

DOCUMENT TITLE: REGULATORY DIRECTIVE ON DONATED MEDICAL PRODUCTS IN NIGERIA		
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**NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL
(NAFDAC)**

REGULATORY DIRECTIVE ON DONATED MEDICAL PRODUCTS IN NIGERIA

1.0 Purpose:

This Regulatory Directive stipulates the discontinued processing and granting of approvals of applications for Donated Medical Products manufactured in facilities not located in/or do not have marketing authorization approval from countries that are World Health Organization-Listed Authorities (WLAs), or International Medical Devices Regulators Forum Management Committee (IMDRF-MC), or Pharmaceutical Inspection Cooperation Scheme (PIC/S) members, as well as those that are not World Health Organization prequalified.

2.0 Scope:

This Regulatory Directive applies to the importation of Donated Medical Products in Nigeria, for which a permit is necessary.

3.0 Directive Details:

NAFDAC will only grant approvals of applications for donated medical products that are manufactured in facilities located in /or have marketing authorization from countries that are World Health Organization-Listed Authorities (WLAs), International Medical Devices Forum Management Committee (IMDRF-MC) or Pharmaceutical Inspection Cooperation Scheme (PIC/S) members and donated medical products that are World Health Organization (WHO) prequalified.

All applications for donated medical products must include evidence of WHO Prequalification, or valid Quality Management System (QMS)/Good Manufacturing Practice (GMP) Certificate, or market authorization approval issued by a WLA, IMDRF-MC, or PIC/S member country.

This is to ensure that all donated medical products permitted for importation into Nigeria are of continued assured quality, safety, efficacy, and performance, as products granted such non-routine approvals are not subjected to the same rigor as products approved through routine authorization processes.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature: 

Date: October 17, 2025