FOOD AND DRUGS AUTHORITY, GHANA

GUIDELINE FOR GDP AND GSP INSPECTION OF STORAGE FACILITIES

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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.

2.0 GLOSSARY

GDP : Good Distribution Practice
GSP : Good Storage Practice
TRS : Technical Report Series
WHO : World Health Organization

3.0 REQUIREMENTS

GDP and GSP 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;

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

(SEE APPENDIX FOR THE TIMELINES FOR INSPECTION ACTIVITIES)

APPENDIX: Timelines for inspection of Storage Facilities