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India to review marketing approval for diabetes drug

BS REPORTER
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The country's drug regulator may soon review the marketing approval given to rosiglitazone, a generic drug for diabetes.

The move comes a day after the European Medicines Agency (EMA), the European drug regulator, decided to ban the medicine and the US Food and Drugs Authority (USFDA) said it would restrict its use. The regulators had found that long-term use of rosiglitazone increases the risk of heart attacks.

India, which does not have an internal mechanism to track the adverse impact of medicines, always weigh decisions of agencies such as EMA or USFDA to frame its own directives.

"A review meeting on the marketing approval given to rosiglitazone will be held soon," a health ministry official confirmed.

Meanwhile, GlaxoSmiKthlime, the company which markets rosiglitazone under the brand name Avandia globally, has passed on the decisions of the European and US drug regulators to the Drugs Controller General of India.