



OPINION

India can be a real alternative to China in pharmaceuticals

Dependence on imported ingredients and quality assurance are being addressed

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May 14, 2024 17:00 JST



A Piramal Pharma lab in Mumbai: Indian companies are investing aggressively to expand their capabilities and offerings into more complex and high-value product lines. © Reuters

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The COVID pandemic was a wake-up call for many governments about the public health and national security risks of overreliance on a narrow set of partner countries for pharmaceuticals, medical technologies and other health care products.

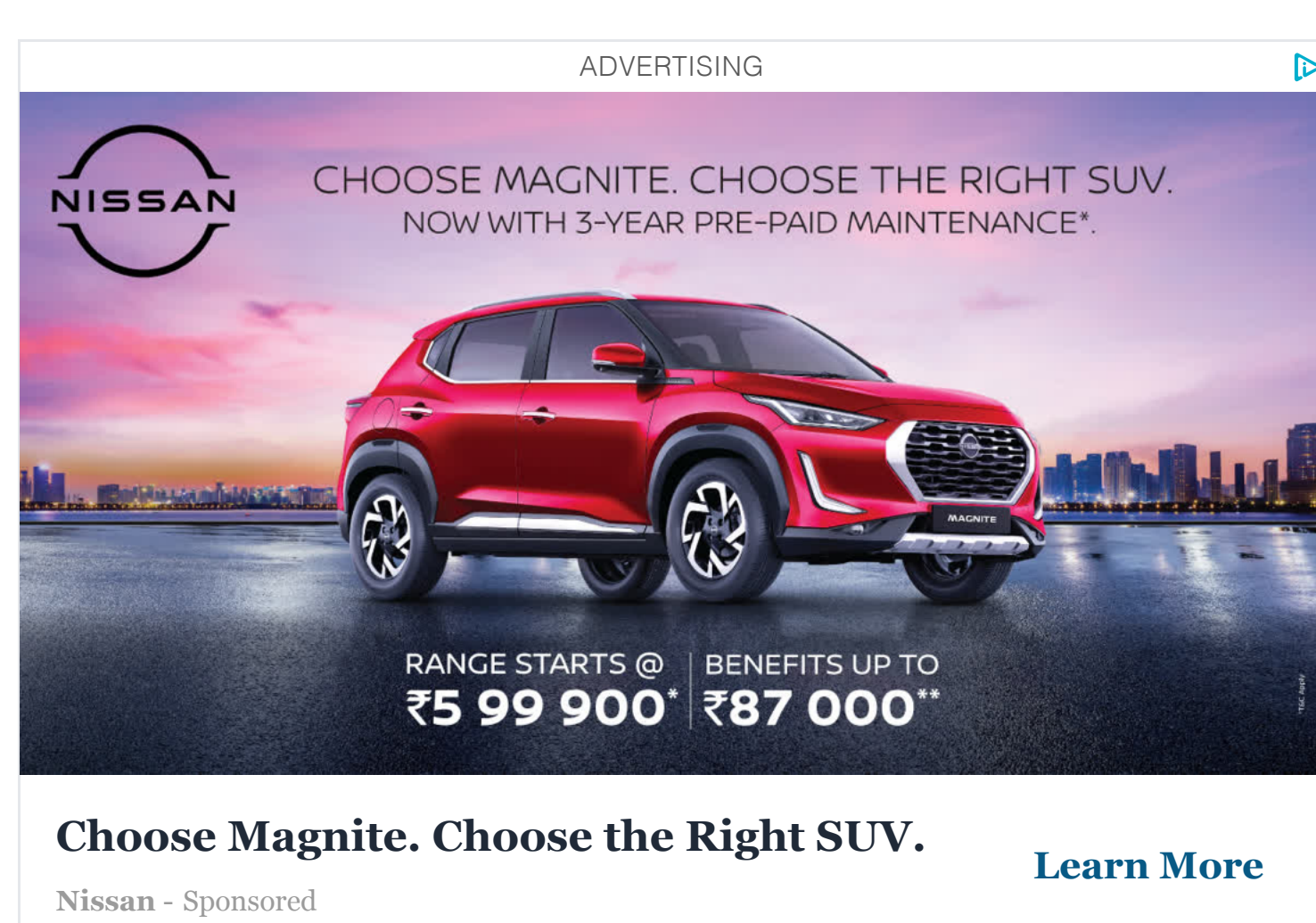
Such risks remain elevated due to the persistence of tensions between China, a key supplier and sometimes the only sources of many medical goods, and other countries including India, Japan, the Philippines and the U.S.

While it is unlikely that any other single country can replicate China's scale and cost-efficiencies, India's capabilities could make it a high-potential hub in more diversified and resilient global supply chains for pharmaceuticals.

The urgent need to review health care supply chains is underscored by continuing shortages.

According to the American Society of Health-System Pharmacists, 323 drugs were in short supply in the U.S. during the first quarter of 2024. A survey in February by the Federation of Pharmaceutical Manufacturers' Associations of Japan found more than a quarter of drugs in use in that country were either in a state of "limited shipment" or "out of stock."

Notwithstanding China's leading overall position in health supply chains, India has sometimes been termed the pharmacy of the world. It supplies 20% of all generic drugs by volume and about 70% of the vaccine doses that global health agencies like the World Health Organization and UNICEF procure on behalf of low- and middle-income countries.



India, though, does not yet have any companies with the scale and capabilities of leading Chinese pharmaceutical contract research, development and manufacturing conglomerates like the WuXi group, but it is quickly catching up.

Indian companies in these areas generated annual revenue of \$15.6 billion in 2023 versus \$27.1 billion for Chinese companies, according to estimates by market research company Mordor Intelligence.

India's largest companies are investing aggressively to expand their capabilities and offerings into more complex and high-value product lines, in some cases by acquiring biotechnology startups and spinoffs from multinational companies.

Despite these signs of promise, a few questions remain about India's ability to offer an alternative for other nations looking for greater resilience and redundancy in their supply chains.

One issue is production inputs. Can India really act as a resilient hub in diversifying supply chains given its dependence on China for key starting materials (KSMs) and active pharmaceutical ingredients (APIs), crucial building blocks in the production of modern drugs?

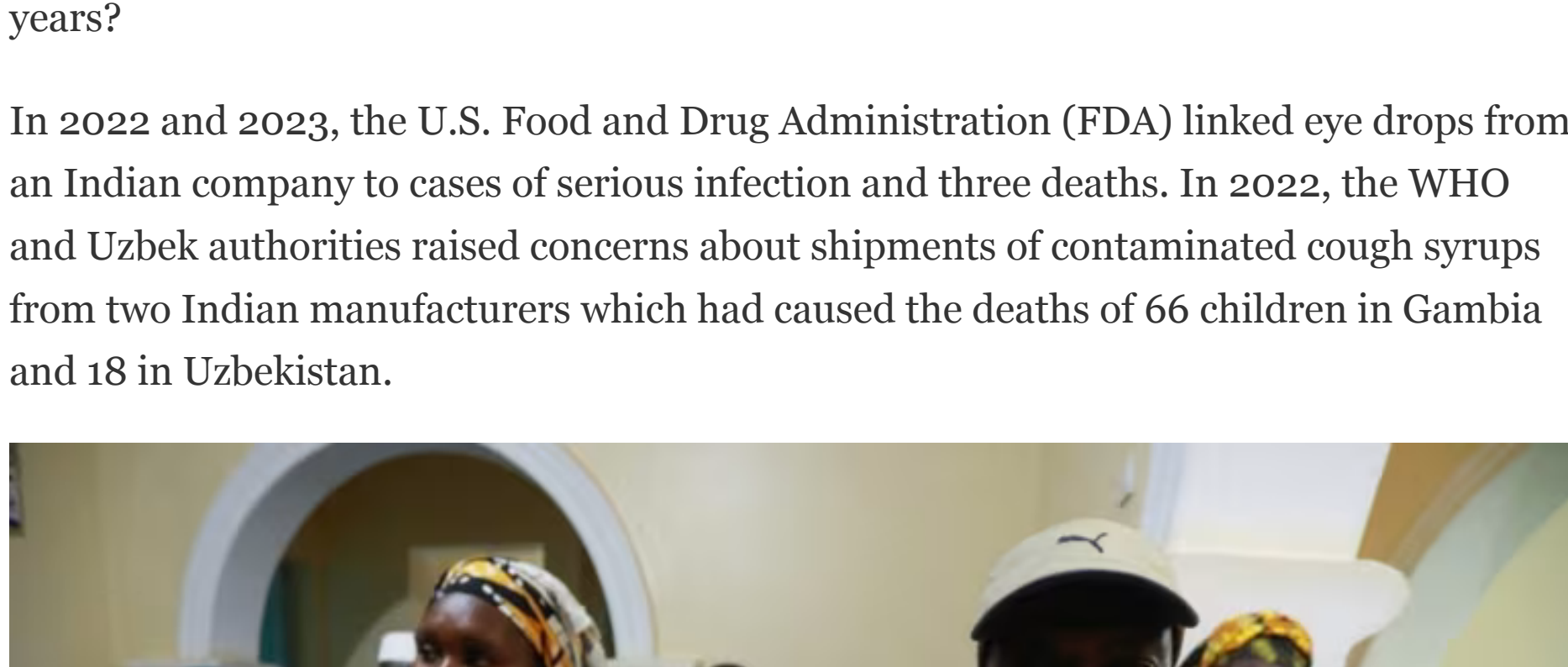
India imports over 80% of its APIs and KSMs for some drugs and formulations, with purchases from China continuing to rise over the last two years.

India is looking to reduce this dependence through initiatives such its production-linked incentive program, which provides subsidies for companies investing in new manufacturing facilities. This effort has already led to increased domestic production of KSMs such as penicillin G and clavulanic acid.

However, it will likely take a few more years and perhaps some tweaks to the subsidy program for India to substantially grow its API and KSM production capacity and reduce import dependence on China to offer a true "de-risked" alternative for global supply chains.

Another issue involves quality control. Can Indian manufacturers be relied upon to ensure high levels of quality, given the issues encountered with some exports in recent years?

In 2022 and 2023, the U.S. Food and Drug Administration (FDA) linked eye drops from an Indian company to cases of serious infection and three deaths. In 2022, the WHO and Uzbek authorities raised concerns about shipments of contaminated cough syrups from two Indian manufacturers which had caused the deaths of 66 children in Gambia and 18 in Uzbekistan.



Gambian parents protest the deaths of children due to toxic Indian-made cough syrup in 2022. The incident has sparked policy moves to improve quality control. © Reuters

In the wake of these incidents, the Indian Ministry of Health and Family Welfare and the Central Drugs Standard Control Organization (CDSCO) have been taking steps to review and improve quality assurance mechanisms.

The CDSCO is now requiring all manufacturers to comply with WHO Good Manufacturing Practices and has increased its inspections of production facilities and drug testing labs. It has reportedly canceled the licenses of 64 companies and 17 labs for not complying with GMP or other shortcomings.

The Health Ministry and the CDSCO are also coordinating more closely with the FDA, including seeking to have the U.S. agency increase its audits of production facilities in India.

While these are positive steps, areas of uncertainty exist in the policy realm that may dampen the enthusiasm of foreign investors and foreign companies seeking partners among Indian pharmaceutical producers.

These include the trajectory of price control mechanisms that could impact sales of drugs produced for India's domestic market, a new legislative draft framework for drugs, medical devices and cosmetics, and revised intellectual property rights rules.

At the same time, the government has taken some reassuring steps, including forming a committee to oversee drug pricing reforms and accepting wide-ranging inputs in the intellectual property rights revisions.

The world would benefit from more diversified global supply chains for pharmaceuticals and India can be an important and resilient hub for this. New international investment into India's pharmaceutical sector would help to make this happen. India still has some ways to go in offering itself as a complete alternative to China but could get there with the government's initiatives and more support from like-minded partners.

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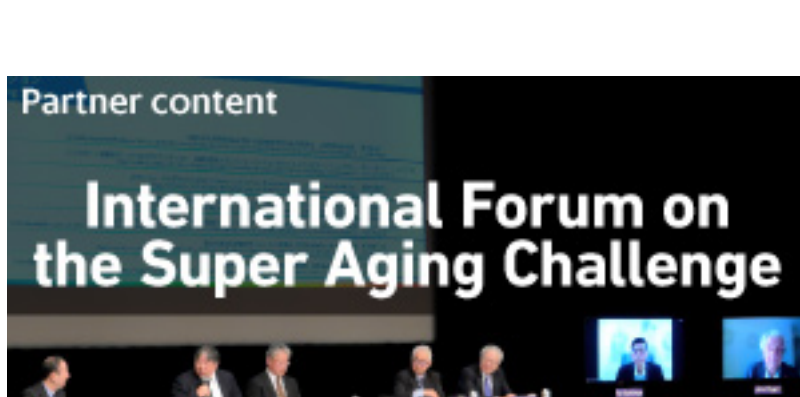
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