

Medicine Manufacturing Establishments Control (Amendment) Directive No. 1040/2025

whereas, it's found necessary to revise The Medicine Manufacturing Establishment and Competence of Certificate issuance and control Directive 1000/2024 to make the title of the Amharic and English language name similar and consistent meaning;

where As, Gaps observed during renewal of competence of certificate its necessary to revise the directive and establishes a consistence renewal system;

NOW THEREFORE, the Ethiopian Food and Drug Authority issue in accordance with Article 71(2) issue this Medicine Manufacturing Establishment control directive.

1. Short Title

This Directive may be cited as ***“Medicine Manufacturing Establishments Control Directive (Amendment) No. 1040/2025”***.

2. Revised

The Medicine Manufacturing Establishment and Competence of Certificate issuance Directive is revised as follow:-

- 1) The title of the Directive is corrected as ” The Medicine Manufacturing Establishment Control Directive”.
- 2) The Article 8 of the Directive require Engineering Head as a key personnel and specifically sub-Article(1(F)) last part of the table which Require key personnel Engineering Head Minimum required qualification – Bachelor Degree in Mechanical Engineering ,Required Experience – A minimum of Five years’ experience in industry in utility and system maintenance and engineering is completely deleted.
- 3) The Directive sub-article (1) of Article 10 is deleted and replaced by the following sub-Article(1)
“1).Any Medicine manufacturer’ Good manufacturing practice shall be renewed every five years, however as the risk level of the manufacturing the inspection may repeatedly made during the five years.”
- 4) Followed by Article 10 sub-Article (5) of the Directive new sub-Article (6) added as follow;
“6). Any Medicine Manufacturing Establishment Competence of Certificate shall be renewed annually.”

3. Effective Date

This Directive will be effective from the date registered by the Ministry of Justice and upload on the Ministry and Food and Drug Authority website.

Heran Gerba
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