

Japan files criminal complaint against Novartis arm

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Japan's health ministry on Thursday filed a criminal complaint against the local arm of Swiss pharmaceutical giant Novartis over alleged exaggerated advertising for a popular blood-pressure drug, the company said.

The ministry lodged its complaint against Novartis Pharma KK following months of scandal after a university said the data in clinical studies might have been skewed to promote <u>blood-pressure</u> <u>drug</u> Diovan, which is also known as Valsartan.

"Today a <u>criminal complaint</u> was filed by the health, labour and welfare ministry against us over doctor-led clinical research on Diovan for alleged exaggerated advertising banned under the pharmaceutical law," a statement on the company's website said.

"We apologise deeply for causing tremendous worries and trouble to patients, their families, medical workers and the public.

"We take this incident extremely gravely and will continue to cooperate fully with the authorities."

Health Minister Norihisa Tamura has characterised as "extremely regrettable" the incident in which an employee of the world's number two drug maker hid his affiliation during a medical study into the effects of the drug.



The resulting studies suggested the drug, which is licensed for use in more than 100 countries, had some additional preventative effect on strokes and angina.

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

There is no suggestion that Diovan is ineffective in combating blood pressure problems.

Under Japan's pharmaceutical law, anyone found guilty of exaggerated advertising can be punished with up to two years in prison or a fine of as much as two million yen (\$19,400).

A ministry panel of experts concluded in September that Novartis Pharma KK should be held responsible for studies at various universities that used manipulated data on the drug.

Novartis Pharmaceuticals chief David Epstein has apologised for the concern the incident caused, but did not say that the company played any role in the allegations.

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