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Eisai pulls drug from Germany due to unsuitable policies

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Singapore: Eisai suspended sales of its epilepsy drug Fycompa (perampanel) in Germany due to unfavorable conditions set by the country's health regulator, German Federal Joint Committee (G-BA). The Japan-based firm said that it was unable to accept the assessment made by the G-BA through the Amnog system of pricing. The Amnog system has come under much criticism from the industry since it was introduced in 2011.

During March 2013, the G-BA decided not to recommend Fycompa, based on an assessment by cost-effectiveness watchdog, German Institute for Quality and Efficiency in Health Care (IQWiG). The watchdog determined that the benefits of the drug as an adjunctive treatment of partial-onset seizures in people were unproven, based on current evidence.

Although Eisai said that it was appalled by this decision, the company went a step further by suspending the product, claiming that the comparators used in the assessment were not applicable. As part of the decision-making process, the G-BA specified that Eisai should present data that compared Fycompa to standard treatment lamotrigine as an add-on therapy if the initial first-line therapy did not contain lamotrigine, while if the first-line therapy did contain lamotrigine, data should be presented comparing Fycompa to Johnson & Johnson's Topamax (topiramate).

However, Eisai did not include a comparison with topiramate in its data, and the company has now said that it is not suitable to compare new anti-epileptic drugs to single substances in the treatment of people with epilepsy whose seizures are not controlled by medicine, also known as refractory epilepsy.

According to the company, this is a view backed by the German Society for Epileptology (DGfE) and German Society for Neurology (DGN), both of which say additional benefit should be assessed by considering efficacy in patients drug-resistant to standard therapies.