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Lenacapavir and the Access Question — India's Generic Pharma as Global Health Infrastructure

INDIAN EXPRESS

25 February 2026

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Lenacapavir and the Access Question — India's Generic Pharma as Global Health Infrastructure

The Indian Express 25 February 2026 GS2 GS3

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INTERVIEW ANGLE

"India's generic pharmaceutical industry has made HIV treatment available to millions in Africa. But innovator companies argue that strong IP protection funds the R&D that creates drugs like Lenacapavir. How should India balance its role as the 'pharmacy of the world' with its obligations under international IP treaties?"

Zimbabwe's rollout of Lenacapavir is a medical milestone. A twice-yearly injection that prevents HIV with near-perfect efficacy can — if access is equitable — fundamentally change the trajectory of the epidemic in sub-Saharan Africa.

The operative phrase is "if access is equitable." And that question leads, as it almost always does in global health, directly to India.

THE PHARMACY OF THE WORLD

India's pharmaceutical industry is not typically discussed as foreign policy or soft power — but it should be. Indian generic manufacturers supply approximately **80% of HIV antiretroviral medicines** used in low-income countries. The price transformation this enabled was extraordinary.

In 2000, a year of HIV treatment cost roughly **$10,000–$15,000** in brand-name drugs — a figure that put treatment completely beyond reach for the 25 million Africans living with HIV at the time. CIPLA's Yusuf Hamied offered a triple ARV combination for **$350/year** in 2001, dropping to under $100 through further generic competition. PEPFAR, launched in 2003 with $15 billion in initial funding, built its entire treatment programme around Indian-manufactured generics.

The consequences have been immense: an estimated **25 million lives** saved through PEPFAR alone, overwhelmingly using medicines made in India.

WHAT THE LENACAPAVIR MOMENT REVEALS

Lenacapavir is priced at approximately **$40,000/year** in the United States — not because manufacturing it costs anywhere near that, but because Gilead Sciences, like all innovator pharmaceutical companies, prices drugs to recapture research and clinical trial costs plus profit. The PURPOSE 1 and 2 trials alone cost hundreds of millions of dollars.

For Zimbabwe, Uganda, South Africa — the countries with the highest HIV burden — this price is irrelevant. What matters is:

- **Whether Gilead grants voluntary licences** to generic manufacturers (it has, through the Medicines Patent Pool — covering 120+ countries)
- **What the generic price will be** — analysts estimate $40–$100/year is achievable at scale
- **Whether Indian manufacturers** — CIPLA, Aurobindo, Hetero, Viatris — move fast enough to build manufacturing capacity before the epidemic window closes

This is where the "pharmacy of the world" framing becomes concrete policy: India's ability to manufacture affordable generics at scale is not just a commercial opportunity, it is global health infrastructure.

THE IPR TENSION — STILL UNRESOLVED

The legal framework that enables this is carefully negotiated. Gilead's voluntary Medicines Patent Pool licence for Lenacapavir covers low- and middle-income countries. Countries not covered — including some middle-income nations in Eastern Europe and Latin America — face the full brand-name price.

This is the **access cliff** that the TRIPS Agreement has never fully resolved. TRIPS allows patent protection for pharmaceuticals for 20 years. TRIPS flexibilities — compulsory licensing (Article 31), parallel imports (Article 6), and the Doha Declaration on TRIPS and Public Health (2001) — provide some relief, but:

- **Compulsory licensing** requires countries to have manufacturing capacity (most don't)
- The **Doha Declaration** eased access for least-developed countries but has not been universally implemented
- **Middle-income countries** — the largest unmet need — often have less flexibility than least-developed countries

India's role in TRIPS negotiations has been to maximally defend these flexibilities. The **Doha Declaration** was largely the result of Indian and African country advocacy. India has also used compulsory licensing domestically — most notably for **Sorafenib** (cancer drug, Natco Pharma, 2012), setting a precedent for its use on grounds of public health and affordability.

BEYOND GENERIC MANUFACTURING: THE INNOVATION AGENDA

The “pharmacy of the world” framing also conceals India’s ambitions and limitations. Indian pharma is a manufacturing and formulation powerhouse, but it contributes relatively little to **novel drug discovery**. CIPLA’s affordable ARVs were generics of drugs invented by US and European companies; Lenacapavir was invented by Gilead.

India’s pharmaceutical R&D investment is approximately **2–3% of revenues**, far below the 15–20% invested by major innovator companies. The Department of Pharmaceuticals has initiatives to change this — including the **PLI (Production Linked Incentive) scheme for pharmaceuticals** — but genuine drug discovery requires decades of consistent R&D investment.

The strategic challenge India faces: it needs to preserve the generic manufacturing model that delivers global health outcomes while also developing the innovation capacity to become a drug discovery country, not just a drug replication one.

These goals are not mutually exclusive — but they require different policies, institutions, and timescales. The Lenacapavir moment is an opportunity to ask not just “how quickly can Indian manufacturers produce generic versions?” but “what would it take for an Indian company to discover the next Lenacapavir?”

INDIA’S HEALTH DIPLOMACY DIVIDEND

The soft power dimension of India’s pharmaceutical role is significant and underutilised. During COVID-19, the **Vaccine Maitri** programme — supplying vaccines under the COVAX framework — generated enormous goodwill in Africa, Southeast Asia, and the Caribbean. That goodwill has not been consistently converted into diplomatic outcomes.

A more systematic approach to health diplomacy would:

- Link generic medicine supply explicitly to India’s foreign policy objectives
- Build permanent pharmaceutical supply arrangements with African Union member states
- Use the “pharmacy of the world” positioning to support India’s case for a permanent UN Security Council seat and increased influence in WHO governance

Zimbabwe’s Lenacapavir rollout is, in part, a story about Indian pharmaceutical generics. India should make sure that story is told.

UPSC RELEVANCE

Lenacapavir, PEPFAR, MPP, TRIPS, Doha Declaration, compulsory licensing, PLI scheme pharma, Vaccine Maitri, COVAX, CIPLA.

MAINS GS-2:

India's health diplomacy; global health governance; TRIPS flexibilities.

GS-3:

Pharmaceutical industry; PLI schemes; R&D investment; generic vs. innovator drug model.

INTERVIEW:

"Can India be both the pharmacy of the world and a drug innovation powerhouse?"

📌 FACTS CORNER — KNOWLEDGEPEDIA

INDIA'S GENERIC PHARMA ROLE IN HIV:

Share of low-income country HIV medicine supply: **~80%**

CIPLA's 2001 ARV price: **$350/year** (down from $10,000–15,000/year brand price)

Key manufacturers: CIPLA, Sun Pharma, Aurobindo, Hetero, Viatris (India operations)

PEPFAR:

Launched: **2003** by US President George W. Bush

Initial funding: **$15 billion** (5-year); now $7+ billion/year

Lives saved: **~25 million** estimated

Uses Indian-manufactured generics extensively

LENACAPAVIR PRICING:

US price: **~$40,000/year**

Projected generic price: **$40–100/year** (Indian manufacturers)

MPP licence: Covers **120+ countries** (mostly Africa + South/Southeast Asia)

TRIPS FLEXIBILITIES:

Compulsory Licensing (Article 31): Government can license generic production without patent holder consent in public health emergencies

Doha Declaration (2001): TRIPS should not prevent countries from protecting public health; TRIPS flexibilities must be used to their full extent

Parallel Imports (Article 6): Countries can import cheapest available version of patented drugs

India's use: Sorafenib compulsory licence (**Natco Pharma, 2012**) — cancer drug

INDIA PHARMA R&D:

R&D investment: **~2–3% of revenues** (vs. 15–20% at innovator companies)

PLI (Production Linked Incentive) Scheme for pharmaceuticals: Promotes API (Active Pharmaceutical Ingredient) domestic manufacturing and drug discovery

Key gap: Novel drug discovery vs. formulation/generic manufacturing

INDIA'S HEALTH DIPLOMACY:

Vaccine Maitri: India supplied 25 million+ COVID vaccines to 25+ countries (2021); paused due to Delta wave; resumed later

COVAX: WHO-led global vaccine sharing facility; India contributed Serum Institute vaccines

India-Africa Pharma: Major supplier of ARVs, antimalarials, and antibiotics to Africa

OTHER RELEVANT FACTS:

Medicines Patent Pool (MPP): UN-backed body; negotiates voluntary licences; founded 2010; based Geneva

WHO Prequalification: Certifies drugs meet quality standards for procurement by UN agencies; Indian generic makers widely prequalified

Gilead Sciences: US biotech; major HIV drug maker (Truvada, Biktarvy, Lenacapavir); granted voluntary licences for Africa

NACO: National AIDS Control Organisation; India's nodal HIV body; ~2.5 million PLHIV in India

Sources: Indian Express, UNAIDS, Medicines Patent Pool

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