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Japan to consider new legislation to regulate clinical studies

August 6, 2013 | Regulatory | By BioSpectrum Bureau



Singapore: Japan is considering new legislation to regulate clinical studies in the country, according to a report published in *The Japan News*.

The move follows recent revelations of data falsification in clinical studies for a high blood pressure drug Diovan by Novartis Pharma KK. The government is discussing establishment of a new law to check similar instances of clinical trial data falsification.

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The publication quoted government sources as saying that it is expected that the researchers carrying out clinical trials will be asked to preserve medical records and other related data, and submit them to the government, and those who fail to comply will face punitive measures.

Also, the Health, Labor and Welfare Ministry has plans to establish a committee to investigate details of the data falsification cases and discuss measures to prevent future incidents. The committee will start debate on Friday, the sources told the publication. The government will finalize discussions about the new law based on the committee's conclusions.