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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

RECALL, HANDLING AND DISPOSAL OF SUBSTANDARD AND FALSIFIED MEDICINAL PRODUCTS REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 84 of 2021

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP N1, LFN), 2004

RECALL, HANDLING AND OF SUBSTANDARD AND FALSIFIED MEDICINAL PRODUCTS REGULATIONS, 2021

[7*th Day of July,* 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap. N1 LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Minister of Health makes the following Regulations—

Scope of application.

1. These Regulations shall apply in the recall, handling, storage and disposal of substandard and falsified (SF) products manufactured, exported, imported, advertised, sold, distributed or used in Nigeria.

Prohibition.

2. Substandard and falsified product shall not be recalled, stored or disposed except in accordance with the provisions of these Regulations.

Reasons for recall.

3. The reasons for the recall of SF product shall include—

(*a*) incorrect labeling of the product ;

(*b*) incorrect formulation of a product ;

(*c*) result of ongoing stability studies (unfavorable) showing negative trends ;

(*d*) poor storage and handling ;

(*e*) physical, chemical or microbiological defect ; and

(*f*) any other reason as may be determined by the Agency.

Initiation of voluntary recall.

4.—(1) A certificate of registration holder shall initiate the voluntary recall of SF product.

(2) The certificate of registration holder shall notify the Agency in writing of the voluntary recall of the substandard products and shall include—

(*a*) product name ;

(*b*) batch number ;

(*c*) manufacturing date ;

(*d*) expiry date ;

(*e*) dosage form ;

(*f*) identified defect ;

(*g*) recall protocol ; and

(*h*) any other information as may be determined by the Agency to make informed decision.

(3) The certificate of registration holder shall notify all the distributors of the product recall, reason for recall and the recall structures.

(4) The Agency shall participate in the recall exercise.

(5) A certificate of registration holder shall bear the cost of the voluntary recall of substandard and falsified product.

Initiation of non-voluntary recall.

5.—(1) The Agency shall initiate the non-voluntary recall of SF product.

(2) The Agency upon the establishment of the reason for recall of SF product shall notify the holder certificate of registration.

(3) The notification referred to in sub-regulation (2) of this regulation shall include the following details of the product—

(*a*) product name ;

(*b*) batch number ;

(*c*) manufacturing date ;

(*d*) expiry date ;

(*e*) dosage form ; and

(*f*) identified defect.

(4) Where there is no identifiable person responsible for the presence of the SF product in Nigeria, the Agency shall request any outlet and the person in possession of the SF product to report to the nearest office of the Agency.

(5) The Holder of a Certificate of Registration shall bear the cost of the recall of Substandard and falsified product.

Recall strategy.

6.—(1) The Holder of a Certificate of Registration shall prepare and obtain approval for the recall strategy.

(2) The recall strategy shall include—

(*a*) the duration for the recall ;

(*b*) the key personnel appointed to coordinate the recall and provide feedback to the Agency at intervals until the completion of the exercise ; and

(*c*) any other strategy as the agency may determine.

Notification and public announcement.

7. Upon the Agency's approval for the recall of the SF product, the Agency shall publicise it at the expense of the Holder of a Certificate of Registration.

Submission of recall report.

8.—(1) The holder of certificate of registration shall submit documented evidence of the recall at the end of the process.

(2) The Agency shall assess the performance of the recall and take necessary action as may be determined by the Agency.

Storage.

9.—(1) The recalled medicinal products shall be transferred to the Agency's storage facility and inventories shall be taken.

(2) The product shall be appropriately stacked and stored until disposal exercise is scheduled.

Decision for disposal of sub-standard and falsified product.

10. The Agency shall determine the disposal of SF products.

Planning for disposal of sub-standard and falsified product.

11. For the purpose of effective disposal of the medicinal products, the following shall be identified—

(*a*) the quantities and dosage forms of the SF products ;

(*b*) the respective disposal methods for all the identified dosage ;

(*c*) the required human resources ;

(*d*) the location, space, equipment, materials and logistics for the volume of SF to be disposed ; and

(*e*) the estimated cost of the disposal exercise.

Health and safety.

12. The Agency shall provide appropriate safety gears and sanitary provision on the site.

Transfer of recalled sub-standard and falsified product to disposal site.

13. The recalled SF products shall be transported to the disposal site in a secured manner and in the company of regulatory officer and security personnel.

Sorting at the disposal site.

14. The recalled SF products shall be sorted at the disposal site according to the identified method of disposal pursuant to regulation 11(*b*) of these Regulations.

Disposal.

15.—(1) The recalled and sorted medicinal products shall be disposed in accordance with the identified disposal method.

(2) The cost of the disposal of the SF product shall be borne by the Holder of a Certificate of Registration or any person found in possession of the SF product.

Security.

16. The Agency shall provide security measures during the transportation, sorting and disposal of the recalled SF products.

Offences and Penalties.

17.—(1) A person who contravenes any of the provisions of these Regulations, commits an offence and shall be liable on conviction, in the case of—

(*a*) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals, every—

(*a*) director, manager, secretary or other similar officer of the body corporate ;

(*b*) partner or officer of the firm ;

(*c*) trustee of the body concerned ;

(*d*) person concerned in the management of the affairs of the association ; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for that offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

18. A person convicted of an offence under these Regulations shall forfeit to the Federal Government—

(*a*) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence ; and

(*b*) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Enforcement of these Regulations.

19. The Agency shall be responsible for the enforcement of these Regulations.

Interpretations.

20. In these Regulations—

"*Agency*" means National Agency for Food and Drug Administration and Control ;

"*Disposal*" means the action or process of getting rid or destruction of substandard and falsified medicinal products ;

"*Falsified product*" means medicinal products that deliberately or fraudulently misrepresent their identity, composition or source. Falsified product also means fake and counterfeit medicine ;

"*Person*"means an individual or corporate body ;

"*Proceeds*" means any property derived or obtained, directly or indirectly, through the Commissionof the offence ;

"*Recall*" means the process for withdrawing or removing of medicinal product from the distribution chain because it is either a substandard or falsified medicine. The recall might be initiated by the manufacturer, importer, distributor or the Agency ;

"*Regulatory officer*" means a staff of the Agency designated to perform regulatory functions ;

"*SF*" means substandard and falsified products ; and

"*Substandard products*" means approved medicinal products that fail to meet either their quality standards or their specifications, or both such as manufacturing error, expired or degraded.

Citation.

21. This Regulation shall be cited as the Recall, Handling and Disposal of Substandard and Falsified Medicinal Product Regulations, 2021

MADE at Abuja this 7th day of July, 2021.

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health