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CPA *REPORT*

U.S. RELIANCE on AUROBINDO

for Generic Drugs Creates Legal, Safety, and National Security Concerns for U.S. Stakeholders

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EXECUTIVE SUMMARY

The position of Aurobindo Pharma Limited (Aurobindo) as the main supplier of generic pharmaceutical prescriptions to the U.S. presents legal, safety, and national security concerns, judging from open-source reporting. Aurobindo's conduct in India, as well as its reliance on suppliers based in the People's Republic of China (PRC)—many of them sanctioned by the U.S., tied to PRC military industries, or to human rights violations—create a range of supply chain risks for U.S. stakeholders, including consumers, professionals, businesses, and government agencies.

Product quality lapses, corruption, and lack of transparency on the part of Aurobindo and its subsidiaries in India create significant risks. Reflecting prevalent quality control shortcomings, corruption, and regulatory capture in the Indian pharmaceutical sector, inspections and investigations of Aurobindo and its subsidiaries by EU and U.S. regulatory agencies during the past five years revealed problems in the manufacturing process and substandard drugs. Several cases led to sanctions of Aurobindo by the European Union (EU), product recalls in the U.S. market, and other regulatory measures. Since 2020, Indian authorities have found Aurobindo involved in insider trading, money laundering, corrupt land dealing, pollution, and workplace injuries and deaths.

The supply chain risks created by Aurobindo also stem from the anti-competitive preferential policies erected by both India and the PRC, and from Aurobindo's heavy reliance on suppliers based in the PRC for precursor chemicals and active pharmaceutical ingredients (APIs)—the raw materials core to manufacturing drugs—and possibly even for finished generics. The Indian government provides export subsidies to pharmaceutical firms, while several Indian states where Aurobindo operates provide tax and production subsidies. The State of Telangana, where Aurobindo is headquartered, provides subsidies specifically for pharmaceutical firms for investment, taxes, land, lease rentals, and energy.

Aurobindo and the Indian pharmaceutical industry's competitiveness are nearly wholly reliant on the PRC's ability to produce cheap APIs. They cannot increase their production of APIs to match the economies of scale generated by PRC producers, according to reports published by Aurobindo and by French think tank Institut Montaigne.

Beijing designates the pharmaceutical industry—and especially its API sector—as an economic development and national security strategic industry in the PRC's 2022 "14th Five-Year Plan for the Development of the Pharmaceutical Industry." PRC local governments also provide financial support to the pharmaceutical industry: they subsidize each enterprise that is approved by a foreign national drug administration—such as the U.S. FDA—and which exports APIs to foreign markets.

Several of the PRC suppliers which Aurobindo relies on have stakeholders, subsidiaries, or business partners sanctioned by the U.S. Sanctions justifications include supporting PRC military industry and participating in PRC government-organized programs that violate human rights. The Communist Party of China (CPC) exerts strong influence over all PRC suppliers through various institutional means.

- ***At least five of fifty Aurobindo suppliers surveyed in this analysis have documented ties to the PRC's military civil fusion policies and/or military industries. The parent companies of four of those five suppliers are under U.S. sanctions for connections to PRC military industries.***

- *At least two of the fifty Aurobindo suppliers have a documented history of producing drugs that may fall below quality standards required by the U.S. FDA. This poses risks to the health of U.S. consumers, including both civilians and members of the U.S. military.*

- *Fifteen of the fifty suppliers have documented ties to Xinjiang, the region in the northwest of the PRC where Beijing has been committing genocide against the local Uyghur population. This likely places Aurobindo in violation of the Uyghur Forced Labor Prevention Act (UFLPA), the law which basically forbids the import to the U.S. of any products made in Xinjiang or by members of the Uyghur ethnic group in any part of the PRC as part of programs that the law defines as forced labor.*

- *Documented evidence demonstrates that thirteen of the fifty suppliers are controlled by ministries and other state entities of the PRC's central government. PRC laws and regulations mandate companies under central government agencies and ministries support and assist the People's Liberation Army (PLA). The CPC mandates that these types of companies lead in pursuing Beijing's priorities communicated through state plans and strategies, including its Military Civil Fusion Development Strategy. The CPC controls such companies -- even in cases when it formally only owns a minority financial stake.*

- *Twenty one of the fifty suppliers have documented control by local governments in the PRC. Companies under provincial and county level government control in the PRC mirror elements of companies under central government control and are similarly highly incentivized to promote the CPC's priorities.*

LARGEST SUPPLIER OF PHARMA GENERICS TO U.S., AUROBINDO EXPANDS IN BOTH U.S. AND PRC

India-headquartered global pharmaceutical firm Aurobindo (NSE: AUROPHARMA) supplies the largest share of the U.S.' generic pharmaceutical prescriptions. Aurobindo is expanding its manufacturing facilities in both the U.S. and the PRC to augment its existing India-based production and suppliers in the PRC.

- *According to Aurobindo's "Integrated Annual Report 2022-2023," a March 2023 quarterly report by global healthcare data and analytics provider IQVIA lists Aurobindo as the largest generic pharmaceutical supplier in the U.S. by prescription volume.[1] Aurobindo also ranked among the top 10 generic pharmaceutical companies in eight European countries. In fiscal year 2023, Aurobindo manufactured approximately 41 billion units of various drugs and introduced 34 new products to the U.S. market.*

- *Aurobindo, established in 1986, is headquartered in Hyderabad, India. The company employs more than 23,000 full-time staff and around 10,000 contractors through its 87 direct and nine indirect subsidiaries around the world. Aurobindo has more than 1,500 scientists and analysts in its research and development (R&D) division globally. Several members of the Reddy Penaka family control Aurobindo.[2]*

- *Aurobindo is in the process of commissioning seven new manufacturing facilities for complex generic products, including three in the U.S. and one in the PRC. Aurobindo has 19 subsidiaries and two joint ventures in India, mostly located in the states of Andhara Pradesh and Telangana. Aurobindo controls 22 manufacturing units in India that have received approvals from regulatory agencies such as the U.S. Food and Drug Administration (U.S. FDA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA), the EU's European Medicines Agency (EMA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and the United Nations' World Health Organization (WHO).[3]*

GOVERNMENT SUPPORTED INDIA PHARMA SECTOR SUPPLIES MAJORITY OF GLOBAL AND U.S. GENERICS

India manufactures most of the world's vaccines and a significant part of the world's generic drugs supply. It is also the main supplier of generic drugs to the U.S. During the last five years, the Indian government has implemented several measures meant to strengthen the pharmaceutical sector. Aurobindo has also been a beneficiary of such government subsidies.

- *The Indian pharmaceutical industry encompasses various segments, including generic drugs, over the counter (OTC) medicines, bulk drugs, vaccines, contract research and manufacturing, biosimilars, and biologics. According to India's national investment promotion and facilitation agency Invest India, the country is one of the largest suppliers of low-cost vaccines, contributing to 60% of the world's production. India's pharmaceutical industry leads in generic medicine production, manufacturing 60,000 different brands across 60 therapeutic categories, constituting 20% of the global generic drug supply. India also accounts for approximately 40% of generic drugs in the U.S.[4] According to Dr. Celia Williams of the U.S. FDA's Division of Drug Information, "FDA-approved generic drugs account for more than 90 percent of prescriptions filled in the United States."[5]*

- *The Indian government implemented a series of measures during the last five years establishing favorable policies and regulatory frameworks to encourage research and development, investment, and innovation within the pharmaceutical sector. These include India's National Pharmaceutical Policy, which is currently being drafted, and aims to provide policy interventions to address challenges in the Indian pharmaceutical industry, and the Scheme for Strengthening of Pharmaceuticals Industry, launched in March 2022, which aims to support existing pharmaceutical clusters and "Micro, Small, and Medium Enterprises" (MSMEs) to improve productivity, quality, and sustainability. [6] [7] In addition to policies for developing the industry, the Indian government also provides export subsidies to pharmaceutical firms, while several states where Aurobindo operates provide tax and production input subsidies.[8][9][10] The State of Telangana in particular provides several subsidies specifically for pharmaceutical firms for investment, taxes, land, lease rentals, and energy.[11][12][13]*

- *Aurobindo has benefited from Indian government's subsidies. In 2022, Aurobindo invested $93 million in a Penicillin-G project in Andhra Pradesh as part of the Indian government's incentive plan meant to boost domestic production.[14][15]*

- *According to the Indian newspaper Financial Express, Aurobindo received the maximum benefits under the Merchandise Export from India Scheme (MEIS) in fiscal year 2018. (The Indian government capped benefits for MEIS during the September – December 2020 period, affecting some large companies including Aurobindo.[16])*

REPORTS OF INDIAN PHARMA SECTOR PRODUCT QUALITY ISSUES

Reports by media and official entities during the last five years recognize corruption and "regulatory capture" in the Indian pharmaceutical sector. Problems noted include negligence and poor regulatory compliance in manufacturing.

- *The accounts of a whistle-blower Dinesh Singh Thakur regarding his former work as a pharmaceutical executive at the Indian generic drug manufacturer Ranbaxy Laboratories, published in two books in 2022, helped draw attention to the problem of fraud and negligence in India's generic drugs industry.[17] As Thakur notes, "the level of [regulatory] capture is by far an order of magnitude worse in India compared to elsewhere."[18]*

- *A 2019 report by Indian publication Business Today and a June 2023 report by Bloomberg note poor compliance from Indian firms, specifically with respect to contaminated drugs, low inspection outcomes, and substandard data practices.[19] [20]*

- *In December 2022, Indian authorities announced efforts to detect problems in the drug manufacturing process. Enforcement exposed problems in a significant number of local drugmakers. However, when 70 children died in Gambia after taking cough syrup manufactured by an Indian drugmaker, Indian health authorities deflected the allegations by the WHO and defended the Indian drugmaker. In a letter to the Haryana Anti-Corruption Bureau, a lawyer accused Indian company Maiden Pharmaceuticals Ltd. of bribing a Haryana state drug controller to switch samples for a cough syrup, which the WHO connected to the Gambia deaths, according to a December 2023 report by Reuters.[21]*

- *According to an August 2023 article on BioSpectrum, a news portal focused on India's health sciences industry, in December 2022 the Central Drugs Standard Control Organization (CDSCO)—India's national regulatory body for cosmetics, pharmaceuticals, and medical devices—announced efforts to detect substandard medicine.[22] Companies began recalling drugs from both local and international markets.[23]*

- *In March 2023, the Drug Controller General of India (DCGI) —responsible for the approval of drug licenses—inspected 76 companies across 20 states and cancelled licenses of 18 pharma companies for producing spurious and adulterated drugs and violating good manufacturing practices (GMP), according to Indian publication The Economic Times.[24] Additionally, the Indian government gave 26 companies show-cause notices, which require the companies to clarify information regarding potential violations.[25]*

- *In a written reply to the Indian legislature's upper house the Rajya Sabha in 2023, Union Health Minister Mansukh Mandaviya shared that following risk-based inspections of 162 pharmaceutical firms, the CDSCO and state licensing authorities issued show-cause notices in 143 cases. Among the regulatory actions taken, Indian authorities issued orders to stop production in 40 cases, while cancellation and suspension of product/section licenses occurred in 66 cases. Additionally, authorities issued warning letters in 21 cases.[26]*

- *Since December 2022, Indian authorities found that more than 65% of MSMEs were manufacturing substandard drugs, according to a November 2023 article in The Economic Times.[27]*

According to Indian government and industry sources, India has the highest number of U.S. FDA compliant pharma plants outside the U.S., and it also receives a large share of U.S. FDA generic drugs market authorization compared to other countries. According to the U.S. FDA, however, India's drug manufacturers perform poorly in inspections, and product recalls are common. The U.S. FDA has expressed concerns about the standards at pharmaceutical factories in India, and frequently issues

warning letters to Indian drugmakers for poor compliance practices. Aurobindo is among the leaders in product recalls by Indian companies.

- ***India has the highest number of U.S. FDA compliant pharma plants outside the U.S., hosting over 3,000 pharmaceutical companies and 10,500 manufacturing facilities, according to a report posted on the government of India's investment promotion agency's website.[28] From 2018 to 2022, the U.S. FDA granted more than 30% of market authorizations for generic drugs to companies from India, according to an annual report posted on the website of an Indian pharmaceutical export promotion council.[29]***

- ***In 2019, the U.S. FDA reported to Congress that India had the lowest percentage of acceptable inspection outcomes.[30]***

- ***In 2019, the Office of Manufacturing Quality (OMQ), a quality and compliance evaluation department in the U.S. FDA, issued twelve warning letters to Indian firms out of a total of fifty, or 24% of the warning letters issued by that office.[31] In 2020 and 2021, during the pandemic, the OMQ issued only five letters to Indian firms. In 2022, the OMQ issued another twelve warning letters to Indian firms out of a total of forty-four, or 27.2% of the total.[32]***

The main causes for drug manufacturing quality control shortcomings in India's pharmaceutical sector include inadequate testing of materials, weak oversight, and corruption. Substandard medicine produced in India has led to injuries and deaths around the world, including in the U.S. In several reported cases, drugmakers producing substandard medicine were located in the states of Telangana and Andhra Pradesh, where a majority of Aurobindo's India-based subsidiaries are located.

- *Eye drops produced by Indian firm Global Pharma Healthcare contained harmful bacteria affecting at least 68 patients in the U.S., leading to three deaths, eyeball removals, and blindness according to an April 2023 report by the Washington Post.[33]*

- *An October 2023 article by BioSpectrum reported council members of the regulatory body the Telangana Pharmacy Council frequently extort money for expedited paperwork.[34] [35]*

- *According to a March 2021 article on FDANews—a website for drug and medical device related news—Dr. Reddy's Laboratories Ltd. (Dr. Reddy) announced a recall in 2021 following the detection of impurities in its Lipitor generic product. The affected products were manufactured at the company's Andhra Pradesh facility. According to a December 2023 article posted on the healthcare portal DrugToday, an October 2023 inspection of Dr. Reddy's Telengana facility by the U.S. FDA found failure to maintain equipment, dirty equipment, as well as "subpar quality control practices, insufficient written specifications, neglect in addressing batch failures and discrepancies, and inadequate responses to both written and oral customer complaints."[36] [37]*

During the last five years, several cases revealed that drugs manufactured by Aurobindo and its subsidiaries were substandard. Some of these cases led to sanctions by the European Union (EU) and product recalls in the U.S. market, according to reports by EU and U.S. regulators.

- *In October 2018, the public health organization the European Directorate for the Quality of Medicines & HealthCare (EDQM) suspended Aurobindo Pharma's certification, effectively halting its supply of the drug irbesartan to the European Union (EU). Low levels of impure NDEA, an organic compound, in Aurobindo's irbesartan product caused the suspension, according to the EMA.[38]*

- *According to the U.S. FDA, Aurobindo is among the leaders in product recalls by Indian companies, with 54 product recalls during the last five years.*[39]

- *In January 2022, Aurobindo's subsidiary Eugia U.S. LLC recalled the antibiotic Polymyxin B for injection as hair was discovered in a vial, according to the U.S. FDA.*[40]

- *In September 2022, Aurobindo's subsidiary Eugia U.S. LLC recalled Acyclovir Sodium Injection due to a product complaint regarding the presence of a dark red, brown, and black particulate inside the vial, according to the U.S. FDA.*[41]

- *In October 2022, Aurobindo's subsidiary Aurobindo Pharma USA, Inc., recalled Quinapril and Hydrochlorothiazide tablets due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril above the proposed interim limit, according to the U.S. FDA.*[42]

- *In September 2023, Aurobindo's subsidiary Eugia U.S. LLC recalled 1,626 vials of Triamcinolone Acetonide Injectable Suspension manufactured in India due to potential glass contamination, according to a U.S. FDA enforcement report. The U.S. FDA classified the recalls as class II, meaning potential but not immediate adverse health consequences.*[43]

The U.S. FDA sent Aurobindo several warning letters following inspections of their India facilities. The warnings reveal deviation from manufacturing protocols, faulty equipment, and failure to maintain and clean equipment. In one instance, an Indian regulatory agency found that Aurobindo failed to fully disclose the results of a U.S. FDA inspection.

- *During the last five years, Aurobindo and its subsidiaries have received at least two warning letters and several inspections from the U.S. FDA. One U.S. FDA inspection of the company's drug manufacturing facilities included 14 observations.*[444546]

- *In 2023, an audit found serious violations at Aurobindo's Anakapalli Plant in eastern India. Auditors uncovered problems with manufacturing equipment cleaning and storage controls during a visit. Sampling tools were not cleaned and maintained to prevent contamination at the plant, which produces certain APIs. "Laboratory controls also didn't include the establishment of scientifically sound and appropriate specification, designed to assure that drug products conform to appropriate standards of identity, quality and purity," according to a Bloomberg's June 2023 article.*[47]

- *In 2022, the U.S. FDA inspected Aurobindo's Unit-VII, which specializes in oral manufacturing, located in Hyderabad. The U.S. FDA's observations raised concerns about adherence to production protocols, equipment standards, and the handling of discrepancies. Notably, this facility had previously received regulatory attention in 2020.*[48]

- *In 2019, the U.S. FDA issued a warning letter to Aurobindo's unit XI in the city of Srikakulam following an inspection. The U.S. FDA highlighted significant deviations in "current good manufacturing practices," including insufficient investigation into impurities, equipment maintenance issues, and failure to report changes.*[49]

- *In June 2022, the Securities and Exchange Board of India (SEBI) issued a warning to Aurobindo for not adequately disclosing information regarding a U.S. FDA audit of its API manufacturing facility. The regulatory body found the company's disclosures to be inadequate and not in compliance with SEBI regulations, highlighting the lack of transparency.*[50]

CDSCO records from 2019 show Aurobindo received approval for export of medicine to the European Union on six occasions from S. Eswara Reddy, a Joint Drugs Controller of the CDSCO, who later was prosecuted in a separate case over receiving bribes for waiving approvals for another pharmaceutical firm.

- *In July 2023, the CBI began prosecution of S. Eswara Reddy over allegations of accepting a bribe to waive Phase 3 clinical trials for Biocon Biologics' Phase 3 "Insulin Aspart" injection after initially charging him in August 2022. L. Praveen Kumar, associate vice president of Biocon Biologics, allegedly made a $509,000 (₹4 Lakh INR) payment to Reddy.*[5152]

- *S. Eswara Reddy, previously provided written confirmation to Aurobindo as part of an export requirement related to manufacturing and exporting medicinal products to the European Union on six occasions in January, June, July, and August 2019.*[53545565758]

FINANCIAL CORRUPTION

Aurobindo and its leadership have also been involved in corruption cases. Indian authorities found Aurobindo was involved in an insider trading case from May 2020, a money laundering case involving an Aurobindo director in November 2022, and an ongoing case related to a corrupt land deal.

- ***In May 2020, Aurobindo and several other entities settled a case with SEBI, paying a penalty of over $2.6 million (₹22 Crore INR) for insider trading.***[59]

- ***One of Aurobindo's non-executive directors, P. Sarath Chandra Reddy is under investigation by the Enforcement Directorate (ED), a national agency which investigates money laundering, for his involvement in possible money laundering in a separate business.***[60]

- ***In March 2012, the Central Bureau of Investigation (CBI), India's central investigative authority for major crimes including government corruption and interstate cases, charged Sarath Reddy for bribing a government official for lower land prices, which also involved a land deal allegedly started by K. Nithyananda Reddy, Sarath's father-in-law and an Aurobindo executive.***[61] ***As of January 2021, the CBI's investigation into the land transfer involving Aurobindo was still ongoing.***[62] ***Aurobindo does not mention the CBI case in any of its annual reports from the last five years.***

ENVIRONMENTAL AND SAFETY ISSUES

A 2018 Dutch documentary investigating how Aurobindo's drugs could be so cheap, found Aurobindo polluted the local environments' water and air, and the links between this type of pollution and the development of drug resistant bacteria. The documentary accused Aurobindo of underpaying labor and employing exploited migrant labor. The Telangana state government is also involved in the allegations, as it bought land from Dalit communities to develop Aurobindo's facilities and promised employment to these communities, which never materialized.[63] Since 2019, Aurobindo and its subsidiaries have received multiple notices and fines from state and central pollution control boards for alleged violations of environmental regulations.[646566676869] Moreover, during the last five years, several safety incidents in Aurobindo's facilities injured and killed several employees.[707172]

PRC'S PHARMACEUTICAL INDUSTRY SUPPORTED BY BEIJING'S SUBSIDIES, LITTLE-SCRUTINIZED BY U.S. FDA

The PRC supplied more than 40% of the world's APIs in 2019. India imports most of its APIs from the PRC, and it relies on PRC supply to remain competitive in the global industry. Aurobindo relies heavily on PRC APIs. The pharmaceutical industry is one of the PRC government's economic development and national security strategic planning priorities, and API is a priority sector within the industry. PRC government policy support to the API manufacturing sector includes financial subsidies that can vary by location. The U.S. government raised repeated concerns with the U.S. FDA over PRC generic drug quality and the effectiveness of foreign inspections by the U.S. FDA. The U.S. FDA only resumed in-person inspections in the PRC in April 2023, after pausing them in March 2020.

- *The PRC supplied more than 40% of the world's APIs in 2019, according to a May 2023 report by Reuters.[73] India imports about 70% of the APIs from the PRC, according to a November 2023 report by Nikkei Asia.[74]*

- *According to a June 2020 report by the French think tank Institut Montaigne, the Indian pharmaceutical industry's competitiveness is nearly wholly reliant on the PRC's ability to produce cheap API's. One pharmaceutical company states: "We cannot increase the production of APIs to an extent where we end up matching the economies of scale generated by Chinese units. Our cost of production for API will be higher, which in turn would hamper export competitiveness of the products." The report states that a transition of India to domestical API production would require large-scale investment to remain competitive.[75]*

- *According to Aurobindo's "Integrated Annual Report 2022-2023, the company has "a high dependence on the China market for import of Key Starting Materials (KSMs), Intermediates and Active Pharmaceutical Ingredients" and "Aurobindo India" receives 89% of its imported pharmaceutical precursors and APIs from the PRC, which constitutes 55% of its total pharmaceutical precursors and APIs."[76]*

- *The PRC government designates the pharmaceutical industry as one of the PRC's economic development and national security strategic industries, according to a Ministry of Industry and Information Technology (MIIT) document rehosted on the official PRC government website. The document states that the PRC's national "14th Five-Year Plan for the Development of the Pharmaceutical Industry" — jointly issued in 2022 by more than nine national government agencies, and led by the MIIT — lists API as a priority sector to develop within its pharmaceutical industry.*

- *PRC local governments provide direct financial support to the pharmaceutical industry. For example, a January 2023 notice posted by an economic policy agency of the Shenzhen Municipal government announced that it would provide up to approximately $273,920 (two million CNY) in annual subsidies for each enterprise that is approved by a foreign national drug administration—such as the U.S. FDA—and which exports APIs to foreign markets.[77]*

- *According to government and news reports, the Biden Administration, Republican representatives in U.S. Congress, the U.S. Department of Defense (DoD), and the U.S. Government Accountability Office (GAO) have raised concerns over generic drug quality issues and the U.S. FDA's inadequate foreign inspections, particularly those conducted on PRC and Indian companies.[78] The GAO noted finding vacancies in five of 15 U.S. FDA drug investigator positions for the PRC and India in November 2021, while the DoD engaged in talks with an outside firm to independently test the safety of generic drugs.[7980] Republican representatives in U.S. Congress on behalf of the Health and Oversight Subcommittee also raised concerns over the quality and quantity of U.S. FDA inspections in the PRC and India.[81]*

- *In total, as of November 17, 2023 1,014 PRC pharmaceutical entities are U.S. FDA registered.[82] Between March 2020 and April 2022, the U.S. FDA stopped in-person inspections, instead conducting voluntary, remote inspections. In the case of the PRC, however, the U.S. FDA*

only resumed in-person inspections in April 2023. Between 2020 and 2022, the U.S. FDA conducted 40 inspections in the PRC, and these were likely all conducted remotely -- and much less frequently than 2019, which saw 131 inspections.[83]

AUROBINDO WHOLLY OR PARTIALLY OWNS PRC-BASED SUBSIDIARIES AND JOINT VENTURES

Aurobindo wholly owns All Pharma (Shanghai) Trading Co., Ltd., a.k.a. Aurobindo Pharma (Shanghai) Trading Co., Ltd. (All Pharma), according to Aurobindo's 2022-2023 annual report.[84] All Pharma appears to act as a shipping intermediary for moving goods from the PRC to Aurobindo subsidiaries.

- *All Pharma sent industrial computers to Gelcaps Industries—an India-based pharmaceutical company under the control of relatives of Aurobindo's owners—and filter equipment to Eugia Pharma Specialties Limited, an Aurobindo India-based subsidiary. The firm also sent Hypromellose Phthalate PH EUR, Starch Pregelatinized PH EUR, and Cellulose Microcrystalline PH EUR to Aurobindo. PH EUR stands for European Pharmacopoeia, a European pharmaceutical standard, which suggests Europe is the final destination for these goods. In 2023, the firm also sought permission to ship Arpiprazole tablets and Donepezil Hydrochloride tablets from the PRC; the supplier and ultimate destination of these goods is unknown. Aurobindo received U.S. FDA approval to manufacture Arpiprazole tablets in October 2015.[85] Aurobindo is also listed on the National Library of Medicine Daily Med database, a database for labelling submitted to the U.S. FDA, as the packager for Donepezil Hydrochloride tablets.[86]*

- *All Pharma is a member of the Pharmaceutical and Health Working Committee (PHWC), which the Shanghai Municipal Government-controlled Shanghai Foreign Investment Association (SFIA) established in 2019. The PHWC is registered with the Shanghai Civil Affairs Bureau, which promotes and implements national and municipal guidelines and policies on the medical and health industry, such as "the 14th Five-Year Plan for the Development of the Pharmaceutical Industry" — jointly issued in 2022 by nine national government agencies led by the MIIT.*

Aurobindo wholly owns the Taizhou, Jiangsu-based subsidiary Aurovitas Pharmaceutical (Taizhou) Co., Ltd. (Aurovitas) through its Netherlands-based subsidiary Helix Healthcare B.V.[87] Aurovitas manufactures and sells pharmaceutical preparations for domestic and export use.[88] It also imports pharmaceutical equipment from India to the PRC.[89]

- *In 2023, Aurobindo completed building a facility in Taizhou, which the company is in the process of commissioning, according to Aurobindo's "Integrated Annual Report 2022-2023."[90]*

- *In 2019, the Center for Drug Evaluation — the technical review and drug authorization organization for the PRC's National Medical Products Administration (the supervisory sub-organization for drug safety, medical devices, and cosmetics under the State Council's State Administration for Market Regulation) — registered Aurovitas' atazanavir capsules for the PRC market. Aurovitas' new Taizhou production line is set to bring a yearly revenue of over $273 million (two billion CNY), according to a July 2022 report by Haitong International Securities Group Limited, an international financial institution with established presence in Hong Kong.[91][92]*

Taizhou's mayor Wan Wenhua meeting with Aurobindo's Whole Time Director Mr. M. Madan Mohan Reddy on January 8, 2024.[9394]

Aurovitas Pharmaceutical (Taizhou) Co., Ltd. (Aurovitas) lab.

Aurobindo owns a minority stake in a joint venture with Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. (Shandong Luoxin) (SHE 002793), a PRC-based pharmaceutical company that has produced sub-standard products. The senior officers of Shandong Luoxin hold leadership positions in CPC

organizations. One of Shandong Luoxin's owners holds a position in a company based in the Xinjiang Uyghur Autonomous Region (hereafter Xinjiang).[95]

- ***Luoxin Aurovitas Pharma (Chengdu) Co., Ltd is located in Chengdu, and is involved in research and development, production, and sales of respiratory pharmaceutical products. Luoxin Aurovitas' products include five U.S. FDA approved inhalers used for respiratory diseases.[96]***

- ***Aurobindo owns 30% of Luoxin Aurovitas through its Netherlands-based full subsidiary Helix Healthcare B.V.[97] Shandong Luoxinowns the remaining stake in Luoxin Aurovitas.***

    - *In 2020 Shandong Provincial Medical Products Administration fined Shandong Luoxin $48,869 (356,817 CNY) for producing and selling sub-standard Ozagrel sodium used for injection.*

    - *Xinjiang-based Karamay Yizhizhi Equity Investment Management Limited Partnership (Karamay Yizhizhi) owns a stake in Shandong Luoxin.*

    - *Liu Zhenteng, who holds senior positions at Luoxin Aurovitas and Shandong Luoxin and indirectly owns a stake in both companies, also holds a position at Karamay Yizhizhi.*

    - *An investor in Shandong Luoxin, Winning Venture Capital Management Co., Ltd. (Winning Venture), has a subsidiary, Xinjiang Tianshan Snow Lotus Pharmaceutical Co., Ltd. (Tianshan Snow Lotus), based in Xinjiang.*

    - *Liu Zhenteng's father, Liu Baoqi, is a controlling owner of Shandong Luoxin and Luoxin Aurovitas. In 2021, Liu Baoqi was a delegate to the 12th Provincial People's Congress of Shandong Province, the 12th session of the provincial legislative body.*

    - *Shandong Luoxin's Vice President Song Aigang is a member of the city of Linyi Municipal Chinese People's Political Consultative Conference.[98] The CPPCC is an advisory body to the Party-state that coordinates between the Party and important social groups including leaders in business, academia, and religious groups to carry out united front work under the guidance of the CPC's United Front Work Department (UFWD). The UFWD contributes significantly to covert overseas operations involving political influence, intelligence collection, and technology transfer.[99]*

AUROBINDO'S PRC SUPPLIERS

This section presents the results of examination of a sample of 50 of Aurobindo's at least 141 suppliers for links to the PRC's defense industry, forced labor of ethnic minorities, potential safety risks to American consumers, ownership by the PRC's central government, and ownership by PRC local governments.

PRC SUPPLIERS WITH DOCUMENTATION OF CONNECTION TO PRC MILITARY INDUSTRY AND POLICY

At least five of the fifty Aurobindo suppliers surveyed have documented ties to the PRC's military civil fusion policies and/or military industries. Four of the five companies are under U.S. Government sanctions for connection to PRC military industries. Aurobindo supplier Henan Topfond Pharmaceutical Chemical Co., Ltd. (Topfond Pharmachem) exemplifies a company with strong ties to

the PRC's defense industry. China Meheco Group Ltd. (Meheco) controls Topfond Pharmachem.[100] Meheco's largest shareholders are the State-owned Assets Supervision and Administration Commission of the State Council (State Council SASAC) and the state-owned hypersonic and laser weapons manufacturer China Aerospace Science & Industry Corporation (CASIC). State Council SASAC manages the PRC's key central state-owned Enterprises (SOEs). CASIC, and several of its subsidiaries and subunits are on the U.S. Entity List, which classifies them as "Communist Chinese Military Companies" that are subject to U.S. export restrictions.[101] Successive White House Executive Orders in November 2020 by President Donald Trump and in June 2021 by President Joseph Biden prohibited investment in PRC military industries designated as "Communist Chinese military companies," CASIC among them.[102]

Sinochem Pharmaceutical Co., Ltd.
Henan Topfond Pharmaceutical Chemical Co., Ltd.
Henan Topfond Technology Co., Ltd.
Shinghwa Amperex Technology (Dongying) Co., Ltd.
Henan Junhua Development Co., Ltd.

PRC SUPPLIERS WITH DOCUMENTED VIOLATIONS OF U.S. PHARMACEUTICAL REGULATION

At least two of the fifty Aurobindo suppliers have a documented history of producing drugs that could fall below quality standards required by the U.S. FDA. Aurobindo is a major supplier of U.S. generic drugs, and the integrity of its supply chain is crucial to the health of U.S. consumers, including both civilians and members of the U.S. military.

The case of Aurobindo supplier Zhejiang Huahai Pharmaceutical Co., Ltd (Huahai Pharma) presents legal and safety concerns for U.S. stakeholders. Huahai Pharma partners with Xinjiang Baihuacun Pharma Tech Co., Ltd. (Baihuacun Pharma) on pharmaceutical research and development. The Xinjiang Production and Construction Corps (XPCC)—a paramilitary, ministry-level PRC central state entity under sanctions by the U.S. government for its involvement in human rights violations in Xinjiang—owns a stake in Baihuacun Pharma. The U.S. FDA placed an import ban on APIs from Huahai Pharma during 2018-2021 after the U.S. FDA found carcinogens in several of its products including a heart medication, Valsartan, according to the Generics and Biosimilars Initiative.[103] In an example of Aurobindo relying on a PRC supplier for a finished generic, Aurobindo imported Valsartan under United States Pharmacopeia (USP)—a quality standard used for U.S. drugs—from Huahai Pharma in 2023, despite U.S. FDA's ban over Huahai Pharma's previous quality issues with Valsartan's production.[104] In 2023, Aurobindo also received shipments of Lisinopril PH EUR and Lisinopril Dihydrate PH EUR from Huahai Pharma.

Zhejiang Huahai Pharmaceutical Co.,
Chongqing Carelife Pharmaceutical Co., Ltd.

PRC SUPPLIERS WITH DOCUMENTATION OF POSSIBLE VIOLATION OF UFPLA PROHIBITION

Fifteen of the fifty suppliers have documented ties to Xinjiang, likely placing Aurobindo in violation of the Uyghur Forced Labor Prevention Act (UFLPA) by U.S. Congress, which forbids the import to the U.S. of any products made in Xinjiang or by members of the Uyghur ethnic group in any part of the PRC as part of "pairing assistance" and "poverty alleviation" programs that the law defines as forced labor.[105] "Poverty alleviation" and "pairing assistance" use forced labor of ethnic minorities as part of a larger program that the CPC terms Xinjiang Aid. [106] The XPCC (see above) manages many of these programs.

In 2023, for example, Yili Chuanning Biotechnology Co., Ltd., based in the city of Horgos, Xinjiang, shipped Aurobindo products under the category of "6-APA (6-aminopenicillanic acid), antibiotics, penicillins and their derivatives with a penicillanic acid structure, and salts thereof." In a second example, Hubei Xingfa Chemicals Group Co., Ltd (Hubei Xingfa), based in Hubei Province, supplied Aurobindo with Dimethyl Sulfoxide in 2023. Hubei Xingfa has a wholly owned subsidiary in Xinjiang which produces Dimethyl Sulfoxide. Importing these products or any drugs made with these products to the U.S. would be a violation of the UFLPA. In an Aurobindo document on its manufacturing processes submitted to the Telangana State Pollution Control Board in June 2019, it shows that Dimethyl Sulfoxide is a component in its production of Zidovudine.[107] The Daily Med database for company submitted labelling to the U.S. FDA, shows Aurobindo submitted an abbreviated new drug application for Zidovudine syrup in July 2022.[108]

Yili Chuanning Biotechnology Co., Ltd.
Hubei Xingfa Chemicals Group Co., Ltd.
Jiangsu GTIG Huatai Co., Ltd.
Sinopharm Weiqida Pharmaceutical Co., Ltd.
Sinochem Pharmaceutical Co., Ltd.
Jiangsu Weiqida Pharmaceutical Co., Ltd.
Zhejiang Huahai Pharmaceutical Co., Ltd.
Shandong Keyuan Pharmaceutical Co., Ltd.
Zhejiang Chemicals Import & Export Corporation
Chongqing Carelife Pharmaceutical Co., Ltd.
Qilu Antibiotics Pharmaceutical Co., Ltd.
Jiangxi Fushine Pharmaceutical Co., Ltd.
Shandong Jincheng Pharmaceutical Group Co., Ltd.
Shandong Jincheng Kerui Chemical Co., Ltd.
Zhejiang Chiral Medicine Chemical Co., Ltd.

PRC SUPPLIERS WITH DOCUMENTATION OF CONTROL BY PRC CENTRAL GOVERNMENT AGENCIES

Documented evidence demonstrates that thirteen of the fifty suppliers are controlled by ministries and other state entities of the PRC's central government, such as State Council SASAC. PRC laws and

regulations mandate companies under State Council SASAC and other central government agencies and ministries work to support and assist the People's Liberation Army (PLA). Like all companies in the PRC, these firms are also mandated to pursue the CPC's priorities communicated through state plans and strategies, including its Military Civil Fusion Development Strategy.

Evidence concerning Aurobindo supplier Sinochem Pharmaceutical Co., Ltd. (Sinochem Pharma; a.k.a. Sinochem Jiangsu Co., Ltd.) demonstrates links to PRC central government control, the PRC's programs in areas with large ethnic minority populations, and the PRC's defense industries. The State Council SASAC controls Sinochem Pharma through State Council SASAC SOE Sinochem Holdings Co., Ltd. (Sinochem Holdings) and Sinochem International Corporation (Sinochem International). Sinochem Holdings indirectly controls two Xinjiang based companies: Sinochem Modern Agriculture (Xinjiang) Co., Ltd. and Sinochem Agriculture (Xinjiang) Biotechnology Co., Ltd. Starting in 2002 and continuing to 2023, Sinochem Holdings has participated in "pairing assistance" programs in Tibet, Qinghai and Xinjiang. On November 12, 2020 and in subsequent updates, U.S. Executive Orders issued by the White House prohibited investments in PRC SOEs designated as "Communist Chinese military companies." Eight Sinochem corporate group members appear on the list, including Sinochem Group and Sinochem International.[109]

Sinopharm Weiqida Pharmaceutical Co., Ltd.
Sinochem Pharmaceutical Co., Ltd.
Jiangsu Weiqida Pharmaceutical Co., Ltd.
Henan Topfond Pharmaceutical Chemical Co., Ltd.
Henan Topfond Technology Co., Ltd.
Shinghwa Amperex Technology (Dongying) Co., Ltd.
Henan Junhua Development Co., Ltd.
Shandong Jincheng Pharmaceutical Group Co., Ltd.
Shandong Jincheng Kerui Chemical Co., Ltd.
Porton Pharma (Jiangxi) Co., Ltd.
Chongqing Tiandi Pharmaceutical Co., Ltd.
Jiangsu Ruike Pharmaceutical Sci-Tech Co., Ltd.
Bright Gene Bio-Medical Technology Co., Ltd.

PRC SUPPLIERS WITH DOCUMENTATION OF CONTROL BY PRC LOCAL GOVERNMENT ENTITIES

Twenty one of the fifty suppliers have documented control by local governments in the PRC. Provincial and county level governments in the PRC mirror certain elements of the central government structure, including administering State-Owned Asset Supervision and Administration Commission (SASAC) entities at their respective provincial, city, or other levels. Local governments own, manage, and supervise many commercial enterprises in their respective jurisdictions. Local government-controlled enterprises are highly incentivized to promote the CPC's national strategies and policies such as Military Civil Fusion and Xinjiang Aid, and to support the state's security and surveillance apparatus.

Aurobindo supplier Shinghwa Amperex Technology (Dongying) Co Ltd. (Shinghwa) demonstrates how a local government-owned company supports the CPC's national Military Civil Fusion Development Strategy. Qingdao West Coast New Area SASAC indirectly controls Shinghwa, in part through the

state-owned Qingdao Military Civil Fusion Development Group Company Limited. State Council SASAC also owns a stake in Shinghwa.

Hubei Xingfa Chemicals Group Co., Ltd.
Jiangsu GTIG Huatai Co., Ltd.
Jiangsu Weiqida Pharmaceutical Co., Ltd.
Zhejiang Chemicals Import & Export Corporation
Chongqing Carelife Pharmaceutical Co., Ltd.
Jiangxi Fushine Pharmaceutical Co., Ltd.
Shinghwa Amperex Technology (Dongying) Co., Ltd.
Zhejiang Medicines & Health Products Imp & Exp Co., Ltd.
Changzhou Pharmaceutical Factory
Porton Pharma (Jiangxi) Co., Ltd.
Zhejiang Hongyuan Pharmaceutical Co., Ltd.
Zhejiang Guobang Pharmaceutical Co., Ltd.
Anhui Biochem Pharmaceutical Co., Ltd.
Fujian South Pharmaceutical Co., Ltd.
Suzhou Lixin Pharmaceutical Co., Ltd.
Cangzhou Senary Chemical Science & Technology Co., Ltd.
Shanghai Desano Chemical Pharmaceuticals Co., Ltd.
Farmasino Pharmaceuticals (Jiangsu) Co., Ltd.
Bright Gene Bio-Medical Technology Co., Ltd.
Shanghai Jinhe Bio-Pharmaceuticals Co., Ltd.
Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd.

PRC SUPPLIERS WITH LITTLE DOCUMENTATION OF POSSIBLE SUPPLY CHAIN RISKS

Initial research found little documentation of possible supply chain risks for fourteen of the fifty suppliers. However, even without having a documented financial stake or presence in a company, the CPC still exerts strong influence through a raft of PRC laws, including the "PRC Company Law" which requires every company to establish an internal CPC organization. Every entity and individual under PRC jurisdiction is subject to CPC control. Moreover, in the PRC's totalitarian political landscape, the CPC incentivizes companies and individuals therein to proactively fulfill CPC goals, even without being explicitly commanded to do so.

Tianjin Tianfa Pharmaceuticals Import & Export Co., Ltd.
Livzon Pharmaceutical Group Co., Ltd.
Shenzhen Haibin Pharmaceutical Co., Ltd.
Zhejiang Shaxing Technology Co., Ltd.
Shenzhen Hepalink Pharmaceutical Group Co., Ltd.
Ningbo Menovo Pharmaceutical Co., Ltd.
Hebei Fude Chemical Technology Co., Ltd.
Nanjing Joyin Parmachem Co., Ltd.
Zhejiang Charioteer Pharmaceutical Co., Ltd.
Hebei Chengxin Co., Ltd.
Ningbo Eshine Pharmaceutical Co., Ltd.

Zhejiang Regen Chemical Co., Ltd.
Reyoung Pharmaceutical Co., Ltd.
Hunan Yuxin Pharmaceutical Co., Ltd.
Ningxia Taikang Pharmaceutical Co., Ltd.

SCOPE NOTE

This study identifies and reports on aspects of pharmaceutical industry production and trade by India-headquartered global pharmaceutical firm Aurobindo Pharma Limited (Aurobindo) during the past five years which are likely to present risk to the U.S., particularly through supply chains. Readers are advised to be aware of the following additional scoping parameters:

- *Information herein comes from preliminary survey of other open sources in English and local languages, such as reporting by or about Aurobindo's suppliers, U.S. and Indian regulatory bodies, and other parties because Aurobindo does not publicly report its specific suppliers or regulatory inspections.*

- *U.S. FDA reporting on producer facility inspections is incomplete—and possibly selective— judging from caveats on the agency's public-facing inspections database indicating that several inspection categories are not included.*

- *This study surveyed fifty (50) of Aurobindo's PRC suppliers, two PRC-based Aurobindo subsidiaries, and one Aurobindo PRC joint venture for connections and actions which may pose supply chain risks or be in violation of U.S. law. While discovered documentation reveals these types of connections and actions for some of these entities, the lack of discoverable documentation for other of these entities is not proof of absence of such structural, institutional connections or actions. Recently increasing requirements from the PRC government mandate that all PRC entities conceal data—including commercial, financial, and other information—from unauthorized access, as defined and enforced by the PRC government. Additionally, PRC agencies' and enterprises' personnel systems are structured to incentivize pursuit and fulfillment of objectives communicated through a variety of general guidance including government-announced strategies, plans, and action programs, in many cases without necessarily requiring explicit commands or other specific documentation. A raft of PRC laws and regulations mandates that all institutions are directly or indirectly subject to supervision and guidance by the CPC, including requirements to establish internal CPC structures and to collaborate with requests and orders made by PRC security services and other government agencies.*

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