

STANDARD OPERATING PROCEDURE FOR INTRODUCTION OF PUBLIC HEALTH INSECTICIDES INCLUDING BIOLARVICIDES IN THE NATIONAL CENTER FOR VECTOR BORNE DISEASES CONTROL

2020



STANDARD OPERATING PROCEDURE (SOP) FOR INTRODUCTION OF PUBLIC HEALTH INSECTICIDES INCLUDING BIOLARVICIDES AND LONG LASTING INSECTICIDAL NETS (LLINs) IN THE NATIONAL CENTER FOR VECTOR BORNE DISEASES CONTROL (NCVBDC)

In India, insecticides are introduced into public health programmes based on entomological parameters and their impact on disease incidence/ prevalence. Insecticides are used in the programme for indoor residual and space spraying, treatment of mosquito nets/ Long Lasting Insecticidal Nets (LLINs) and larval control for containment of vector borne diseases. The revised procedure to be adopted for the introduction of newer insecticides or insecticide formulations for public health use (under National Center for Vector Borne Disease Control (NCVBDC) is depicted in the Flow chart.

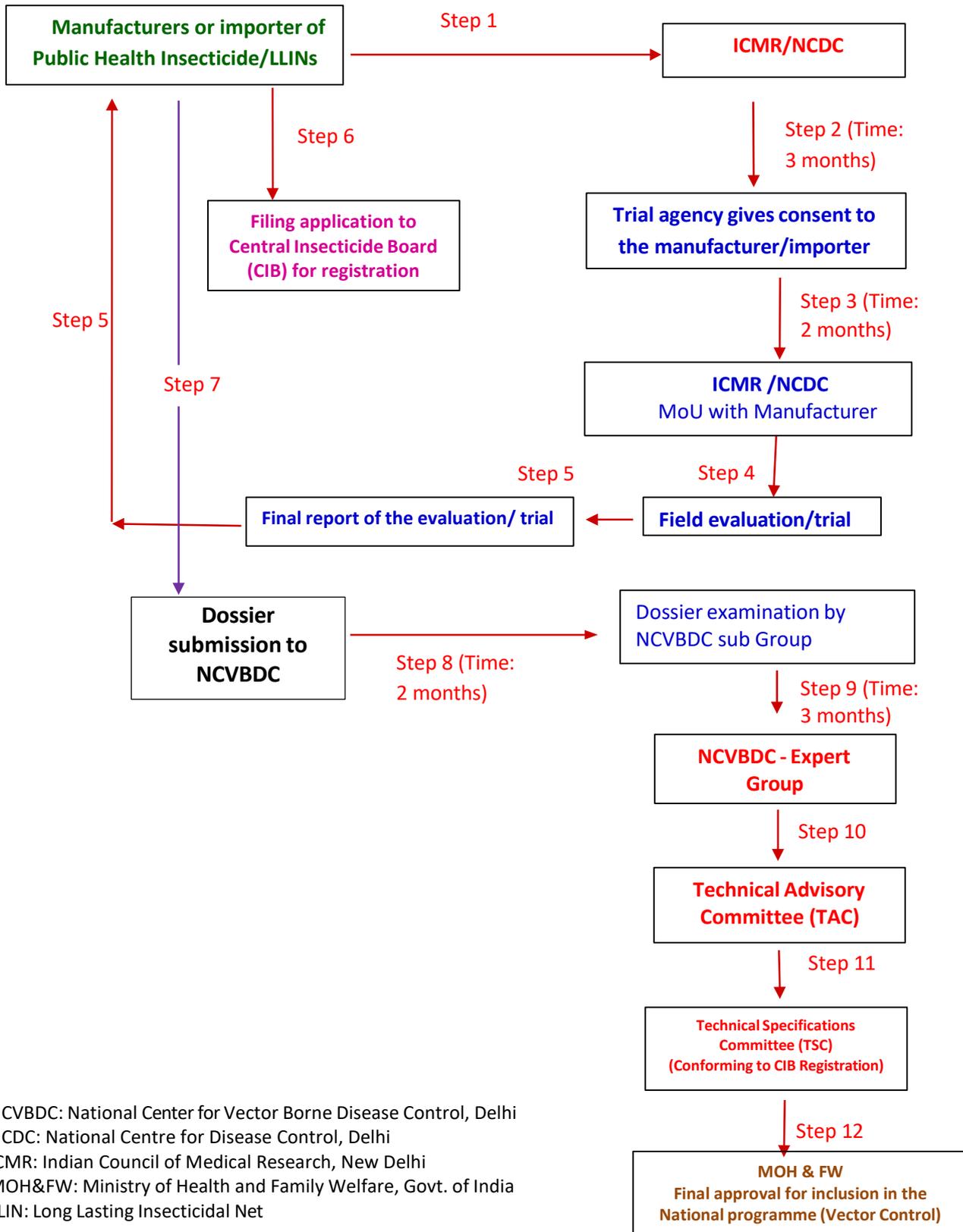
The NCVBDC considers introduction of new Public Health Insecticide/LLINs and/or deletion of Public Health Insecticide/LLINs for use under the programme on the basis of registration/de-registration of product by CIB&RC. Technical Advisory Committee (TAC) of GoI deliberates on the data generated on bio- efficacy, vector susceptibility and epidemiological impact etc. by the institute(s) that conduct field trials as per approved revised common protocol based on the technical specification of the Public Health Insecticide/LLINs by Technical Specification Committee (TSC). The inclusion/deletion of a Public Health Insecticide is made with the approval of Ministry of Health and Family Welfare, Government of India

The manufacturers/importers of new insecticides/formulations of insecticides listed under the schedule of Insecticides Act (1968) need to submit requisite data to get it registered with Central Insecticides Board (CIB) before submitting the proposal to NCVBDC for its inclusion under NCVBDC for use in programme. The steps involved in the process (Flow chart) of getting the insecticides evaluated for efficacy against disease vectors, registration and approval for their use in the national programme are described below:

1. The manufacturer(s) or importer of insecticides who intends to get their product included for use in the public health programme will submit an application to ICMR/NCDC requesting them to initiate necessary steps to generate data through laboratory and field trials strictly as per the latest Revised Common Protocol for Uniform Evaluation of Public Health Insecticides including Bio-larvicides for use in Vector Control displayed on website of NCVBDC/ICMR/ NCDC/CIB. For research trial and testing (RTT) samples, permission from Registration Committee of CIB is required prior to import (if sample is to be brought from outside country). Data requirement for registration by CIB & RC in respect of chemistry, bio-efficacy, toxicology and packaging is available at www.cibrc.nic.in in which may be obtained directly from CIB.
2. The ICMR/NCDC will examine such applications for their scientific merit through a review process. Only after meeting the eligibility criteria, proposal will be prepared (with appropriate budget component) in accordance with the latest Revised Common Protocol and after approval in their respective system, convey to the requesting manufacturer or importer for their consent (within 3 months). In case of the proposals requiring clearance from Human Ethics Committee and /or Animal Ethics Committee, the institutes will obtain it within this period. The entire process should be completed at the earliest but not exceeding 3 months.

3. On receipt of the concurrence of the manufacturer/importer for conduct of trial, the ICMR/NCDC will initiate the process of evaluation. The manufacturer/ importer will enter into a Memorandum of Understanding (MoU) as per the need of the trial agency and transfer the funds as well as the product to be tested to the institute. In the MoU, it should be clearly mentioned that the disposal of wastes and insecticide containers will be done following standard guidelines and also to be specified that who will be responsible for this. It should also be mentioned especially that the plastic covers and used LLINs will be disposed of by manufacturer/importer following standard Guidelines. All the activities under this step of SOP need to be completed within 2 months, excluding the trial period specified in latest Revised Common Protocol for evaluation of product.
4. The identified Institute will conduct the trial as per the latest Revised Common Protocol and ethical guidelines as required for respective institutes and approval and review norms in their respective system.
5. The final report will be sent by trial agency to the firm following respective review and approval norms.
6. The manufacturer/importer, with the final trial report received from the trial agency, can file an application with the Central Insecticide Board (CIB) & RC for registration of the product.
7. The manufacturer/ importer can approach NCVBDC with a complete dossier including registration certificate issued by CIB & RC including label claim and the Phase-I, Phase-II and Phase-III trial reports- for consideration for inclusion of the product in the programme.
8. The NCVBDC will place the application with all documents of the manufacturer/importer to the Sub Group of NCVBDC to examine for the scientific merit of the product (within 2 months).
9. Based on recommendations of Sub-Group, NCVBDC will process the application for deliberation of NCVBDC Expert Group (within 3 months). The recommendations of Expert Group will be processed by the NCVBDC for deliberations in the Technical Advisory Committee (TAC).
10. The TAC will deliberate on recommendations of the Expert Group of NCVBDC and will grant its approval for inclusion of the Public Health Insecticide/LLINs under the programme. In case the product is not recommended by TAC, the manufacturer/ importer will be informed accordingly.
11. Once TAC recommends for inclusion of the Public Health Insecticide/LLINs in the programme, NCVBDC Technical Specification Committee (TSC) finalizes the Public Health Insecticide/LLINs technical specifications, based on Registration Certificate issued by CIB & RC and BIS specifications, wherever needed.
12. TAC recommendations and technical specifications approved by TSC will be submitted to Ministry of Health & Family Welfare, Govt. of India for consideration for approval towards inclusion of the Public Health Insecticide/LLINs under the programme.

FLOW CHART OF THE STANDARD OPERATING PROCEDURE FOR INTRODUCTION OF PUBLIC HEALTH INSECTICIDES INCLUDING BIOLARVICIDES AND LONG LASTING INSECTICIDAL NETS IN THE NATIONAL CENTER FOR VECTOR BORNE DISEASE CONTROL



NCVBDC: National Center for Vector Borne Disease Control, Delhi
 NCDC: National Centre for Disease Control, Delhi
 ICMR: Indian Council of Medical Research, New Delhi
 MOH&FW: Ministry of Health and Family Welfare, Govt. of India
 LLIN: Long Lasting Insecticidal Net

Composition and Terms of Reference of Sub Group/Expert Group/Committees

I. NCVBDC Sub Group

Composition

1. Head Entomology, NCVBDC, New Delhi
2. Subject expert from NCDC, New Delhi
3. Subject expert from ICMR New Delhi and/or nominated expert from ICMR Institutes
4. Representative from CIB, Faridabad, Haryana
5. Expert of Chemistry or Toxicology from Delhi University
6. Independent Subject Experts (2-3)

Terms of reference

Screening of the dossier with requisite documents submitted by the manufacturer/importer to NCVBDC requesting for consideration to include under the Programme before submission to the NCVBDC Expert Group.

II. NCVBDC Expert Group

Composition

1. Chairperson (external)
2. Director, NCDC, Delhi
3. Director, NCVBDC, Delhi
4. Head, Epidemiology and Communicable Diseases, ICMR
5. Director of ICMR-NIMR
6. Representative of CIB & RC
7. External subject experts- Entomology (Three)
8. Subject Expert in Chemistry and Toxicology (one each)
9. Municipal Health Officers, three Delhi Municipal Corporations
10. Member of Civil Society (one)
11. HOD, Entomology, NCVBDC (Member Secretary)

Terms of reference

Deliberations on the recommendations of the NCVBDC Sub Group and on Public Health Insecticide/LLINs issue/s. Advise the programme on Public Health Insecticide/LLINs issue/s. Convey the specific recommendation/s to TAC.

III. Expert Committee of respective institutions (ICMR/ NCDC)

Composition

1. Chairperson (An external eminent subject expert)
2. Three additional subject experts (External, one each in Entomology, Chemistry and Toxicology).
3. Expert from public health for Phase III trials wherever needed
4. Scientist from institutes
5. Director, NCDC or nominee
6. Head, ECD Division, ICMR or nominee
7. Secretary, CIB & RC or nominee
8. Head, Concerned Division of ICMR/NCDC- Member Secretary.

Terms of reference

- a. To examine the scientific merit of the applications submitted by the manufacturer/importer and identify the research institute for evaluation following the latest Revised Common Protocol.
- b. To review the progress of the evaluation/trial on the projects.
- c. Approval of the final evaluation report for communicating to the manufacturer/importer.

IV. Technical Advisory Committee (TAC), NCVBDC

Composition

1. The Director General of Health Services, Directorate of General of Health Services, Government of India, Chairperson
2. Director, NCVBDC as the Member Secretary.
3. Compositions of the Committee as approved by DGHS and Ministry of Health & Family Welfare
4. Representative from WHO could be invited to attend the meetings, whenever necessary.
5. The Chairman is empowered to co-opt any expert, so required, to assist the committee from time to time.

Terms of reference

1. To review the recommendations of the NCVBDC Expert Group and approve the Public Health Insecticide/LLINs for introduction under the programme
2. To review drug policy and suggest alternative drugs for treatment of malaria and other VBD cases.
3. To review and suggest diagnostics and case management practices under NCVBDC for all vector borne diseases.
4. To identify and review whether the preventive measures undertaken have been consistent with the agreed plan of action and or leading to measurable target of achievements.
5. To suggest mid-course changes in strategy including use of insecticides, diagnostics and drugs, if resistant patterns are evident.
6. Any other technical issue/s related to programme strategies and implementation.

V. Technical Specification Committee (TSC), NCVBDC

- The Special/Additional Director General of Health Services, Dte. of GHS, Gol, Chairperson
- Director, NCVBDC - Member Secretary.

Composition of the Committee as approved by DGHS and Ministry of Health & Family Welfare.

Terms of reference

1. To finalize the technical specifications/parameters of the Public Health Insecticide/LLINs recommended by TAC for inclusion under the programme.