

# Novartis' top Japan executives quit over cancer drug scandal (Update)

April 3 2014, by Kyoko Hasegawa

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Swiss pharmaceutical giant Novartis said Thursday it was replacing the top executives at its Japanese unit over allegations the division hid serious potential side effects of leukaemia treatments from regulators.

The company also said it was freezing funding for clinical trials in the country in the wake of the scandal, which David Epstein, head of the firm's pharmaceutical division, branded "unacceptable and a clear violation of our code of conduct".

Epstein told a press briefing in Tokyo that the senior managers "resigned, they are out of the company".

"I'd like to once again apologise for Novartis' involvement in this issue," he said.

A "few" other employees were sacked in recent days amid claims some staff shredded documents, while more firings are a possibility, he added.

"If some of them have destroyed documents, it's a pure violation of our code of conduct and that employee has to leave as soon as we discover that," Epstein said.

The move comes after a panel of outside lawyers hired by the company said earlier Thursday that sales staff also hid their improper involvement in drug studies probing possible side effects of cancer treatments.

The claims marked a fresh blow for the drugmaker, less than two months after Japanese prosecutors raided its Tokyo office over claims Novartis exaggerated the benefits of a popular blood-pressure drug.

In the latest case, the panel found staff had removed evidence from the Novartis office of their links to the research, which pointed to at least two cases of severe reactions in patients undergoing leukaemia drugs testing.

The probe found sales staff had acted inappropriately by involving themselves in the clinical research at nearly two dozen medical institutions in Japan.

The panel did not find evidence that the data were falsified, but "we noted that there were several irregular practices", said a lawyer speaking on behalf of committee head Kunio Harada.

## **Second scandal in two months**

On Thursday, Novartis also said it would freeze funding to doctor-led clinical trials in Japan until its probe is finished. Drugmakers funding such trials is a widespread practice in Japan, but it has raised conflict-of-interest concerns.

"We have to restore trust in our company," Epstein said Thursday.

"We have to put the patient first, patient confidentiality is key. Separation of commercial from development is absolutely key, shredding a document is unacceptable. Any unethical behaviour is unacceptable for a global company like Novartis," he added.

Failing to report the side effects of a drug could violate pharmaceutical law "which could mean an administrative penalty," a health ministry

official told AFP.

"We are communicating with Novartis officials over the issue," he added.

The company hired the outside lawyers to conduct an in-house probe after allegations surfaced in press reports earlier this year about employees being involved in the testing, which should have only been led by doctors.

The firm said Briton Michael Ferris would replace Hiroko Ishikawa as president of Novartis Holdings Japan, while German Dirk Kosche would replace Yoshiyasu Ninomiya as head of Novartis Pharma, also part of the global firm's Japanese business.

Canadian Francis Bouchard is to succeed Kazuo Asakawa as director of the Pharma division's oncology business.

In February, prosecutors raided the Novartis office after the health ministry filed a criminal complaint against the global firm, which has been under fire since a university said the data in clinical studies might have been skewed to promote the blood-pressure drug Valsartan.

The studies suggested the drug—sold under the name Diovan in Japan, and licensed for use in more than 100 countries—could help prevent strokes and angina.

The firm used data from the studies to market its drug, playing up its supposed additional benefits.

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

Novartis has said it had no knowledge of the wrongdoing.

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