

Novartis Japan facing penalty over drug side effects

February 4 2015

Japanese health authorities said Wednesday that they will soon make a decision on a possible penalty against the local unit of Swiss pharmaceutical giant Novartis for failing to report drug side effects.

That followed media reports which said regulators would slap a 15-day suspension order on the firm, meaning the company could not sell most of its drugs during the two-week period—a first for a pharmaceutical firm operating in Japan.

Tokyo-based Novartis Pharma K.K. in December admitted it failed to report more than 3,000 cases of patient health problems that may have been caused by adverse effects from about two dozen company drugs.

The Swiss firm's Japanese unit declined to comment Wednesday, while the health ministry said that a decision was imminent.

"We haven't decided anything yet, but it should be announced soon," a spokesman told AFP.

The possible penalty marks the latest headache for the drugmaker in Japan.

In July it was handed a business improvement order for failing to properly report [side effects](#) of two leukaemia drugs.

Also in July prosecutors laid charges against the unit over claims that

falsified data were used to exaggerate the benefits of a popular blood-pressure drug.

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

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