

FEATURE



DRUG INDUSTRY

Health camps and surveys: marketing an unproved, unapproved drug in India

A US drug maker encouraged Indian doctors to prescribe a drug unproven for diabetic neuropathy that until recently lacked central government approval. **Frederik Joelving** investigates

Frederik Joelving *freelance journalist*

Copenhagen, Denmark

It was an attractive invitation: outside doctors' offices throughout India, where hundreds of millions of people struggle to afford basic healthcare, posters from a subsidiary of the US drug company Abbott Laboratories advertised free neuropathy tests for anyone with symptoms such as tingling or numbness in the feet.

But those who took up the offer may have spent their money on a product useless for treating neuropathy.

According to internal Abbott communications, published by the *New York Times* in August,¹ people who tested positive at the drug maker's "neuropathy camps" were prescribed Abbott India's Surbex Star, a mix of antioxidants, minerals, and B vitamins that the company promotes for the treatment of diabetic neuropathy. *The BMJ* was unable to find any evidence that this product had been clinically tested, much less proved effective for this indication.

"These combination supplements, unless you're deficient in something, they really don't do anything," said Christopher Gibbons, head of the neuropathy clinic at the Joslin Diabetes Center in Boston. The one possible exception is the antioxidant α -lipoic acid in Surbex Star, he told *The BMJ*. Studies show that it can improve neuropathic pain when given intravenously, though oral therapy (Surbex Star is taken orally) may not have clinically significant benefits.²

An Abbott spokesman declined to discuss the science behind Surbex Star, which in India is considered a drug because it is marketed to treat a disease.

The lack of evidence did not deter the drug maker. In March 2015 an email from an Abbott India sales representative to his manager described a neuropathy camp as a "big success," noting that all 30 patients with positive neuropathy tests had been prescribed Surbex Star.

Corporate social responsibility

Screening and diagnostic testing are key parts of Abbott's initiatives for corporate social responsibility, which earned the company an award from the Indian government earlier this year. A 2012 Abbott report boasted that the Chicago based multinational ran "numerous screening programmes around the world to help identify patients at risk for specific diseases and refer them to appropriate treatment."³

"For example," the report went on, "each of our business divisions in India hosts a variety of health camps targeting remote and underserved populations."

An investigation by *The BMJ* last December showed that these "health camps" have become an industry-wide marketing gimmick in India.⁴ Violating national law, pharmaceutical sales agents test patients for several chronic diseases at clinics or community events, attracting new customers for doctors who, in return, prescribe the companies' products.

But Abbott has repeatedly denied any link between its health camps and sales. A spokesman told *The BMJ* that "Employees are not permitted to perform diagnostic tests."

At more than 17 Indian rupees a capsule (£0.21,€0.23; \$0.26), Surbex Star can be a substantial expense for many people in India, said Anurag Bhargava, a professor of medicine at Yenepoya Medical College in Mangalore. He worries that poorer patients may skip essential drugs like metformin to be able to fill a prescription for this unproved product.

"A lot of people in India are not making 100 rupees a day," said Bhargava, who is also a member of All India Drug Action Network, an independent group advocating rational drug use. "What patients should be getting is advice on foot care rather than these wishy washy drugs, that don't do anything but cost a packet."

Belated approval

Like many of the drug cocktails for sale in India, Surbex Star was put on the market without the approval of the Drugs Controller General of India (DCGI). However, the state drug controller of Tamil Nadu had issued a licence to the third party manufacturer that Abbott uses, the Chennai based Softgel Healthcare. This breached national rules that require central approval for new drug combinations before states can grant manufacturing licences.^{5,6}

In January 2013—the same month that Surbex Star was approved in Tamil Nadu, according to Abbott spokesman Jonathon Hamilton—the DCGI announced that new fixed dose combinations licensed by states after 1 October 2012 without central approval would be “considered for being prohibited for manufacturing and marketing in the country.”

In emailed statements, Hamilton said that Softgel had subsequently submitted documentation on safety and efficacy to the regulator. Both Abbott and Softgel declined to share or discuss this information, but Hamilton said that the formulation of Surbex Star had been declared “safe and effective” by a committee appointed by the Indian government.

That committee was given the task in 2014 of reviewing more than 6200 applications from companies with unapproved drug combinations on the market. When it presented its findings it categorised Surbex Star as a “rational” combination but did not mention the indication for which the medicine was deemed effective. Chandrakant Kokate, a pharmacist who chaired the committee and is vice chancellor of KLE University in Belagavi, Karnataka, declined to be interviewed for this story, citing a confidentiality agreement.

On 22 August 2016—more than a year after the documented neuropathy camps took place—the DCGI approved Surbex Star as a prescription drug, according to a certificate seen by *The BMJ*.

The DCGI, G N Singh, declined to answer questions about Surbex Star, except to say that it had been approved. The regulator has licensed dozens of other vitamin combinations “for the treatment of diabetic neuropathy,” but would not comment on the supporting evidence. A study published earlier this year found that less than one fifth of the drug combinations approved in India from 2009 to 2014 were rational.⁷

The Tamil Nadu drug controller also confirmed that Softgel had been granted a manufacturing licence for Surbex Star, but did not answer questions about the legality of this licence or what evidence had been submitted in support of it.

Market research survey

The neuropathy camps were not the only means by which Abbott India sought to win new customers, according to Vivek Gupta, a former sales manager whose team promoted Surbex Star. Gupta was fired from Abbott India in 2015 after complaining to senior managers about what he believed were unethical practices at the company.¹

To help promote the drug after it was launched in 2013, the company offered doctors 5000 rupees for completing a market research survey, according to a contract seen by *The BMJ*. Details of the survey are published here for the first time.

“Your encouraging support for Surbex Star speaks volumes of your commitment towards your patients,” Abbott India told doctors in the survey booklet, which *The BMJ* has also seen.

It added that the drug was indicated for the treatment of diabetic neuropathy and other conditions, and that, given the company’s

“strong philosophy for generation of scientific data,” the survey aimed to determine “the number of patients seen, the duration of therapy of Surbex Star, and the overall opinion about use of Surbex Star in the management of neurological disorders.”

The booklet included 10 simple multiple choice questions, such as “How do you rate the efficacy of Surbex Star in the management of neuropathy?” The data for the survey, Abbott India told participants, would be based on “at least” 20 patients prescribed Surbex Star for each doctor. For each patient, doctors would receive 200 rupees to cover “administrative charges”—more than many health providers in India charge for a standard consultation.

Gupta, who was involved in collecting the completed questionnaires, called the survey a bribe in disguise. “It was a marketing tool to get prescriptions from doctors,” he told *The BMJ*.

In response to the allegations, Abbott’s Hamilton repeated the survey’s stated objective and said that physicians were paid “a small honorarium for their time.” He said that the honorarium was capped at 4000 rupees, in contradiction with the contract seen by *The BMJ*. While Hamilton said that only 20 doctors participated, Gupta maintained that the survey was distributed nationwide.

A current sales rep from a different division of Abbott’s India business told *The BMJ* that he had been involved in similar activities, referred to as post-marketing studies. “This is nothing but quid pro quo,” said the rep, who spoke on condition of anonymity.

Bhargava and Gibbons echoed this interpretation when shown the survey booklet.

“This is pure and outright pandering and manipulation through payment,” said Gibbons, who is also an associate professor of neurology at Harvard Medical School and president of the American Autonomic Society. “It is clearly a kickback, and as a consequence it is not clear that any of the data acquired is of value.”

Bhargava added that the booklet promoted “irrational practice” by referring to neuropathy as if it were a single entity needing the same treatment regardless of aetiology—“like talking about an antibiotic for ‘fever.’”

For Gibbons, Abbott’s promotion of Surbex Star helps to explain a puzzling observation. During programmes that he and his colleagues have hosted to educate physicians from around the world, he said, Indian doctors often ask why he doesn’t recommend B vitamins or α -lipoic acid as standard therapy for diabetic neuropathy.

“Now it makes much more sense where this is coming from,” Gibbons said.

Competing interests: I have read and understood the BMJ’s policy on declaration of interests and have no relevant interests to declare.

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