

High demand, strict inspections — how Biden's presidency could impact India's pharma sector

US is the biggest market for Indian pharmaceutical companies and Biden's presidency is expected to bring with it some favourable changes that could have a long-ranging impact.

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US President-elect Joe Biden (file photo) | Michael Robertson/Twitter

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Higher demand for medicines manufactured in India, faster clearance of new drug applications and stricter inspections — these are some of the ways Joe Biden's presidency is likely to impact Indian pharmaceutical companies.

US is the largest market of Indian medicines and the change in presidency is expected to have long-ranging impacts on these firms.

One of the ways in which Biden could affect Indian pharma companies is through his campaign promise to **strengthen** the Affordable Care Act, also known as Obamacare. The Act, introduced by former US president Barack Obama, aims at reducing healthcare costs and increasing access to healthcare insurance.

Biden's plan is expected to push for generic drugs, which will favour Indian-origin manufacturers. Generic drugs are **equally effective substitutes** of branded medicines, and are manufactured as cheaper alternatives once the latter have had an exclusive hold on the market for a certain period.

Vinita Gupta, CEO of Mumbai-based drugmaker Lupin, told ThePrint that “with the President-elect's campaign promise of lowering healthcare costs, we expect there to be an even stronger focus on generics to introduce material savings”.

Lupin is the **third-largest pharmaceutical firm** in the US in terms of prescriptions and its American wing is headquartered in Baltimore, Maryland.

“Localising manufacturing in the US has also been a subject of focus, though with it would come an increase in cost compared with India-based production,” she said, adding that

the company remains open to the discussion of localising manufacturing if the new government offers relief on pricing.

“We would be well positioned to meet this need from both a product portfolio and capability perspective,” said Gupta.

Positive impact expected

Several public health experts noted that Biden’s presidency may prove to be advantageous for Indian companies.

“The arrival of the new president looks positive for Indian generic companies till now as he plans to push affordable health insurance among lower-income groups in the US,” said B.R Sikri, chairman of the Federation of Pharma Entrepreneurs (FOPE), a lobby representing domestic drug makers.

This was also echoed by Sudarshan Jain, secretary-general of the Indian Pharmaceutical Alliance, another lobby of drug makers that represents top Indian companies such as Sun Pharma, Dr Reddy’s and Aurobindo, among others.

“The India-US relationship will continue to strengthen in the Biden administration,” said Jain.

Jain also pointed out that while the Indian pharmaceutical industry has been playing an important role in the US healthcare system, including providing crucial medicines during the Covid-19 pandemic, an analysis of the impact of Biden’s presidency will be an ongoing process.

“It would be too early to comment on specific areas just now and it will evolve over a period of time,” he said.

However, the new administration could also lead to stricter inspections by the US Food and Drug Administration (FDA) — the country’s apex drug regulating body.

An industry official working with a top pharmaceutical firm in Mumbai said, “As we expect more demand for our drugs, we must expect higher expectations from the US FDA in terms of harder inspections and more warning letters.”

To boost pharma investments, Modi govt sets up panel to revamp policies & draw up action plan

Why US market is important

According to data from Pharmaceuticals Export Promotion Council of India (Pharmexcil), India’s exports to the US in 2019-20 stood at \$6.74 billion, of which formulations (generics) exports were pegged at \$6.25 billion.

Pharmexcil is a pharma export body under the Ministry of Commerce and Industry.

In the US, Indian imports accounted for 24 per cent of medicines in 2018 and every third tablet sold there is from India.

The Indian pharmaceutical industry has also received more than 5,000 approvals from the US on new drug applications submitted for exports as of April 2020.

Decisions to watch out for

According to industry experts, when Biden assumes office on 20 January, the proposed **increase in corporate tax** by his administration will be something pharmaceutical firms will have to watch out for.

“The move may help bring fresh investments and more US firms to India as Americans would want to evade higher corporate tax,” said Sikri.

“However, on the other hand, it could also pose a challenge for subsidiaries of Indian companies in the US,” he added.

“Our industry’s biggest expectation from Biden is promotion of generics and faster ANDA (Abbreviated New Drug Application) approvals. We are also expecting doing away of Generic Drug User Fee Act (GDUFA),” Sikri said.

The GDUFA is a law that mandates a payment of fees by firms which sell generic drugs in the US market.

Experts also pointed that the Modi government’s recent **Production Linked Incentives (PLI)** — which is meant to boost domestic manufacturing of active pharmaceutical ingredients (API) and Key Starting Materials (KSMs) of medicines — could play an important role in diverting investment from China to India.

“The scheme’s objective to boost the production of key raw materials for making medicine may position India better in terms of supplying drugs and raw materials at competitive prices against China. Till now, they (Chinese companies) lead in supplying APIs and KSMs,” the company official quoted above said.

But not everyone agrees that Biden may have an immediate impact on the industry.

“Right now, Biden is more concerned about handling Covid-19 impact,” said Sujay Shetty, pharma life sciences leader, India, for PricewaterhouseCoopers (PwC).

“Going forward, we need to look if Biden would plan on bringing onshore manufacturing and direct govt purchases — which we had seen in former President Trump’s Executive Order,” he said.

On 6 August, Trump **had signed an executive order**, directing federal agencies to prioritise purchasing selected domestically-manufactured drugs and medical materials.

The move was **termed favourable** for India by the Pharmexcil as it was expected to help India compete much better with other countries that supply medical products to the US.

With the implementation of this order, India would safely fall in the bracket of countries where the procurement cost is less by 30-40 per cent.

Watchdog on pharma ethics violations says it has no such power in RTI reply, takes U-turn later
