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EDITORIAL ANALYSIS

Looking Beyond Generics: Why AMR Is Rewriting India's Pharma Challenge

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Looking Beyond Generics: Why AMR Is Rewriting India's Pharma Challenge

Business Standard 7 July 2026 GS3 GS2

Source: ujiyari.com — researched, fact-checked & UPSC-mapped

INTERVIEW ANGLE

"India is the pharmacy of the world in volume but small in value and R&D. With antimicrobial resistance rising, is the low-cost generics model a strength that has become a trap, and can Zaynich-style innovation actually be scaled?"

Source: Original editorial ↗ Business Standard

Every fact web-verified against primary sources (https://ujiyari.com/how-we-verify/)

THE LIFT LINE

> *"For decades India answered the world"s medical needs by making old drugs cheaply. Antimicrobial resistance is asking a harder question: can it make new ones?"*

On **June 1, 2026**, the US FDA approved **Zaynich (cefepime-zidebactam)**, an intravenous antibiotic from the Indian firm **Wockhardt**, the **first new chemical entity discovered and developed by an Indian company** to win FDA approval. It arrived at the very moment **antimicrobial resistance (AMR)** is turning India"s cheap-generics strength into an incomplete answer. This editorial argues that AMR is shifting the pharma challenge from **access to innovation**, and India must move up the value chain.

WHY THIS EDITORIAL MATTERS FOR YOUR EXAM

GS Paper 3: Science and technology developments and their applications; indigenisation (https://ujiyari.com/vocab/indigenisation/) of technology and developing new technology; issues relating to intellectual property rights. It also links to GS Paper 2 through health policy, the National Action Plan on AMR and the governance of a public-health threat.

This theme lets you connect public health, the economics of innovation, self-reliance in high technology and India"s global role in medicine into a single argument, useful for GS3 science-and-tech and GS2 health-governance answers alike.

BACKGROUND AND CONTEXT

Antimicrobial resistance (AMR) occurs when bacteria, viruses, fungi and parasites evolve to resist the drugs designed to kill them, rendering standard treatments ineffective.

The burden is enormous. A **Lancet GRAM study (published 2022)** attributed about **1.27 million deaths directly** and 4.95 million associated deaths to bacterial AMR in **2019**, more than HIV or malaria. A **2024 GRAM forecast** projects **more than 39 million cumulative directly attributable deaths between 2025 and 2050**.

India is a global **AMR hotspot**. Per **NARS-Net (National Antimicrobial Resistance Surveillance Network)** data, over half of *Klebsiella pneumoniae* isolates are carbapenem-resistant, and colistin resistance, a last-resort concern, is rising. Drivers include over-the-counter sales, overuse in humans and livestock, weak stewardship and pharmaceutical effluent.

THE CORE ARGUMENT / ISSUE

The central claim is that AMR **transforms the pharmaceutical challenge itself**. India"s greatness has been in access, making existing drugs affordable, but AMR demands **new molecules**, which requires discovery, not just manufacturing.

The Generics Strength and Its Ceiling

METRIC	INDIA"S POSITION
Share of global generics by volume	About 20 per cent
Global vaccines supplied	About 60 per cent
Pharma industry rank by volume	Third-largest
Pharma industry rank by value	Only fourteenth
Pharma exports (FY2024-25)	About 30 billion dollars
Gross R&D as share of GDP	About 0.64 per cent

India is the **pharmacy of the world** in volume but small in value. India"s overall research intensity is low at about 0.64 per cent of GDP, and its drugmakers reinvest a far smaller share of revenue in research than innovator pharma, which spends about 15 to 21 per cent of revenue. A model built on making old drugs

cheaply cannot, by itself, defeat pathogens that outrun those drugs.

Zaynich as a Marker

Zaynich (cefepime-zidebactam, developmental code WCK 5222) is FDA-approved for **complicated urinary tract infections including pyelonephritis** caused by susceptible Gram-negative bacteria. Its significance is larger than its label: it works even in the presence of many beta-lactamases, including metallo-beta-lactamases that defeat carbapenems, and in a Phase 3 trial (ENHANCE-1) showed a composite success rate of about 89 per cent versus 68 per cent for meropenem. It proves an Indian firm can discover, not just copy.

The Policy Response

India"s **National Action Plan on AMR (NAP-AMR) 2.0**, launched **November 18, 2025** for **2025-2029**, places intersectoral oversight under **NITI Aayog** with a **One Health** approach across 20-plus ministries. It builds on the 2016 **Red Line Campaign** (a red vertical line marks prescription-only antibiotics) and **Schedule H1** restrictions on over-the-counter antibiotic sales, both weakened by poor enforcement.

The Honest Counter

Antibiotic R&D faces a **structural market failure**: a good new antibiotic must be *conserved*, used as little as possible to preserve its power, which collapses sales volume and returns. This is why global pharma largely exited antibiotic discovery, and why one Indian success cannot alone fix the broken economics or India"s low R&D intensity.

HOW TO THINK ABOUT THIS (ANALYTICAL FRAME)

> *For most diseases India"s challenge is delivering existing drugs cheaply, a strength. For AMR, existing drugs are the problem, because resistance is outpacing the generic arsenal. Ask which problem a given policy solves. Price controls and generics serve access; pull incentives, stewardship and R&D funding serve innovation. Conflating the two produces cheap drugs that no longer work. AMR is the case where India must consciously fund the second problem.*

THE DIAGRAM IN WORDS

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AMR rising -> 1.27 million direct deaths (2019), 39 million+ projected cumulative 2025-2050 -> India a hotspot (over 50% Klebsiella carbapenem-resistant) -> existing generics failing against resistant bugs -> India strong in access (20% of global generics by volume) but weak in value (14th) and R&D (0.64% of GDP) -> access model cannot beat resistance -> need new molecules -> Zaynich (cefepime-zidebactam), first Indian FDA new
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chemical entity, June 1 2026, works vs many resistant Gram-negatives -> but antibiotic economics broken (conserve = low sales) -> fix: NAP-AMR 2.0 + stewardship + Schedule H1 enforcement + pull incentives + higher R&D -> move from pharmacy of the world to discoverer of new drugs

WAY FORWARD

1. **Implement NAP-AMR 2.0 fully.** Use its NITI Aayog oversight and One Health design to enforce time-bound, budgeted accountability across ministries.
2. **Strengthen stewardship and Schedule H1.** Curb over-the-counter antibiotic sales, enforce the Red Line, and improve diagnostics so antibiotics are used correctly.
3. **Fix the innovation economics.** Adopt pull incentives, subscription or delinked-payment models like the UK"s, and partner with bodies such as GARDP to fund novel antibiotics that must be conserved.
4. **Raise pharma R&D intensity.** Support translational research, public-private discovery and value-chain movement so more new chemical entities emerge from India, not just generics.

PYQ LINKAGE AND PRACTICE

- **UPSC GS3 (2019):** "How is the Government of India protecting traditional knowledge of medicine from patenting by pharmaceutical companies?" (pharma and IP)
- **UPSC GS2 (2018):** "Appropriate local community-level healthcare intervention is a prerequisite to achieve 'Health for All' in India. Explain."
- **UPSC GS3 (2015):** Questions on India"s scientific research and the role of R&D.

Practice Mains question (250 words, 15 marks): "Antimicrobial resistance is shifting India"s pharmaceutical challenge from access to innovation. Discuss the limits of the low-cost generics model, the significance of India"s first FDA-approved new molecule, and the reforms needed to make original antibiotic discovery viable."

Sources: Business Standard (https://www.business-standard.com/opinion), PIB (https://pib.gov.in), Ministry of Health and Family Welfare (https://mohfw.gov.in)

KEY ARGUMENTS AT A GLANCE

Rising antimicrobial resistance is changing India''s pharmaceutical challenge from one of access, where cheap generics excel, to one of innovation, where new molecules are needed, and Wockhardt''s FDA-approved antibiotic Zaynich shows that Indian firms can move up the value chain from generic manufacturing to original drug discovery.

✓ SUPPORTING

- AMR is a silent pandemic, directly causing about 1.27 million deaths in 2019 and projected to be directly responsible for more than 39 million cumulative deaths between 2025 and 2050, with India a global hotspot for carbapenem and colistin resistance.
- India supplies about 20 per cent of the world''s generic drugs by volume and is the third-largest pharma industry by volume but only fourteenth by value, exposing the limits of a low-margin, no-new-molecule model.
- Zaynich (cefepime-zidebactam), approved by the US FDA on June 1, 2026, is the first new chemical entity discovered and developed by an Indian company to win FDA approval, proving domestic innovation is possible.

⚠ COUNTER

Critics note that antibiotic R&D suffers a structural market failure, because a good new antibiotic must be conserved and used sparingly, which collapses sales, so one Indian success does not fix the broken economics or India''s low R&D intensity.

→ WAY FORWARD

Fully implement the National Action Plan on AMR 2.0, strengthen antibiotic stewardship and Schedule H1 enforcement, adopt pull incentives such as subscription or delinked-payment models to fund novel antibiotics, and raise pharma R&D intensity so India moves from the pharmacy of the world to a discoverer of new drugs.

MAINS ANSWER FRAMEWORK

QUESTION

"Antimicrobial resistance is transforming the nature of India''s pharmaceutical challenge from access to innovation." Discuss with reference to India''s generics strength, the National Action Plan on AMR and the case for original drug discovery. (250 words)

INTRODUCTION

India''s pharmaceutical success has rested on making existing drugs cheaply and at scale, earning it the title pharmacy of the world. Antimicrobial resistance is now changing the challenge itself, from delivering old medicines to discovering new ones, because the pathogens are outrunning the generics.

BODY

Antimicrobial resistance is a slow-moving pandemic. A Lancet GRAM study attributed about 1.27 million deaths directly to bacterial AMR in 2019, and a 2024 forecast projects more than 39 million cumulative directly attributable deaths between 2025 and 2050.

India is a hotspot, with over half of Klebsiella pneumoniae isolates resistant to carbapenems per NARS-Net surveillance, driven by over-the-counter access, overuse in humans and animals, and pharmaceutical effluent. India''s answer at the policy level is the National Action Plan on AMR 2.0, launched in November 2025 for 2025-2029, placing intersectoral oversight under NITI Aayog with a One Health approach.

But the deeper shift is industrial. India makes about 20 per cent of the world''s generics by volume yet ranks only fourteenth by value.

India''s overall research intensity is low, at roughly 0.64 per cent of GDP, and its drugmakers spend a far smaller share of revenue on research than innovator pharma, which reinvests about 15 to 21 per cent of revenue. Wockhardt''s Zaynich, cefepime-zidebactam, FDA-approved on June 1, 2026 for complicated urinary tract infections, is the first new chemical entity discovered and developed by an Indian company to win FDA approval, and works even against many drug-resistant Gram-negative bacteria.

The obstacle is economics: a conserved antibiotic earns little, so pull incentives and stewardship are essential.

CONCLUSION

AMR has turned India''s pharma challenge from access into innovation. The task is to keep generics affordable while building stewardship, R&D capacity and incentive models that let more Zaynich-style discoveries emerge, moving India up the value chain.

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