

Novartis Japan unit charged over research manipulation

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Japanese prosecutors Tuesday laid charges against the local unit of Swiss pharmaceutical giant Novartis in a widening scandal over claims that falsified data were used to exaggerate the benefits of a popular bloodpressure drug.

Prosecutors also indicted former employee Nobuo Shirahashi, 63, alleging he manipulated the data in clinical studies that were later used in marketing the drug Valsartan.

The dual charges laid by the Tokyo District Public Prosecutor's Office—which allege that Novartis bore responsibility for Shirahashi's actions—came several weeks after he was first arrested and authorities raided the offices of Novartis Pharma KK in the Japanese capital.

The drug studies suggested Valsartan—sold under the brand name Diovan in Japan, and licensed for use in more than 100 countries—could help prevent strokes and angina, in addition to its acknowledged benefits in combating <u>blood pressure</u>.

The firm used data from those studies to market its <u>drug</u>, playing up its supposed additional benefits.

"We take the arrest of our former employee and the indictment of our company very seriously," the unit said in a statement on its website.

"We deeply apologise to patients, their families and medical workers as



well as Japanese people for causing these concerns and trouble," it added.

The <u>pharmaceutical giant</u>'s Japan unit has also been embroiled in another scandal over allegations it did not properly disclose the possible side effects of leukaemia treatments.

In April, Novartis replaced the top executives at its Japanese arm over those allegations.

Under the country's pharmaceutical law, anyone found guilty of exaggerating advertising can face up to two years in prison or a fine of as much as two million yen (\$19,000).

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