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Epilepsy Foundation asks DEA to better review process

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Singapore: Epilepsy Foundation of US has called on the Drug Enforcement Administration (DEA), US, to revise its process for reviewing new treatments, which currently lack innovation and transparency for both consumers and the industry.

Currently, when a new treatment with abuse potential is approved by the FDA, the sponsors may not commercially market the drug until it has been scheduled by the DEA and labeled with the controlled substance schedule.

This delay between FDA approval and DEA scheduling has no set time limit, and there is no formal deadline or requirement that a timeline for agency action be provided to patients or physicians. During this interim timeframe, patients may not access these new therapies, regardless of FDA approval. The unpredictable DEA process results in patients being denied access to important medicines that can improve, and in some cases save, their lives.

"People with epilepsy, their caregivers, or parents of children with epilepsy find it very frustrating to wait for an additional treatment option for seizure control due to DEA delay," said Mr Phil Gattone, president and CEO, Epilepsy Foundation. "It is even more disheartening to know that the system is not required to have a clear timeline for consumers."

Access to new therapies is particularly important for the 20-to-30 percent of people living with epilepsy, who experience intractable or uncontrolled seizures or have significant adverse effects to medication. Patients who have drug-resistant epilepsy, defined as a failure to achieve seizure freedom after adequate trials of two tolerated, appropriately chosen and used antiepileptic drug schedules (whether as monotherapies or in combination), can develop brain damage or experience other life threatening effects.