



Guidance for Producers and Registration holders of neem-based products

In the fight against malaria, the United Nations Industrial Development Organization (UNIDO) and United Nations Environment Programme (UNEP), supported by the Global Environment Facility (GEF), are working with India to develop and promote non-persistent organic pollutants (POPs) alternatives to dichlorodiphenyltrichloroethane (DDT). These include Neem (*Azadirachta indica*) based bio-pesticides, highly potent, with their derived products showing diverse insecticidal properties against a wide range of vector-borne diseases, including malaria. Neem-based products are safe, environmentally friendly and act as sustainable alternatives to DDT for malaria control.

In India, neem-based products are only accessible in retail markets. In light of the country's commitment to phase out DDT production and the predicted rise in demand for DDT alternatives, there is a significant opportunity for

new producers, importers and exporters of neem-based products.

Under the present regulatory set up in the country, neem-based products for mosquito control can either be registered as insecticides or as drugs, depending on the composition of the product. Consequently, the producers must follow different regulatory regimes to register, produce and distribute their respective neem-based products.

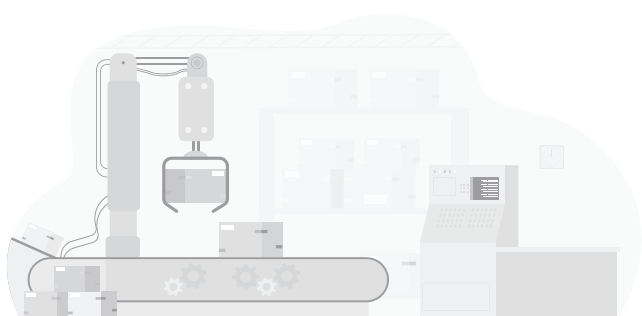
Important Regulations

- Insecticides Act, 1968 and Rules, 1971
- Essential Commodities Act, 1955
- Drugs and Cosmetic Act, 1940 and Rules 1945
- Solid Waste Management Rules, 2016

PART 1

GUIDANCE FOR PRODUCERS, IMPORTERS, AND EXPORTERS OF NEEM-BASED INSECTICIDES

All the neem-based products that contain **Azadirachtin (an active principle in neem) as primary component for use as household insecticides** have to be registered only with the Central Insecticides Board & the Registration Committee (CIB&RC).



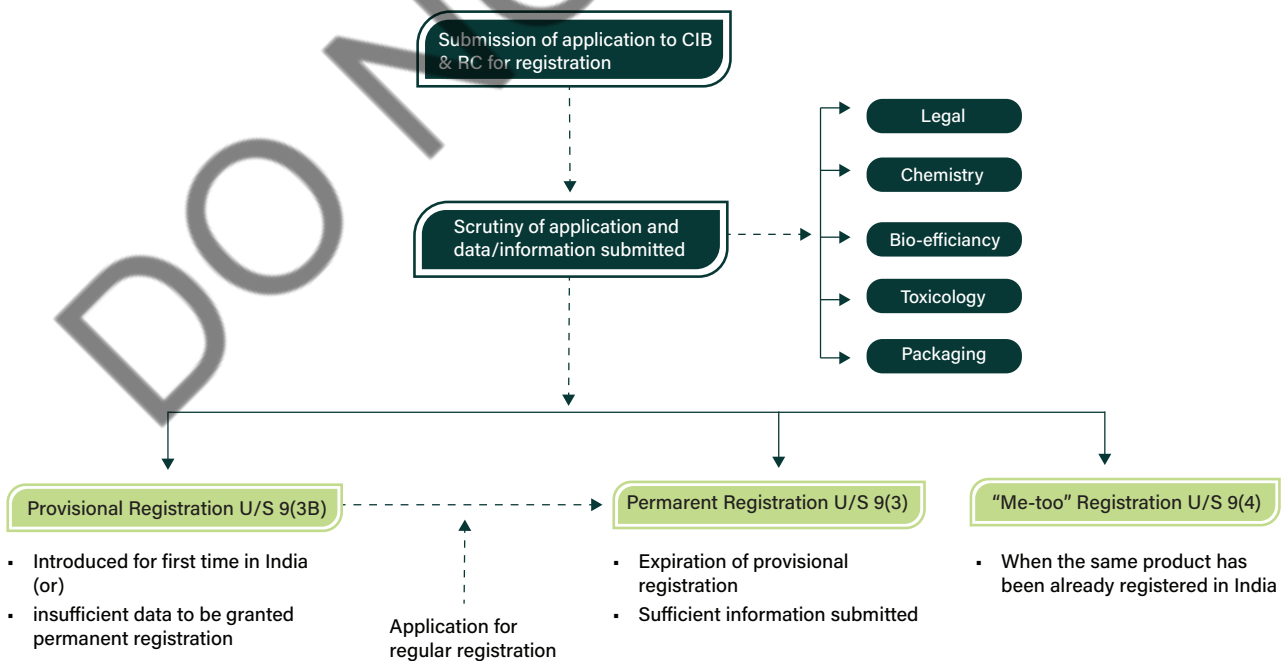
- ✓ Regulatory processes to be followed for setting up a manufacturing unit for indigenous use as well as export

Regulatory processes to be followed to start a new business/manufacturing facility in India¹



- ✓ Mandatory registration of neem-based insecticide by all domestic producers as well as importers with CIB&RC

Registration process of neem-based insecticides



- ✓ Approval from the respective state governments, where the production unit is set up (Manufacturing license)
- ✓ Complying with Regulations for neem-based products as **insecticides**
 - Compliance with stipulated conditions (for example, technical specifications, labelling and packaging, safety precautions etc.) specified in the Certificate of Registration issued by CIB&RC
 - Fulfilling regulatory requirements before and after the commissioning of the production facility (Simultaneous applications for registration of the product and necessary clearances are possible)
 - Compliance with regulations for export and import purposes (only for exporters and importers)

GUIDANCE FOR REGISTRATION HOLDERS OF NEEM-BASED INSECTICIDES

All neem-based insecticides intended for sale, export, or import must be registered individually with CIB&RC. Once the Certificate of Registration is issued to the producers, they become the registration holders.

- ✓ At present, neem-based insecticides are not included under public health program, therefore, products can also be sold in the retail markets
- ✓ Neem-based insecticides for vector control should be sold for the said purpose only
- ✓ Need to apply for the Grant of Licence to sell, stock or exhibit for sale or distribute neem-based products at the state level

Exporters can refer to the guidelines provided by WHO and Food and Agriculture Organisation



[Guidelines on Good Labelling Practice for Pesticides. International code of conduct on pesticide management²](#)



[Guidance on the management of household pesticides³](#)

PART 2

GUIDANCE FOR PRODUCERS, IMPORTERS, AND EXPORTERS OF NEEM-BASED AYURVEDIC DRUGS

Any formulation containing any part(s) of the neem plant as a wholesome ingredient are considered Ayurvedic drugs and regulated under the **Drugs and Cosmetics Act, 1940** and **Rules 1945** (for example, neem-based mosquito repellent creams, liquid vaporizers, room spray, incense sticks, and so on).

- ✓ Setting up a Manufacturing Unit for domestic use as well as export. The requirements are same as for neem-based insecticides
- ✓ Application for license to the concerned State Licensing Authority for Ayurvedic, Siddha and Unani (ASU) drugs to produce, sale or distribute Ayurvedic drugs in the respective state (<http://e-aushadhi.gov.in/>)⁴
- ✓ Compliance of regulations and guidelines for **neem-based products as drugs**
 - Compliance with stipulated conditions specified in the license issued by the State Licensing Authority
 - Following the general guidelines for developing neem-based Ayurvedic formulations for the production of drugs for mosquito control published by Ministry of Ayush

[General guidelines provided by the Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH⁵](#)

- Adhering to the various provisions on quality standards of neem-based products issued by concerned agencies (e.g. Ayurvedic Pharmacopoeia published by [Pharmacopoeia Commission for Indian Medicine & Homoeopathy⁶](#), [Quality Standards of Indian Medicinal Plants⁷](#), Herbal Monographs by [Indian Pharmacopoeia Commission⁸](#), etc.)
- Compliance with regulations for export and import purposes
- Compliance with other regulations specific to neem products (**Plant Quarantine (Regulation of Import into India) Order, 2003** and state-specific regulations, if any (for example, **Protection of Trees in Rural and Hill Areas Act, 1976** in Tamil Nadu)

Exporters should also know about the WHO guidelines⁹



[Guidelines for efficacy testing of mosquito repellents for human skin](#)

GUIDANCE FOR LICENSE HOLDERS OF NEEM-BASED DRUGS

- ✓ Approval from the respective state governments, where the production unit is set up (license to manufacture for sale)
- ✓ Compliance to Good Manufacturing Practices (GMP) and the standards prescribed in the Ayurvedic Pharmacopoeia.

IMPORTANT WEB LINKS

Central Insecticides Board & Registration Committee (CIB&RC)	ppqs.gov.in/divisions/central-insecticides-board-registration-committee
Bureau of Indian Standards (BIS)	www.bis.gov.in/
Ministry of Ayush, Government of India	www.ayush.gov.in
Indian Pharmacopoeia Commission	www.ipc.gov.in
Pharmacopoeia Commission for Indian Medicine & Homoeopathy	www.pcimh.gov.in
Indian Council of Medical Research	www.icmr.gov.in

1. https://dpiit.gov.in/sites/default/files/approval_clearances_required_for_new_projects.pdf
2. <https://www.who.int/publications-detail-redirect/9789240053014>
3. <https://www.who.int/publications/i/item/9789240011915>
4. <http://e-aushadhi.gov.in/>
5. <http://ccras.nic.in/content/general-guideline-series>
6. <https://pcimh.gov.in/>
7. https://main.icmr.nic.in/priced-publications/1352?title=Quality&field_select_category_tid=1352&page=1
8. <https://www.ipc.gov.in/>
9. https://apps.who.int/iris/bitstream/handle/10665/70072/WHO_HTM_NTD_WHOPES_2009.4_eng.pdf?sequence=1&isAllowed=y