

MAJOR REGULATORY REFORM IN ETHIOPIA'S HEALTHCARE SECTOR



The new directive establishes a significantly enhanced regulatory framework governing the prescribing, dispensing, compounding, monitoring, and promotion of medicines in Ethiopia. The reform reflects the evolving needs of the healthcare sector and introduces measures designed to improve patient safety, strengthen accountability among healthcare professionals, support the digitalization of healthcare services, and address the growing global challenge of antimicrobial resistance.

The directive represents one of the most comprehensive updates to Ethiopia's medicine-use regulatory framework in recent years and will require healthcare institutions and professionals to review their existing policies, procedures, and operational practices to ensure compliance.

Key Highlights of the New Directive

Modernized Regulatory Framework

The new directive introduces a more comprehensive and detailed approach to the regulation of medicine use. Several definitions and regulatory concepts have been updated to align with current healthcare practices and international standards.

Important concepts such as antimicrobial resistance, trade names, and transcription papers have been expressly defined, while the qualifications and licensing requirements of healthcare professionals are articulated with greater clarity. These updates provide improved legal certainty and facilitate more consistent implementation across healthcare institutions.

Enhanced Prescription Standards

The directive strengthens prescription requirements by introducing a more standardized prescription format and imposing additional obligations on prescribing professionals.

Prescription documentation is expected to contain more detailed information and follow stricter procedural requirements aimed at improving patient safety, reducing medication errors, and enhancing accountability throughout the prescribing process.

Healthcare institutions should review their prescription forms and related procedures to ensure alignment with the new standards.

New Controls on Prescription Validity

One of the most significant reforms introduced by the directive relates to the validity period of prescriptions. While ordinary prescriptions continue to have a validity period of thirty days, prescriptions for antimicrobial medicines are now subject to a substantially shorter validity period. This measure is intended to discourage delayed use of antimicrobial medicines, promote timely treatment, and contribute to national efforts aimed at combating antimicrobial resistance.

The change reflects a growing global emphasis on responsible antibiotic use and stewardship.

Stricter Prescribing Practices

The directive introduces stronger safeguards against inappropriate prescribing and polypharmacy.

Healthcare professionals are now subject to clearer limitations regarding the number of medicines that may be prescribed under a single prescription. The directive also reinforces the principle that medicines should generally be prescribed using their generic names rather than brand names.

Prescription by trade name remains permissible only under limited and justifiable circumstances. Where such prescribing occurs, the reason must be properly documented. This approach seeks to improve affordability, encourage rational medicine use, and promote consistency in pharmaceutical care.

The directive also provides greater flexibility for patients requiring long-term treatment by allowing extended prescription periods in appropriate circumstances, particularly where supported by recognized treatment guidelines.

Comprehensive Regulation of Electronic Prescriptions

Recognizing the increasing role of digital technologies in healthcare delivery, the directive introduces detailed requirements governing electronic prescription systems.

Healthcare institutions utilizing electronic prescribing platforms are required to ensure that such systems meet appropriate standards relating to validation, interoperability, security, reliability, and record retention. The framework is designed to promote trust in digital health systems while safeguarding patient information and preserving the integrity of prescription records.

The directive further protects patient choice by ensuring that patients who prefer to obtain medicines elsewhere can still receive a paper prescription where necessary.

Strengthened Antimicrobial Resistance Prevention Measures

A defining feature of the new directive is its strong focus on antimicrobial resistance prevention and control. For the first time, the directive establishes a dedicated regulatory framework aimed at promoting responsible antimicrobial use within healthcare institutions. Hospitals, health centers, and specialized healthcare facilities are required to establish Antimicrobial Stewardship Committees tasked with overseeing the appropriate selection, prescribing, dispensing, and monitoring of antimicrobial medicines.

The directive also introduces safeguards intended to preserve the effectiveness of critical antibiotics and ensure that high-priority antimicrobial medicines remain available for situations where they are genuinely needed.

These measures align Ethiopia's regulatory framework with international efforts to address one of the most pressing public health challenges of the modern era.

Enhanced Dispensing Requirements

The directive introduces clearer and more detailed requirements governing medicine dispensing activities. Pharmacy professionals are expected to exercise greater diligence when processing prescriptions, issuing transcription papers, substituting medicines, and managing prescription refills. Additional documentation and verification requirements have been introduced to improve traceability and reduce the risk of medication errors.

The framework also strengthens the professional responsibilities of pharmacists by requiring more active involvement in ensuring patient safety and appropriate medicine use.

Stronger Regulation of Medicine Compounding

Healthcare institutions engaged in the compounding of medicines are now subject to enhanced quality assurance obligations.

The directive requires the implementation of standardized procedures, improved documentation practices, and comprehensive labeling requirements. Greater emphasis is placed on quality control, traceability, and the use of appropriate pharmaceutical-grade ingredients.

Importantly, the directive establishes clearer accountability mechanisms where harm results from non-compliance with compounding standards, thereby encouraging higher levels of professional diligence and institutional oversight.

Expanded Patient Counselling and Information Services

The new directive strengthens patient-centered care by expanding the counselling obligations of pharmacy professionals.

Patients must be provided with adequate information regarding the safe and effective use of medicines through communication methods appropriate to their level of understanding. Written guidance, verbal explanations, and practical demonstrations may all be required depending on the circumstances.

Healthcare institutions are also expected to establish medicine information services that provide accurate, objective, and evidence-based information while avoiding promotional or misleading practices.

These requirements are intended to improve patient understanding, encourage treatment adherence, and reduce medication-related risks.

More Structured Enforcement and Compliance Mechanisms

The directive introduces a more detailed and transparent administrative enforcement framework. Violations are categorized according to their severity, with regulatory responses ranging from written warnings for minor infractions to suspension and eventual revocation of professional licenses or certificates for repeated or serious violations. The graduated enforcement structure provides greater predictability while reinforcing the importance of compliance with professional and institutional obligations.

Implications for Healthcare Institutions and Professionals

The introduction of the new directive will require healthcare institutions and professionals to undertake comprehensive compliance reviews. Particular attention should be given to prescribing practices, antimicrobial stewardship programs, pharmacy operations, medicine compounding activities, patient counselling procedures, record management systems, and electronic prescription platforms.

Healthcare facilities should also consider conducting staff training and awareness programs to ensure that healthcare professionals understand the new regulatory requirements and their practical implications. Failure to adapt institutional practices to the new framework may expose organizations and professionals to administrative sanctions and other regulatory consequences.

Conclusion

The Rational Medicine Use Control Directive No. 1138/2026 represents a significant modernization of Ethiopia's pharmaceutical and healthcare regulatory landscape. The directive strengthens patient protection, promotes responsible medicine use, supports digital health innovation, enhances accountability among healthcare professionals, and introduces robust mechanisms to address antimicrobial resistance.

As the healthcare sector transitions to this new regulatory regime, proactive compliance efforts will be essential. Healthcare institutions, pharmacies, pharmaceutical businesses, and medical professionals should carefully assess their existing practices and implement the necessary operational and policy changes to ensure full compliance.

DISCLAIMER

This legal update has been prepared by Hirko & Associates Law Office for general informational purposes only and provides a summary of selected aspects of the Rational Medicine Use Control Directive No. 1138/2018 (the "Health Directive"), which repeals and replaces the former Rational Medicine Use Control Directive No. 346/2013.

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