

# Novartis Japan hit with suspension over side-effect reporting

February 27 2015

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Japanese health authorities said Friday that they have ordered the local unit of Swiss pharmaceutical giant Novartis to temporarily suspend its operations for failing to report drug side effects.

The health ministry's 15-day suspension—reportedly a first for a pharmaceutical firm operating in Japan—means the company will not be able to sell most of its drugs during that period, which is to start from March 5.

Tokyo-based Novartis Pharma K.K. in December admitted it failed to promptly report more than 3,000 cases of adverse effects from about two dozen company drugs. Drugmakers are required to report serious side effects to the ministry within 15 to 30 days.

The Novartis unit declined to comment when contacted by AFP on Friday.

The 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 Diovan. The [drug](#)'s generic name is Valsartan.

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