology as compared to global counterparts as well as global best practices
- b. Explore opportunities to fill the technology gap, if any, along with recent developments by DSIR in this regard.
- c. Means to facilitate vibrant and robust industry-academia engagement and networking for development and commercialization of API related technologies.

Background

Indian pharmaceutical sector's growing dependence on import is quite evident. High reliance on one country poses a significant risk of supply shortage. In order to remain self-reliant and competitive it is imperative for India to build an ecosystem to support the growth of domestic bulk drug industry.

Scope of study:

- a. Review of globally available novel / innovative and cost-effective technologies for route of synthesis to decrease domestic cost of production of APIs which are currently being imported tPo
- b. Identify issues and challenges of cost-effective technologies
- c. Survey of ongoing research in API manufacturing technologies across public and private sector in India.
- d. Policy recommendations to promote and incentivize novel / innovative and cost-effective technologies for route of synthesis to decrease cost of production of APIs
- e. Recommendations to establish vibrant and close industry-academia engagement and networking for development and commercialization of API related technologies.

Time frame of the study: Four months

<u>Study No. 9</u>: Strategy for Leveraging ASEAN FTA and trade potential with the Middle East Countries for Pharma Sector in India

Terms of Reference:

- a. Assess the trends in trade flows with ASEAN FTA and Middle East countries thus far (both in relative terms vis-à-vis trade with rest of the world as well as absolute terms) along with export potential
- b. Identify challenges of market access including non-tariff barriers, regulatory issues, etc.
- c. Recommend strategies to leverage the ASEAN FTA and potential trade with Middle East Countries in fuller measure keeping in view the strengths of the Indian Industry

Background

Trade in goods agreement with ASEAN can benefit Indian pharma companies to leverage such markets with customized therapeutic offerings. Regions working towards reducing the healthcare costs and with the upcoming patent cliff opportunity across formulations both chemical and biologics, could boost growth, create newer export corridors for Indian companies. With its strong vaccine manufacturing capability and capacity, India will play a critical role in meeting the demand of COVID-19 vaccines with ASEAN, in addition to availability of essential drugs given the opportunities to exploit the advantage of Indian proximity to ASEAN as compared to their other major trading partners.

Scope of study:

- a. Assessment of trade flows and potential with ASEAN FTA and the Middle East Countries for Pharma Sector in India
- b. To analyse the growth outlook and development challenges for ASEAN, Middle East Countries and India in the COVID-19 period.
- c. ASEAN, Middle East Countries-India trade relations: Emerging trends, challenges, and opportunities including market access and regulatory issues
- d. To understand the Trends in India's Trade and Investment with ASEAN, Middle East Countries with respect to Pharma Sector.
- e. SWOT Analysis
- f. Recommend strategies to leverage the ASEAN FTA and potential trade with Middle East Countries in fuller measure keeping in view the strengths of the Indian Industry across all product categories

Time frame of the study: Six months

Annexure-II

AGREEMENT BETWEEN DEPARTMENT OF PHARMACEUTICALS, GOVERNMENT OF INDIA AND THE AGENCY OFFERING TO CONDUCT STUDY UNDER THE PHARMACEUTICAL PROMOTION AND DEVELOPMENT SCHEME.

This Agreement for conducting Study ("Agreement") is entered into this _____th day of _____ 2021 by and between the parties:

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, functioning at its premises at Shastri Bhawan New Delhi-110001, represented by authorized by the_____, (____) Department of Pharmaceuticals (hereinafter referred to as the "DoP" which expression shall, unless it be repugnant to the subject or context thereof, include its successors and permitted assigns);

AND

M/s., ______ (hereinafter referred to as "Agency") the expression including successor, legal heirs and permitted assigns as party of other part.

DoP and the Agency are hereinafter individually referred to as "Party" and collectively as "Parties".

WHEREAS, the objective of the Pharmaceutical Promotion and Development Scheme (the "Scheme") is to promote, develop and to encourage pharmaceutical sector by extending financial support for conduct of seminars, conferences, exhibitions, studies, consultancies etc. for facilitating growth of Pharmaceuticals and medical devices sector.

WHEREAS, sealed quotations are invited by the DoP under the two-stage system viz. (i) Technical Bid; and (ii) Financial Bid, for Selection of empanelled Agency with Government of India for conducting Study of _____.

WHEREAS, M/s. _____ has submitted its bid vide letter no. _____ dated _____ 2021, offering its services in terms of DoP RFP No. _____ dated _____ 2021 representing that it possesses the required means, skills, know-how, expertise and competence to accomplish the task. WHEREAS, based on the evaluation and recommendation of the Evaluation Committee[s], DoP has approved the bid of M/s. ______ vide its letter No. ______ dated _____ 2021 and offered to engage it as an Agency for offering necessary services as outlined in the RFP.

WHEREAS, the Agency declares its commitment to the spirit of the Scheme and the objectives it seeks to achieve, as set out in sub para [3] of Para-1 of the Scheme.

WHEREAS, it is reasonable, prudent and necessary for the parties to understand their obligations.

NOW, THEREFORE, in consideration of the mutual promises, covenants, and considerations herein contained and for the benefit of the pharma industry, DoP, and the Agency hereby enter into this AGREEMENT.

Article-I.

Engagement

1.1 The term of this Agreement shall be effective from the date first set forth above through, the date scheduled for submission of the study report ("Term"). The Agency shall submit a comprehensive report on or before 20.

Article-II.

Payments to the Agency

2.1 Upon signing this Agreement by the parties, DoP shall pay to the Agency, an Agreement not exceeding the sum quoted in the RFP and in a manner established in the Scheme. Payment schedule is comprehensive and described below:

2.1.1 30 % will be released as advance after signing of the AGREEMENT by both the parties concerned and after executing a surety bond in the prescribed format on a Rs. 100/- stamp paper duly signed by the obligers, 2 sureties and 2 witnesses;

2.1.2 30 % will be released on submission of the draft report along with Agency summary.

2.1.3 40 % will be released on submission and acceptance of the final report (10 hard copies and CDs) by DoP.

2.2 The Parties understand that the cost of accomplishing the Study may increase at any time from the Agreement set out in the RFP and/or the approval by DoP. Notwithstanding this potential variation, the DoP's liability to pay shall base on Agreement mentioned in the RfP and any increase remains the sole responsibility of the Agency.

2.3 If the DoP does not pay within the time limits, if any, for payment, the Agency is not entitled to late-payment interest.

2.4 Costs of the payment transfers shall be borne by the Agency.

2.5 The Agency shall not assign any of its claims for payment against the DoP to any third party.

Article-III. <u>Responsibilities of the Agency</u>

3.1 In connection with the _____ (Name of the Study), the Agency understands, and undertakes to:

| a | |
|---------------------|--|
| b | |
| c | |
| d. | (Description of activities to be performed |
| against each study) | |

Article-IV.

Confidential Information

4.1 From time to time during the Term, either Party (as the "Disclosing Party") may disclose or make available to the other Party (as the "Receiving Party") information about its business affairs, goods and services (including any Forecasts), confidential information and materials comprising or trade secrets, third-party confidential information and other sensitive or proprietary information. Such information, as well as other information that by its nature can reasonably be expected to be considered confidential, whether orally or in written, electronic or other form or media, and whether or not marked, designated or otherwise identified as "confidential" constitutes "Confidential Information" hereunder.

4.2 Confidential Information does not include information that at the time of disclosure: (a) is or becomes generally available to and known by the public; (b) is or becomes available to the Receiving Party on a non-confidential basis from a third-party source, provided that such third party is not and was not prohibited from disclosing such Confidential Information; (c) was known by or in the possession of the Receiving Party or its Representatives prior to being disclosed by or on behalf of the Disclosing Party; (d) was or is independently developed by the Receiving Party without reference

to or use of, in whole or in part, any of the Disclosing Party's Confidential Information; or (e) is required to be disclosed pursuant to applicable Law.

4.3 The Receiving Party shall, from disclosure of any Confidential Information: (a) protect and safeguard the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care as the Receiving Party would protect its own Confidential Information, but in no event with less than a commercially reasonable degree of care; (b) not use the Disclosing Party's Confidential Information, or permit it to be accessed or used, for any purpose other than to exercise its rights or perform its obligations under this Agreement; and (c) not disclose any such Confidential Information to any Person, except to the Receiving Party's Representatives who need to know the Confidential Information to assist the Receiving Party, or act on its behalf, to exercise its rights or perform its obligations under this obligations under this Agreement. The Receiving Party shall be responsible for any breach of this para caused by any of its Representatives.

4.4 On the expiration or earlier termination of this Agreement or at any time during or after the Term, at the Disclosing Party's written request, the Receiving Party and its Representatives shall, promptly return or permanently destroy all Confidential Information and copies thereof that it has received under this Agreement, except were prohibited by applicable Law.

4.5 The Parties acknowledge and agree that: (a) a breach or threatened breach by a Party of any of its obligations under Para-4.3 would give rise to irreparable harm to the other Party for which monetary damages would not be an adequate remedy and (b) in the event of a breach or a threatened breach by a Party of any such obligations, the Parties shall, in addition to any and all other rights and remedies that may be available to a Party at law, at equity or otherwise in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance and any other relief that may be available from a court or an arbitral tribunal or a tribunal or a nappropriate machinery of dispute resolution of competent jurisdiction, without any requirement to prove actual damages.

4.6 Each party shall notify its officers, agents, employees, attorneys, and any other person in active concert with Scheme activities (particularly the study undertaken) of the obligations, duties, and responsibilities imposed on them by this Agreement.

Article-V. Anti-corruption

5.1 With the aim of achieving a balance between the interest of Parties to avoid corruption the Agency agree and undertakes that, at all times in connection with and throughout the term of the Agreement and thereafter, it will prohibit the following practices, in relation with a public official at the international, national or local level, an official or candidate to political office, and an officer, employee or a professional engaged whole time or fixed term basis of DoP, whether these practices are engaged in directly or indirectly, including through third parties:

- a. <u>Bribery</u> is the offering, promising, giving, authorizing or accepting of any undue pecuniary or other advantage to, by or for any of the persons listed above or for anyone else in order to obtain or retain a business or other improper advantage, e.g. in connection with public or private procurement contract, grants, regulatory permits, taxation, customs, judicial and legislative proceedings. Bribery often includes: (i) kicking back a portion of a contract payment to government or party officials or to employees of the other contracting Party, their close relatives, friends or business partners or (ii) using intermediaries such as agents, subcontractors, consultants or other third parties, to channel payments to government or party officials, or to employees of the other contracting Party, their relatives, friends or business partners.
- b. <u>Extortion or Solicitation</u> is the demanding of a bribe, whether or not coupled with a threat if the demand is refused. Agency will oppose any attempt of Extortion or Solicitation and is encouraged to report such attempts through available formal reporting mechanisms.
- c. <u>Trading in Influence</u> is the offering or Solicitation of an undue advantage in order to exert an improper, real, or supposed influence with a view of obtaining from a public official an undue advantage for the original instigator of the act or for any other person.
- d. <u>Laundering the proceeds</u> of the Corrupt Practices mentioned above is the concealing or disguising the illicit origin, source, location, disposition, movement or ownership of property, knowing that such property is the proceeds of crime.

Article-VI.

Other Provisions

6.1 Indemnity and Hold Harmless. The Agency assumes any and all liability for any damages, injury and claims related to the Study. The Agency agrees to indemnify and hold the DoP and its Staff, and Officers harmless from and against any and all loss, damages, claims, lawsuits, actions, liability, debts, attorneys' fees, costs, litigation expenses, interest, late charges, demands, suits and judgments arising out of or relating to the Study. All indemnities survive termination of this Agreement.

6.2 Force majeure. It is mutually understood that inability to comply with any term of this Agreement or any obligation attached hereto shall be excused if and to the extent caused by a *force majeure* event, which includes war (whether declared or not), hostilities, invasion, act of foreign enemies, extensive military mobilization; civil war, riot, rebellion and revolution, military or usurped power, insurrection, act of terrorism, sabotage or piracy; currency and trade restriction, embargo, sanction; act of authority whether lawful or unlawful, compliance with any law or governmental order, expropriation, seizure of works, requisition, nationalization; plague, epidemic, natural disaster or extreme natural event; explosion, fire, destruction of equipment, prolonged break-down of transport, telecommunication, information system or energy; or any other similar cause(s) beyond the reasonable control of the party, and shall release both parties from their future respective obligations under this Agreement, provided that (i) written notice setting forth in detail the nature of any delay or suspension is given by such party to the other party within 48 hours of the scheduled performance; and (ii) such party shall use all commercially reasonable efforts to minimize the extent of such force majeure delay. Where an affected party terminates the Agreement, by reason of anything done by another party in the performance of the Agreement, derived a benefit before the *force majeure* event, the party deriving such a benefit shall pay to the other party a sum of money equivalent to the value of such benefit.

6.3 Relationship. The parties agree that nothing in this Agreement shall constitute a partnership, employer/employee relationship or joint venture arrangement between them.

6.4 Entire Agreement/ Authority to Enter Agreement. This Agreement contains the full and complete understanding of the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous agreements, representations, and understandings, whether oral or written, with respect to the subject matter hereof. Any amendments to the Agreement must be provided in writing and executed by authorized representatives of both parties. The person signing this Agreement on behalf of Agency warrants that he is authorized agent and, as such, has the right to enter into this Agreement and that no other authorization is necessary. Each amendment or counterpart executed simultaneously, shall be deemed to be an original having identical legal effect.

6.5 Further Assurances. Upon the request of DoP, the Agency will deliver such further documents, execute and deliver such instruments, undertakings, memoranda or perform such further acts as may be necessary, desirable or proper to carry out more effectively the purpose of this Agreement.

6.6 Severability. If any clause or part thereof in this Agreement becomes invalid or is rendered unenforceable or prohibited then such clause(s), or part thereof, will be severable

without invalidating or affecting the validity of the remainder of this Agreement, which shall continue in full force and effect.

6.7 Interpretation. In this Agreement, unless the context otherwise requires: (a) headings are for convenience only and do not affect interpretation; (b) the singular includes the plural and *vice versa*; and (c) a gender includes every gender.

6.8 Independent Legal Advice. The DoP has recommended to the Agency that it obtain independent legal advice prior to signing this Agreement. The Agency acknowledges that it has received independent legal advice or has waived the opportunity to do so and have elected to proceed without benefit of same.

6.9 Time is of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

6.10 Binding on Successors. This Agreement shall be binding upon the parties hereto and their respective heirs, executors, administrators, successors, personal representatives, and permitted assigns.

6.11 Assignments. The Services to be performed by Agency hereunder are professional in nature, and DoP has engaged Agency as a result of Agency's expertise relating to such Services. Agency, therefore, acknowledge that it will not assign, sell, transfer, delegate or otherwise dispose of this Agreement or any right, duty or obligation under this Agreement without the prior written consent of the DoP, which consent shall be within the sole and absolute discretion of DoP.

Article-VII. Termination

7.1 Agency may terminate the Study or any part of it, if exceptional circumstances make such implementation impossible or excessively difficult, in particular in the event of *force majeure*.

7.2 This Agreement may be terminated by DoP (i) upon breach by the Agency of any of the material provisions and/or conditions of this Agreement, which breach remains uncured for Seven (07) days from the date of receipt of written notice from the non-breaching party to the other party specifying such breach; or (ii) if it suspects substantial errors, irregularities, or fraud committed by the Agency in the seeking approval or while implementing the Study. Upon termination, DoP may, in addition to any of its other rights under this Agreement or applicable Law, without any liability of DoP to the Agency, at its election, recover any and all damages (including direct, indirect, incidental and

consequential damages), costs (including attorneys' and other professionals' fees and costs), expenses and losses paid/incurred by DoP, for any breach of this Agreement by Agency.

7.3 This Agreement may be terminated by the mutual consent of the parties.

Article-VIII. Settlement of Disputes

8.1 The parties hereto recognize and unconditionally agrees that any and all disputes arising out of or in connection with the present Agreement, shall be submitted to the Delhi International Arbitration Centre (DIAC) and shall be finally settled under the Rules of Arbitration of the DIAC by binding decision of sole arbitrator appointed in accordance with the said Rules. If a party has any questions about the DIAC, or wishes to obtain a copy of the DIAC's rules and forms, such party may visit the DIAC's website at www.dacdelhi.org. The arbitration shall be held in New Delhi, India. If any part of this arbitration provision is deemed to be invalid, unenforceable or illegal, or otherwise conflicts with the rules of DIAC, then the balance of this arbitration provision shall remain in effect and shall be construed in accordance with its terms as if the invalid, unenforceable, illegal or conflicting provision were not contained herein. Each party hereby waives any and all rights and benefits which it might otherwise have or be entitled to under Indian law(s) to litigate any such dispute in court, it being the intention of the parties to arbitrate all such disputes.

Article-IX. Notices

9.1 All notices, requests, consents, claims, demands, waivers and other communications under this Agreement (each, a "Notice") must be in writing, and addressed to the other Party at its address set forth below (or to such other address that the receiving Party may designate from time to time in accordance with this Article). All Notices must be delivered by personal delivery, courier, post, or registered e-mail. Except as otherwise provided in this Agreement, a Notice is effective only (a) on receipt by the receiving Party, and (b) if the Party giving the Notice has complied with the requirements of this Article.

a. DoP's authorized representative for the purposes of administration of this Agreement is ______ or successor Phone-______; Email: ______. b. Agency's authorized representative for the purposes of administration of this _____ or successor. Agreement is Phone-; Email:

Article-IX. **Original Work**

10.1 Agency agrees that Agency shall not include any material owned by a third party in any written, copyrightable or patentable material furnished or delivered by Agency under this Agreement without the unconditional written consent of the owner of such intellectual property rights.

10.2 Agency also agrees that all work (or tangible expression of an idea) that Agency creates or contributes to DoP in the course of studying the given area will be created solely by the Agency, will be original, and will be free of any third party claims or interests. Agency further agrees that contents in the Study made by Agency under this Agreement shall be the Agency's original work created during the term of this Agreement.

10.3 The Agency acknowledges that Intellectual Property rights that he created as an Agency of the DoP are solely owned by the DoP.

IN WITNESS WHEREOF, the parties hereto, through their duly authorized officers, have executed this Agreement in duplicate original as of the effective date above written.

Department of Pharmaceuticals (DoP)

Name: Designation:

| M/s |
|--------------|
| |
| Name: |
| Designation: |

Witness:

| 1 | 1 | |
|---|-------|---|
| 2 | 2. | _ |
| | * * * | |