FOOD AND DRUGS AUTHORITY

28th August 2024
FDA/SFD/GDL – 01/02
Governing Board / CEO, Food and Drugs Authority

GUIDELINE ON INSPECTION OF MEDICAL PRODUCTS STORAGE FACILITIES

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This guideline replaces 'Guideline or GDP And GSP Inspection of Storage Facilities (FDA/DRID/DID/GL-WDI/2020/01)'.

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Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
01/03/2020	01	Initial Issue
29/08/2024	**02**	**i. General review of document to align with new organogram and QMS requirements.** **ii. Inclusion of 3.1.1.7 signed by CEO** **iii. 3.1.1.10, 3.1.2.4 Submission of application to FDA Regional offices (Appendix 3)** **iv. 3.1.2.3 WHO's landing page: https://www.who.int/publications/who-guidelines** **v. Appendix 3 - List of Regional Offices**

Acknowledgements

It is acknowledged that, in the development of this Guideline, reference was made to the following sources:

- Public Health Act, 2012 (Act 851)
- All WHO Guidelines related to Good Distribution Practices (GDP) and Good Storage Practices (GSP) Practices for Medical Products
  WHO Technical Report Series, https://www.who.int/publications/who-guidelines

Executive Summary

This document is a guideline that prescribes how applications for the Inspection and Licensing of Medical Products Storage Facilities shall be made to the Food and Drugs Authority Ghana.

The guideline highlights the format of the application, and the processes involved leading to licensing of a storage facility, including the facility inspection and timelines for each activity in the licensing process.

The objective of this guideline is to serve as a guide to applicants, increase transparency in the FDA's operations and build confidence and accountability in the licensing structure via public availability of information on the licensing process.

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 In pursuance to **Sections 130 and 131 of the Public Health Act, 2012, Act 851 of the Republic of Ghana,** these guidelines are hereby made to provide prospective applicants with information on the general requirements for the inspection of pharmaceutical product, herbal product and food supplement storage facilities.

1.2 These Guidelines apply to business entities duly registered by the Registrar-General Department with intention to establish storage facilities and distribute pharmaceutical products, herbal products and food supplements.

1.3 The guidelines also apply to facilities/entities who intend to obtain authorization to import the stated products in 1.1.

1.1 Legal Basis

1.1.1 The following sections of the Public Health Act 2012, Act 851 mandates the Authority to carry out inspections and licensing of manufacturing facilities to achieve the desired safety, quality, and efficacy of the products for human and animal use regulated by the Authority.

- Section 130: Registration of premises
- Section 131: Licences and permits.

1.1.2 Section 148 of The Public Health Act, 2012, Act 851 further mandates the Authority to issue guidelines and codes of practice in connection with products regulated by the Authority to persons in the industry and are required to comply. It is based on this legal provision that this guideline has been developed.

1.1.3 In accordance with Section 130(1) of the Public Health Act, 2012 (Act 851), the supply or storage of drugs/ medical products shall not be carried out except in premises registered (licensed) by the Food and Drugs Authority (FDA) for that purpose.

1.1.4 Pursuant to Section 118(1), drugs/ medical products imported, exported, distributed, sold, supplied by business entities are required to be registered with the Authority before placing them on the Ghanaian market.

1.2 Scope

1.2.1 This Guideline applies to all business entities duly registered by the Registrar-General Department with intention to establish a medical product storage facility in Ghana.

1.2.2 This guideline applies to facilities that store and distribute drugs or pharmaceutical or nutraceutical dosage forms or any medical products. This includes oral tablets., oral liquids, suppositories, topical preparations, parenterals, inhalers, patches, medical devices etc.

1.2.3 Storage and Distribution entities will be inspected to confirm compliance to the Authority's guideline on Good Storage and Distribution Practice (GSDP) requirements for medical products and other applicable regulatory requirements for drugs.

1.2.4 Applicants are therefore advised to observe the provisions of this Guideline before applying for licensing or re-licensing of their premise(s) for the storage and distribution of drugs/ medical products.

2.0 DEFINITIONS AND ABBREVIATIONS

GSDP : Good Storage and Distribution Practice
ID : Inspectorate Directorate
SFD : Storage Facility Department
TOD : Technical Operations Division
QMS: Quality Management System
TRS : Technical Report Series
WHO : World Health Organization

3.0 REQUIREMENTS

APPLICATION REQUIREMENTS

3.1.1 New Applications

3.1.1.1 An application to register and license a new facility for the storage and distribution of cosmetics and household chemical substances shall be made in writing by submitting a completed application form with a cover letter addressed to:

The Chief Executive Officer
Food and Drugs Authority
GA-237-7316
Accra

3.1.1.2 The completed application form shall be dated, signed and stamped by the applicant and shall provide the following minimum information as part of the licence acquisition:

(a) The name, full business address, location/site address and telephone numbers (including mobile telephone numbers) of the applicant.

(b) Addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of cosmetics and household chemical substances. If the storage facility is owned by a third party other than the owner of the business, the details of the third party, should also be provided.

(c) The type of ownership of the premise (i.e. whether applicant-owned or third-party owned) and the name(s) of owner(s)

(d) The type of business operation (i.e., partnership, corporation, or sole proprietorship); and the name(s) of the partner(s)/director(s)/proprietor(s) of the applicant.

3.1.1.3 The completed application form shall be accompanied by:

(a) Non-refundable application fee as specified in the Authority's Fee Schedule.

(b) Certified true copies of Certificate of Incorporation and Certificate to Commence Business from Registrar General's Department

3.1.1.4 In situations where the storage facility is more than one, a separate application is required for each premise, except where a group of buildings on one or more sites are engaged in storing and distributing the same kind of product under the same direct storage and distribution management.

3.1.1.5 The Authority shall consider, as a minimum, the following factors in reviewing the qualifications of applicants:

(a) Any convictions of the applicant relating to FDA-regulated products.

(b) The applicant's history of regulatory compliance in the storage and distribution of FDA-regulated products.

(c) The applicant has provided the Authority with false or fraudulent information or material in respect of its application for FDA-regulated products.

(d) The applicant's licence has been suspended or revoked by the Authority for violation of any FDA law, and

(e) Any other requirements the Authority may from time to time prescribe.

3.1.1.6 The Authority may approve, defer or refuse an application following assessment including GSDP inspection findings which shall be duly communicated to the applicant.

3.1.1.7 A licence **signed by the CEO** issued under this Guideline shall be valid for one (1) year and shall be renewable.

3.1.1.8 The Authority shall exercise the right to cancel or suspend a licence in accordance with the law.

3.1.1.9 An applicant shall submit any and all changes in their application information to the Authority prior to amending or changing its existing records or information.

3.1.1.10 An application for licensing of a storage facility for medical products can be submitted at any of the FDA offices. (Appendix 3)

3.1.2 Renewal Applications

3.1.2.1 The registration and licensing of the premises shall be renewed annually.

3.1.2.2 An application for renewal of the registration of premises shall be made at least 3 months before the expiry of the existing licence by submitting with a cover letter the following:
(a) Duly completed application form.
(b) Non-refundable application fee in accordance with the FDA fee schedule.

3.1.2.3 The applicant's compliance with GSP/GDP shall be a key determinant to the renewal of the registration and licensing of the premises.

3.1.2.4 A Renewal application for licensing of a storage facility for medical products shall be submitted to the FDA offices (Appendix 3).

GSDP inspections of storage and distribution facilities of pharmaceutical products, herbal products and food supplements shall be conducted in line with relevant WHO guidelines and their stated references. The latest versions of each guideline as revised by the WHO shall be applicable in each case. **For all relevant publications, GDP/GSP/GSDP Technical Report Series (TRS) information and the latest updates, visit the WHO's landing page: https://www.who.int/publications/who-guidelines**

GSP/GDP/ GSDP REQUIREMENTS

3.1 Guide to good storage practices for pharmaceuticals. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-seventh report. Geneva, World Health Organization, 2003, Annex 9 (WHO Technical Report Series, No. 908). https://apps.who.int/iris/bitstream/handle/10665/42613/WHO_TRS_908.pdf?sequence=1

3.2 WHO good distribution practice for pharmaceutical products. In WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth report. Geneva, World Health Organization, 2010, Annex 5 (WHO Technical Report Series, No. 957). https://www.who.int/medicines/publications/TRS957_2010.pdf

3.3 Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products (jointly with the Expert committee on Biological standardization) in WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth report. Geneva, World Health Organization, 2011, Annex 9 (WHO Technical Report Series, No. 961). https://apps.who.int/iris/bitstream/handle/10665/44079/WHO_TRS_961_eng.pdf?sequence=1

3.4 Technical supplement to Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products (Supplement 01-16). In WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth report. Geneva, World Health Organization, 2014, Annex 5 (WHO Technical Report Series, No. 992). https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page109

3.4.1 supplement 1: Selecting sites for storage facilities. https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page114

3.4.2 supplement 2: Design and procurement of storage facilities. https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page115

3.4.3 supplement 3: Estimating the capacity of storage facilities. https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page117

3.4.4 supplement 4: Building security and fire protection. https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page118

3.4.5 supplement 5: Maintenance of storage facilities. https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page120

3.4.6 supplement 6: Temperature and humidity monitoring systems for fixed storage areas. https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page121

3.4.7 supplement 7: Qualification of temperature-controlled storage areas https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page123

3.4.8 supplement 8: Temperature mapping of storage areas. https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page125

3.4.9 supplement 9: Maintenance of refrigeration equipment.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page126

3.4.10 supplement 10: Checking the accuracy of temperature control and monitoring devices.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page128

3.4.11 supplement 11: Qualification of refrigerated road vehicles.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page129

3.4.12 supplement 12: Temperature-controlled transport operations by road and by air.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page131

3.4.13 supplement 13: Qualification of shipping containers.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page132

3.4.14 supplement 14: Transport route profiling qualification.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page133

3.4.15 supplement 15: Temperature and humidity monitoring systems for transport operations.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page134

3.4.16 supplement 16: Environmental management of refrigeration equipment.
https://apps.who.int/medicinedocs/documents/s21891en/s2189en.pdf#page135

3.4 Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection. In WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eighth Report. Geneva, World Health Organization, 2013, Annex 4 (WHO Technical Report Series, No. 986).
https://apps.who.int/medicinedocs/documents/s21464en/s21464en.pdf

3.5 Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. In WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report. Geneva, World Health Organization, 2011, Annex 8 (WHO Technical Report Series, No. 961).
https://apps.who.int/iris/bitstream/handle/10665/44079/WHO_TRS_961_eng.pdf?sequence=1

3.6 Good trade and distribution practices for pharmaceutical starting materials. In WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth report.

Geneva, World Health Organization, 2015, Annex 6 (WHO Technical Report Series, No. 996).
https://apps.who.int/medicinedocs/documents/s22397en/s22397en.pdf

3.7 Guidelines on the conduct of surveys of the quality of medicines. In WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth report. Geneva, World Health Organization, 2015, Annex 6 (WHO Technical Report Series, No. 996). https://apps.who.int/medicinedocs/documents/s22397en/s22397en.pdf

3.8 Good storage and distribution practices for medical products, World Health Organization, 2020, Annex 7 (WHO Technical Report Series, No. 1025).
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs1025-annex7-(1).pdf?sfvrsn=1f96888d_4&download=true

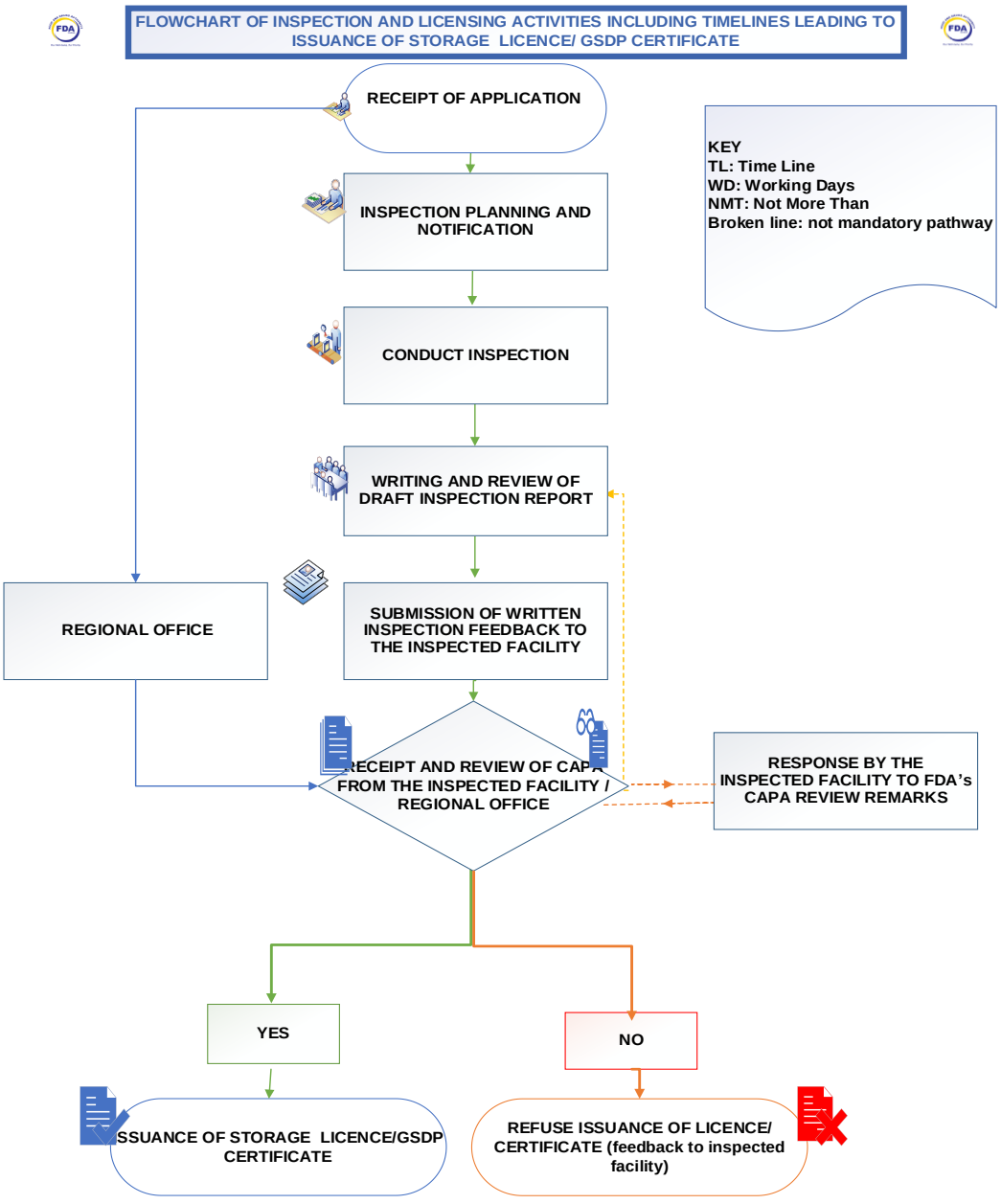
(SEE APPENDIX FOR THE TIMELINES FOR INSPECTION ACTIVITIES)

ANNEX 1: REQUIRMENTS FOR APPLICATION FOR VARIATION TO A DRUG STORAGE FACILITY

MAJOR VARIATION		
DESCRIPTION OF VARIATION	**CONDITION**	**DOCUMENTS REQUIRED**
Change of ownership	If there is change of ownership of the Storage facility licensed	1. Application letter 2. Proof of business name registration reflecting the name of new owner 3. Deed of sale or transfer of 4. Proof of payment
Transfer of location	If the location of the facility has been physically transferred with changes in previously approved address	1. Application letter 2. Proof of business name registration reflecting the new address 3. New location address 4. Proof of payment
Additional Activity	**If there is an addition of a new storage category (Ambient or Cold Storage) to a previously approved location/address**	**1. Application letter** **2. Proof of business name registration reflecting the new address** **3. Application Forms** **4. Proof of payment**
MINOR VARIATIONS		
VARIATION	**CONDITION**	**DOCUMENTS REQUIRED**
Change of activity	Change in the initial license activity	1. Application letter 2. Contract agreement to proof activity. 3. Proof of payment
Expansion of establishments	Expansion adjacent to existing licensed facility. Includes additional floors as well.	1. Application letter 2. Proof of payment
Change of business name	Change of business name without change in location of business owner	1. Application letter 2. Proof of business name registration reflecting the new name of the drug establishment 3. Proof of payment
Zonal change in address	Refers to change in the name/number of the street/building without physical transfer of the facility	1. Application letter 2. Document issued by the local authority as proof of zonal change. 3. Proof of payment

MINOR VARIATIONS- NOTIFICATIONS		
VARIATION	**CONDITION**	**DOCUMENTS REQUIRED**
Deletion of activity	Deletion of any approved/added distributor activity	1. Application letter 2. Termination of contract or conformance letter 3. Proof of payment
Transfer/addition of warehouse	Refers to the physical transfer of warehouse. Also refers to the addition of warehouse the existing or previously inspected warehouse.	1. Application letter 2. New location plan 3. Proof of payment

ANNEX 2: FLOW CHART



TIMELINES

LOCAL FACILITIES: NMT 3 months after receipt

NMT 5 WD

NMT 45 WD after the conduct of inspection

COMPANY: 25 WD to respond. (*may be varied*)
FDA: 20WD to review.
FOLLOW-UP INSPECTION REQUIRED: 20 WD after CAPA review.

NMT 10WD on approval

NMT 40 WD on issuance of licence/certificate.

ANNEX 3 : LIST OF REGIONAL OFFICES

OFFICE	ADDRESS	CONTACT
Head Office	No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie P.O, Box CT 2783 Accra. GPS: GA–237–7316	03022 35100
FDA Tema Heights	FDA Tema Heights, opposite Meridian Hotel, Tema	0551112225/0556759925/0264407571
Western Regional Office	Adjacent Fidelity Bank, Ghana Post Building, Takoradi Harbour P. O. Box MC 2129, Takoradi GPS: WS-406-1927	031 202 7558, 0544 338 829
Western North Regional Office	P. O. Box WS 51.Wiaso, W/R WH-0071-8745	0244470413/0207944200
Volta Regional Office	Agbasiape, Ho, close to St. Cecilia Roman Catholic Church GPS VH-0010-3089.	03620 26659, 0244399632, 0247 978 956
Upper West Regional Office	Controller Block, Ministries, P. O. Box 291 Wa. GPS: SW–022–9492	03920-20111, 0244 470 413
Upper East Regional Office	Regional Administration Building, P. O. Box 612, Bolgatanga ‘ GPS: UB-0034-4017	0247 717 744
Northern Regional Office	Regional Administration Building, P. O. Box TL 1763, Tamale GPS: NT–0066–3381	03672024935
North East Regional Office	North East Regional Coordinating Council (RCC) Nalerigu-Ghana GPS:ME-8358-6858	0244721831
Eastern Regional Office	Hospital Road, Opposite Assemblies of God Church,	0277 705 752

	P. O. Box KF 2431, Koforidua GPS: EN-011-2579	
Central Regional Office	UCC Credit Union Building Adjacent, CEDECOM Building, Pedu Junction P. O. Box CC 1373, Cape Coast GPS: CC-097-0402	033090110, 0245839521, 0504422905
Bono Regional Office	House No. 61A, Nkwabeng Extention, Sunyani. Near St. Mary's School. Opposite Goode Goode Spot. Postal address PMB, Sunyani GPS: BS-0054-2542	0352028791, 0265062697
Ashanti Regional Office	Regional Coordinating Council (RCC), next to Electoral Commission's Office P. O. Box ST 402, Kumasi GPS: AK-133-7324	0302-203-6027/70, 0507-187-420/1/2