

Regulatory Oversight in Action: How EDA Safeguards Public Health

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The Egyptian Drug Authority (EDA) plays a critical role in protecting public health by ensuring that all human pharmaceutical products in the market maintain a positive benefit–risk balance. While granting a Marketing Authorization (MA) license signifies confidence in a product’s quality, safety, and efficacy, the process does not end there. Continuous post-market monitoring is central to EDA’s regulatory philosophy.

When new safety information emerges often as products are used in larger populations over extended periods, EDA evaluates whether the benefit–risk profile remains acceptable. This may involve actions such as updating product labeling with new warnings, restricting indications, or, in severe cases, suspending or revoking the product’s marketing authorization.

This robust system is legally grounded in the Pharmacy Profession Practice Law (No. 127/1955) and Law No. 151/2019, which empower EDA to act decisively on quality, safety, or efficacy issues. EDA applies evidence-based and risk-based assessment strategies, relying on validated scientific data, international regulatory benchmarks, and expert committee recommendations.

Crucially, the process includes input from the Pharmacovigilance Committee and Scientific Evaluation Committees, ensuring that decisions are both scientifically sound and aligned with public health priorities. Transparency is also emphasized, with final decisions published on EDA’s website, and marketing authorization holders are given the right to appeal within 60 days.