Journal raises concern about blood-thinning drug

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A medical journal raised concerns Wednesday about a blood-thinning drug widely used by people at risk of stroke, accusing its manufacturer of concealing safety data and regulators of laxness.

A key selling point of the drug known as dabigatran or Pradaxa was that it required no blood-level monitoring, as does competitor warfarin.

Dabigatran's maker, Boehringer Ingelheim, had said the drug was better than warfarin at reducing stroke in people with irregular heart rhythm, with a similar risk of major bleeds, according to the *British Medical Journal* (*BMJ*).

Based on its own probe, the journal accused Boehringer of concealing information that blood-level monitoring could in fact reduce major bleeds by up to 30-40 percent compared to warfarin.

"The BMJ has found that neither doctors nor regulators have ever been aware of these calculations," said a statement.

Irregular heart rhythm (atrial fibrillation) affects about 800,000 Britons and over three million Americans.

According to BMJ investigations editor Deborah Cohen, who conducted the research, millions of people take the anti-clotting drug, with blood levels found to vary greatly between patients.

"These analyses suggest that dabigatran could be made safer," she told AFP by email.

A one-off test may be sufficient to check how a particular patient was reacting to the drug, which seeks to keep the blood thin enough to protect against stroke, but not so thin to pose a major bleed risk.

The BMJ said the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), in 2010 and 2011 respectively, approved the drug without the need for blood tests, despite concerns.

"Once licensed, dabigatran proved a financial success, but by the end of 2011 concerns about fatal bleeds were beginning to emerge," it wrote.

In May, the manufacturer settled for $650 million (480 million euros) in 4,000 cases in the United States linked to use of its blood-thinner.

The FDA told AFP its approval of the drug had been based on information supplied by Boehringer.

"The FDA is constantly examining product labelling to make sure the label reflects the current knowledge with regard to the benefits and risks of the product," the agency said, adding it had published "several" drug safety tips about Pradaxa over the years.

The EMA said it was evaluating whether any relevant information had not been submitted.

"In case of any new evidence, the EMA will take action as necessary to guarantee the safety of patients," it said.

Boehringer UK in a tweet advised patients not to stop taking the drug, but consult their doctor if they were concerned.

"We remain confident in our medicine's benefits and safety profile which have been reaffirmed by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and others," it tweeted.