# ディオバンをめぐる不正事件が提起した課題

## ― NGO活動を踏まえた検討 ―

**水口真寿美**
薬害オンブズパースン会議

# What should be done to tackle the issues raised by the Diovan data-manipulation scandal?

## ― Proposals from Medwatcher Japan ―

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**Abstract**

The Diovan® (generic name valsartan) data-manipulation scandal stems from an unhealthy relationship between pharmaceutical companies and academia.

A report by the Ministry of Health, Labor and Welfare's advisory committee states that this scandal has shaken confidence in Japan's clinical trials. However, the most serious problem is the violation of the human rights of those participating in clinical trials and patients who used Diovan believing in Novartis Pharma KK's advertisements.

Medwatcher Japan (a drug watchdog in Japan), released a statement on September 11th 2013, and filed a criminal complaint with the Tokyo District Public Prosecutors Office against Novartis, accusing the firm of violating the Pharmaceutical Affairs Law and the Unfair Competition Prevention Act on November 1st 2013.

To tackle the issue raised by the scandal, I propose the following based on Medwatcher Japan's activities: enact a new legislation to protect the human rights of clinical trial participants and regulate by law not only clinical trials conducted for the marketing approval of drugs but also those that don't require marketing authorization, establish a new system and office to investigate unfair practice in medical research, set up a public fund for clinical trials based on the model of AIFA (The Italian Medicines Agency)'s system, enact a Japanese version of the 'Sunshine Act' and oblige doctors to report their sources of funding, ban any donations to universities for specific clinical trials, recommend contracts to clarify sponsors, revise the pharmaceutical affairs law and regulate not only "advertisements" but also all "promotions" by pharmaceutical companies.

**Key words**

Diovan (generic name valsartan), data-manipulation, conflict of interest (COI), clinical trials, promotion

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