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NEWS

Indian Labs Deleted Test Results for U.S. Drugs, Documents Show

By Anna Edney
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Bloomberg News

A chemist performs new drug discovery research at a research and devolopment facility of Ranbaxy Laboratories Limited in New Delhi.
Photographer: Zoriah/Redux

December 3, 2014 – In a lab in an Indian village during the height of monsoon season in 2011, a technician hit a delete button – a keystroke that would have consequences three years later.

The quality-control employee of Sun Pharmaceutical Industries Ltd. had run high-powered chemical analyses on a drug sample to check for impurities that day. A certain level of impurity means the whole batch is supposed to be thrown out.

That's not what happened. Instead, the results of the failed tests were deleted, according to a previously undisclosed account detailed in a November 2013 FDA document obtained by Bloomberg News. The following day, workers used a sample from the same batch that passed the test. That result got entered, and the entire batch was declared clean and ready to ship abroad, eventually to be used by patients in the U.S. The FDA's computer forensics experts eventually found 5,301 additional deleted results from chromatography tests at the facility.

"Our review found that analysts regularly delete undesirable chromatographic results, and products are retested without initiating an investigation as required," inspectors wrote in the document. The incident "raises concerns about the integrity of all data generated by your firm," the FDA wrote in a separate warning letter to Sun in May. Two months earlier, the agency had banned imports from the plant, near the western city of Vadodara.

The name of the drug or ingredient that the company was testing was redacted in documents Bloomberg obtained from the FDA under a Freedom of Information Act request. Frederick Castro, a spokesman for Sun Pharma, declined to comment.

Not Isolated

The incident wasn't isolated to Sun. A review of FDA documents by Bloomberg News found

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that similar actions on quality tests have happened at dozens of other companies' plants across India that make drug ingredients and pills for export to the U.S. While not as visible as the dead frogs and flies inspectors have found in other Indian labs, the pattern of data integrity breaches worries doctors in the U.S. and elsewhere. They say they fear prescribing generic drugs that may not do what they're supposed to.

"If they make multiple batches, does it come out the same, with the same amount of drug in it? And when you give it to a patient, can you assume it will work consistently?" said Harry Lever, a cardiologist at the Cleveland Clinic.

Reporting Failures

A review of inspection documents and warning letters shows that at least 12 drug companies with Indian facilities banned from sending pharmaceutical products to the U.S. since last year – many of which supplied Americans' most vital medicines – are accused of failing to report data from tests that were supposed to confirm the drugs were safe and would work.

India is the second-largest drug exporter to the U.S., and companies there mainly produce generic drugs and active ingredients for medicine. The top 10 pharmaceutical companies based in the country generate $15 billion in annual sales, according to data compiled by Bloomberg.

The U.S. doesn't require tests of imported drugs as they cross the border. The FDA relies on factories themselves to conduct quality tests and report accurate results, only performing its own studies if it gets enough complaints about a medicine.

The agency has about a dozen staff members in India to police about 600 factories registered there with the U.S. This year, the FDA had conducted 97 inspections of drug manufacturers as of the end of October, said Tara Goodin, an agency spokeswoman.

Antibiotic Recall

Sun Pharma has 25 manufacturing facilities worldwide, including 11 in India and seven in the U.S. The plant near Vadodara was approved to make generic cephalosporin, a class of a popular antibiotic. Three years after the incident highlighted by the FDA, Sun's Caraco Pharmaceutical Laboratories Ltd. in Detroit recalled 450,000 bottles of cephalexin, a type of cephalosporin. The active ingredient made by Sun wasn't produced using good manufacturing practices, the FDA said in an enforcement report in August, without providing details. It's unclear whether the Detroit plant and the India plant processed the same products.

About 22 million prescriptions of cephalexin, which is made by several generic companies, are written each year in the U.S., according to data compiled by Bloomberg. Caraco representatives didn't return phone messages.

Exacting Process

The FDA told Bloomberg it could only handle requests for four inspection documents, known as Form 483s, at a time without making the process lengthier and more complicated. With about 600 FDA-registered factories in India, that makes it difficult to get a snapshot of data integrity across the entire industry.

Warning letters are public and don't require

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a Freedom of Information Act request. However, not every red flag in an inspection results in a warning letter, meaning the full extent of violations may not be publicly available.

Sometimes there's a lag between an FDA inspection and an export prohibition. A banned Ranbaxy Laboratories Ltd. plant in Toansa was inspected Jan. 5 to 11, and the FDA stopped allowing its product into the U.S. about two weeks later.

Sun's plant was banned four months after its inspection. A senior quality control officer told FDA investigators lab employees there frequently pre-tested samples before recording a final result, according to the agency's warning letter to Sun. The practice is unacceptable, the FDA said. The missing results were in an obscure "default" folder in a software program called Empower, according to a Form 483.

Staying Compliant

The maker of Empower, Waters Corp., said the chromatography data system, or CDS, software is designed to help labs comply with government regulations.

"One of the goals of compliant CDS software is that controls are in place so data cannot be deleted, either accidentally or maliciously, and that the data is always maintained," Jeff Tarmy, a spokesman for the Milford, Massachusetts-based company, said in an e-mail. He said he couldn't comment on a specific investigation or client.

The data-integrity incidents detected at Indian plants are the subject of stepped-up scrutiny from regulators. Guragon, India-based Ranbaxy pleaded guilty last year to felony charges for similar violations and paid $500 million in fines. In a statement last year, Ranbaxy Chief Executive Officer Arun Sawhney said the company was "disappointed by the conduct of the past" and is "pleased to continue bringing safe, effective and quality medicines to market."

A spokesman for Ranbaxy, which is being acquired by Sun, declined to comment.

Pattern of Conduct

"There's a pattern of conduct at other companies that are similar, if not identical, to the Ranbaxy problems," said Andrew Beato, the Washington-based lawyer who helped a whistle-blower expose Ranbaxy.

Reporting on product safety and effectiveness is only valuable "when it is reliable, truthful and accurate," Goodin, the FDA spokeswoman, said in an e-mail. When it's not, "those manufacturers' practices raise questions about the accuracy, reliability, and truthfulness of all the data and information they collect and report," she said.

Asked whether felony prosecutions were possible for any of the 12 companies with plants in India on the banned list, Goodin said: "Firms unable to demonstrate control over their processes and testing may not be producing safe, high-quality products and therefore may be subject to enforcement action."

Data-integrity breaches weren't just limited to plants in India that are banned from exporting to the U.S. They also happened in places that haven't been prohibited thus far, according to FDA observation reports and warning letters.

Missing Papers

At a plant in India run by Lake Forest, Illinois-based Hospira Inc., the FDA said in a December

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2013 document that workers didn't make available records on drug production. Then investigators saw two boxes of what appeared to be paper records locked in a janitor room, they said in their report. Key in hand an hour later, investigators found one of the boxes removed, and when it was returned from the "waste area," the papers were missing, according to the Form 483. The document didn't say how investigators first spotted the boxes in the locked room.

The Hospira plant had already received a warning letter in May 2013 following an October 2012 inspection. It's not clear if any new action resulted from the December 2013 inspection. Hospira representatives didn't return phone messages.

International Expectations

While the Indian government has had good manufacturing practices for drugmakers to follow for years, it hasn't had strict guidelines for testing laboratories, said India Drugs Controller General G.N. Singh, the pharmaceutical industry's top regulator in the country. The government introduced laboratory guidelines to manufacturers in 2012 and made it a requirement last year to comply, he said. Over time, the new rules will help Indian companies avoid the lapses cited by the FDA, he said.

"It normally takes a few years to catch on, get adopted fully, and the training the industry gives to the analysts takes some time," he said. "Now the results will start coming, as per the international expectations."

Many of the companies in India on the FDA's banned list supplied vital therapies or ingredients. For example, India- based Smruthi Organics Ltd. supplied the active ingredient in the antibiotic Noroxin to Merck & Co., the second-largest drugmaker in the U.S., according to the U.S. National Library of Medicine.

A Smruthi plant was banned from sending its product to the U.S. in June 2013. The company was formally warned by the FDA in March on its facility, where the agency said workers blended failed batches of active ingredients with passing ones and destroyed any related documentation. FDA staff also observed pooled urine in bathrooms that lacked drainage and no soap for hand washing in two bathrooms.

FDA Testing

Merck confirmed it "no longer sources" ingredients from Smruthi, and the company discontinued Noroxin in April. Mylan Inc., the largest generic drugmaker in the U.S., also suspended a relationship with Smruthi, which supplied ingredients for 12 Mylan products – all of which Mylan recalled. The plant remains closed. Neither Merck nor Mylan were found to be in violation of FDA rules.

Eaga Purushotham, managing director of Smruthi Organics, didn't respond to e-mails and calls seeking comment. Smruthi "is making every attempt to resolve regulatory issues," which contributed to a loss in the quarter that ended in September, the company said in a filing last month.

FDA Commissioner Margaret Hamburg traveled to India in February and vowed to step up efforts to help companies there overcome hurdles on compliance. She also pledged to increase the FDA's personnel in India to 19, though staffing remained at 12 as of the end of October.

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'Similar Culture'

Meetings with the FDA have helped Indian regulators make progress on meeting international standards, said Singh, the drugs controller.

India's national drug regulator, the Central Drugs Standard Control Organisation, has 400 staff, aided by about 1,500 additional personnel in the offices of individual state regulators. Singh said he aims to raise the total number to 10,000 to 12,000 in the next three to five years.

"We want to have a similar culture as what the other regulators are expecting," he said.

FDA-BANNED FACTORIES AND THEIR OWNERS' RESPONSES

Besides Sun, Ranbaxy and Smruthi, these nine companies own factories whose exports were prohibited by the FDA. They are listed with their comments or with Bloomberg's attempts to reach them via phone and e-mail.

Amsal Chem Pvt. Ltd. – *The company has sent a response to the FDA and is awaiting its feedback, Director Subhash Majithia said in an e-mail. The company has "a continuous process of upgrading in all areas," Majithia said.*

Apotex Inc. – *"We are actively working with the agency and independent consultants to implement measures that will enhance our quality assurance protocol," Apotex said in a statement. "We stand fully behind the safety and efficacy of our products and are staunchly dedicated to further enhancing our global quality systems."*

Canton Laboratories Pvt. Ltd. – *No response.*

Amanta Healthcare Ltd. – *No response.*

Micro Labs Ltd. – *No response.*

RPG Life Sciences Ltd. – *No response.*

Sentiss Pharma Pvt. Ltd. – *"We received the import alert from FDA and since then have been working diligently to comply with all requirements of FDA," the company said in a statement.*

Accordingly, necessary responses have been sent to FDA for their consideration and approval. We have also hired the services of a reputed GMP consultant from USA who have been assisting us in our efforts. We strongly believe in complying with all requirements of regulatory agencies of the countries that we work in."

J.B. Chemicals & Pharmaceuticals Ltd. – *The company closed down its Unique Chemicals facility in Rabale, India, in 2010, said Secretary Mayur Mehta. The company hasn't received communication from the FDA about an import alert for the facility, Mehta said. The FDA said its inspection in 2013 was to verify that the facility was no longer operating, and the agency put the plant on import alert to make sure its previously manufactured products weren't exported to the U.S.*

Wockhardt Ltd. – *No response.*

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Flies Found in India Factory Threaten U.S. Pipeline of Generics

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A man walks though a field of mustard flowers near the Ranbaxy Laboratories Ltd. facility in Toansa, on the outskirts of Chandigarh, Punjab, India.
Photographer: Dhiraj Singh/Bloomberg

March 8, 2014 – America's $93 billion pipeline of generic pharmaceuticals often starts in places like Toansa, a village in northern India where a drug-making facility rises up beside mustard fields and manure-flecked ox-cart tracks.

Toansa's factory complex – owned by Ranbaxy Laboratories Ltd., one of India's largest drugmakers – has for years produced ingredients for dozens of pharmaceuticals sold to Americans, including AstraZeneca Plc's top-selling heartburn medication Nexium, as well as its own generic copies of drugs including Pfizer Inc.'s Lipitor.

Ranbaxy and its Toansa factory are in the crosshairs of the U.S. Food and Drug Administration, which has recently taken a tougher stance on the quality of generic drugs originating in India amid complaints by doctors and others. The agency said last month that it has begun a $20 million program to test generic drugs.

In January, FDA inspectors paid a surprise visit to the facility in Toansa, in a rural area north of New Delhi, and found broken equipment, windows stuck open and flies "too numerous to count," according to the FDA's report of its inspection. Workers ran quality tests over and over until they got the results they wanted, the FDA noted.

Shortly after, the FDA banned the import of drug components made at the Toansa plant.

Ranbaxy voluntarily suspended all shipments of active pharmaceutical ingredients, or APIs, from Toansa and a second Indian plant, Dewas, after the FDA ban, Ranbaxy's parent company, Tokyo-based Daiichi Sankyo Co., said in a Feb. 25 statement. Ranbaxy is continuing to make drugs for non-U.S. markets using API inventory from Toansa and Dewas and from external sources, Yasuki Minobe, a Daiichi spokesman, said by telephone March 4.

Beyond T-Shirts

A recent visit to Toansa found a town deeply dependent on the fortunes of Ranbaxy. While consumers in rich nations have learned about the

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A Ranbaxy Laboratories Ltd. facility stands in Toansa, Punjab, India.
Photographer: Dhiraj Singh/Bloomberg

workers who make their T-shirts and tennis shoes, less light has been shed on those who make medications that save and extend lives. The happenings in Toansa help illuminate working conditions in India's pharmaceuticals industry, which has grown as wealthy governments seek to reduce the costs of medical treatments.

In August, a machine explosion at the Toansa facility left worker Rajan Sikka with shattered bones in his face, memory loss and partial paralysis. In early October, a contract worker there died from inhaling poisonous gas, according to a police account cited in his postmortem report. The worker had been handling chemicals after being asked to fill in for a technician who went on a break, according to a coworker and family members citing accounts from the worker's colleagues.

Grim Sweep

Ranbaxy said there had been no gas in the area of the deceased worker, a 28-year-old who it said apparently died of cardiac arrest. It said Sikka, the injured worker, is recovering at home. Ranbaxy strives to "continuously strengthen and improve our systems, processes and occupational health and safety procedures," a spokesman said in a Feb. 24 e-mail.

The FDA's Toansa ban completed a grim sweep: Ranbaxy, based in Gurgaon in northern India, once had four Indian facilities registered with the FDA to send drugs and drug components to America. Toansa was the last of the four to have its products suspended from U.S. sale for failing to meet the FDA's so-called current Good Manufacturing Practices.

Those last two suspensions came after Ranbaxy agreed last year to pay a $500 million settlement in the U.S., in which it admitted it sold batches of drugs that were improperly manufactured, stored and tested. It also pleaded guilty to four felony counts of knowingly making false statements to the FDA.

Strong Records

Several makers of generic drugs in India and elsewhere have maintained strong track records. "Unfortunately, the many Indian companies that understand good manufacturing and quality processes have been overshadowed by recent lapses in quality at a handful of pharmaceutical firms," FDA Commissioner Margaret Hamburg said in a blog post while on a trip to India last month, during which she said the FDA would step up inspections of plants in India.

Pharmaceutical production in India has boomed in recent years. Indian companies sold about $5 billion worth of generics to the U.S. in the year that ended March 2013, according to an estimate from Hitesh Mahida, an analyst at KR Choksey Shares & Securities Pvt. in Mumbai.

While Indian producers accounted for 6 percent of the dollar value of all generic drugs

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sold in the U.S., they accounted for one-quarter of generics sold by volume, according to Standard Chartered, which analyzed data from IMS Health.

In 2012, branded drugs represented a $232.9 billion market in the U.S., with branded and unbranded generics accounting for another $92.6 billion, according to Standard Chartered.

Job Creator

India's pharmaceuticals boom has created more than 4 million jobs, according to the Organisation of Pharmaceutical Producers of India, which includes positions in thousands of factories producing for domestic and international markets. The country has more than 500 factories registered with the FDA.

Drug manufacturing in India costs about half as much as in Western industrialized countries, according to PricewaterhouseCoopers. India's wage costs are one-fifth of the level in the U.S. and 30 percent of those in Europe, PwC said.

Much of India's pharmaceuticals industry is located in rural and small regional centers, according to the International Labour Organization, where there are parcels of land large enough for the factories. State governments have sought to benefit by wooing industries that promise to alleviate high unemployment.

'Moxie Plant'

Ranbaxy started production in Toansa, a scattering of farmhouses on a fertile plain near Pakistan, in 1987.

It has opened facilities elsewhere in Punjab and in Madhya Pradesh and Himachal Pradesh

A farmer throws a basket full of dung onto a pile as the Ranbaxy Laboratories Ltd. facility stands the background in Toansa, Punjab, India.
Photographer: Dhiraj Singh/Bloomberg

states. Ranbaxy purchased Ohm Laboratories Inc. in New Jersey, which formulates medications and distributes them in the U.S., and by 2006 it had bought generics businesses belonging to Bayer AG in Germany, Aventis SA in France, GlaxoSmithKline Plc in Italy and Spain and generic drugmakers in Romania and South Africa. Daiichi Sankyo bought its majority stake in Ranbaxy from its Indian owners in 2008.

In a Toansa farmhouse, a woman who said her husband worked on-site for 16 years points across the mustard fields to a complex that by local count includes 14 production buildings: There's the "Moxie plant," she said, which makes the antibiotic amoxicillin, and the "Doxie plant," which makes the antibiotic doxycycline.

At full capacity, the facility employed approximately 2,000 workers, said Sandeep Kumar, who said he supplies laborers to Ranbaxy through the agency he owns, Ramlal & Sons. Many factory employees come from the surrounding countryside, where men generally finish school before age 16.

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Temp Workers

The plant's many skilled employees often commute from neighboring towns. The plant also hires temporary workers for basic labor through a handful of local contracting firms. Laborers who handle chemicals at the Ranbaxy factory are required to train for a month and a half, said Amrik Mahi, whose agency, Mahi Enterprises, recruits workers for Ranbaxy and other companies.

However, two former contract workers said they received three to four days of training before starting work. Their duties included handling solvents and packing finished products, said the two workers, who, like several laborers and villagers who spoke about the plant, declined to be identified because they didn't want to hurt their employment prospects.

Ranbaxy declined to confirm details of the plant's size or employment numbers and didn't respond to requests for comment about contract-worker qualifications.

Surprise Visitor

Toansa's fortunes shifted on Jan. 5 when a Toyota Innova minivan arrived bearing an FDA inspector, five villagers recounted.

The factory's planning department had counted on an audit in February, a plant technician said. At the time of the snap visit, construction was underway in the quality-control lab, another worker said. Managers were preparing to fix a broken piece of equipment in a different lab by February, he said.

In its week-long inspection, the FDA found the quality control and microbiology labs were in "significant disrepair," according to the inspection report filed by the FDA that detailed eight possible violations of the Food Drug and Cosmetic Act. On Jan. 23, the FDA blocked exports to the U.S. from the Toansa factory of all ingredients.

"We are taking swift action to prevent substandard quality products from reaching U.S. consumers," Carol Bennett, acting director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research, said in a statement.

Ranbaxy Disappointment

The statement advised patients to continue taking Ranbaxy drugs that are already in the U.S. market. Ranbaxy's Ohm facility in New Jersey can still supply finished drugs to the U.S.

In a statement Jan. 24, Ranbaxy said it had suspended U.S.- bound shipments of API from Toansa once it received the FDA's inspection results. It expressed disappointment at the ban, apologizing to stakeholders "for the inconvenience caused by the suspension of shipment."

Ranbaxy's move a month later to temporarily halt API shipments from Toansa to all other markets will let the company evaluate and inspect its manufacturing and quality control, Daiichi said in a Feb. 25 public statement.

Among those affected by the Toansa suspension was AstraZeneca, which has sourced esomeprazole magnesium, used in Nexium sold in the U.S., from facilities in France and in Toansa, said spokeswoman Vanessa Rhodes. AstraZeneca is now getting the ingredient from its French source, she said, adding that it has found no problems with the quality of its products already on the market.

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A man walks a bycycle past cows near Ranbaxy Laboratories Ltd. pharmaceutical plant, background left, in Toansa, Punjab, India.
Photographer: Dhiraj Singh/Bloomberg

Worker Safety

The FDA's efforts don't extend to assessing worker safety. That issue is often overlooked in India's pharmaceutical factories, according to the People's Training and Research Centre, an Indian nonprofit that works on occupational safety issues. India's government doesn't release consistent annual accident data, said the center's director, Jagdish Patel.

Labor inspectors appointed in each state have the authority to inspect factories and penalize them for noncompliance. But there is a "chronic shortage" of inspectors in most states, Patel said.

The blast that injured Sikka, a 43-year-old father of two who had worked at the Ranbaxy factory for more than 20 years, came near the end of his shift on Aug. 23, according to a colleague at the factory.

Medical Bills

A door blew off of a vacuum device used to dry chemicals, sending a piece of steel that pinned Sikka against the wall, according to the colleague. It wasn't clear if the incident was investigated. Workers weren't informed of the circumstances leading up to the incident, the colleague said.

Sikka's injuries left him largely confined to his bed and with swallowing difficulties that require him to take some nutrition through a tube into his stomach.

Ranbaxy covered medical bills for Sikka's hospitalization and is funding his medications, a full-time caregiver and his salary, according to his doctor and receipts reviewed by Bloomberg News. Ranbaxy "provides best possible medical treatment," compensation and support to the family in case of unfortunate circumstances, the Ranbaxy spokesman said.

On a recent Friday afternoon at Sikka's home, his two teenage boys sat next to him on the bed doing their homework as a television set played a Hindi sitcom. Sikka slept, not responding to calls of his name.

A preliminary inquiry into Sikka's injury by Punjab's labor department found that the workers and supervisory staff at the plant had been insufficiently trained for their jobs, said assistant director of factories Narinder Singh, the official responsible for ensuring compliance in the Toansa area.

No Fines

The regulator asked Ranbaxy to ensure that its workers and equipment maintenance staff are better trained, Singh said in an interview. It hasn't levied a fine on Ranbaxy, he said.

Ranbaxy declined to respond to requests for comment about training. Punjab state labor commissioner Harbhupinder Singh wasn't available

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at his office and didn't respond to calls to his mobile phone.

Ranbaxy requires workers to wear safety gear, said three current and former contract workers citing company rules. Those requirements are haphazardly enforced or ignored, workers said. One said he prefers not to wear the required goggles because they fog up. Men who wear large cloth turbans, a tenet of the Sikh religion practiced in the area, often find safety helmets unwieldy, one technician said.

Other workers said contract laborers sometimes do work for which they aren't trained or outfitted.

Unresponsive Worker

In early October, contract employee Kulwinder Singh was asked to fill in for a technician in a job that involved unloading chemicals when he inhaled fumes, according to two workers and family members who said their information was based on accounts by workers in his unit.

Singh was found sitting, unresponsive, and was taken to a health center by ambulance and later transferred to a civil hospital in Balachaur, the Ranbaxy spokesman said. Singh was declared dead on arrival at the hospital, according to records at the nearby Kathgarh police station, examined by Bloomberg News.

The postmortem report prepared by medical officer Renu Mittal at the public hospital in Balachaur, about 30 kilometers away, stated that according to preliminary information from the police, Singh died from "inhalation of poisonous gas." The police based the assessment on interviews with workers at the accident site, according to Sukhpal Singh, the head constable in the Ansron post.

Awaiting Biopsies

The final determination on the cause of death, Mittal wrote, is pending a final biopsy.

Five months after Singh's death, no such determination has been made public. Constable Singh said results from chemical and pathology tests run at two government labs remain pending.

At one of those facilities, the Punjab Chemical Laboratory in Kharar, an unrelated corruption investigation had delayed work by up to six months, said lab head Rakesh Kashyap. In the other case, results from the Government Medical College in Amritsar were completed and mailed last month to Balachaur hospital, said the college's head of pathology, Amarjit Singh. Mittal said in an interview that the Balachaur hospital hadn't received the pathology report.

Ranbaxy declined to comment on the police report that cited gas inhalation. The Ranbaxy spokesman said by e-mail that there had been no vapors or gas in the area and that the worker had been wearing protective gear.

Accounts of incidents at the plant haven't discouraged Toansa's workers. The family of Singh, the deceased worker, is seeking a settlement from Ranbaxy that would include a job for his younger brother.

Locals still prefer to work at the factory than in the fields, said Krishan Kumar, chief of Toansa's village council.

"You couldn't find a single man who's unemployed in this village because of this factory," Kumar said in an interview. "Even people who've only passed fifth grade, they got jobs."

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