

DOCUMENT TITLE: REGULATORY DIRECTIVE ON THE DISCONTINUATION OF THE REGISTRATION, IMPORTATION, MANUFACTURE, DISTRIBUTION, SALE AND USE OF LEVAMISOLE-CONTAINING HUMAN MEDICINAL PRODUCTS		
DOC. REF. NO.: NAFDAC-RD-DRL-047	EFFECTIVE DATE: 18-08-2026	REVIEW DUE DATE: 17-08-2031



NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

REGULATORY DIRECTIVE ON THE DISCONTINUATION OF THE REGISTRATION, IMPORTATION, MANUFACTURE, DISTRIBUTION, SALE, AND USE OF LEVAMISOLE CONTAINING HUMAN MEDICINAL PRODUCTS

1.0 Purpose

- 1.1** This Regulatory Directive stipulates the discontinuation of the registration, manufacture, importation, distribution, sale and use of all **Levamisole-containing human medicinal products** in Nigeria.
- 1.2** Levamisole is an anthelmintic and immunomodulatory medicine that was previously indicated for the treatment of helminthic infections and certain immune-related disorders. Advancement in medical practice have resulted in the availability of safer and more effective therapeutic alternatives with significantly improved safety profiles.
- 1.3** Comprehensive reviews of global pharmacovigilance data and scientific evidence have demonstrated that Levamisole is associated with serious and potentially life-threatening conditions, including but not limited to:
 - Low white blood cells / agranulocytosis
 - Skin and blood-vessel injury
 - Digestive and neurologic toxicity
 - Heart and circulation effects
 - Liver and other organ injury
- 1.4** The Agency has determined that the overall benefit-risk profile of Levamisole-containing human medicinal products is no longer favorable, particularly considering the availability of safer therapeutic alternatives.

2.0 Scope

- 2.1** This Regulatory Directive applies to all:

- Marketing Authorization Holders;
- Importers;
- Local manufacturers;
- Distributors;
- Wholesalers;
- Community and hospital pharmacies;
- Healthcare institutions;
- Healthcare professionals; and

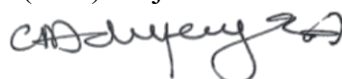
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- All other stakeholders involved in the registration, manufacture, importation, distribution, supply, sale, prescribing and use of Levamisole-containing human medicinal products in Nigeria.

3.0 Directive Details

- 3.1** NAFDAC shall no longer accept new applications for the registration of Levamisole-containing human medicinal products.
- 3.2** All pending applications for the registration of Levamisole-containing human medicinal products shall be discontinued.
- 3.3** All existing Certificates of Registration (Marketing Authorizations) for Levamisole-containing human medicinal products are hereby cancelled with effect from the effective date of this Directive.
- 3.4** The importation of Levamisole-containing human medicinal products into Nigeria is hereby prohibited.
- 3.5** The local manufacture of Levamisole-containing human medicinal products shall cease immediately upon the effective date of this Directive.
- 3.6** The distribution, wholesale supply, retail sales and dispensing of Levamisole-containing human medicinal products are hereby prohibited.
- 3.7** Healthcare professionals shall discontinue the prescribing and administration of Levamisole-containing human medicinal products and, where clinically appropriate, transition affected patients to safer therapeutic alternatives.
- 3.8** Marketing Authorization Holders shall initiate an immediate nationwide recall of all Levamisole-containing human medicinal products from every level of the supply chain in accordance with the NAFDAC Product Recall Guidelines.
- 3.9** Marketing Authorization Holders shall notify the Agency of the commencement of recall activities within fourteen (14) days of issuance of this Directive and submit all recalled to the nearest NAFDAC office
- 3.10** Healthcare professionals are encouraged to report all suspected adverse drug reactions associated with Levamisole to the National Pharmacovigilance Centre through established reporting channels.
- 3.12** Failure to comply with this Directive shall constitute a violation of applicable regulatory requirements and shall attract appropriate administrative and legal sanctions under the relevant laws of the Federal Republic of Nigeria.

Approved By:
Director-General (NAFDAC)
Prof. (Mrs.) Mojisola Christianah Adeyeye



Signature:

Date: August 18, 2026