Ethiopian Food and Drug Authority

Medicine Good Manufacturing Practice (GMP)

Inspection Procedure Directive

Number 830/2021

July 2021

Addis Ababa, Ethiopia

Preamble

WHEREAS, ensuring compliance with the current Good manufacturing practice (GMP) of pharmaceutical products is necessary condition for pre and post approval of Marketing Authorization.

WHEREAS it is necessary to ensure products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by the product specification

WHEREAS it is necessary to utilize qualified expertise for foreign and local GMP inspection program who have extensive experience in conducting Pharmaceutical Quality Assessment, Quality Assurance and inspections with demonstrated track records of working effectively in the given time frame.

WHEREAS, considering the resource-intensive nature of the foreign GMP inspection and the current focus of the government on local manufacturers, it has become clear that effective and efficient inspection coverage is crucial to the successful management of the program and that can be achieved through maintenance of consistency and uniformity of inspection activities.

WHEREAS, it has become increasingly evident that a formal inspection guidance is necessary to address the issues specific to the foreign and local medicine inspection operations as the Authority needs to broaden the group of personnel to meet the objective of the program through this directive, the Authority strives to ensure that it continues to realize the consistency and uniformity in the overall inspectional activities.

WHEREAS is it necessary to provide specific direction on how to accept and process applications, address logistical issues, and handle compliant on an inspection to be carried out on both local and foreign establishments.

NOW, THEREFORE, this directive is issued in accordance with Article 71 (2) of the Food and Medicine Administration Proclamation No.1112/2019.

PART ONE
GENERAL

1. Short title

This directive may be cited as "Medicine Good Manufacturing Practice (GMP) Inspection Procedure Directive No 830/2021."

2. Definitions

In this directive, unless the context otherwise requires:

1) "Applicant" means the person or entity who submits a GMP inspection application to the Authority, and responsible for information provided in the application.
2) "Manufacturer" means a company that carries out operations listed under Article 2 sub-article (54) of the Food and Medicine Administration Proclamation No. 1112/2019
3) "Good Manufacturing Practice (GMP)" means a part of quality assurance which ensures medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing Authorization or product specification.
4) "Marketing Authorization" means an official document issued for the purpose of marketing or free distribution of a product after evaluation of safety, efficacy, and quality of the product.
5) "Stringent Regulatory Authority" means regulatory authorities which are recognized and listed as a stringent by the Authority.
6) "Conflict of interest (COI) "means any interest declared by an expert that may affect or reasonably be perceived to affect the expert's objectivity and independence in providing decision-making, and/or create an unfair competitive advantage for the expert or person with whom the expert has financial or business interests .

7) "GMP inspector" means a person who is appointed by the Authority as an Auditor or assessor in order to verify cGMP compliance of a manufacturing site.
8) "Lead GMP inspector" means GMP inspector who fulfills the requirement of lead GMP inspector and assigned with the responsibility of leading a GMP inspection team carrying out inspection of a specified Pharmaceutical manufacturing site.
9) "Exam organizing Entity"means a government or Non-government organization and or EFDA that organizes an exam to GMP Inspectors for evaluation of their capabilities of inspections and knowledge assessment.
10) "Critical observation" means any non-conformance, which can affect the purity, strength and safety of the medicines that pose a serious health risk to the users or potentially life threatening.
11) "Major observation" means any deviation from the established procedure, process, system and practice which could cause illness or improper treatment but are not critical.
12) "Minor/Others" means deficiencies that are not classified as critical or major observations
13) "Authority" means the Ethiopian Food and Drug Authority.
14) "Proclamation" means the Food and Medicine Administration Proclamation No. 1112/2019.
15) Other definitions provided under Article 2 of the Proclamation shall be applicable to this Directive.
16) Any expression in the masculine gender shall also apply to the feminine gender

3. Scope

1) This Directive shall be applicable on all local and foreign finished pharmaceutical manufacturing plants.
2) Notwithstanding sub-article (1) of this article, GMP inspections for active pharmaceutical ingredients manufacturing plants shall not be covered by this directive.

PART TWO

Type and Frequency of Inspection

4. General

1) Pharmaceutical manufacturing site shall only be inspected if it has been licensed to manufacture medicines by the licensing Authority of the country of origin and it has continued production of its products in the country of origin for a period of not less than one year.

2) Both local and foreign manufacturers of pharmaceutical shall only be licensed if the Authority is convinced by compliance of the manufacturing site with the current good manufacturing practice in the production of medicines, unless otherwise justified.

3) All finished pharmaceutical manufacturing facilities shall be subjected to site GMP inspection once every five years (as a requirement for complement of re registration), unless otherwise notified.

4) Site GMP inspection shall be carried out after dossier evaluation is completed.

5) Notwithstanding Sub-article (4) of this article, the authority may conduct inspection before completion of dossier evaluation.

6) A manufacturer approved by Stringent Regulatory Authorities (SRAs) and World Health Organization (WHO) prequalified product shall be subjected to GMP inspection based on related documents review.

7) Notwithstanding Sub-article (6) of this article, whenever necessary, an onsite inspection may be carried out by the authority.

8) The Authority will provide a temporary GMP certificate for the purpose of re registration in the time of pandemics and other challenging conditions by taking into consideration of the actual inspection to be carried out in the future.

9) Whenever necessary, GMP inspection shall be carried out with mutual recognition with identified and selected regulatory Authorities and IGAD. The Authority shall accept GMP Inspection report from these regulatory Authorities with pre agreed conditions.

10) In response to the application submitted for inspection of pharmaceutical manufacturer production sites, at least three-member inspection team shall be assigned.

11) Production lines and utilities shall run a major processing activity during the inspection to enable the team to evaluate their performance.

12) Onsite inspection on manufacturing site shall be carried out after the payment is effective.

13) Notwithstanding Sub-article (11) of this article; the authority may waive the payment for special or investigative inspection.

14) GMP inspection shall be carried out using Ethiopian National GMP Guideline and/or the World Health Organization (WHO) GMP Guideline.

15) Quality Assurance team constituting experts from the Medicine Facility Inspection Directorate, other Directorate and external experts, as appropriate, under inspection directorate shall be organized to ensure the quality of GMP inspection activities. Inspectors shall present the inspection outcomes and findings. The quality assurance team members shall be requested for advice during the time of hearing.

5. Routine inspection

1) Routine inspection shall be a full review of all aspects and components of GMP within a Manufacturing facility.
2) Routine inspection shall be conducted under an announcement for a newly established manufacturing facility, when GMP certification has expired within 5 years or a manufacturer who has expressed interest of expanding manufacturing activities including, premises change or modification.
3) These inspections will be carried out by a virtual team organized by Medicine Facility Inspection Directorate (MFID) from different Directorate.

6. Concise inspection

1) Concise inspection shall be conducted when a limited number of requirements selected to serve as indicators of the overall compliance to the manufacturer and reserve for establishments that have been previously inspected for good manufacturing practice.
2) The inspectors shall identify and evaluate any significant changes that might have been introduced by the establishment since its previous inspection.
3) If the concise inspection uncovers evidence that the level of compliance has fallen, comprehensive or full inspection should be performed soon after the concise inspection.

4) This type of inspections shall be carried by a virtual team composed from different Directorates.

7. Follow up inspection

1) Follow up inspection shall be conducted specifically to monitor the result of corrective actions of the manufacturer following a previous inspection.
2) Depending on the nature of the defects, the risks associated with the nonconformance and the work required, follow-up inspection shall be carried out within reasonable time after the previous inspection.
3) Follow-up inspection shall be limited to specified GMP non compliances that have been observed during the previous inspection.
4) The manufacture shall submit the CAPA within 6 months after receiving official inspection reports, otherwise a full inspection shall be initiated.
5) Notwithstanding Sub-article (4) of this article, due to the nature of the previous observations, the manufacturer may be allowed to submit corrective and preventive action (CAPA) longer than 6 months after receiving official inspection reports.
6) A maximum of three corrective and preventive action (CAPA) plan can be submitted otherwise; it will be considered as new application.
7) These inspections will be carried out by a virtual team organized by Medicine Facility from different Directorate.

8. Special inspection

1) Special inspection shall undertake to conduct “spot checks” which could focus on one product, a group of related products, or a specific operation such as manufacturing, sterilization, labeling, and storage practice.
2) Special inspection shall be conducted when there are complaints about a specific product that suggest a defect, non-compliance with good manufacturing practice or performance of new establishment whose scope of operation was previously unknown, when there is a product recall due to adverse drug reaction and post market surveillance, to gather

specific information, to investigate specific operations e.g. mixing, or labeling or when there is information of serious gaps/deficiencies/lapses.

3) Special inspection can be conducted for mutual inspections organized by groups, Communities, IGAD and other organization for the purpose of harmonization of inspection activities
4) These inspections will be carried out by staffs of MFID. However, the directorate may assign appropriate experts from other directorates for investigation.

9. Inspection of SRA approved company

1) The authority may waive the onsite inspection of SRA approved companies based on required GMP related documents for desk review as per the authority update list of SRA.
2) Notwithstanding of sub article 1 of this article, confirmatory onsite inspection on randomly selected SRA approved facilities may be conducted to check related documents submitted for desk review.
3) The document for desk review will include valid cGMP certificate from SRA or Pre-qualification evidence from WHO, Site master file ,Market authorization and Other related document requested by the authority.
4) This type of inspections shall be carried by a virtual team composed from different Directorates.

10.Remote Inspection

1)The authority may conduct remote inspection considering different scenarios when necessary.
2)The authority will develop detail guidance document for remote inspection procedure.

11.Frequency of inspection

1) Manufacturer's sites shall be inspected once every 5 year for the purpose of registration of their products, unless otherwise notified by the Authority.
2) Without prejudice to sub-article (1) of this article, depending on the type of inspection to be performed and whenever it is deemed necessary Manufacturers may be inspected

more than once within a 5-year period and a risk based inspection may b**PART THREE**

Role, Responsibility, Qualification and Assignment of GMP Inspector

12.Role and Responsibility of Inspector

1) GMP inspector shall prepare and get ready before undertaking a GMP inspection.
2) GMP inspector shall inspect a facility in a professionally oriented practice and team focus.
3) GMP inspector shall report individual findings and recommendations of the inspection within the agreed time to the GMP lead inspector.
4) GMP inspector shall evaluate his/her daily activity performance and get prepared for the next inspection.
5) The inspector shall evaluate the overall performance of the team leader and propose possible solution for any problem which arises during the inspection time.
6) GMP inspector shall respect cultural integrity of the country where the facility is situated.

13.Role and Responsibility of GMP lead Inspector

1) The GMP lead inspector shall perform the following listed role and responsibilities
   a. notify the manufacturer about the inspection agenda at least one week ahead of the inspection.
   b. notwithstanding sub article (1a) of this article ,for investigative inspection the manufacturer may or may not be aware in advance of the inspection.
   c. shall effectively and efficiently lead members of the inspection team.
   d. shall prepare for and organize preparation for inspection with the help of mock audit.
   e. shall act as a liaison to communicate responsible contact person of the facility and assure all logistics are finalized before travelling.
   f. shall ensure inspection is carried out based on the direction given from MFID

g. shall report the compiled findings and recommendations of the inspection within the given time frame to the MFID and GMP quality assurance as appropriate
h. shall evaluate the overall performance of the team members and propose possible solution for any problem which arises during the inspection time
i. shall evaluate daily performance of the inspection team and shall undertake the required preparation for the next inspection.
j. GMP lead inspector shall respect cultural integrity of the country where the facility is situated.

14.GMP quality assurance

1. The members of the GMP Quality Assurance team will be proposed by Medicine facility Inspection Directorate and approved and formed by Deputy Director General of Medicine Regulation
2. For the purpose of effecincy and monitoring of activities, the GMP Quality Assurance shall be within Medicine Facility Inspection Directorate.
3. The validity period of membership is five years
4. The GMP quality assurance team will prepare its own terms of reference
5. GMP quality assurance is responsible to evaluate final inspection report, as incase requested by the Directorate, and give advice on final decision for MFID before distributing to manufacturer.
6. The GMP quality assurance team may propose internal capacity building program, evaluation of inspector and different strategies related to GMP inspection.

15.Profession, Qualification and Competency of GMP Inspector

1) All assigned inspectors shall have bachelor's degree in pharmacy in profession. However, other professionals (chemist, microbiologist, and biologist) with acceptable qualification and competency might be assigned whenever necessary.
2) All inspectors shall be qualified to be nominated as inspector and have to take advanced GMP training and examination organized by the responsible body. The potential nominee shall pass the evaluation examination (for the first time) with a minimum passing mark of 60

3) Without prejudice to sub-article (2) of this article, the exam preparation, examination and evaluation of inspectors shall be supervised, monitored and lead by Deputy Director General of Medicine Sector.
4) Inspectors shall take acceptable credit hours of a continuous professional development courses specifically to GMP inspection (in house designed CPD equivalent Scheme). The number of credit hours, protocols and procedures shall be developed by Human Resource Managing Directorate in consultation with Medicine facility Inspection Directorate.
5) Each inspector shall fully take the credit hours within five years to renew its inspection membership
6) Lead inspector shall have :
    a. specific specialization in Pharmaceutics or Pharmaceutical analysis and Quality Assurance or Industrial Pharmacy or Pharmaceutical Regulatory affair or Pharmaceutical Microbiology or Pharmacology having at least two round inspection experience as inspector.
    b. Pharmacists having three round GMP inspection experience as an inspector and working in relevant regulatory function. However, whenever necessary, pharmacists having two round inspection experience as an inspector and working in quality control, dossier assessment and inspection activity shall be assigned as lead inspector along with inspector having same level of qualification.
7) Without prejudice to sub-article (1), (2), (3) and (4) of this article, any inspector who have conducted four or more round of GMP inspection and an expert who fulfills requirements prescribed under Article 16 sub-art (2,4) of this directive and experts having a two round GMP inspection experience and working as WHO Dossier Evaluator or WHO GMP inspector or WHO Laboratory Analyst shall be exempted from examination and continual professional development schemes.

16.Assignment of Inspector

1. Experts having a minimum of three years' experience in regulatory functions of appropriate department of EFDA with the required qualification, training, competency and appropriate previous ethical make up shall be assigned as GMP inspector.

2. Without prejudice to sub-article (1) of this article, if it is deemed to be necessary, experts having a minimum of 6 years' experience of working in prequalified and/or GMP complied medicine manufacturing companies of Production and Quality Assurance department may be assigned, whenever necessary.
3. Experts having a minimum of 6 years' experience in Regulatory functions at Dossier Evaluation, Medicine Quality Control Laboratory and Medicine Facility Inspection; and having the required qualification, training and competency shall be given priority to be assigned as Lead inspector.
4. International experts from WHO, PIC/s, EMA and other organizations having the required qualification, experience, and competency as per the above stated provisions may be assigned as inspector whenever necessary.

17. Code of conduct of Inspectors

1. GMP inspector shall behave in an ethical manner and do the task assigned to him/her by the lead GMP inspector.
2. GMP inspector shall respect cultural integrity of the country where the facility is situated.
3. Inspectors shall strive to achieve the highest ethical and performance standard in carrying out the inspection activities and shall conduct the inspection with National integrity.
4. Inspectors shall uphold the honor and dignity of a GMP Inspector and avoid association with any enterprise of questionable character or apparent conflict of interest.
5. Any assigned inspector shall not use his/her position for personal gain, and he/she shall not receive presents in any form.
6. Inspectors shall conduct inspection in a manner that will assure independence from outside influence and interest that would result in compromise of his ability to render a fair and impartial opinion regarding the inspection conducted.
7. Inspectors shall maintain personal hygiene and dress in respectable attire in accordance with acceptable norms.
8. Without prejudice of the above articles ,the inspectors shall be governed by organizational code conduct.

PART FOUR

Application and program Administration

18.Application procedure

1) Applicant or manufacturer shall submit a written application for medicine inspection directorate of the Authority or can submit the application through its Regulatory Information System (https://ilicense.efda.gov.et) .
2) All correspondence and documents required to be submitted shall be in English. If the document required is not in English, it should be accompanied by a certified translation.

19.Program Administration and Management

1) Both the local and foreign inspection program shall be managed and directed by MFID. The inspection directorate shall schedule the inspection trips and provide all the documentations necessary for the program activities.
2) The MFID of the Authority shall ensure in advance the presence of any conflict of interest among the assigned inspectors.
3) Inspectors and Lead Inspectors shall be nominated by MFID and appointed by respective Deputy Director General or Director General of the Authority.
4) All local facilities inspection Management, including but not limited to assignment and approval of inspectors, evaluation of the inspection report will be handled by MFID.
5) Without prejudice to sub article (4) of this article, the MFID may assign appropriate experts from other directorates of the Authority.
6) A maximum of Five facilities oversees and not more than three countries shall be assigned for inspection on a single trip.
7) The inspection time schedule shall be decided based on manufacturing complexity and manufactured product properties. The detail inspection time schedule shall be as per attached time schedule of this directive.

20.Exceptional conditions for local pharmaceutical companies

1) The inspection shall be conducted by MFID expert
2) Without prejudice to sub article 1 of this article, if needed MFID may participate expertise from different directorate of the Authority
3) Inspection may be initiated by the company or the authority at any time.
4) For new and renewal GMP inspection, inspection shall be carried out where payment is effective. However Inspection fee may not be requested for other inspection types.
5) Validity of the GMP certificate shall be for five years; however the inspection shall be conducted at any times within the validity period.
6) Article 4 of sub-article (1) of this directive is not applicable to local manufacturers.
7) The incompliance for GMP requirements by Existing local industries may be acceptable for a defined period of time. In such cases, an investigation of the quality through laboratory testing shall be required. However, any new establishments shall be allowed to market if and only if they comply the requirements for GMP

21.Inspection planning

1) Earliest inspection application shall be given priority during inspection planning or scheduling.
2) Without prejudice to sub-article (1) of this article, sites whose inspection would be crucial in making an ongoing regulatory decision or meeting an emergency or a public health issue shall be given priority during inspection planning,

22.Classification and Recommendation of Observation

1) Situations involving fraud, misrepresentation or falsification of source data or records linked with pharmaceutical manufacturing shall result in a non-compliance rating.
2) Non-compliance should be noted by inspectors and classified as critical, major, and others deficiency.
3) Manufacturer with noncompliance even with single critical finding shall be refused from acceptance for GMP licensing. If six and more major findings are found in five critical areas of manufacturing facilities (Warehouse, Production, Quality Control, Utilities,

Documentation, and premises) are observed, manufacturer shall be refused from GMP certification.

4) Without prejudice to sub-article (3) of this article, if the total major findings are more than 15 irrespective of the critical areas of manufacturing, the authority may refuse from GMP certification.
5) Without prejudice to sub-article (3 and 4) of this articles, corrective and preventive measures taken by the manufacturer may be submitted to the Authority within 90 working days after receiving formal report for Non-compliance of major and other observations. However, onsite re- inspection may be required to decide the compliance of the facility.
6) If company is not granted GMP compliance certificate , the company can apply for re-inspection along with the previous inspection CAPA program and report.

23.Inspection Report Writing, Reviewing and Approval Process

1) The inspection observation shall be recorded immediately on each day after completing the daily inspections according to standard operating procedures for preparing and reviewing GMP inspection report.
2) The compiled report shall be submitted to MFID within 15 calendar days upon completion of inspection and return back home.
3) The MFID of the Authority shall distribute the foreign facility report for reviewing process to GMP quality assurance team within 3 working days upon receipt from the inspection team.
4) The GMP quality assurance team shall review the report within five –ten working days of receipt.
5) The MFID of the Authority shall make sure that the GMP inspection report is sent to the inspected manufacturer within forty-five calendar days from the last day of the inspection and back home.
6) The Inspection report shall be specific and provided with sufficient details in order to allow an independent assessment, comprehension and easy decision making.
7) Observations that are considered to be inconsistent with GMP requirements shall be listed and referenced with Ethiopian National GMP Guideline and/or the World Health Organization (WHO) GMP Guideline. Where observations are included in the report,

clear distinction shall be made between “compliances” and “non-compliances”, and Non-compliance observations shall be classified as “critical”, “major” and “others”.

24. Role of Director General and Deputy Director General in Coordinating of Activities

1) The inspection activities shall be supervised with respective Deputy Director General of the Authority, whenever necessary, including the Director General shall be involved in follow up inspection to clear complain, proposing future strategies and promoting overall regulatory activities, whenever necessary.

2) Without prejudice to sub-article (1) of this article, DG and DDG, Medicine Sector shall travel to the manufacturing site to supervise, monitor, and have a look of the inspection.

3) Trend reports of successive inspection report shall be statistically evaluated and consumed for further regulatory measures.

PART FIVE

Administrative Measure and Compliant Handling Procedure

Section-One

Administrative Measure

25.Corrective Notification

1) Corrective notification shall be given by the MFID director when violations are significant enough for the issuance of a corrective notification letter and reasonable expectation exist that the inspector will correct the violation.
2) Corrective measure shall be given by MFID director in written form immediately after completion of the inspection.

26.Issuance of warning letter

3) When minor violation occurred the Deputy Director General, Medicine Sector shall give a warning letter to the inspector for the following violations.

    a) If the inspector or lead inspector did not submit the inspection report within the time frame
    b) If the inspector or lead inspector did not follow the inspection report writing procedure
    c) If the inspector or lead inspector did not follow the role and responsibilities
    d) If the inspector or lead inspector did not obey the code of conduct.

1) Warning letter shall be issued within a reasonable period of time not exceeding ten working days of the knowledge of the violation by Deputy Director General, Medicine Sector.

27.Rigorous disciplinary measure

1) Any rigorous violation of the inspector shall be considered as rigorous disciplinary violation and shall be governed by the Federal Civil Servants Proclamation No.1064/2017 and take appropriate measures according to the violation of the law.
2) Notwithstanding sub article (1) of this article, disciplinary violations shall be presented to the Authority's Disciplinary Committee based on Federal Government Regulation No. 77/94.

28.Manufacturer

1. Any manufacturer who tries to corrupt or deceive the inspectors in which the authority has an evidence of such act, it shall be subjected to rejection of inspection for at least five years.
2. Notwithstanding sub article (1) of this article, any manufacturer who provided false information as an evidence of compliance for cGMP shall be rejected and blacklisted for consecutive three years.
3. Any manufacturer who became absent deliberately during the inspection process shall be considered as inspected and it shall be rejected. If the manufacturer wants to be inspected in the future, it shall pay the inspection fee based on the information on Service fee Regulation.
4. A manufacturer who showed or tried to show a manufacturing facility other than the site located on site master file is subjected to rejection.

Section-Two

Complaint Handling Procedure

29.Complaint related to assignment of inspector

1) Any candidate inspector shall submit his/her complaint on assignment of inspectors for GMP inspection to the Deputy Director General, Medicine Sector within two working days after the announcement of the inspection team.
2) The compliant prepared in accordance with sub-article (1) of this article shall be in written form and shall also provide appropriate documentary evidence and other evidences relevant to the case.
3) Where the compliant fulfills the above stated requirements, the Deputy Director General, Medicine Sector shall notify its final decision to the complainant within 2 days from the receipt of the compliant.
4) The decision to the compliant prepared in accordance with sub-article (3) of this article shall, at least, include the reason why the compliant should not be acceptable for any reasonable ground.

5) If the candidate inspector does not accept and satisfied with the decision of Deputy Director General, Medicine Sector, she/he may take the compliant to the authority compliant handling committee.

30. Complaint related to inspection finding and decision

1) Any manufacturer may appeal against any decision of the Authority within 30 working days from the receipt of official letter from the Authority.
2) The compliant prepared in accordance with sub-article (1) of this article shall, at least state, the Authorities' alleged reason to take the measure, decision of the Authority, reasons of the complainant why he/she believes the measure is unjustifiable or inappropriate and shall be signed and dated by the complainant.
3) The compliant prepared in accordance with sub-article (1) of this article shall be in written form and shall also provide appropriate documentary evidence and other evidences relevant to the case.
4) Where the compliant fulfills the above stated requirements, the DG shall submit to compliant handling committee or other appropriate body
5) The compliant handling committee or other appropriate body shall review the complaint within 60 days and shall present the decision to DG of the Authority
6) The DG of the Authority shall present the final decision to the manufacturer
7) The manufacturer should appeal to court incase if still not satisfied by the final decision made by the Director General of the Authority.

PART SIX

Miscellaneous

31.Confidentiality and conflicts of interest

1) The selected inspector shall declare and sign the conflicts of interest and confidentiality agreement before participating the GMP inspection and shall follow respective MFID SOPs and directions
2) The inspector shall properly maintain confidential information of the manufacturer unless it is disclosed by the manufacturer.
3) The inspectors shall properly maintain confidential information unless it is required by judiciary body.

32.Record handling

The inspection directorate shall keep all relevant documents pertaining to GMP inspection activities including inspection report for at least until re- inspection done and shall fulfill the requirements on Record Handling Directive.

33.Service Fee

Any person who seeks regulatory service under this directive may be required to pay applicable service in accordance with current rate of service fees regulation .

34.Inapplicable laws

1) With respect to matters provided by this directive, Pharmaceutical Manufacturer GMP inspection Directive, which is currently under use, is hereby repealed.
2) Any customary practice which is inconsistent with this directive shall not be applicable with respect to those matters provided for in this directive.

35.Effective date

This directive shall enter into force on the date of _____ July 2021.

Heran Gerba

Ethiopian Food and Drug Authority

Director General

ANNEXE

Annex 1: GMP Inspection Report form

Annex 2: GMP Inspection Report form

Annex 3:GMP inspection notification letter for fully accepted or not accept manufacturers

Annex 4: Sample GMP inspection notification letter for partially accepted manufacturers

Annex 5: Pharmaceutical manufacturer GMP Inspection Application Form

Annex 6: Inspection Agenda's

Annex 7: Inspection check list

Annex 8: Conflict of Interest declaration format

Annex 9: GMP Certificate Template

Annex 1

Table 1: Number of Inspection days allocated

Facility Type	**Number of Days allocated for Inspection**
Facilities having four production lines and below for re inspection for English and Non English Speaking Countries.	**2**
Facilities having five production lines and more for re inspection for English and Non-English-Speaking Countries	**3**
Facilities having up to four production lines for New, Renewal, Sudden, Special and Investigation inspection for English and Non English Speaking Countries	**3**
Facilities having above five to six production lines for New, Renewal, Sudden, Special and Investigation inspection for English and Non English Speaking Countries	**4**
Facilities having above Seven and above production lines for New, Renewal, Sudden, Special and Investigation inspection for English-Speaking Countries	**5**
Report Writing	**1** (For every 2.5 Facilities)