EOI No.

Expression of Interest (EoI)

Indian Council of Medical Research, New Delhi Invites EoI for

Transfer of Technology for the production of Bacillus thuringiensis var. israelensis (VCRC B17) useful for the control of mosquitoes and black flies

Indian Council of Medical Research

(Department of Health Research, GoI) V. Ramalingaswami Bhawan, P.O. Box No. 4911, Ansari Nagar, New Delhi - 110029, India

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Letter of Invitation

1. INVITATION OF EXPRESSION OF INTEREST

Indian Council of Medical Research, New Delhi, invites Expression of Interest (EoI) through email from experienced manufacturer of biopesticides for the 'Transfer of Technology for the production of *Bacillus thuringiensis* var. *israelensis* (VCRC B17), useful in the control of mosquitoes and black flies, for its manufacturing/commercialization etc.

The EoI Document containing the details of qualification criteria, submission details, brief objective & scope of work and evaluation criteria etc. can be downloaded from the ICMR website (https://www.icmr.gov.in) (https://main.icmr.nic.in)

The schedule for the Proponents is as under:

EoI Document Number	ICMR/EoI/Bti VCRC B17/2022dated
Date of Publication	Date:

Note: The EoI may be submitted through email to <u>jitendra.narayan@gov.in</u>. Shortlisted firm(s)/organization(s) shall only be contacted for the further process of finalization of agreement.

ICMR reserves the right to cancel this EoI and/ or invite a fresh with or without amendments, without liability or any obligation for such EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EOI, as may be desired by the competent authority at ICMR and duly notified on its website.

2. Background

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address the growing demands of scientific advances in biomedical research on the one hand and to the need of finding practical solutions to the health problems of the country, on the other.

ICMR-Vector Control Research Centre (ICMR-VCRC), Puducherry, one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi had indigenously isolated a strain of *Bacillus thuringiensis* var. *israelensis* (*Bti*VCRC B17) useful in the control of mosquitoes and black flies. This strain has very high larvicidal activity against mosquito species belonging to *Culex*, *Anopheles* and *Aedes*, as assessed by the Institute Pasteur, Paris and designated as 'Indian standard strain' by the Central Insecticide Board (CIB). The isolate was further characterized by sequencing its toxin genes. A simple and low-cost pilot-scale fermentation technology for the production of this bacterium, using locally available raw materials has been developed. Two formulations viz., aqueous suspension (AS 5.0%) and water dispersible powder (WP) formulations of the biolarvicide have been developed. The formulations have been tested, both in the laboratory and under field conditions in different

climatic conditions, extensively and found to be highly effective in controlling the larvae of disease and nuisance causing mosquitoes. The biolarvicide was found to be safe against honey bees, silk worms, mammals and also non-target organisms occurring in the mosquito breeding habitats.

ICMR reserves all the Intellectual Property Rights and Commercialization Rights of the said TECHNOLOGY. ICMR is lawfully entitled to enter into any form of non-exclusive agreements with experienced manufacturers through defined agreement for manufacturing activities using *Bti* VCRC B17strain for the development biolarvicide formulations, hereinafter referred to as the 'Product'.

3. Objective

To make available the 'Technology for the production of *Bacillus thuringiensis* var. *israelensis* (*Bti* VCRC B17), useful in the control of mosquitoes and black flies, for manufacturing and marketing activities'.

4. Broad Scope of Work

- i. ICMR is willing to transfer the said technology to the manufacturer on an **Upfront and Royalty** basis on fixed-term contract conditions for manufacturing and marketing of biolarvicide formulation using the characterized *Bti* VCRC B17strain. The Upfront fees for the Technology shall be determined by a Committee constituted by ICMR experts on the basis of Technology Readiness Level (TRL), Technology Valuation etc.
- ii. The firm(s)/organization(s) would be granted rights to undertake manufacture, sell, and commercialize the end products viz., aforesaid **formulations of** *Bti* **VCRC B17 strain**.
- iii. The Agreement, following EoI is proposed to be executed on "Non-Exclusive" basis with single/multiple firms, due to the extensive demand for *Bti* based biolarvicides.
- iv. ICMR-Vector Control Research Centre (ICMR-VCRC), Puducherry has in its possession of *Bacillus thuringiensis* var. *israelensis* (*Bti*VCRC B17) strain, useful in the control of mosquitoes and black flies, which can be used for manufacturing and marketing activities. ICMR-VCRC has expertise in various techniques, methods and information relating to these strains, productionand quality control of the Product. ICMR-VCRC will provide expert guidance & technical support on the production of the product, in all phases.
- v. The process developed is owned by ICMR and holds the IP, which shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents; and shall include without limitation, the Technology, Licensed Patents and Licensed Trademarks developed/ created pursuant to this EoI through ICMR support.

5. Intellectual Property Rights

ICMR-Vector Control Research Centre (VCRC), Puducherry, one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi, has indigenously isolated a strain of *Bacillus thuringiensis* var. *israelensis* (*Bti* VCRC B17) and developed formulations useful in the control of mosquitoes and blackflies, and is the owner of the said TECHNOLOGY, including any underlying Intellectual Property(ies) and Commercialization rights. ICMR legally possess the rights and authority to retain full or part of the 'TECHNOLOGY' by itself or to assign at its discretion full or part of the TECHNOLOGY including any patent(s) or intellectual property rights(s) or the invention(s), and/or ICMR is lawfully entitled to enter into any form of non-exclusive license agreements with selected biolarvicide manufacturer(s) including transfer of the TECHNOLOGY through suitable agreement.

6. Revenue upon Technology Rights/Royalty Payouts

Interested companies/manufacturers with demonstrated capabilities and appropriate facilities in biolarvicide manufacturing are invited to obtain the license for the 'Technology for the production of *Bacillus thuringiensis* var. *israelensis* (*Bti* VCRC B17) strain useful in the control of mosquitoes and black flies' on conditions set by ICMR.

The manufacturers/companies interested in obtaining the license may quote an upfront licensing fee (INR) and **Royalty** not less than 5% (five percent) on **Net Sales** of the ENDPRODUCT, GST shall be applicable over and above the Net sales, (currently @18%) which is subjected to change as per GoI rules/amendments from time to time on half yearly basis as entered in the books of account maintained by Company/Manufacturer, up to 31st March and up to 30th September respectively every year regularly and punctually and in any event not later than the last day of April and last day of October immediately following in every such year provided that the liability of the Company/Manufacturer to pay royalty shall accrue upon the commencement of the commercial sale of the Product ("**Royalty**") manufactured at the plant, as per the terms of ICMR-Technology Transfer and Revenue Sharing Guidelines 2021 and as per the amendments approved by the competent authority from time to time. If the Licensee intends to sell the product in foreign countries, 1-2% higher royalty rate on Net Sales of the product sold shall be applicable as per the ICMR guidelines on technology transfer and revenue sharing 2021.

In the event of default in payment of royalty as above, interest @ 12% (twelve percent) per annum on the Royalty due shall be charged for the first six months. If default persists for more than six months interest at a similar rate will be charged on the accrued interest also from the due dates of payments till the realization/recovery of such amounts by the ICMR. Taxes and levies, as made applicable by the Government, shall be charged at the time of payments made to ICMR over and above the payments that shall be applicable as per terms of the specified license Agreement to be executed with selected companies.

"NET SALES" shall mean Revenue from sales of goods or services by all Licensees/Sublicensee(s) based on the net sales realization from operations, net of discounts, and indirect taxes, as defined by the Cost Accounting Standards – 24 (CAS-24) and duly certified by the Chartered Accountant.

7. Validity of contract

 An Agreement shall be executed with Company/Manufacturer to decide conditions for execution of this collaborative activity. The Agreement shall have a defined time line, and financial term for licensing which will be decided mutually by both the parties, considering the R&D requirements for product development.

ii. The Agreement shall be valid from the EFFECTIVE DATE and subject to covenants and conditions herein contained and shall remain in force for a specific period which shall not be less than twenty (20) years or shall be decided mutually with the approval of competent authority, commencing from the accrual of Company's obligation to pay **Royalty** to ICMR, after the commercialization of the Product (the "Term"). After the end of LICENSE term, the product will be royalty free. However, the LICENCE fees will be charged based on the current valuation of the technology at that point in time.

8. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, the scope of work for execution & requirements with respect to technical/financial capabilities for acceptance and submission of documents for verification by ICMR.

Documents to be furnished are:

- i. Authorization Letter (Format -1)
- ii. Declaration Expression of Interest (Format -2)
- iii. Undertaking with regard to Blacklisting (Format-3)
- iv. Undertaking with regard to laboratory facilities (Format -4)
- v. Undertaking with regard to Non-Litigation (Format -5)
- vi. Production Capacity Undertaking (Format-6)
- vii. Royalty Offer (Format-7)
- viii. EOI document with each page duly stamped and signed by the Authorized signatory.
- ix. Supporting documents, as mentioned in Format-2
- x. MSME Certificate (if applicable)
- xi. Concept note on business plan
- xii. Any other information which proponent may like to provide.
- xiii. ROC's certificate

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgment in evaluation.

9. Rejection Criteria

The application is liable to be rejected if:

- The proposal is not submitted as per the requirements indicated in the EOI.
- Not in the prescribed format.
- Not properly stamped and signed as per requirements.
- Received after the expiry of due date and time.
- All relevant supporting documents are not furnished with the Pre-Qualification criteria.
- The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.

10. Evaluation Methodology

Screening of EOIs shall be carried out as per Pre-Qualification criteria mentioned in the EOI document and based on verification of documents submitted. Only shortlisted proponents shall

be contacted for execution of the License agreement.

11. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	Pre-Qualification Criteria for Indian manufacturers and companies	Supporting copy of documents required (All documents must be self-attested by the authorized person of the proponent)		
	For Indian manufacturers and companies			
1	The proponent shall be a legal entity, registered as Institution/Company/LLP/Society/ partnership firm/ proprietorship firm under respective acts in India.	Registration of firm/organization/Company Incorporation Certificate from ROC/Partnership deed etc. whichever is applicable		
2	The proponent must be registered in India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card		
3	The proponent should have prior experience in R&D and manufacturing of biopesticides/drugs/pharma product for any infectious disease and must have marketed such products in three (3) immediate preceding years.	Research paper/Pamphlet/brochure of the product/DCGI License for existing product.		
4	The proponent has to be profitable and should not have incurred overall loss in past three (3) years. (applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.		
5	The proponent should have good track record and not black-listed by any Central/State Government/Public Sector Undertaking, Govt. of India, at least in three (3) immediate preceding years. (applicable on commercial firms/organizations only)	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).		
6	The proponent should have a registered office, manufacturing unit in India	Registration copies of both, and also DSIR certificate		
7	The proponent should have functional laboratory and appropriate facilities for manufacturing the product.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)		
8	The proponent should not be involved in any major litigation that may have an impact of affecting or compromising the conditions required under this EOI and in the MoU.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)		

9	GMP and ISO Certification (applicable on commercial firms/organizations	Registration copies of both
10	only) Capacity to produce at least 50000 litres /annum of 5% AS formulation	Undertaking (As per format – 6)
11	Royalty offer	(As per format – 7)
12	Business Plan	A brief concept note on planning & execution, regulatory approvals, production, marketing etc. (not more than 5 pages)
For International Manufacturers/ Firms		
13	Should have place of business in India and must be registered under relevant act and rules of India	A copy of the Registration Certificate.
14	Global experience in handling similar projects	Copy of Global Client List/Purchase order.
15	Should be a reputed manufacturer or have established production facility in India with a valid license	Undertaking in this regard and copy of license/certifications
16	Turn over figure for the last three Financial years indicating sales in India	Audited balance sheets for the last three financial years.
17	Average Net Profit for the last three years	Audited Profit and Loss statement duly signed by the chartered Accountant.

12. Disclaimer

- ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
- ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.
- ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.
- To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

13. Contacts

In case of any clarification required, please contact:

For scientific issues-

Dr. Ashwani Kumar Director, ICMR-VCRC, Puducherry, Email: - director.vcrc@icmr.gov.in; ashwani07@gmail.com

For Administrative issues

Dr. R. Lakshminarayanan, DDG (Admin), ICMR HQ, New Delhi

Email: -lakshminarayanan.r@icmr.gov.in

Authorization Letter

(To be submitted on Agency's Letter Head)

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The Director General, Indian Council of Medical Research, Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory Ref: EoI No. ICMR/EoI/Bti VCRC B17/2022 dated Sir, This has reference to your above-mentioned Expression of Interest (EoI) for Transfer of Technology for the production of Bacillus thuringiensis var. israelensis (VCRC B17) useful for the control of mosquitoes and black flies. Mr./Ms./Mrs./Dr.....is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s...... (Agency Name)....., who's signature is below. (Specimen Signature of Representative) Date: Place: Yours faithfully, (Signature of the Authorized signatory) Name:.... Designation:....

Seal:....

Expression of Interest

(To be submitted on Agency's Letter Head)

To,

The Director General,

Indian Council of Medical Research, Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EOI) for Transfer of Technology for the production of *Bacillus thuringiensis* var. *israelensis* (VCRC B17) useful for the control of mosquitoes and black flies.

Ref: ICMR/EOI/OS/ Bti VCRC B17/2022 dated

Sir,

The undersigned having read and examined in detail all the EOI documents pertaining to your transfer of technology, and do hereby express the interest to undertake the commercialization /manufacture/sell of the product as mentioned in the EOI document. The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person	
(to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	Documents required	Type of document	Page No.
		attached	
1	Company Incorporation Certificate		
	from ROC/Partnership deed etc.		
2	GST Registration or GST exemption		
	certificate/ PAN Card.		
3	DCGI/CDSCO license for the		
	existing products available in the		
	market		
4	Certificate from the Chartered		
	Accountant of the		
	Organization/Audited Balance		
	sheets for last three financial years,		
	Income Tax return.		
5	Proof of a registered office and a		
	manufacturing Unit in India, and		
	also DSIR certificate.		
6	GMP and ISO Certification.		
	Registration copies of both		

7	Authorization Letter	As per format – 1
8	Undertaking on the Letter Head of the Proponent duly signed& Stamped by Authorized Signatory	As per format – 3
9	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4
10	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 5
11	Undertaking for declaring capacity to produce at least one lakh doses per week	As per format – 6
12	Royalty Offer	As per format – 7
13	MSME Certificate (if have any)	
14	Business Plan	A brief concept note on planning & execution, regulatory approvals, production, marketing etc. (not more than 5 pages)

I/we hereby declare that my/our EOI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:

Place:

Undertaking with regard to blacklisting

(To be submitted on Agency's Letter Head)

To,

The Director General, Indian Council of Medical Research, Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment. **Ref:** ICMR/EoI/OS/ **Bti VCRC B17**/2022 dated

Sir,

It is hereby confirmed and declared that M/s......has not been blacklisted/debarredbyanyGovernmentDepartment/PublicSectorUndertaking/oranyotheragency forwhichworks/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorized signatory)
Name:.....
Designation:.....
Seal:.....

Place:

Undertaking with regard to laboratory facility (To be submitted on Agency's Letter Head)

To,	
The Director General, Indian Council of Medical Research,	
Ansari Nagar, New Delhi.	
Subject: Undertaking regarding laboratory infrastruction Ref: ICMR/EoI/OS/ Bti VCRC B17/2022 dated	cture.
Sir,	
It is hereby confirmed and declared that equipped laboratory/manufacturing infrastructure a produce/manufacture the mosquito biolarvicides.	-
	Yours faithfully,
	(Signature of the Authorized signatory) Name: Designation: Seal:
	Place:

<u>Undertaking with regard to Non-Litigation</u> (To be submitted on Agency's Letter Head)

To, The Director General, Indian Council of Medical Research, Ansari Nagar, New Delhi.	
Subject: Undertaking regarding Litigation. Ref: ICMR/EoI/OS/ Bti VCRC B17/2022 dated	
Sir,	
It is hereby confirmed and declared that M/s firm/board of directors, donot have any litigation / arbitration pe	
Y	Yours faithfully,
n I	Name:
I	Place:

Undertaking with regard to production capacity (To be submitted on Agency's Letter Head)

To, The Director General, Indian Council of Medical Research, Ansari Nagar, New Delhi.
Subject: Undertaking with regard to production capacity. Ref: ICMR/EoI/OS/ Bti VCRC B17/2022 dated
Sir,
It is hereby confirmed and declared that M/s
Yours faithfully,
(Signature of the Authorized signatory) Name: Designation: Seal:

Place:

<u>Undertaking for Royalty</u> (To be submitted on Agency's Letter Head)

To, The Director General, Indian Council of Medical Research, Ansari Nagar, New Delhi.
Subject: Undertaking for Royalty. Ref: ICMR/EoI/Bti VCRC B17/2022 dated
Sir,
It is hereby confirmed that M/s, agrees to pay an upfront payment of INR and a Royalty of % (Percent) to the ICMR to be calculated against the Net Sales done with respect to the product marketed under this agreement.
(As per the terms of ICMR-Technology Transfer and Revenue Sharing Conditions, the "NET SALES" means Revenue from sales of goods or services by all ICMR Licensee(s)/Sublicesee(s) based on the net sales realization from operations, net of discounts and indirect taxes, as defined by the Cost Accounting Standards -24 and certified by the Chartered Accountant). If we intend to sell the product in Foreign countries, a 1-2% higher royalty rate (as decided by the competent authority, ICMR) on Net Sales of the product sold, shall be applicable.
Yours faithfully,
(Signature of the Authorized signatory) Name: Designation: Seal:
Place:

SCHEDULE – (A)

Transfer of Technology for the production of *Bacillus thuringiensis* var. *israelensis* (VCRC B17) useful for the control of mosquitoes and black flies

i. About the Technology/Product/Process:

The technology for the production of the mosquito biolarvicide was developed indigenously. This technology is based on a bacterium, *Bacillus thuringiensis* var. *israelensis* (*Bti* ICMR-VCRC B17), isolated in the year 1980 from a soil sample collected from Puducherry.

In laboratory tests the biolarvicide, *Bti* ICMR-VCRC B17, was found to be highly toxic to larvae (water stages) of mosquitoes transmitting malaria (*Anopheline* sp.), filariasis and Japanese encephalitis (Culicine sp.), dengue, chikungunya and Zika diseases (*Aedes* spp.). *Bti* ICMR-VCRC B17 kills mosquito larvae by destroying their gut, within 10-30 min upon treatment. Its identity and larvicidal activity were confirmed by the WHO Reference Centre, Institute Pasteur, Paris, and rated equivalent to the global standard strain ONR 60A (WHO). The mosquito larvicidal activity of this bacterium is due to a protein endotoxin complex produced during the sporulation stage. The toxicity, the crystal composition and the genes encoding the toxic polypeptides were also confirmed by the above Reference Centre.

A pilot-scale (100 litres capacity) technology for the production of the biolarvicide has been perfected at ICMR-VCRC. The biolarvicide can be produced using locally available agriculture-based raw materials and hence it is cost-effective and environmentally friendly. An aqueous formulation (AS 5%) has been developed using the bacterium and a patent (No. 192055) has been granted on July 11, 2005, by the Indian Patent Office for this technology.

It is important to note that the powder preparation of *Bti* ICMR-VCRC B17 has been recognized as the 'Indian Standard' [ISBTI2021 (ICMR-VCRC)] by the Central Insecticide Board, a wing of the Ministry of Agriculture and Farmers Welfare, Govt. of India. The standard preparation of *Bti* ICMR-VCRC B17 has mosquito larvicidal potency of 15,000 International Toxic Units (ITUs) against III instar larvae of *Aedes aegypti* Indian strain, similar to that of IPS-82 of WHO reference Centre, Institute Pasteur, Paris, which is unavailable for 3 decades; now, recognition of ICMR-VCRC Bti B-17 strain by CIB as the Indian standard fills this gap.

The safety of the *Bti* ICMR-VCRC B-17 strain has been extensively tested. Its activity was found to be highly specific, killing only mosquito and blackfly larvae. Blackflies transmit river blindness in African countries. Hence, there is enough scope for its export to other countries, including the African continent for the control of mosquitoes and blackflies. It was found to be safe to economically important insects viz., honey bees, and silkworms (Apiary and sericulture are major agri-based industries in India). It is also safe for other non-target aquatic fauna such as copepods, beetles, dragonfly naiads, notonectids, and fishes occurring in association with mosquito larvae in breeding sites that are natural bioregulators of mosquito populations in the ecosystem and hence environmental friendly. It was found safe for birds and mammals as well.

The mosquito larvicidal efficacy of ICMR-VCRC Bti B-17 has been extensively and independently evaluated by different research institutions, in various habitats against a

variety of mosquito species in field trials at several locations in India, Indonesia, and the USA, and during different seasons. The trials have shown that the biolarvicide is highly efficacious with larvicidal activity lasting for 7-15 days in different mosquito larval breeding habitats and in different geo-climatic conditions.

ii. Need and utility of invention:

Mosquitoes, apart from being nuisance, transmit several diseases such as malaria, filariasis, Japanese encephalitis, dengue, chikungunya, and Zika leading to heavy morbidity and mortality, as also impacting social well-being. For almost a century, mosquito control programmes have relied mainly on chemical insecticides. This over-reliance is presently being challenged due to the high costs, development of insecticide resistance, health and environmental hazards, depleting raw material resources which are mainly petrochemical-based.

Moreover, the development of resistance to chemical insecticides in mosquitoes is a major concern and impediment to their control. Hence, in recent times, the focus has shifted to the use of biocontrol agents. Recently, the UNIDO has mandated the countries to phase out the DDT and replace with environment friendly alternatives such as *Bti*. Currently, *Bti* is largely imported in the country and hence the indigenous product of VCRC strain will be a major import substitution, saving the precious foreign exchange reserves. The technology of *Bti* ICMR-VCRC B-17 will be a game-changer in the control of mosquito-borne diseases, not only in the country but also in the entire tropical belt.

iii. Scope of Agreement:

This agreement will enable the licensees to manufacture and market the mosquito biolarvicide prepared using *Bacillus thuringiensis* var. *israelensis* (*Bti* VCRC B17) strain, useful in the control of mosquitoes and black flies.

iv. Role of ICMR

- a. ICMR would provide technical support through team of experienced scientist in study planning, product development, development of clinical trial protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, and other, if deemed fit upon the mutual understanding between ICMR and collaborative company.
- b. ICMR-VCRC shall provide the seed culture and complete dossier of *Bacillus* thuringiensis var. israelensis (Bti VCRC B17) strain for producing the biolarvicide and registering with Central Insecticide Boardand NCVBDC.

v. Role of company

- a. The Company will undertake the scale-up as required, manufacturing and commercialization of the *Bti* VCRC B17 biolarvicide.
- b. The company will share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.
- c. The company will allow authorized personnel/scientist/team of ICMR to visit the production facility as and when required, as envisaged under this EoI and subsequent MoA/MoU.
- d. The company shall be responsible for obtaining all the regulatory approvals required commercialization.

vi. Methodology/process:

The complete methodology of production, formulation and quality checking is detailed in the Dossier, which will be provided to the firm to which the technology is transferred under an agreement. Also, the complete data for registration with Central Insecticide Board and National Centre for Vector Borne Disease Control generated by VCRC will also be provided, along the technology knowhow package.

vii. Envisaged outcome:

Transfer of Technology for the production of *Bacillus thuringiensis* var. *israelensis* (*Bti* VCRC B17) useful for the control of mosquitoes and blackflies.
