F. No. AYU-11/15/2024-eoffice
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ayush Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 06 JUL 2026

CIRCULAR

To,

All the State/UT Drug Controllers

Subject: Manufacturing and marketing of Homoeopathic medicines containing Phenolphthalein – reg.

It has been brought to the notice of this directorate that medicines containing "Phenolphthalein", are being manufactured and marketed, labelled as Homoeopathic medicines.

The matter has been examined in consultation with Ministry of Ayush and it was found that any combination of Homoeopathic medicine containing phenolphthalein, does not fulfil the criteria to be labelled as a 'Homoeopathic medicine' per the mandate of Rule 2(dd), of the Drug Rules 1945. The approval of such combinations compromises patient safety and may lead to adverse drug reactions. Consequently, the permission to manufacture the product may be withdrawn as per the provisions of Drug Rules 1945 on the grounds of statutory non-conformity.

Accordingly, all the State/ UT Drugs Controllers are requested to ensure that the aforesaid combination shall not be allowed for manufacture, sale, & distribution in the country as a Homoeopathic medicine. Action taken may be intimated to this office

This matter may be taken up on priority.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to,

1. **PPS to Secretary (H), Ministry of Ministry of Health & Family Welfare**
2. **Sr.PPS to Secretary, Ministry of Ayush.**
3. **PPS to JS(R), Ministry of Ministry of Health & Family Welfare.**
4. **PPS to Advisor (Ayu.), Ministry of Ayush.**