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Review Article

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Bridging the gap: Novel antifungal agents and the challenge of equitable access in low- and middle-income countries

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ABSTRACT

Invasive fungal infections are a major, yet under-recognized, global health threat, accounting for an estimated 1.6–1.7 million deaths annually–on par with tuberculosis and surpassing many neglected tropical diseases. The disproportionate burden in low- and middle-income countries (LMICs) is compounded by poor diagnostic capacity, outdated treatment options, and lack of access to novel antifungals. This review provides a critical analysis of newly approved and late-stage antifungal agents, evaluates their clinical profiles and regulatory progress, and explores the systemic barriers to affordability and accessibility in LMICs. A narrative review approach was employed, drawing on literature from PubMed, Scopus, Web of Science, and policy databases between 2018 and 2025. The review integrates clinical trial data, pharmacoeconomic assessments, and global access policies, with a focus on seven agents: ibrexafungerp, rezafungin, fosmanogepix, olorofim, oteseconazole, opelconazole, and MAT2203. While these agents represent significant therapeutic advances–targeting drug–resistant Candida auris, azole–resistant Aspergillus, and rare molds–barriers remain formidable. High prices driven by orphan drug status, patent protections, limited registration in LMICs, inadequate fungal diagnostics, and supply chain inequities obstruct access.Strategic interventions are needed, including tiered pricing, pooled procurement, inclusion of antifungals on the WHO Essential Medicines List, and public–private models with access clauses. Furthermore, decentralized trials, local manufacturing, and diagnostic innovation will be essential to align antifungal R&D with global health equity goals. Novel antifungal agents offer transformative potential for managing invasive fungal infections, but without coordinated policy, financing, and access initiatives, LMICs will continue to face unacceptable treatment gaps. Bridging innovation and implementation must become a core global health priority.

KEYWORDS: Antifungal resistance; Emerging antifungals; Drug access in LMICs; Invasive fungal infections; Essential medicines policy

1. Introduction

Fungal infections represent a growing, yet persistently overlooked, global health threat. Each year, over one billion individuals are affected by fungal diseases, with an estimated 1.6 to 1.7 million deaths attributable to invasive fungal infections (IFIs) – a mortality burden rivaling that of tuberculosis and exceeding many neglected tropical diseases[1,2]. Despite their lethal nature and increasing incidence, especially among immunocompromised individuals and in the context of emerging drug resistance, fungal infections have received minimal attention in global public health policy and research funding agendas.

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The urgency of this crisis was underscored when the World Health Organization (WHO) released its first–ever Fungal Priority Pathogens List (FPPL). This document classified nineteen fungal pathogens into critical, high, and medium priority tiers, based on factors such as mortality, treatment difficulty, antifungal resistance, and public health impact. The critical group included Candida auris, Candida albicans, Aspergillus fumigatus, and Cryptococcus neoformans–pathogens that disproportionately affect patients in low– and middle–income countries (LMICs) where diagnostic and therapeutic capacity is limited[3].

At the heart of the challenge lies the antifungal research and development (R&D) gap. While antibacterial R&D has benefited from robust public–private partnerships and market incentives, antifungal pipelines have historically remained sparse. Until recently, therapeutic innovation was stagnant, with no new class of antifungals approved for nearly two decades. However, the past five years have seen a cautious resurgence, with several novel antifungal agents–such as ibrexafungerp, olorofim, rezafungin, fosmanogepix, and oteseconazole–progressing through late-stage clinical trials or gaining regulatory approval[4,5].

Despite this progress, a critical gap persists in ensuring equitable access to these promising therapies. High development costs, patent barriers, and limited production capacity mean that newer antifungals are often unavailable or unaffordable in LMICs–regions that bear a disproportionate share of the fungal disease burden. Moreover, lack of surveillance systems, limited diagnostic infrastructure, and weak regulatory pathways further exacerbate access disparities.

This review aims to present an updated overview of the most promising antifungal agents targeting critical fungal pathogens; Evaluate their current regulatory status, therapeutic potential, and mechanisms of action; Critically assess the barriers to affordability, availability, and implementation of these agents in LMICs; and propose actionable strategies to close the innovation-access divide.

By addressing both the scientific advancements and systemic barriers surrounding novel antifungal accessibility, this review seeks to support global policy, regulatory, and clinical efforts aimed at reducing fungal mortality and improving equity in infectious disease therapeutics.

2. Methods

This article is structured as a narrative review synthesizing recent evidence on emerging antifungal agents, with a focused lens on their accessibility and affordability in LMICs. The review combines a structured literature search with critical analysis of regulatory trends, clinical trials, pharmacoeconomic evaluations, and access frameworks.

2.1. Literature search strategy

We conducted a comprehensive literature search across multiple databases, including PubMed, Scopus, Web of Science, and Google Scholar, covering the period from January 2018 to June 2025. Key search terms included combinations of: 1) “novel antifungals”, “emerging antifungal agents”, “rezafungin”, “ibrexafungerp”, “olorofim”, “fosmanogepix”, “opelconazole”, “oteseconazole”, “MAT2203”; 2) “Candida auris”, “Aspergillus fumigatus”, “Cryptococcus neoformans”, “invasive fungal infections”; 3) “drug access”, “antifungal affordability”, “availability in LMICs”, “essential medicines list”, “orphan drugs”, “drug pricing”, and “regulatory challenges in LMICs”.

Articles were limited to English–language publications and included peer–reviewed articles, clinical trial reports, policy briefs, WHO and EMA/FDA guidance, and relevant pharmacoeconomic analyses.

2.2. Selection criteria

We included studies and reviews that met the following criteria: 1) Reported on clinical development, regulatory status, or pharmacokinetics/pharmacodynamics (PK/PD) of antifungal agents approved since 2020 or in advanced clinical trials (Phase Ⅱ or Ⅲ); 2) Provided access–related insights, including pricing, licensing, availability, or inclusion on national or international essential medicines lists; 3) Focused on antifungal use in LMIC contexts, or included stratified data relevant to those regions.

Papers focused solely on veterinary use or environmental applications were excluded.

2.3. Data extraction and synthesis

Relevant data were extracted and synthesized under the following thematic domains: 1) Clinical efficacy and safety profiles of novel antifungal agents; 2) Mechanism of action and resistance potential; 3) Regulatory approvals and orphan drug designations; 4) Barriers to access in LMICs: pricing, procurement, manufacturing, and policy; 5) Strategies for improving availability and affordability: tiered pricing, local manufacturing, pooled procurement, and WHO EML inclusion.

Each domain was analyzed in the context of WHO Fungal Priority Pathogens and mapped to current epidemiological and healthcare access patterns in LMICs. Descriptive statistics were included when applicable.

2.4. Quality assurance

To enhance validity, findings were cross–referenced with reports from: 1) WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS); 2) The Global Action Fund for Fungal Infections (GAFFI); 3) Regulatory authorities (FDA, EMA, CDSCO, *etc*.); 4) ClinicalTrials.gov and EU Clinical Trials Register.

Where data were conflicting or incomplete, conservative interpretations were made, and limitations clearly noted.

A comprehensive overview of the clinically relevant characteristics of each novel antifungal agent is presented in Table 1 and 2[6–12]. This table synthesizes critical information including mechanism of action, target pathogens, drug-resistance profile, regulatory status, and route of administration, serving as a practical comparative reference to evaluate their suitability and implementation potential in LMIC settings.

3. Challenges in LMICs: affordability and access

Despite promising advances in antifungal drug development, the translation of innovation into equitable accessremains a formidable challenge in LMICs. These regions bear a disproportionate burden of fungal disease–particularly among populations with HIV/AIDS, tuberculosis, and hematological malignancies–yet consistently face systemic obstacles that hinder the availability, affordability, and implementation of antifungal therapies[13].

Table 1. Summary of findings.

Antifungal agent	Class/mechanism of action	Target pathogens	Drug-resistant activity	Regulatory status	Administration route
Ibrexafungerp	Triterpenoid; Glucan synthase inhibitor	Candida spp., Aspergillus spp.	Active against azole- and echinocandin-resistant Candida; azole-resistant Aspergillus	FDA approved (2021); Orphan status in US & EU	Oral
Rezafungin	Echinocandin; Long-acting β-1,3-glucan synthase inhibitor	Candida spp.(incl. C. auris), Aspergillus spp.	Active against echinocandin-resistant Candida; reduced FKS mutation risk	FDA approved (2023); EMA under review	IV
Fosmanogepix	Gwt1 inhibitor; GPI-anchor biosynthesis disruption	Candida spp., Aspergillus spp., rare molds	Effective against echinocandin- and azole-resistant isolates	Phase 3; Orphan status (FDA & EMA)	Oral and IV
Olorofim	Orotomide; Inhibits DHODH (pyrimidine synthesis)	Aspergillus spp., Scedosporium spp., Histoplasma	Potent against azole-resistant Aspergillus; limited cross-resistance	Phase 2b/3; Regulatory submission expected	Oral
Oteseconazole	Tetrazole; Highly selective CYP51 inhibitor	Candida albicans, azole-resistant Candida spp.	Demonstrated efficacy against azole-resistant Candida	FDA approved (2022) for recurrent vulvovaginal candidiasis	Oral
Opelconazole	Inhaled triazole; CYP51 inhibitor	Aspergillus fumigatus, A. terreus	Under evaluation; potential efficacy against azole-resistant Aspergillus	Phase 2/3 trials ongoing	Inhaled
MAT2203	Encochleated amphotericin B; membrane binder	Candida spp., Cryptococcus spp., Aspergillus spp.	Broad activity with classic amphotericin spectrum; reduced toxicity	Phase 2; FDA Fast Track status	Oral

Table 2. Approved uses , cost and availability of the FDA approved novel antifungals[6,7,10].

Antifungal agent	Conditions for which approved for use (FDA)	Dosage	Cost of drug (approx)	Availability in LMIC countries
Ibrexafungerp	Acute vulvovaginal candidiasis (VVC): DOVE trial Recurrent vulvovaginal candidiasis (RVVC): CANDLE trial	VVC- 300 mg PO q12 hr × 1 day RVVC- 300 mg PO q12 hr × 1 day; repeat monthly for 6 months	$ 535 (4 tablets)	Mostly unavailable
Rezafungin	Approved for adults for resistant candidemia and invasive candidiasis : ReSTORE Trial	400 mg IV ×1 dose Then 200 mg IV qweek ; Efficacy and safety not established beyond 4 weekly doses	$ 2 000 for 200 mg IV powder for injection	Unavailable
Oteseconazole	Recurrent vulvovaginal candidiasis (RVVC) in females who are not of reproductive potential	Oteseconazole only regimen: Day 1: 600 mg PO × 1 dose then Day 2: 450 mg PO × 1 dose Beginning on Day 14 150 mg PO qweek for 11 weeks Fluconazole plus oteseconazole regimen : Days 1,4,7- Fluconazole 150 mg PO ×1 dose, then Days 14 to 20 : Oteseconazole 150 mg PO qday 7 days, then Beginning on Day 28-Oteseconazole 150 mg PO qweek for 11 weeks (weeks 4 to 14)	$ 3 000 for 18 capsules 150 mg	Unavailable

3.1. Market dynamics and pricing

One of the primary barriers to antifungal access in LMICs is the market–driven pricing structure associated with novel therapeutics. Most of the recently approved agents–such as ibrexafungerp, rezafungin, fosmanogepix, and olorofim–have been granted orphan drug status in the United States and European Union. While this designation incentivizes R&D for rare and neglected diseases, it also confers extended market exclusivity, often leading to high launch pricesand restricted distribution channels[11].

For instance, fosmanogepix and ibrexafungerp are protected by multiple patents that prevent the entry of affordable generic versions, especially in jurisdictions where TRIPS flexibilities (e. g. compulsory licensing) are underutilized. Furthermore, the lack of differential pricing strategies and absence of global pooled procurement mechanisms for antifungals exacerbate disparities. This results in price points that are prohibitive for public sector procurement in LMICs, effectively excluding these regions from the global supply chain.

3.2. Regulatory barriers

LMICs often lack robust regulatory frameworks to facilitate accelerated approval, emergency–use authorization, or compassionate access programs for novel antifungal drugs. Unlike the US FDA or EMA, many national regulatory authorities in LMICs do not have the capacity or policy mechanisms to fast–track essential antifungal agents during outbreaks (e.g. Candida auris) or in immunocompromised populations.

Additionally, limited pharmacovigilance infrastructure impairs post–marketing surveillance, making it difficult to track adverse drug reactions, resistance emergence, or drug–drug interactions–particularly critical for antifungals used in complex comorbid settings such as HIV or cancer care. These regulatory gaps further delay access and diminish clinical confidence in adopting newer agents[14].

3.3. Infrastructure deficits

A critical challenge in LMICs is the widespread absence of fungal diagnostics, particularly for invasive infections. Most public hospitals in sub-Saharan Africa, Southeast Asia, and parts of Latin America lack fungal culture facilities, antigen detection assays (e.g. galactomannan, β–D–glucan), or molecular diagnostics. This leads to substantial underdiagnosis and misdiagnosis of IFIs, delaying treatment and inflating mortality.

Moreover, injectable antifungals such as amphotericin B–still a mainstay in many LMIC treatment protocols–require cold chain logistics, trained personnel for IV administration, and intensive renal monitoring, all of which are often unavailable. While newer agents offer oral formulations and better safety profiles, their inaccessibility means that health systems remain dependent on older, more toxic drugs that are logistically burdensome[15].

3.4. Global supply chain inequities

The global antifungal supply chain remains skewed toward high–income markets, particularly in the post–approval phase. Manufacturers often delay registration or market entry in LMICs due to perceived low profitability, lack of local demand forecasting, and absence of formal procurement mechanisms. As a result, drugs like olorofim or rezafunginremain inaccessible even years after approval in the Global North[16].

Additionally, procurement costs for LMICs are inflated by fragmented health systems, lack of centralized purchasing, and low–volume orders that reduce economies of scale. Without donor–funded procurement (e.g. via GAVI or the Global Fund) or technology transfer agreements, access to novel antifungals will remain limited to private markets–thereby excluding the most vulnerable patients from life-saving therapies.

4. Opportunities and policy recommendations

To close the gap between antifungal innovation and equitable access, a multi-sectoral approach is needed that aligns drug development, regulatory policy, market incentives, and implementation science with the realities of LMICs. The following strategies offer practical pathways to enhance the availability and affordability of novel antifungal agents in resource-limited settings.

4.1. Tiered pricing and pooled procurement

A key strategy to improve affordability is the adoption of tiered pricing models, where the price of antifungals is adjusted based on country income level or health system capacity. This approach has been effectively implemented for vaccines, HIV/AIDS medications, and antimalarials, and could be adapted for antifungals through advanced market commitments or access agreements. In parallel, a pooled procurement mechanism, similar to those employed by Gavi or the Global Fund, could reduce unit costs and increase purchasing leverage for LMICs. Pooled demand forecasts and centralized negotiations would incentivize manufacturers to scale production and prioritize LMIC markets. This effort could be strengthened by using the WHO Essential Medicines List (EML) designation as a policy lever: inclusion of agents like ibrexafungerp or fosmanogepix on the EML would not only signal public health priority but also streamline national-level reimbursement and importation[17].

4.2. Decentralized clinical trials in LMICs

To improve registration and uptake in LMICs, decentralized and locally embedded clinical trials are essential. The participation of LMIC institutions in pivotal trials–particularly for pathogens of local relevance such as Candida auris or azole-resistant Aspergillus–would yield several benefits. This includes–Facilitated local regulatory approval, as clinical data would be population–specific; Increased physician familiarity and trust in the use of novel antifungalsand

also, Capacity building in mycology diagnostics, pharmacovigilance, and data infrastructure.

Trial decentralization also aligns with WHO's call for regional research equity, reducing dependency on extrapolated data from high-income settings and enabling context–specific stewardship strategies[18].

4.3. Innovation incentives with access clauses

To ensure that future antifungal development translates into global benefit, innovation incentives must be conditioned with access requirements. The Drugs for Neglected Diseases initiative (DNDi) offers a scalable model: public–private product development partnerships (PDPs) that combine R&D funding with binding affordability, licensing, and distribution provisions[19].

Antifungal R&D initiatives–especially those supported by public funds, philanthropic foundations, or development banks-should embed access clauses that mandate: Timely registration in LMICs, Non–exclusive licensing to generic producers and Tiered pricing commitments for public sector purchasers.

Such models can de-risk early development while ensuring that market exclusivity does not equate to market exclusion.

4.4. Local manufacturing and licensing

To ensure long-term sustainability and reduce reliance on imports, LMICs should be supported in developing local antifungal manufacturing capabilities through: Voluntary licensing agreements from originator companies; Technology transfer partnerships facilitated by WHO prequalification and regulatory harmonization and Regional hubs for formulation, packaging, and quality assurance (e.g. in Africa, Southeast Asia, Latin America).

This approach not only mitigates supply chain disruptions but also stimulates regional economic development and enhances drug security. Local production of antifungal agents–especially oral formulations like MAT2203 or olorofim-could significantly improve access in remote or under–resourced areas.

Collectively, these strategies represent actionable, evidence–based opportunities to transform antifungal access in LMICs–from patchwork availability to strategic inclusion in essential treatment frameworks. Policymakers, donors, regulators, and industry must collaborate to ensure that scientific progress is matched by systemic equity.

5. Future directions and research gaps

While the development of novel antifungal agents signals a long-overdue renaissance in fungal therapeutics, several critical research and implementation gaps remain–particularly within the context of LMICs. Addressing these will be essential to ensure that innovation translates into equitable and sustainable clinical impact.

5.1. Cost–effectiveness analysis in LMIC settings

Despite promising clinical data, cost–effectiveness analyses of new antifungals remain scarce, especially in LMIC contexts where health budgets are constrained and competing priorities are numerous. Most economic evaluations to date have focused on high-income countries, using models that do not adequately reflect: Local epidemiology of IFIs, diagnostic delays, and differences in healthcare infrastructure.

Future studies must generate context–specific cost–utility models that evaluate the impact of new agents–such as rezafungin or fosmanogepix–compared to standard care (e.g. amphotericin B) in terms of DALYs averted, mortality reduction, and resource savings from fewer adverse events or shorter hospital stays. These data will be critical for national decision-makers to justify inclusion on essential drug lists or health insurance formularies.

5.2. Surveillance of antifungal resistance in LMICs

The growing prevalence of azole–resistant Aspergillus and multi–drug resistant Candida auris highlights the urgent need for robust fungal resistance surveillance systems–an area that remains severely underdeveloped in LMICs. Most countries lack integrated antifungal resistance reporting networks, standardized AST protocols, or the laboratory infrastructure to detect resistance genes.

Building regional reference laboratories, integrating resistance tracking into existing AMR platforms (e.g. WHO GLASS), and supporting capacity–building for mycology laboratories will be essential for detecting emerging resistance patterns, Guiding empirical therapy with newer agents and Informing national antifungal stewardship programs.

5.3. Development of rapid diagnostics compatible with new agents

Many of the novel antifungal agents-particularly those with narrow or mold–specific spectra, such as olorofim or opelconazole–require precise etiological diagnosis to guide appropriate use. However, the lack of rapid, affordable, point–of–care diagnostics for fungal infections remains a major bottleneck in LMICs.

Future investment should prioritize the development of low-cost antigen or molecular assays that are compatible with peripheral or district–level laboratories, offer species–level identification and resistance marker detection, and Can be integrated into multiplex platforms for syndromic testing (e.g. febrile illness panels).

Linking diagnostics to treatment access programs will help ensure that new agents are used judiciously, thereby preserving their efficacy and improving clinical outcomes.

6. Conclusions

The global burden of fungal infections continues to rise, driven by expanding immunosuppressed populations, emerging drug resistance, and growing recognition of fungal disease mortality. Against this backdrop, the development of novel antifungal agents–including ibrexafungerp, rezafungin, fosmanogepix, olorofim, and others–marks a historic advancement in clinical mycology. These agents offer distinct advantages in terms of mechanism of action, pharmacokinetics, and resistance profiles, and are poised to

redefine the treatment landscape for IFIs.

However, scientific progress alone is insufficient. Without parallel strategies to ensure affordability, availability, and health system integration–especially in LMICs, where the disease burden is greatest–these advances risk becoming exclusive solutions for high–income populations. Global health equity demands a coordinated response that aligns innovation with access, fosters regulatory inclusion, and invests in diagnostic, manufacturing, and surveillance infrastructure.

Realizing the full potential of novel antifungal agents will depend not only on scientific excellence but on policy will, global solidarity, and implementation science that puts patients at the center-regardless of geography or income.

Conflict of interest statement

The authors claim there is no conflict of interest.

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Data availability statement

The data supporting the findings of this study are available from the corresponding author upon request.

Authors' contributions

Samajdar SS and Chatterjee R contributed in study conceptualization and data acquisition. Chatterjee R and Mukherjee S contributed in manuscript writing. All authors read and approved the final manuscript.

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